

Bangor University

## DOCTOR OF PHILOSOPHY

### Compulsory Licensing of Patented Pharmaceuticals in the Developing World. A Legitimate or Illegitimate Way to Enhance the Access to Medicines?

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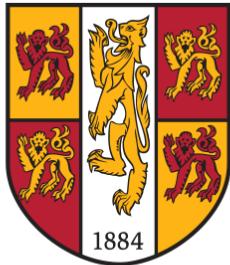
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P R I F Y S G O L  
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U N I V E R S I T Y

Compulsory Licensing of Patented Pharmaceuticals in  
the Developing World. A Legitimate or Illegitimate  
Way to Enhance the Access to Medicines?

A thesis submitted for the degree of Doctor of Philosophy in Law

31 July 2018

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Dr Mark Hyland

Dr Wei Shi

## **Dedication**

‘Ba mẹ là lá chắn che chở suốt đời con’

Cho con – Phạm Trọng Cầu

I would like to dedicate this PhD to my parents and my brother – the endless love of my life.

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# Abbreviations

ARV	Antiretroviral
ASEAN	Association of Southeast Asian Nations
DIPP	Department of Industrial Policy and Promotion
EC	European Community
EU	European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GNI	Gross National Income
GPO	Government Pharmaceutical Organisation
GSP	Generalized System of Preferences
IP	Intellectual Property
IPC	Intellectual Property Committee
IPRs	Intellectual Property Rights
ITC	International Trade Commission
LDCs	Least-developed Countries
MSF	Médecins Sans Frontières
NGO	Non-Governmental Organisation
NME	New Molecular Entity
OECD	Organisation for Economic Co-operation and Development
PCT	Patent Cooperation Treaty
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
SCP	Standing Committee on the Law of Patents
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
USTR	United States Trade Representative
WB	World Bank
WHA	World Health Assembly
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

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## **Abstract**

The objective of this thesis is to examine the implementation by three carefully selected developing countries of one of the most significant and controversial TRIPS flexibilities – compulsory licensing – so as to meet their differing pharmaceutical needs. This objective will be achieved by adopting a comparative approach between international (TRIPS) and domestic (India, Brazil and Thailand) patent laws, and by conducting a cross-national study of these patent regimes. This thesis critically evaluates the compulsory licensing mechanism of the aforementioned countries, each considered to be an emerging economy, capable of challenging the dominance of OECD nations.

The findings suggest that each country's application of compulsory licensing is closely linked to two factors: how it has implemented TRIPS and, its pharmaceutical manufacturing capacity. Where a state capitalises on TRIPS flexibilities and has a well-developed manufacturing capacity, it is unlikely to use compulsory licensing (e.g. India). In contrast, where TRIPS flexibilities are underutilised combined with a low industrial development, then the grant of compulsory licences is highly likely (e.g. Brazil and Thailand).

On the one hand, all the compulsory licence grants, to some extent, produced significant effects on society. In the short-term run, these licences eroded the monopoly of patent holding companies, driving down the price of medicine, thereby increasing the number of patients in treatment. Furthermore, as regards India and Brazil, mandatory licensing also resulted in price deductions for other medicines which were not subject to the compulsory licence. Somewhat surprisingly, in all three country case studies, the generics were not made at the cheapest price, compared with the substitutes available on the market, an important consideration for parties seeking a compulsory licence.

This work concludes that each country case study has developed its own distinctive regime. The fact that India's compulsory licences were initiated by private companies signifies that this legal tool has mainly served its thriving pharmaceutical industry. An absence of governmental participation in India has caused the country's mandatory licensing to be seen as purely a legal issue. Meanwhile, Brazil and Thailand applied government use licences to respond to their national health needs. This gave a strong political hue to the compulsory licensing regimes in those countries, particularly Thailand's. While Brazil efficiently employed these licences as

strategic threats in return for price cuts offered by patent holding companies, the seven licences issued by Thailand's post-coup government are considered extraordinary. It was viewed that an unlawful government was trying to curry favour with the Thai people. The legitimacy of the Thai licences was placed in significant doubt. Given each country's unique characteristics, it is clear that compulsory licensing should not be regarded as a 'one-size-fits-all' solution to combat all healthcare issues in less-developed nations.

In addition, this work seeks to achieve a secondary objective of critically evaluating the position of the following multilateral organisations on the issue of compulsory licensing of pharmaceutical products: the EU, WIPO, the WHO, and health-related NGOs. While the EU has built an image as a quiet and tactful player, WIPO displays subtle opposition to compulsory licensing. The WHO attempts to maintain a neutral stance in the ongoing deliberations while the NGOs want to dismantle any barriers to the access to medicines, created by TRIPS.

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# CHAPTER 1: INTRODUCTION TO THE

## RESEARCH

### 1.1 The objectives

This research is at the epicentre of the debate about patents and access to medicines<sup>1</sup> in developing countries,<sup>2</sup> the one which is described as ‘the most heated, sometimes divisive, and potentially explosive’.<sup>3</sup> While health activists criticise the patent system as a major cause of the lack of access to medicines in the developing world, pharmaceutical companies consider patent as an essential component of business operation. Indeed, the conflict between patent policy and public health arose from the creation of TRIPS<sup>4</sup> and has stood since then. While acknowledging the ideological differences, this thesis mainly aims to critically evaluate the implementation by developing countries of one of the most significant and controversial TRIPS flexibilities<sup>5</sup> – compulsory licensing – to meet their differing pharmaceutical needs. (The

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<sup>1</sup> The terms ‘medicine’ or ‘pharmaceutical’ or ‘drug’ which are used interchangeably in this thesis refers to conventional drugs that are synthetically produced. They differ from those manufactured biologically (biologics). Synthesised medicines are delivered to patients in pill form and make up a very large percentage of the drugs on the market today.

<sup>2</sup> According to Goode, ‘Developing country’ is an imprecise term applied to a country that does not consider itself or is not considered by others as a developed country. Developing country status remains largely self-declared. Sometime, developing countries are referred to collectively as **the South** since many of them are located in the Southern hemisphere. Meanwhile, ‘Developed country’ is usually applied to **OECD members**. Sometime, developed countries are referred to collectively as **the North** since many of them are located in the Northern hemisphere. See Walter Goode, *Dictionary of Trade Policy Terms* (5<sup>th</sup> edn, CUP 2007) 122 – 123.

For this reason, the terms, ‘developing country’ and ‘the South’; ‘developed country’, ‘OECD’ and ‘the north’ are used interchangeably in this thesis. In addition, it is generally accepted that 2/3 of all WTO members are developing countries, including India, Brazil and Thailand.

<sup>3</sup> Suerie Moon, ‘WHO’s role in the global health system: what can be learned from global R&D debates?’ (2014) 128 *Public Health* 167, 169, quoting the WHO Director-General Margaret Chan stating that ‘Of all the issues discussed at WHO governing bodies, access to medicines consistently sparks the most heated, sometimes divisive, and potentially explosive debates’.

<sup>4</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994, as amended on 23 January 2017) LT/UR/A-1C/IP/1 (hereinafter: TRIPS)

<sup>5</sup> The term ‘flexibilities’ is not used by TRIPS. However, according a WIPO definition, this term refers to different options through which, TRIPS obligations can be transposed into national law, so that national interests are accommodated, and TRIPS provisions and principles are also complied with. See WIPO, ‘Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels’ (18 August 2010) CDIP/5/4REV, par. 34. In addition to this document, WIPO has published other studies regarding flexibilities in the area of patents. They are:

- Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part II (18 April 2012) CDIP/7/3 ADD.
- Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part III (16 February 2015) CDIP/13/10 REV.
- Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part IV (20 October 2015) CDIP/15/6 CORR.

In 2010, WIPO developed the ‘Database on Flexibilities in the Intellectual Property System’ which enables searches for implementation of flexibilities in national IP laws in selected jurisdictions <<http://www.wipo.int/ip-development/en/agenda/flexibilities/database.html>> accessed 30 October 2017.

concept of compulsory licensing will be returned to in the next section and then deeply dealt with in Chapter 4.)

The primary objective of this thesis will be achieved by adopting a comparative approach between international (TRIPS) and domestic (India, Brazil and Thailand) patent laws, and by conducting a cross-national study of these jurisdictions. This thesis critically evaluates the compulsory licensing mechanism of countries that are considered to be emerging economies and are capable of challenging the dominance of OECD nations. In addition, this work seeks to achieve a subsidiary objective that is to critically assess the position of the following multilateral organisations on the issue of compulsory licensing of pharmaceutical products: the EU, WIPO, the WHO, and NGOs. Such inclusion will be justified in Section 1.4.1.

In this age of globalization and the complexity and entwinement of international and domestic law, legal comparison of three different compulsory licensing systems of India, Brazil and Thailand, has important implications. Firstly, the fact that compulsory licences in the medicine sector have been mainly used by many countries in the South signifies an acute understanding of their pharmaceutical needs. To the nations which are considering whether or not to implement this policy, comparative law of such leading examples can therefore provide various solutions, from which they can establish their ‘best’ model. Secondly, legal comparison can lead to a better understanding of global business activities and better cooperation between international trading partners. As will be demonstrated in this thesis (Chapters 5, 6 and 7), compulsory licensing in the developing world has always provoked political responses from the developed countries and prompted retaliation from the patent holding companies. It sometimes affects the partnership between Western pharmaceutical corporations and domestic companies. This thesis is hence of benefit to interested parties and stakeholders as it presents a ‘menu of choices’ of how to act accordingly or how to mitigate the conflict arisen in a compulsory licensing situation. Finally, this work does not only determine the similarities and differences of India, Brazil and Thailand, but also highlights the underpinnings for such

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In fact, it should be noted that there are various TRIPS flexibilities dealing with access to medicines such as exhaustion of rights, patentability criteria, research exception, transition period.... However, compulsory licensing is considered as the most effective measure, thereby has been widely used by developing countries. See Ellen FM ‘t Hoen *et al.*, ‘Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016’ (2018) 96 Bulletin WHO 185, 186. See also Mohammed El Said and Amy Kapczynski, ‘Access to Medicines: the Role of Intellectual property Law and Policy’ (2012) Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law 6 <<https://hivlawcommission.org/report-resources/working-papers/>> accessed 5 July 2018.

diversity. It is argued that only by comprehending the fundamental legal and political processes taking place within each case study can the policy-makers formulate a specific framework and coherent policy, which can cater for their country's individual situation. In this way, the legislators, through law reform, can suggest a suitable use of compulsory licensing to address a single goal, or set of goals, that they wish to pursue.

Present international discussions take place within the context of the TRIPS Agreement provisions relating to the patentability of medicines. This multilateral agreement, which came into force in 1995, imposes on all signatories to provide patent protection for pharmaceutical products and processes for a minimum of 20 years, regardless of the level of development of each member state. TRIPS sets a minimum harmonisation in the field of IP law since it provides the lowest standards for IP protection, which can be exercised differently in national legislation.<sup>6</sup> As a result, TRIPS has been a milestone in the history of international patent law. It is the most far-reaching and comprehensive IP treaty ever to be adopted, and the one that has exerted the greatest influence on national laws. The TRIPS Agreement therefore forms my primary research component.

However, there are other international agreements, apart from TRIPS, that feature prominently in this work. These are the Paris Convention<sup>7</sup> and the Doha Declaration.<sup>8</sup> Since the Paris Convention was the first international treaty to contain compulsory licensing provisions (and other IP matters), and the Doha Declaration tackled directly this legal mechanism within the TRIPS context, their treatment in this thesis is inevitable.

Particularly, debates over medicine patents and public health are critical because prior to TRIPS, more than 50 countries, including developed nations like Portugal and Spain, as well as developing countries, such as India, Brazil, and Thailand had excluded pharmaceutical products from patent protection.<sup>9</sup> Suddenly, under TRIPS, the patenting of medicines was made mandatory in all WTO member states.<sup>10</sup> Developed countries, where the majority of

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<sup>6</sup> TRIPS, art 1.

<sup>7</sup> The Paris Convention for the Protection of Industrial Property adopted in Paris on 20 March 1883 (hereinafter: the Paris Convention).

<sup>8</sup> Declaration on the TRIPS agreement and public health (14 November 2001) WT/MIN(01)/DEC/2 ((hereinafter: the Doha Declaration)

<sup>9</sup> WHO, 'The TRIPS Agreement and Pharmaceuticals. Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals' (Jakarta, 2 - 4 May 2000) 11

<<http://apps.who.int/medicinedocs/en/d/Jh1459e/5.3.html>> accessed 13 February 2018.

<sup>10</sup> This issue will be fully discussed later in Section 3.3.

pharmaceutical companies<sup>11</sup> are headquartered, are considered to reap all the benefits of TRIPS, whereas developing nations, as being portrayed as the net IP consumers, likely have their health policies adversely affected. The ‘one-size-fits-all’ policy of TRIPS patenting has, therefore, been harshly criticized.<sup>12</sup>

Against the backdrop of a globalised patent regime under TRIPS, many developing countries including India, Brazil, and Thailand constantly challenge this system through compulsory licensing – a simple but very controversial concept. It should be emphasised that the term ‘compulsory licence’ has neither appeared under the patent section of TRIPS, but the term is used in the trademark section instead.<sup>13</sup> Nevertheless, it is generally accepted that Article 31 contained in the patent section, ‘Other use without authorization of the right holder’,<sup>14</sup> has traditionally referred to this phenomenon.<sup>15</sup> A full account of this Article will be discussed in detail in Section 4.2.1.

## 1.2 Setting the scene

### 1.2.1 The theory of the patent system

The term ‘patent’, or ‘letters patent’, is derived from the Latin ‘litterae patentes’, meaning official documents by which certain rights, privileges, ranks, or titles are conferred.<sup>16</sup> The word ‘patent’, as an adjective, means ‘open’ which indicates that such letters were open to the public

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<sup>11</sup> The pharmaceuticals industry is composed of a varied range of companies, small and medium-sized enterprises as well as giant international corporations. They differ hugely in size, spheres of operation, research interests and in many other ways. The central focus of this thesis is on the pharmaceutical innovators that lead the industry and have a substantial impact on the sector, rather than on the medium and small enterprises. Therefore, the term ‘pharmaceutical companies’ or similar words refers only to well-known companies, for example Bayer, Roche, GSK, Pfizer, Abbott, Novartis, AstraZeneca, and BMS... They are loosely defined as research-based companies.

<sup>12</sup> Susan K. Sell, *Private Power, Public Law – The Globalization of Intellectual Property* (CUP 2003) 13; Frederick M. Abbott, ‘Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines’ in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (CUP 2005) 393, 408–10; Uché Ewelukwa, ‘Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade’ (2005) 59 University of Miami Law Review 203, 215; Riadh Quadi, ‘Patent Stalemate? The WTO’s Essential Medicines Impasse Between Pharmas and Least Developed Countries’ (2009) 61 Rutgers Law Review 437, 450.

<sup>13</sup> TRIPS, art 21.

<sup>14</sup> TRIPS, art 31, footnote 7: “Other use” refers to use other than that allowed under Article 30.

<sup>15</sup> Jacques J. Gorlin, *An Analysis of The Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement* (IP Institute 1999) 36; UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 460; Feldman Jamie, ‘Compulsory Licenses: The Dangers Behind the Current Practice’ (2009) 8 Journal of International Business and Law, 137; Jerome H. Reichman, ‘Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) 37 Journal of Law, Medicine and Ethics 247; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 492; Carlos M. Correa, ‘Patent rights’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade. The TRIPS Agreement* (3<sup>rd</sup> edn, Wolters Kluwer 2016) 292.

<sup>16</sup> Fritz Machlup, *An Economic Review of the Patent System* (US government printing office 1958) 1.

(as opposed to sealed closed documents – ‘litterae clausae’).<sup>17</sup> Letters patent can be patents of appointment, patents of nobility, patents of precedence, patents of land conveyance, patents of monopoly, or, patents of invention, the current subject of this work.<sup>18</sup>

According to a WIPO definition, a patent is a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent.<sup>19</sup> To put it simply, a patent permits its owner to exclude third parties, for a specified number of years, from making commercial use of a clearly identified invention. Patent rights are therefore regarded as negative rights to stop others from performing certain acts in relation to the patentee’s invention, rather than positive rights describing duties regarding the invention.

Such exclusivity encapsulated in a patent, on the one hand, generally constitutes an indispensable incentive for continuous innovation in the pharmaceutical industry, where the development of a new medicine is costly,<sup>20</sup> but where imitation is relatively easy and cheap.<sup>21</sup> On the other hand, patents, unlike other forms of IPR, such as copyrights and (possibly) trademarks which are harmless to public health, are likely to threaten human welfare when absolute rights are misused. The government-bestowed monopoly, embodied in a patented medicine, permits the rightful owner to drive other competitors out of a particular market, making him the sole supplier of that product for a period of time. In some extreme forms, the abuse of patent rights might lead to scarcity or exorbitant prices, posing a latent danger to the whole society. The interface between patent protection and pharmaceuticals will be explored in detail in Chapter 3. It is worth mentioning at the outset, however, that there is a cross-over between these two elements, and this has sown the seed of current debates.

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<sup>17</sup> William Blackstone, *Commentaries on the Laws of England* (1768) 316 – 317.

<sup>18</sup> Fritz Machlup, *An Economic Review of the Patent System* (US government printing office 1958) 1.

<sup>19</sup> WIPO, *Intellectual Property Handbook: Policy, Law and Use* (2<sup>nd</sup> edn, WIPO 2004), 17. Throughout this thesis, the following terms, ‘patent rights’, ‘exclusive rights’ and ‘monopoly right’ are used interchangeably.

<sup>20</sup> The cost to make a new drug is claimed up to \$1, 395 billion in 2016. Joseph A. DiMasi *et al.*, ‘Innovation in the pharmaceutical industry: New Estimate of R&D cost’ (2016) 47 Journal of Health Economics 20.

<sup>21</sup> According to Forbes, the cost of a generic drug is 80 to 85% lower than the brand name (patented) product. See ‘Why Are Generic Drug Prices Shooting Up?’ (Forbes, 27 February 2015)

<<https://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/#6ad940833877>> accessed 13 December 2017.

Because of the exclusivity, the patent system, since its inception, has been criticised for hindering free trade, causing more losses than profits to society, and barring a person's use of his own idea just because some other person has patented the related invention first.<sup>22</sup> At certain times in the past, patents were under threat of abolition, as will be seen in Section 3.1.1. Even though, with the implementation of TRIPS, a worldwide patent regime came into force, the spectre of abolition still lingers.<sup>23</sup> It is not the purpose of this chapter to debate the economic or political value of the patent system, because currently it is simply a matter of fact that most countries have some sort of patent law so as to comply with their TRIPS obligations.

It is frequently argued that a patent owner, being the only supplier, can manipulate the market by setting an unreasonably high price for their patented products, compared to the price level in a competitive market. Such price gouging poses a serious threat to consumers, particularly with regard to health-related goods. So, what purposes does patent law serve? Although a number of different justifications exist, this thesis will briefly sketch the four most popular theories: the natural law (moral rights) theory; the contract theory (disclosure); the reward theory; and the incentive theory.<sup>24</sup> These theories have coexisted side by side and are mutually inclusive.

### **Natural law/moral rights theory**

John Locke is considered to be the father of the natural law theory, in which inventions are regarded as products of mental labour.<sup>25</sup> In Locke's view, patents (and other IPRs) should be entitled to the same level of protection as tangible properties; patentees can enjoy and reap the entire benefits from their rights. Patents should be protected from theft and patent rights should not be limited in duration.<sup>26</sup>

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<sup>22</sup> Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 *The Journal of Economic History* 14.

<sup>23</sup> James Love, 'The Role of Prizes in Stimulating R&D' (KEI, Comment to WHO IGWG, 30 September 2007) <[http://www.who.int/phi/public\\_hearings/second/contributions\\_section2/en/](http://www.who.int/phi/public_hearings/second/contributions_section2/en/)> accessed 8 March 2018; Midjohodo Franck Gloglo, 'Legislative Comment: Pharmaceutical Patent Controversy Rises with Senator Bernard Sanders's Proposed Bill' (2013) 35 EIPR 527.

<sup>24</sup> Fritz Machlup, *An Economic Review of the Patent System* (US government printing office 1958) 21.

<sup>25</sup> Pia Weiss, *Patent Policy: Legal-economic Effects in a National and International Framework* (Routledge 2010) 22.

<sup>26</sup> *Ibid.*

### **The contract theory**

The contract theory looks upon patents as a social contract between the inventor and the society. This view, which derives from the French philosopher, Jean Jacques Rousseau, was later adapted to the patent system by two French economists - De-Bouffler and Louis Wolowski.<sup>27</sup> According to this theory, the government offers the patentee the price of a patent term in return for his disclosure of the new knowledge embodied in the creative object.<sup>28</sup> The theory asserts that disclosure is a central prerequisite for the grant of a patent; otherwise the inventor would be likely to keep his invention secret, instead of sharing it with the public.<sup>29</sup>

### **The reward theory**

The reward theory considers a patent as a reward for the inventor's time, effort, money, and even risk involved in discovering an invention. This philosophy stems from the utilitarianism theory of Jeremy Bentham, who strongly emphasised the necessity of IPRs as a precondition for innovation and creativity to flourish.<sup>30</sup> The theory concluded that the absence of a strong IP protection would lead to a decrease in inventive activities. Social welfare would thus be affected: no new products/processes would be manufactured and the access to human knowledge would be curtailed.

### **The incentive theory**

To the pharmaceuticals sector, the incentive theory stands as the most compelling justification. Like the reward theory, the incentive justification believes that patents incentivise innovation and invention. However, while the reward philosophy is a retrospective approach, the incentive theory is a forward-looking one. If the former awards the inventors for the time and effort that the inventor has invested in the past, the latter treats patents as an engine to encourage the owner to be more creative in the future.<sup>31</sup> Due to the special nature of R&D pharmaceutical activities, which will be described in section 3.4, the patent mechanism, in the industry's view, is the determinant factor in the existence of new drugs: 'without patents there would be far

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<sup>27</sup> Meir Perez Pugatch, 'Introduction: Debating IPRs' in Meir Perez Pugatch (ed), *The intellectual property debate: perspectives from law, economics and political economy* (EE 2006) 4.

<sup>28</sup> Hector MacQueen *et al.*, *Contemporary Intellectual Property: Law and Policy* (2<sup>nd</sup> edn, OUP 2011) 377.

<sup>29</sup> David I. Bainbridge, *Intellectual Property* (9<sup>th</sup> edn, Pearson Education Limited 2012) 389.

<sup>30</sup> Pia Weiss, *Patent Policy: Legal-economic Effects in a National and International Framework* (Routledge 2010) 24.

<sup>31</sup> David I. Bainbridge, *Intellectual Property* (9<sup>th</sup> edn, Pearson Education Limited 2012) 396.

fewer drugs around for people to access. One cannot have access to something that does not exist'.<sup>32</sup>

### 1.2.2 Compulsory licensing

If patents are generally accepted as a means to encourage inventions thanks to the monopoly given to the right owners, compulsory licensing is viewed as a limitation to patent rights. Traditionally, a compulsory licence is a remedy issued by a court (or a patent office), based on the request of a non-IPR holder, that allow him to exploit the protected technology, regardless of the consent of the right holder.<sup>33</sup> In other words, by the grant of such a licence, a private competitor can enter a particular market which is being monopolised by a patent owner before. *Magill*,<sup>34</sup> *Microsoft*,<sup>35</sup> or *IMS Health*<sup>36</sup> are such examples.

However, within contemporary debates, compulsory licensing is often used as an umbrella term for many types of non-voluntary authorization by the State (or by some part of the State's machinery) to exercise a patentee's rights without the latter's authorisation, in the form, for example, of ex officio licences, government use, crown (or government) use, licences to remedy anti-competitive practices, mandatory licences, and statutory licences.<sup>37</sup>

In contrast to voluntary licences, where the patent owner is willing to trade his invention with a prospective licensee in exchange for a royalty agreed by two parties, in the compulsory licence, the owner is forced to hand over his patent in exchange for a fixed royalty, settled by competent authorities. Needless to say, although the right holder is compensated for sharing his monopoly, such compensation is likely to be far less than the amount he could obtain in a free market. For this reason, a compulsory licence is described as 'an involuntary contract between a willing buyer and an unwilling seller, imposed and enforced by the state'.<sup>38</sup>

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<sup>32</sup> Martin J. Adelman, 'Compulsory Licensing of Drugs: TRIPS Context' (ATRIP Annual Meeting, Tokyo, 4 August 2003).

<sup>33</sup> Charlotte Waelde *et al.*, *Contemporary Intellectual Property. Law and Policy* (4<sup>th</sup> edn OUP 2016) 461; Paul Torremans, *Intellectual Property Law* (8<sup>th</sup> edn, OUP 2016) 115 – 117.

<sup>34</sup> Joined cases C-241/91 P and C-242/91 P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities*, ECR [1995] I-00743.

<sup>35</sup> Case T-201/04 *Microsoft Corp. v Commission*, ECR [2007] II-3601.

<sup>36</sup> Case C-418/01 *IMS Health GmbH and Co. OHG v NDC Health GmbH and Co. KG* [2004] ECR I-05039.

<sup>37</sup> Coenraad Visser, 'Patent Exceptions and Limitations in the Health Context' (WIPO, 2 September 2010) SCP/15/3 Annex V, 10.

<sup>38</sup> Gianna Julian-Arnold, 'International Compulsory Licensing: The Rationales and the Reality' (1993) 22 The Journal of Law and Technology 349, 349 (quoting P. Gorecky, 'Regulating the Price of Prescription Drugs in

However, it is worth noting that a compulsory licence does not entirely deprive the owner of his patent rights but modifies such rights instead. By the issue of a non-voluntary licence, the patent exclusivity is transformed into a shared privilege. The right owner is no longer the only exploiter on a particular market, he now has to share the market with the licensee. While a compulsory licence does not significantly alter the legal rights of a patent, it, nevertheless, impairs the economic value. The degree to which such damage occurs depends considerably on a number of factors. The type of the industry and the product, the category of the patent, the technology used to manufacture the patented article, the stage when the licensee enters the market, or the compensation... can attribute towards economic loss of the rightful owner. This is another research area but falls outside the scope of this thesis.

### **1.2.3 Access to medicines and compulsory licensing in developing countries**

According to the UN, ‘access to medicines’ is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population.<sup>39</sup> Similarly, the WHO defined access to medicines in four distinct factors: availability, affordability, accessibility and acceptability.<sup>40</sup> It is clear from these definitions that ‘access to medicines’ is not a one-dimensional issue related to price, but one that encompasses multiple factors.

Accordingly, the reasons for the lack of access can be attributed to these factors individually or collectively. Nevertheless, there is no global evidence that specifies a proportionate contribution of each factor to the issue.<sup>41</sup> In many cases, however, high prices are seen as a key barrier to the required treatment and, at the international level, the debate has overwhelmingly focused on unaffordability as the result of strong patent protection under TRIPS.<sup>42</sup>

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Canada: Compulsory licensing, Product Selection, and Government Reimbursement Programmes’ - Economic Council of Canada, 1981).

<sup>39</sup> United Nations Development Group, *Indicators for Monitoring the Millennium Development Goals* (UN 2003) 89.

<sup>40</sup> Martha Embrey, ‘Towards Sustainable Access to Medicines’ in *MDS-3: Managing Access to Medicines and Health Technologies* (Management Sciences for Health 2012) 1.8.

<sup>41</sup> Erdem Erginol, ‘European Commission Activities on Access to Medicines at the Global Level’ (EC, Global Health Policy Forum, 20 March 2014) 10

<[https://ec.europa.eu/health/international\\_cooperation/events/ev\\_20140320\\_en](https://ec.europa.eu/health/international_cooperation/events/ev_20140320_en)> accessed 16 March 2018.

<sup>42</sup> UK Commission on IPRs, ‘Integrating Intellectual Property Rights and Development Policy’ (2002) <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018; F.M. Scherer and Jayashree Watal, ‘Post-TRIPS Options for Access to Patented Medicines in Developing Countries’ (2002) 5

In developing countries where the healthcare infrastructure is poor, and the insurance system is inadequate, the compulsory licence is therefore an effective tool, allowing the market entry of generics,<sup>43</sup> which are more affordable to patients. As a result, the grants of such licences have occurred predominantly in a specialised field (medicines) in the Southern hemisphere, whereas the patent holding companies are located in the Northern hemisphere.<sup>44</sup>

Until the year 2012, the actual occurrence of compulsory licensing in the world, within the TRIPS context, was propelled by the need of a public authority, and *not* a private party, to ameliorate a national health problem. The majority of country users are middle-income economies, featured as developing countries, in which Brazil and Thailand are the most active using nations.<sup>45</sup> The year 2012 marked a turning point when in March, the Indian Controller of Patents granted a compulsory licence to an Indian *private* company to manufacture a patented medicine owned by Bayer.<sup>46</sup>

Recently, there has been a call for the increasingly routine use of compulsory licences for the market entry of generics in the developing world.<sup>47</sup> A number of developing countries, for

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Journal of International Economic Law 913; Susan K. Sell, ‘TRIPS and the Access to Medicines Campaign’ (2002) 20 Wisconsin International Law Journal 481; Ellen F.M. ‘t Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’ in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 42; Amir H. Khoury, ‘The “public health” of the Conventional International Patent Regime and the Ethics of “ethical”: Access to Patented Medicines’ (2008) 26 Cardozo Arts and Entertainment Law Journal 25; E. Richard Gold *et al.*, ‘Are Patents Impeding Medical Care and Innovation?’ (2009) 7 PLoS Medicine 1; Alexandra Cameron *et al.*, ‘Medicine Prices, Availability and Affordability’ in *The World Medicines Situation 2011* (3<sup>rd</sup> edn, WHO 2011) 1 <[http://www.who.int/medicines/areas/policy/world\\_medicines\\_situation/en/](http://www.who.int/medicines/areas/policy/world_medicines_situation/en/)> accessed 5 March 2018; Anand Grover *et al.*, ‘Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability under the Right to Health’ (2012) 40 Journal of Law, Medicines and Ethics 234; Ping Xiong, *An Interpretation of the TRIPS Agreement in Relation to the Right to Health* (Martinus nijhoff Publishers 2012); Saeed Ahmadiani and Shekoufeh Nikfar, ‘Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective’ (2016) 24 DARU Journal of Pharmaceutical Sciences 1.

<sup>43</sup> Generic drugs, which are reverse-engineered based on the original medicines, are named after the active ingredients given by an expert committee and accepted internationally. For example, Paracetamol is an active ingredient of many painkillers that exist under the brand name of Panadol and under the generic name of Acetaminophen or Paracetamol. In the past, generic drugs were produced by the generic drug companies only. However, nowadays they are also manufactured by research-based pharmaceutical companies. For example, an American-based company, Pfizer, owns a brand name medicine to treat cholesterol, Lipitor, and also a generic drug division named Greenstone. However, in this thesis, use of the words ‘**generic manufacturer**’ or some similar terms, is limited to the description of companies whose main activity is the manufacture of drugs developed by others.

<sup>44</sup> The world’s largest pharmaceutical companies have their headquarters mostly in Europe or the US: AstraZeneca (the UK), GSK (the UK), Bayer (Germany), Novartis (Switzerland), Roche (Switzerland), Sanofi (France), Merck (the US), Abbott (the US), Pfizer (the US), BMS (the US).

<sup>45</sup> Reed Beall and Randall Kuhn, ‘Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis’ (2012) 9 PLoS Medicine 1, 3.

<sup>46</sup> *Natco Pharma Limited v. Bayer Corporation* (Controller of Patents, 2012).

<sup>47</sup> UN, ‘High-level Panel on Access to Medicines’ (Report, September 2016) <<http://www.unsgaccessmeds.org/final-report/>> accessed 16 March 2018; Ellen F M ‘t Hoen ‘Indian hepatitis C

example, Chile (2017)<sup>48</sup> and Peru (2017),<sup>49</sup> are seeking the government use of compulsory licences to import or manufacture patented medicines to supply their own citizens. In the most recent move, Malaysia announced a compulsory licence in September 2017 for a patented medicine treating hepatitis C.<sup>50</sup> One consequence of such practices is that developing countries have become a compelling subject for IP-based research in relation to access to medicines. These countries have utilised compulsory licences to make up for the losses incurred by their agreement to the extension of patents to medicines in the conclusion of TRIPS. (The history of drafting TRIPS will be described in Section 3.2.)

However, it is very surprising to observe that the compulsory licensing practice has recently emerged in Europe and Russia. For example, in 2017 and 2018, a number of European countries such as Ireland,<sup>51</sup> the Netherlands,<sup>52</sup> Switzerland,<sup>53</sup> the UK (Scotland)<sup>54</sup> considered this option to make medicine price more affordable to their citizens, even though none of these proposals was supported by their respective governments. In contrast, both Germany (2017)<sup>55</sup> and Russia

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drug patent decision shakes public health community' (2016) 387 *The Lancet* 2272; MSF, 'MSF challenges patent on key hepatitis C drug' (27 March 2017) <<https://www.msf.org.uk/article/msf-challenges-patent-key-hepatitis-c-drug>> accessed 13 December 2017; Ellen FM 't Hoen *et al.*, 'Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 *Bulletin WHO* 185.

<sup>48</sup> Chile's Resolution No.798, Session 120 dated 25 January 2017 (in Spanish); Kim Treanor, 'Resolution On Compulsory Licences For Patented Medicines Passes In Chile' (IP Watch 1 February 2017) <<https://www.ip-watch.org/2017/02/01/resolution-compulsory-licences-patented-medicines-passes-chile/>> accessed 16 August 2017.

<sup>49</sup> Ed Silverman 'Peruvian lawmakers seek a compulsory license for a Bristol HIV drug' (Statnews 26 May 2017) <<https://www.statnews.com/pharmalot/2017/05/26/peru-compulsory-license-bristol-drug/>> accessed 16 August 2017.

<sup>50</sup> Malaysia's Minister of Health, 'Implementation of the Rights of Government for Sofosbuvir Tablet to Increase Access for Hepatitis C Treatment in Malaysia' (Press Statement, 20 September 2017) <<https://kpkesihatan.com/2017/09/20/press-statement-minister-of-health-20th-september-2017-implementation-of-the-rights-of-government-for-sofosbuvir-tablet-to-increase-access-for-hepatitis-c-treatment-in-malaysia/>> accessed 10 April 2018.

<sup>51</sup> General Motions 2017, Session 2 (Irish Medical Organisation, 21 April 2017) <<https://www.imo.ie/news-media/agm/agm-2017/motions/general-motions-2017/>> accessed 2 May 2018.

<sup>52</sup> The Netherlands's Council for Public Health and Society, 'Development of new medicines. Better, faster, cheaper' (The Hague, 2017) 30 – 31 <<https://www.raadrvs.nl/en/item/development-of-new-medicines.-better-faster-cheaper>> accessed 1 April 2018.

<sup>53</sup> Public Eye, 'Public Eye calls on Swiss Federal Council to use compulsory licensing against exorbitant drug prices' (22 May 2018) <[https://www.publiceye.ch/en/media/press-release/public\\_eye\\_calls\\_on\\_swiss\\_federal\\_council\\_to\\_use\\_compulsory\\_licensing\\_against\\_exorbitant\\_drug\\_prices/](https://www.publiceye.ch/en/media/press-release/public_eye_calls_on_swiss_federal_council_to_use_compulsory_licensing_against_exorbitant_drug_prices/)> accessed 9 June 2018.

<sup>54</sup> Nick Paul Taylor, 'EU Regulatory Roundup: Scottish Government Dismisses Talk of Compulsory Licensing of Roche Cancer Drug' (Raps, 7 June 2018) <<https://www.raps.org/news-and-articles/news-articles/2018/6/eu-regulatory-roundup-scottish-government-dismiss>> accessed 17 June 2018.

<sup>55</sup> BGH, Urteil vom 17.07.2017 - AZ: X ZB 2/17.

(2018),<sup>56</sup> for the first time ever in their patent law history, granted a compulsory licence on the ground of public interest. It is to suggest that this is a new phenomenon but has gained general currency in the industrialised world. Although developed countries are not the research subjects to this thesis, the author will touch upon this recent development in the EU in Section 9.1.

### **1.2.4 Compulsory licensing vs. Patent: Beauty and the Beast?**

A compulsory licence can be given for any kind of IP, and there is no doubt that it is frequently used in the copyright domain.<sup>57</sup> In no other field, however, has it been more debated, contextualized and disputed than in the case of pharmaceutical patents.<sup>58</sup> On the one hand, patents are the strongest IPR, compared with others such as copyrights, trademarks, to protect medicines adequately. On the other hand, medicines are fundamentally important to human lives, to which anyone must have the access regardless of his or her financial situation. For this reason, while compulsory licensing is viewed as a patent enemy, it is hailed as a magic tool to bring drugs more affordable.

Since TRIPS came into effect, pharmaceuticals are patented globally. Where can people find generics? Firstly, generics can be produced in jurisdictions where pharmaceuticals are not subject to patents. (However, since almost the entire world now is a part of the WTO, this option is not feasible.<sup>59</sup>) Secondly, generics can only be made after the patents expire. In such cases, if the society needs an immediate medical intervention, compulsory licensing appeals as a good remedy to achieve that end.

The argument supporting this legal device is that patent protection has caused higher medicine prices and has therefore impeded access to drugs. With the issue of such licences, the patent barrier to a life-saving medicine is virtually removed because governments can authorise the

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<sup>56</sup> Russian Court provides first compulsory license for production of a US drug' (The Pharma letter 15 June 2018) <<https://www.thepharmaletter.com/article/russian-court-provides-first-compulsory-license-for-production-of-us-a-drug>> accessed 2 July 2018.

<sup>57</sup> Joined cases C-241/91 P and C-242/91 P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities*, ECR [1995] I-00743; Case T-201/04 *Microsoft Corp. v Commission*, ECR [2007] II-3601; Case C-418/01 *IMS Health GmbH and Co. OHG v NDC Health GmbH and Co. KG* [2004] ECR I-05039.

<sup>58</sup> Padmanabha Ramanujam and Yugank Goyal, 'One View of Compulsory Licensing: Comparative Perspectives from India and Canada' (2014) 18 Marquette Intellectual Property Law Review 369, 378; Chang-fa Lo, 'Compulsory licensing. Threats, Use and Recent Trends' in Bryan Mercurio and Daria Kim (eds), *Contemporary Issues in Pharmaceutical Patent Law. Setting the Framework and Exploring Policy Options* (Routledge 2017) 147.

<sup>59</sup> As of 29 July 2016, the WTO has 164 members and 22 observer governments. See WTO, 'Members and Observers' <[https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm)> accessed 9 May 2018.

production of essential drugs at no cost or at a cost affordable to poor consumers, thereby bringing more patients into treatment. Compulsory licensing is used more frequently for pharmaceuticals than for any other type of products to address the public health crisis in the Third World.

On the other hand, the pharmaceutical industry has in mind the vital role of patents, to which compulsory licensing constitutes a derogation of exclusivity. It argued that without strong patent protection, it would be unable to recoup the substantial investment involved in developing new medicines.<sup>60</sup> There exists a belief that a broad compulsory licensing regime, which is synonymous with weak patent protection, could put pharmaceutical companies at risk.<sup>61</sup> (The nature of pharmaceuticals and the role of patents to the industry will be discussed in detail in Section 3.3.) The industry acknowledges that compulsory licensing is one of the flexibilities of TRIPS, but regards it as an option, not a solution. Therefore, it can only be issued under specific, exceptional circumstances. (However, the grounds upon which a compulsory licence can be sought will be discussed in detail in Section 4.2.2.)

Global debates over pro-and anti-compulsory patent licensing have been tense in recent years. This dichotomy manifests the conflict of interests between the North and the South during the writing of TRIPS, as well as the interface between patents and access to medicines when TRIPS entered the implementation phase. Whenever a compulsory patent licence is granted for a particular medicine, both the granting countries and the patent holders are involved in emotional and political public relations battles, where the former wins a pyrrhic victory and the latter is usually a loser. Nevertheless, Owen argues that while the access to medicine activities led to the increase of aid funding and the decrease of medicine prices, ‘the IP infrastructure is left largely intact’.<sup>62</sup> Therefore, while health activists seemed to achieve the ‘victory’ in the media, they ultimately lost the war.<sup>63</sup>

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<sup>60</sup> GSK, ‘Compulsory Licensing’ (Public policy positions, November 2017) <<https://www.gsk.com/en-gb/about-us/policies-codes-and-standards/#tab-6155>> accessed 6 February 2018; AstraZeneca, ‘Compulsory Licensing’ (Public Policy Issue, April 2016) <<https://www.astazeneca.com/content/dam/az/PDF/Public%20Policy%20Issue%20Compulsory%20Licensing.pdf>> accessed 23 March 2017.

<sup>61</sup> Richard P. Rozek and Renee L. Rainey, ‘Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy’ (2001) 4 *The Journal of World Intellectual Property* 463.

<sup>62</sup> Thomas Owen, ‘Patents, Pills, the Press and the Poor: Discourse and Hegemony in News Coverage of the Global ‘Access to medicines’ Dispute, 1997 – 2003’ (PhD thesis, Massey University 2012) 4.

<sup>63</sup> *Ibid.*

The cross between patent rights and patient rights leaves us to surmise whether compulsory licensing should be perceived as a ‘one-size-fits-all’ solution for public health issues in developing countries, and to consider, in cases where a compulsory licence is inevitable, how to limit the damage inflicted on both sides. The answer to these questions will be found in the final chapter of this work (Chapter 10).

### **1.3 Research questions and research structure**

This thesis will answer the following five research questions.

- Question No.1: How has patent law evolved within the international context? Why and to what extent do pharmaceuticals insist on the value of patents?**

This question will be answered in Chapter 3, which offers a study of the historical development and political conditions of the patent system from the earliest stage to the modern arena, with a great emphasis on TRIPS. Chapter 3 will go through a number of TRIPS provisions which relate to medicines in order to critically evaluate how the TRIPS Agreement has drastically overhauled the world’s pharmaceutical landscape. This chapter aims to provide an insight into the relationship between patent protection and the pharmaceutical industry by putting the two in a historical context. This chapter is important in shedding light on the reasons for the pharmaceutical companies’ unconcealed antipathy towards compulsory licensing.

- Question No.2: How has compulsory licensing developed within international patent law and to what extent has it affected pharmaceutical innovation?**

The answer to this question can be found in Chapter 4, which provides an in-depth analysis of compulsory licensing, following the linear fashion of Chapter 3. In this chapter, the negotiation history of Article 5(A) of the Paris Convention and Article 31 of TRIPS are studied in depth. A significant effort will be devoted to explaining Article 31, as it has laid the foundation for legal frameworks in national laws. Following Chapter 3 which examines the dependence of pharmaceuticals on patents, Chapter 4 will assess how the compulsory licence has affected R&D activities in the medicine sector.

- **Question No.3: How have three strategically selected countries of India, Brazil and Thailand, implemented a compulsory licence regime which caters for their own interests?**

This question will be answered in chapters devoted to each country respectively. Chapters 5, 6, and 7 investigate the domestic law and practice of India, Brazil and Thailand concerning compulsory licensing. In each country chapter, relevant provisions and their practice will be under close scrutiny. The author will not look into the whole compulsory licence regime in every jurisdiction, but will instead focus on potential grounds, upon which a non-voluntary licence for a medicine might be sought.

- **Question No.4: What are similarities and differences in the compulsory licensing regimes of India, Brazil and Thailand? Why is there such a variety?**

The answer to this question is largely found in Chapter 8, which provides a critical comparative analysis. In this chapter, the resemblances and variances of the law-in-words and the law-in-actions between the three countries will be underlined. Chapter 8 also explains why divergence as well as convergence exists among them. On the basis of these highlighted features, other developing countries can potentially learn from the legislation and experiences of the three said nations and possibly implement relevant changes in their own compulsory licensing systems.

- **Question No.5: What are the philosophical approaches of multilateral organisations in the debate on access to medicines in developing countries?**

Chapter 9 offers a critical analysis of multilateral organisations, namely, the EU, WIPO, the WHO and the NGOs. Understanding the intrinsic character of these actors will facilitate the development of a proper course of action to be undertaken of developing countries. Moreover, as will be mentioned later in the next section, compulsory licensing and access to medicines have progressed beyond the competence of TRIPS, and Chapter 9 aims to shed as much light as possible on the complex ideologies of the organisations named above.

Chapter 10 contains final conclusions and delivers answers to the proposed research questions. It also lists recommendations on how to make compulsory licences less damaging both to the patentee and to the grantee when they come to exist.<sup>64</sup>

## 1.4 Defining the scope

### 1.4.1 The geographical scope

The primary geographical scope of this research is developing countries, as explained in Section 1.2.3. It would certainly not be possible, in this doctoral thesis, to cover all the nations that have granted compulsory licences. For that reason, certain criteria for the choice of countries have been strategically chosen.

Firstly, as the focus of this thesis is the TRIPS Agreement under the auspices of the WTO, the selected country must be a WTO member. Secondly, the examined nation must have issued at least one compulsory licence in the field of pharmaceuticals under its patent law. Thirdly, as a matter of practicability, the relevant legislation and literature must be available in English, to a degree sufficient to allow in-depth research. Fourthly, the practice in these countries must have had a sizeable impact on global compulsory licensing activities. Using these criteria, India, Brazil and Thailand have been chosen by the author as case studies in this work.<sup>65</sup>

All three countries are considered to be rising economies. India and Brazil belong to the BRIC countries – a grouping acronym that refers to the countries of Brazil, Russia, India and China, which have been projected as the fastest growing market economies.<sup>66</sup> Regardless that this study was decried as dam lies and needed to be treated with caution,<sup>67</sup> BRICs are the most-watched power nowadays. Thailand, on the other hand, is a member of ASEAN, a major trading

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<sup>64</sup> Developing countries that issue compulsory licences or favour a flexible compulsory licensing system, usually face economic coercion from nations sponsoring patent holding companies and retaliation from the patent owners. This practice will be illustrated in Chapters 5 (India), 6 (Brazil), and 7 (Thailand).

<sup>65</sup> For the comparative purpose, detailed discussions of access to medicines and pharmaceutical patents in Arabic countries can be found in Mohammed El Said, ‘The Road from TRIPS-Minus to TRIPS to TRIPS-Plus: Implications of IPRs for the Arab World’ (2005) 8 *The Journal of World Intellectual Property* 53; Mohammed El Said, ‘The Implementation Paradox: Intellectual Property Regulation in the Arab World’ (2010) 9 *Journal of International Trade Law and Policy* 221; Mohammed El Said, ‘IP Policy and Regulation in the Arab World: Changes, Challenges and Opportunities’ in Frederick M. Abbott and others (eds), *Emerging Markets and the World Patent Order* (EE 2013) 329-349.

<sup>66</sup> Dominic Wilson and Roopa Purushothaman, ‘Dreaming with BRICs: The Path to 2050’ (Goldman Sachs 2003) <<http://www.goldmansachs.com/our-thinking/archive/brics-dream.html>> accessed 19 March 2018.

<sup>67</sup> Robert C. Bird and Daniel R. Cahoy, ‘The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement’ (2007) 3 *Northwestern Journal of Technology and Intellectual Property* 400, 401.

bloc in Asia with the economic size of almost \$2.6 trillion in 2016, making the bloc the 6<sup>th</sup> largest economy in global trade.<sup>68</sup>

It should be noted that India, Brazil and Thailand are seen by the pharmaceutical companies as trouble-makers. In 2012, India, an up-and-coming economic power in South Asia, granted a compulsory licence to Natco – a local company - to manufacture and sell a patented medicine, Nexavar.<sup>69</sup> This decision has captured the world's attention for an important reason as it was the first Indian compulsory licence since the reintroduction of patent protection for pharmaceuticals in the country's patent law in 2005, and also the world's first, post-TRIPS compulsory licence in the traditional sense, as mentioned in Section 1.2.2. Prior to Natco's grant, all compulsory licences were characterized as a governmental measure. The Nexava licence has therefore created a new category of market-initiated compulsory licences which, previously only existed in principle.<sup>70</sup>

Brazil, an emerging economy in Latin America was the first WTO member to start post-TRIPS compulsory licensing, which took place in 2001. Its activities were mainly in support of the country's anti-HIV/AIDS campaigns. Uniquely, Brazil employed compulsory licences as a strategic threat in price negotiations with pharmaceutical companies. Brazil's strategy, backed up by its local manufacturing capacity, bore fruit during the period 2001 – 2006, when certain pharmaceutical companies offered discounted prices to the country's government.<sup>71</sup> In 2007, when the threat was no longer credible, Brazil was unsuccessful in its attempts to get further reductions. As a result, the government granted a compulsory licence for the patented AIDS drug, Efavirenz, owned by Merck.<sup>72</sup> To date, this has been the only example of Brazil's use of compulsory licensing.

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<sup>68</sup> This number is calculated by the author, based on the GDP of ASEAN countries. See WB, 'Gross Domestic Product 2016' (World Development Indicators, 15 December 2017)

<<http://databank.worldbank.org/data/download/GDP.pdf>> accessed 5 March 2018.

<sup>69</sup> *Natco v. Bayer* (Controller of Patents, 2012).

<sup>70</sup> Feroz Ali, *The Access Regime: Patent Law Reforms for Affordable Medicines?* (OUP 2016) 134.

<sup>71</sup> For example, in 2001, Merck and Roche agreed to lower prices of some medicine prices by 59% and 40%, respectively. In 2003, they again offered price cuts. Abbott in 2003 and 2005 offered the discounted price at 13% and 46%. See Jennryn Wetzel, 'Timeline on Brazil's compulsory licensing' (American University, Program on Information Justice and Intellectual Property, 2008); Jennifer L. Rich, 'Roche Reaches Accord on Drug with Brazil' *New York Times* (1 September 2001) <<http://www.nytimes.com/2001/09/01/business/roche-reaches-accord-on-drug-with-brazil.html>> accessed 26 November 2015. See further at Chapter 6, Section 6.4.

<sup>72</sup> Brazil's Decree No. 6,108, of 4<sup>th</sup> May 2007 in relation to compulsory licensing for Efavirenz, for non-commercial public use.

Thailand, a growing but smaller market in South-East Asia, commenced government use licences in 2006, citing public health as a ground to justify its actions. The Thai government issued seven compulsory licences in two relatively short periods: November 2006 – January 2007 and January 2008.<sup>73</sup> In addition to the quantity, Thai use was controversial because Thailand was the first country to test this legal mechanism on medicines for the treatment of chronic diseases (cardiovascular diseases and cancers).<sup>74</sup> That contradicted the traditional belief that, compulsory licensing was confined only to drugs for infectious diseases<sup>75</sup> or epidemics such as HIV/AIDS. The controversy was further exacerbated by the fact that Thai government use licensing was initiated by a military-backed government that was regarded as illegitimate.

Given that the patent holders of the medicines subject to compulsory licences reside in the US or European countries,<sup>76</sup> and that this thesis lies at the interface between IP and access to medicines, it is impossible to totally exclude from this thesis other relevant, albeit non-developing, actors. The entities that fall outside the primary scope of the research are:

- The EU
- WIPO
- The WHO
- Health-related NGOs

These components are principally researched in Chapter 9. Certainly, there are other multilateral organisations which are also involved in the discussion such as the OECD and the WB. However, their participation is limited at advocacy purpose and offering guidance rather

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<sup>73</sup> The notifications of these compulsory licences are reprinted in the documents below:

- The Ministry of Public Health and the National Health Security Office Thailand, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand* (February 2007), hereinafter referred to as ‘the White Paper 2007’.
- The Ministry of Public Health and the National Health Security Office Thailand, *the 10 Burning Questions on the Government Use of Patents on the four anti-cancer drugs in Thailand* (February 2008), hereinafter referred to as ‘the White Paper 2008’.

<sup>74</sup> According to the WHO, chronic diseases, also known as Noncommunicable diseases (NCDs), are not passed from person to person. They are of long duration and generally slow progression. The four main types of NCDs are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes. WHO, ‘Noncommunicable diseases’ <[http://www.who.int/topics/noncommunicable\\_diseases/en/](http://www.who.int/topics/noncommunicable_diseases/en/)> accessed 30 October 2017.

<sup>75</sup> According to the WHO, infectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another. See WHO, ‘Infectious Diseases’ <[http://www.who.int/topics/infectious\\_diseases/en/](http://www.who.int/topics/infectious_diseases/en/)> accessed 21 March 2018.

<sup>76</sup> The patent owner in the Indian compulsory licences is Bayer Corporation, an American company. In the case of Thailand, they were Merck (the US), Abbott (the US), BMS (the US), Novartis (Switzerland), Roche (Switzerland) and Sanofi (France). In the example of Brazil, it was Merck.

than governing and shaping the IP global regime. For this reason, they are excluded from discussions in this thesis.

The EU (and Switzerland)<sup>77</sup> feature in this thesis because its stance has been more complex than first appears. In the first place, not only are they the proponents of a strong patent regime but also, they were closest allies of the US working towards the conclusion of TRIPS. However, the EU later quietly supported developing countries in the adoption of the Doha Declaration, the document which reaffirmed the freedom of WTO members to use compulsory licences. When developing countries issued or were about to issue such licences, the EU subtly expressed opposition. Interestingly, more recently, the voice calling for the possibility of granting compulsory licences to bring medicine prices cheaper for EU citizens has been getting louder on the continent. Accordingly, a better understanding of EU policies on this perspective is much needed.

The involvement of WIPO and the WHO is no less important, because they represent the competing interests of the patentee community (WIPO), and the affected individuals (WHO), two interconnected parties in this thesis. As observed by a commentator and as will be later demonstrated in this thesis, these two organisations have become the venues in which two opposing parties – patent advocates and health activists - all claim to score ‘victories’.<sup>78</sup> Their involvement further complicates the medicine access debates. Their roles, however, are largely overlooked in the available literature. In fact, the current debate on compulsory licensing is no longer the exclusive reserve of IP experts: health activists are also participating, as we shall see throughout this research. The juxtaposition of public interest and private rights, as well as a scarcity of topics on the WHO and WIPO, makes this an opportune time for the present research project.

The health-related NGOs are worth mentioning since they are influential stakeholders who encourage and support compulsory licence activities in Third World countries, and their role is substantially important for the setting of international IP norms. For example, they played an essential part in the adoption of the Doha Declaration by forming a coalition with developing

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<sup>77</sup> It is important to clarify here that Switzerland is a European country but not an EU member state. However, it is still a part of the single market. Switzerland and the EU are attached to each other through a series of bilateral agreements. Both are among each other's top destinations for foreign investment. Therefore, Switzerland features in this section because of its economic relationship with the EU.

<sup>78</sup> Susan K. Sell, ‘The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions’ (2004) 77 Temp. L. Rev. 363, 365.

countries,<sup>79</sup> as will be seen in Section 9.4. At the national level, thanks to their tireless efforts, nations like Thailand and Brazil stood firm against the pharmaceutical companies and the sponsoring countries and included compulsory licences in their policies for national health. Indeed, the role of NGOs in the current debates has gone beyond the service function to shaping global policies. Their activities are not necessarily limited to health advocacy but also extend to the political aspect.

### **1.4.2 The research scope**

Firstly, this thesis will address only the compulsory licence provision of Article 31 of TRIPS, *not* Article 31bis which is the new compulsory licensing system set up by the 2003 Decision of the WTO Council<sup>80</sup> and came into force on 23 January 2017.<sup>81</sup> TRIPS thus became the first WTO Agreement to be altered since the organisation establishment in 1995. The first reason is because some countries, for example, Brazil (Chapter 6) and Thailand (Chapter 7) have not incorporated the new article in their patent laws yet. The second reason is that, so far, only Rwanda announced the use of the new system on 19 July 2007.<sup>82</sup> Such a rarity in both theory and practice makes it difficult to enable an in-depth and comprehensive research on Article 31bis. A cross-study amongst WTO members cannot be conducted. The new regime is therefore not an analytical focus of this thesis. However, it will be summarised briefly in Section 4.3.3 so as to provide some analytical balance. It should be noted that Articles 31 and 31bis are two separate compulsory licensing regimes which exist side-by-side.

The reason for the new insertion is because Article 31(f) stipulates that products made under compulsory licensing must be predominantly supplied to the domestic market. This requirement was criticized for creating an export barrier, thereby weakening the power of compulsory licensing, and making this tool unworkable for the countries needing medicines but possessing little or no pharmaceutical production capacity. Therefore, Article 31bis

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<sup>79</sup> Peter Drahos, ‘Four lessons for developing countries from the trade negotiations over access to medicines’ (2007) 28 Liverpool Law Review 11.

<sup>80</sup> WTO General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health* (Decision of 30 August 2003) WT/L/540.

<sup>81</sup> ‘WTO IP rules amended to ease poor countries’ access to affordable medicines’ (23 January 2017) <[https://www.wto.org/english/news\\_e/news17\\_e/trip\\_23jan17\\_e.htm](https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm)> accessed 22 May 2017.

<sup>82</sup> Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health (Rwanda, IP/N/9/RWA/1, 19 July 2007).

removed such a barrier, facilitating the exportation to countries in need under certain conditions.

Secondly, despite the fact that there are many grounds for granting a compulsory licence, as will be seen later in Chapter 4, only two form the main discussion of this work: market-initiated and government use compulsory licences. The reason for their choice is that they provide the most essential avenues which introduce the market entry of generics. The market-induced licence is triggered by a private entity to address a gap in a specific pharmaceutical market as will be demonstrated in the chapter on India (Chapter 5). On the other hand, the government use licence, driven by the need to protect public health, is illustrated in the chapters on Brazil and Thailand (Chapters 6 and 7).

## 1.5 The originality

The originality of this thesis lies in the critical evaluation and comparison of the compulsory licensing regimes in India, Brazil, and Thailand. The laws of these countries are, for the first time, examined in a *systematic and interconnected* way to highlight the convergences and divergences between them as well as presenting the rationales behind their policies and practices. By investigating the compulsory licensing systems in the three aforementioned countries, this thesis submits that the legal mechanism of compulsory licensing is a tool to not only respond to public health but also promote industrial policies. The boundary between these two functions has become blurred, as will be seen in each individual country's chapter.

Another contribution of this work is to include the political dimension of the government use licence. This dimension is strongly present in the practice of Thailand, where such licences were granted by a *de facto* military-backed government. It also features in the case of Brazil, to a lesser degree, where compulsory licensing twice coincided with presidential elections in the country. The political element, by contrast, was insignificant in the context of India, in which the compulsory licence was commenced due to the market demand.

By drawing such a comparison, other developing countries, given their individual situations, can reflect on how to carve out the policies and whether to issue a compulsory licence in a particular situation. As indicated in Section 1.2.4, compulsory licensing for patented medicines has captured the world's attention over the past two decades. Consequently, a significant amount of work has been done on this topic, and India, Brazil, and Thailand have featured

prominently in the academic literature on this subject.<sup>83</sup> This thesis ‘leverages’ existing research on three country case studies so as to gain unique and novel insights on their compulsory licensing regimes. This research, however, is distinct from other research, for the following reasons.

Firstly, most of the relevant literature consists of either small-scale studies<sup>84</sup> or explores compulsory licensing in different research areas rather than law. For example, some PhD theses were carried out in the field population health,<sup>85</sup> social policy,<sup>86</sup> economic and policy studies,<sup>87</sup> or even communication and journalism.<sup>88</sup> Even where compulsory licensing was viewed under the eye of the law, it was approached from the precautionary principle borrowed from environmental law.<sup>89</sup> This doctoral thesis, however, places compulsory licensing at the centre of the legal analysis, scrutinizing it through a micro-lens. This thesis does not examine compulsory licensing as a component of a national health strategy, but as a separate legal element of patent law, and aims to assess deeply and critically the degree to which the countries have made use of TRIPS allowances.

Secondly, this work does not stop at scrutinising the relevant legal provisions. It also draws an important conclusion, which is that compulsory licensing is not a purely moral issue, as some

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<sup>83</sup> Robert C. Bird and Daniel R. Cahoy, ‘The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement’ (2007) 3 Northwestern Journal of Technology and Intellectual Property 400; James Packard Love, ‘Recent examples of the use of compulsory licenses on patents’ (KEI Research note 2007) <<https://www.keionline.org/book/publications-and-research-notes/kei-rn-2007-2-recent-examples-of-compulsory-licensing-of-patents>> accessed 16 March 2018; Peter K. Yu, ‘Access to Medicines, BRICS Alliances, and Collective Action’ (2008) 34 American Journal of Law and Medicines 345; Kristina M. Lybecker and Elisabeth Fowler, ‘Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules’ (2009) 37 Journal of Law, Medicine and Ethics 222; Beatrice Stirner, ‘Learning from Practice: Compulsory Licensing Cases and Access to Medicines’ (2012) 1 Pharmaceutical Patent Analyst 555; M. Monirul Azam, ‘The Experiences of TRIPS-compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh’ (2014) 7 Akron Intellectual Property Journal 61.

<sup>84</sup> Nathan Ford *et al.*, ‘Sustaining Access to Antiretroviral Therapy in Developing Countries: Lessons from Brazil and Thailand’ (2007) 21 AIDS 21; Thomas Eimer and Susanne Lütz, ‘Developmental States, civil society, and public health: Patent regulation for HIV/AIDS pharmaceuticals in India and Brazil’ (2010) 4 Regulation & Governance 135.

<sup>85</sup> Reed Beall, ‘What Is the International Landscape of Essential Medicine Patent Protection and How Can Developing Countries’ Medicine Access Be Accelerated Within It?’ (PhD thesis, University of Ottawa 2017), Chapter 5.

<sup>86</sup> Elize Massard da Fonseca, ‘Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil’ (PhD thesis, University of Edinburgh 2011).

<sup>87</sup> Eduardo Muniz Pereira Urias, ‘Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?’ (PhD thesis, University of Maastricht 2015).

<sup>88</sup> Thomas Owen, ‘Patents, Pills, the Press and the Poor: Discourse and Hegemony in News Coverage of the Global ‘Access to medicines’ Dispute, 1997 – 2003’ (PhD thesis, Massey University 2012).

<sup>89</sup> Phoebe Hung Li, ‘Revisiting Public Health Emergency in International Law: A Precautionary Approach’ (PhD thesis, University of Edinburgh 2012).

claim.<sup>90</sup> Compulsory licensing can also be a potent weapon to encourage industrial development. This is apparent in the case of India (Chapter 5) and is subtler in the examples of Brazil (Chapter 6) and Thailand (Chapter 7). Moreover, it can be used as a populist tactic to gain public support, as will be clearly demonstrated in the use of Brazil and Thailand.

Thirdly, this thesis submits that whatever the scenario is, a well-managed compulsory licensing system is necessary because the mere presence of such a system in national law can affect the dynamic bargaining between the patent holder and the prospective licensee/granting government. However, while various grounds for compulsory licences have attracted extensive study, the procedure of granting such a licence in domestic laws has been mostly ignored. Consequently, this aspect will be examined in considerable detail. This author argues further that, if a country's legal actions are consonant with international obligations, that country will have the advantage of a firm foundation for its claims when it is involved in any international legal dispute.

Fourthly, despite an extensive literature on compulsory licensing in India, Brazil and Thailand, comparison of their regimes has been limited. Research on these countries has been conducted mainly in the form of individual case studies,<sup>91</sup> or with others.<sup>92</sup> Even when the three were

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<sup>90</sup> Ellen 't Hoen and Jorge Bermudez, "Compulsory Licenses for Medicines" (2015) 34 *Health Affairs* 1068; Ellen F.M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers 2009); Beatrice Stirner, 'Learning from Practice: Compulsory Licensing Cases and Access to Medicines' (2012) 1 *Pharmaceutical Patent Analyst* 555; Letter of UNAIDS to the Thai Minister of Health (26<sup>th</sup> December 2006) and Letter of Medicines Sans Frontières (Doctors Without Borders) to the Ambassador Susan Schwab, USTR (29 December 2006) in White Paper 2007, *supra* note 73.

<sup>91</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 *University of Pittsburgh Law Review* 491; Amy Kapczynsky, 'Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 *California Law Review* 1571; J. Kuanpoch, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (EE 2010); Jiraporn Limpananont and Kannikar Kijtiwatchakul, 'TRIPS Flexibilities in Thailand: Between Law and Politics' in Gaëlle Krikorian and Amy Kapczynski (eds) *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010); Samira Guennif, 'Access to essential drugs in Thailand: Intellectual property rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen *et al.* (eds) *Intellectual property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries* (EE 2011); Elize Massard da Fonseca, 'Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil' (PhD thesis, University of Edinburgh 2011); V.K. Unni, 'Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Contest of Public Policy and Health' (2012) 25 *Global Business and Development Law Journal* 323; Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015); Viviane Yumy Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft, 2015).

<sup>92</sup> Brenda Pamela Mey, *The Legal Duel: The TRIPS Agreement and Drug Access Issues. Is the Agreement Actually the Cunning Manoeuvre it has been dubbed? Kenya-India Case Studies* (Peter Lang 2013); Jennifer Sellin, *Access to Medicines: The interface between patents and human rights. Does one size fit all?* (Intersentia 2014).

studied together, less attention has been paid to the law or the critical comparison has not been dealt with in depth.<sup>93</sup> This work will therefore critically evaluate these three important WTO members *inter se*, where the emphasis is on the law of compulsory licensing, so as to produce a more comprehensive picture. India, Brazil and Thailand carry a degree of resemblances (emerging economies and having a certain degree of innovation) and distinctiveness (politics, health policies and trading strategy) at the same time. The author therefore argues that the interconnection of three distinct compulsory licensing regimes of the developing world enables a critical assessment of their commonalities and divergences.

Fifthly, this thesis will focus on certain aspects of these countries' compulsory licensing which have been largely ignored by existing literature. For example, the author will analyse the requests for compulsory licences in India which did not succeed, so as to fully understand the philosophy of the Indian competent authorities. This research also covers the agreement between Brazil and Abbott - a pharmaceutical company, known as 'Kaletra deal' where the country's Minister of Health broke his promise to compulsorily license the patented medicine Kaletra. In the case of Thailand, the author will touch upon Thai licensing from the health and economic perspectives, where it is found that some licences did not result in significant savings.

Finally, in addition to these selected countries, the originality of this research is also linked to different philosophies on compulsory licensing of multilateral organisations. As mentioned in section 1.4.1, the topic of compulsory licensing and access to medicines no longer belongs to an exclusive club of IP experts or the US. The EU, WIPO, the WHO and NGOs have all developed their own individual and distinct thinking on this subject which reflect the mission, structure and even the financial situation of each organisation. Particularly, as briefly noted in Section 1.2.3, suggesting the compulsory licence for the public health purpose has been recently extended its territorial application to European countries. This research therefore

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<sup>93</sup> Nathan Ford *et al.*, 'Sustaining Access to Antiretroviral Therapy in Developing Countries: Lessons from Brazil and Thailand' (2007) 21 AIDS 21; Jeremiah Norris, 'The Unravelling of Compulsory Licenses – Evidence from Thailand and India' (International Policy Network, May 2007); Daniel Benoliel and Bruno Salama, 'Towards an Intellectual Property Bargaining Theory: The Post-WTO Era' (2010) 32 U.Pa.J. Int'l L. 265; Thomas Eimer and Susanne Lütz, 'Developmental States, civil society, and public health: Patent regulation for HIV/AIDS pharmaceuticals in India and Brazil' (2010) 4 Regulation & Governance 135; Sarath K. Ganji, 'TRIPS Implementation and Strategic Health Policy in India and Brazil' (2011) Josef Korbel Journal of Advanced International Studies 29; Piergiuseppe Pusceddu, 'Access to Medicines and TRIPS compliance in India and Brazil' (2014) 36 EIPR 790; Satish Saroha *et al.*, 'Compulsory Licensing of Drug Products in Developing Countries' (2015) 12 Journal of Generic Medicines; Omar Serrano and Mira Burri, 'Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India' (2016) World Trade Institute Working Paper no. 1 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2748447](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2748447)> accessed 7 March 2018.

comes at an opportune moment and contributes to the continuing debate of access to medicines as the problem does not only remains but is also widespread.

## 1.6 Research methods

### 1.6.1 Comparative legal research

The objective of this research is to examine the implementation of TRIPS compulsory licensing in India, Brazil and Thailand, and to draw similarities and differences from these experiences. The main approach will therefore be comparative research. The comparisons applied in this work are double-tiered. In the first tier, the national laws of India, Brazil and Thailand are compared with international law (mainly TRIPS); while a second tier consists of a cross study of the resemblances and national specificities in the three current legal frameworks. Visible and hidden patterns within these different systems will be traced; and finally, where necessary, legislative changes will be proposed.

In order to accomplish such double-tiered comparative analysis, the author will apply the four critical steps that were established by Eberle.<sup>94</sup> They are: (1) to acquire the skills of a comparatist so as to evaluate the laws clearly, objectively and neutrally, (2) to examine what is referred to as external law - the words, actions, or orality of the law in each case (3) to evaluate how the law operates within the culture, which is referred to as internal law, and (4) to formulate comparative observations.<sup>95</sup>

These four steps will be achieved through the adoption of a number of different methodologies.<sup>96</sup>

First of all, a structural method will be applied in order to compare the substantive and procedural provisions of international law and national laws. This method will aid comprehension of the extent to which these countries comply with TRIPS.

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<sup>94</sup> Edward J. Eberle, ‘The Method and Role of Comparative Law’ (2009) 8 Washington University Global Studies Law Review 451.

<sup>95</sup> *Ibid.*

<sup>96</sup> Mark Van Hoecke, ‘Methodology of Comparative Legal Research’ (2015) Law and Method 1. In this article, the author discussed six methodologies in comparative legal research. They are (i) the functional method, (ii) the structural method, (iii) the analytical method, (iv) the law-in-context method, (v) the historical method, and (vi) the common-core method.

Secondly, historical comparison is necessary to achieve an understanding of the origins and rationale of the divergences and convergences of the countries under examination. History is of interest in itself, but also helps to shed light on the underlying reasons for each government's current policies, as it is not enough simply to compare the letter of the law.<sup>97</sup> Law is driven and influenced by a culture which is created by historical factors, amongst others, and the acquisition of such an understanding will add to the quality of this research.

Lastly, the functional method, which is accompanied by practical problems when applied to the granting of compulsory licences in real cases. Functionalism will shed light on the discrepancy between the law in words and the law in action in India, Brazil and Thailand. By the identification of practical issues, lessons for other developing countries will be made available.

It is far from true that developing countries are homogeneous. In fact, the opposite is true. As was explained briefly in Section 1.4.1 of this chapter and as we shall see in Chapter 8, the selected countries are heterogeneous and have little in common. They differ in their healthcare systems, economic structures, industrial capacities, political system, legal tradition and much more. All these factors have led to divergences in their respective IP policies, which are formulated to accommodate each country individually. Therefore, only relative and relevant provisions, as opposed to some universal yardstick, will serve as a basis for such comparisons.

## 1.6.2 Doctrinal legal research

Besides being under the *chapeau* of the comparative methodology, the author also applies the method of doctrinal legal research by assembling relevant material.<sup>98</sup> There are two types of sources: normative sources: statutory texts, treaties, general principles of law, customary law, binding precedents, and the like; and authoritative sources: case law, and scholarly legal writings.<sup>99</sup>

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<sup>97</sup> Edward J. Eberle, 'The Method and Role of Comparative Law' (2009) 8 Washington University Global Studies Law Review 451, 452 – 453.

<sup>98</sup> Paul Chynoweth, 'Legal research' in Andrew Knight and Les Ruddock (eds), *Advanced Research Methods in the Built Environment* (Blackwell Publishing 2008) 29.

<sup>99</sup> Mark Van Hoecke, 'Legal doctrine: Which method(s) for What kind of Discipline?' in Mark Van Hoecke and François Ost (eds), *Methodologies of Legal research: Which kind of method for What kind of Discipline?* (Hart Publishing 2011) 11.

Following the above hierarchy and given the main focus of this research – TRIPS compulsory licensing – the author will therefore consider Article 31 as a normative source. In addition, the Doha Declaration is considered as a subsequent agreement between the negotiating parties. This document, which will be examined in Section 4.3, forms a crucial part of the current discussion. At the same time, TRIPS incorporated the Paris Convention, wherein compulsory licensing is regulated by Article 5A. This Article will be heavily discussed in Section 4.1.2, and elsewhere when necessary.

Turning to authoritative sources, the author also conducted a careful research on WTO trade disputes and found that there are no WTO Panel or Appellate Body reports that address compulsory licensing. Only once did the USA file a case against Brazil regarding the “local working provision”, under Article 68 of Brazil’s Law No. 9.279/1996 (Law on Industrial Property).<sup>100</sup> However the two parties agreed to settle the case through a bilateral channel,<sup>101</sup> therefore the WTO missed an opportunity to establish a precedent. This case will be subject to a more detail analysis in Section 6.3.2.

In addition, this thesis makes use of carefully selected works of leading authors in the field, particularly, in Chapters 3 and 4, where there is a historical review of the negotiations of TRIPS and Article 31, and the reflections of those who took part in drafting such works. Moreover, numerous references have been made to relevant publications from the WTO, WIPO and the WHO: these feature prominently in Chapter 9.

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<sup>100</sup> WTO, *Brazil: Measure Affecting Patent Protection. Request for Consultations by the United States* (8 June 2000) WT/DS199/1.

<sup>101</sup> WTO, *Brazil: Measure Affecting Patent Protection. Notification of Mutually Agreed Solution* (19 July 2001) WT/DS199/4.

## CHAPTER 2: LITERATURE REVIEW

As indicated in the first chapter, although considerable research has been devoted to the potential effects of compulsory licensing in widening access to medicines, less attention has been paid to a comparative analysis of compulsory licensing in developing countries. Where the comparison is made, it is either over-simplistic or lacks a comprehensive and critical examination in terms of the law. This chapter will set out and evaluate existing comparative literature in order to explore advances in the study of relevant policies, to identify key areas of investigation, and to highlight the originality of this thesis.

In addition, this chapter will include various themes where necessary, because while this thesis focuses mainly on the legal aspects of compulsory licensing, it is critical to understand this legal measure in a much broader context. For this reason, in addition to reviewing classical academic literature such as journal articles, books, monographs... the author will include some compelling relevant PhD theses that examine compulsory licensing in both law and non-law areas. They are: Beall's research (2017) in the field of population health,<sup>102</sup> Urias's study (2015) through the lens of economic and policy studies,<sup>103</sup> Owen's work (2012) in the context of communication and journalism,<sup>104</sup> and Fonseca's thesis (2011) of social policy.<sup>105</sup> Because studies of compulsory licensing has been undertaken in different disciplines, Chapter 2, instead of providing an in-depth review, aims to expound a cross-disciplinary view of the topic.

This chapter is organised hierarchically, starting with the most relevant theme: comparative studies, then moving to the empirical research on compulsory licensing. The next section will highlight carefully selected works written on India, Brazil and Thailand individually, and then followed by a discussion about 'for and against' the compulsory licence. The literature review will finish with the section on historical and interpretative studies of TRIPS Article 31, the important provision which mandates the current compulsory licensing regime.

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<sup>102</sup> Reed Beall, 'What Is the International Landscape of Essential Medicine Patent Protection and How Can Developing Countries' Medicine Access Be Accelerated Within It?' (PhD thesis, University of Ottawa 2017), Chapter 5.

<sup>103</sup> Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015).

<sup>104</sup> Thomas Owen, 'Patents, Pills, the Press and the Poor: Discourse and Hegemony in News Coverage of the Global 'Access to medicines' Dispute, 1997 – 2003' (PhD thesis, Massey University 2012).

<sup>105</sup> Elize Massard da Fonseca, 'Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil' (PhD thesis, University of Edinburgh 2011).

## 2.1 Comparative studies

Comparative research on compulsory licences in developing countries can be grouped under three main themes: bargaining power, domestic implementation of TRIPS and access to medicines. However, some works could feasibly be accommodated under all three themes.

### Bargaining Power

It could be argued that the article written by Benoliel and Salama, '*Towards an Intellectual Property Bargaining Theory: The Post-WTO Era*', is the most prominent work referring to the first theme.<sup>106</sup> It is an original research which critically investigates compulsory licensing as a working example of a bargaining theory for IP in the post TRIPS era. The authors identify three factors which significantly affect the position of a developing country in a price negotiation with a patent holder. They are: the country's outside option (compulsory licensing), inside options (national opportunism within TRIPS including compulsory licensing) and market power (the ability of a country to pay less than the competitive price).<sup>107</sup>

On the basis of the aforementioned variables, Benoliel and Salama arrived at interesting conclusions. They found that countries, such as Thailand and Brazil, where there is an absence of local innovation in the pharmaceutical industry, in fact, increase their ability to issue compulsory licences.<sup>108</sup> These nations are therefore classified as being part of the high bargaining power model. In contrast, a country which has developed a higher degree of pharmaceutical innovations like India, paradoxically reduces the possibility to resort to compulsory licensing.<sup>109</sup> For this reason, India is characterised as being a medium bargaining power model.

According to Benoliel and Salama, such findings contravene conventional analyses stating that bargaining power is decided by the overall size and diversity of each country's economy (market size).<sup>110</sup> Their article is, arguably, one of the very rare studies where comparison of the compulsory licensing regimes in India, Brazil and Thailand was carried out in a very

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<sup>106</sup> Daniel Benoliel and Bruno Salama, 'Towards an Intellectual Property Bargaining Theory: The Post-WTO Era' (2010) 32 U.Pa.J. Int'l L. 265.

<sup>107</sup> *Ibid.*, 290. As Benoliel and Salama explained, 'an inside option differs from an outside option in that as a result of the latter negotiations break up and the parties stop bargaining whereas the former assumes continued bargaining'.

<sup>108</sup> *Ibid.*, 312.

<sup>109</sup> *Ibid.*, 312.

<sup>110</sup> *Ibid.*, 217.

comprehensive way. The author of this thesis, however, argues that Benoliel and Salama did not either look into the domestic legal frameworks or expound further on why and how a country's ability to innovate can affect its ability to issue mandatory licences for pharmaceutical products. These unaddressed issues will be clarified in this thesis, particularly, in Chapter 8.

## Domestic Implementation of TRIPS

With regards to the second theme, much light has been shed on how differences in TRIPS implementations led to differing responses to compulsory licensing in developing countries. Interestingly, many authors such as Bird and Cahoy,<sup>111</sup> Ganji,<sup>112</sup> Pusceddu,<sup>113</sup> Serrano and Burri<sup>114</sup> reached the same conclusion. They all found that while the delay in implementing TRIPS helped India to preserve its national interest, the rushed adoption of TRIPS by Brazil hampered its health policies, and that, in turn, resulted in the country's aggressive use of compulsory licences to recover lost ground.<sup>115</sup>

Nevertheless, these studies mainly addressed BRIC economies, rather than smaller markets, such as Thailand. For example, Pusceddu in '*Access to medicines and TRIPS compliance in India and Brazil*', Ganji in '*TRIPS Implementation and Strategic Health Policy in India and Brazil*' or Serrano and Burri in '*Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India*' largely emphasise the underlying process of TRIPS compliance in these countries. Differences between Indian market-driven compulsory licensing and Brazilian government use was, however, not systematically evaluated. Meanwhile, as noted in Section 1.5, this thesis will narrow the lens to closely examine relevant provisions of compulsory licensing while leveraging existing

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<sup>111</sup> Robert C. Bird and Daniel R. Cahoy, 'The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement' (2007) 3 North-western Journal of Technology and Intellectual Property 400.

<sup>112</sup> Sarath K. Ganji, 'TRIPS Implementation and Strategic Health Policy in India and Brazil' (2011) Josef Korbel Journal of Advanced International Studies 29.

<sup>113</sup> Piergiuseppe Pusceddu, 'Access to medicines and TRIPS compliance in India and Brazil' (2014) 36 EIPR 790

<sup>114</sup> Omar Serrano and Mira Burri, 'Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India' (2016) World Trade Institute Working Paper no. 1 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2748447](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2748447)> accessed 7 March 2018.

<sup>115</sup> See also Robert C. Bird, 'Defending Intellectual Property Rights in the BRIC Economies' (2006) 43 American Business Law Journal 317; Peter K. Yu, 'Access to Medicines, BRICS Alliances, and Collective Action' (2008) 34 American Journal of Law and Medicines 345; Lawrence A. Kogran, 'Commercial High Technology Innovations Face Uncertain Future Amid Emerging "BRICS" Compulsory Licensing and IP Interoperability Frameworks' (2011) 13 San Diego International Law Journal 1.

literature. The author will consider the extent to which India, Brazil and Thailand have differed in the use of compulsory licensing to meet their pharmaceutical needs.

## Access to medicines

As regards the last theme where compulsory licensing is considered as a tool to enhance the access to medicines, there has been abundant research but most of it is in the form of small-scale studies, as described in Section 1.5. After careful consideration, the author will focus on four books written by Sundaram,<sup>116</sup> Sellin,<sup>117</sup> Pamela,<sup>118</sup> and Kuanporth<sup>119</sup> amongst which Sundaram's books is the most up-to-date relevant literature which is published in May 2018. In these four books, all the authors used India as one of their case studies proving the importance of this country. However, because compulsory licensing is not a central theme of these works but, is analysed together with other TRIPS flexibilities, this legal mechanism is not examined in depth. Moreover, the country case studies in these aforementioned works are not truly examined in a comparative manner because each country's chapter stands separately with little or no close association. As a result, differences and similarities of the countries examined are not clearly highlighted.

Sundaram provides a critical analysis of exploring TRIPS flexibilities to improve the access to medicines in developing countries and LDCs through the examples of Brazil, China, India, South Africa and Kenya. While Sellin looks into India in association with South Africa and Uganda, Pamela compares India with Kenya, Kuanporth compares India and Thailand. All four authors claim that India has exploited all TRIPS flexibilities, while other countries, for instance, Uganda, has complied with TRIPS patents before the deadline for LDCs in order to gain a trade-off in foreign investment, as analysed in chapter 8 of Sellin's book. In particular, this author has established that Uganda has the most restrictive grounds upon which a

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<sup>116</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018).

<sup>117</sup> Jennifer Sellin, *Access to Medicines: The interface between patents and human rights. Does one size fit all?* (Intersentia 2014).

<sup>118</sup> Brenda Pamela Mey, *The Legal Duel: The TRIPS Agreement and Drug Access Issues. Is the Agreement Actually the Cunning Manoeuvre it has been dubbed? Kenya-India Case Studies* (Peter Lang 2013).

<sup>119</sup> J. Kuanporth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (EE 2010).

compulsory licence can be granted. She therefore suggests a simple and effective compulsory licensing system.<sup>120</sup>

In the meanwhile, Kuanporth indicates that India's highly independent pharmaceutical industry has helped the country to attain dual goals: compliance with international obligations and maintenance of a burgeoning domestic industry. At the same time, Thailand, due to its poor industrial technology, heavily relied on imported medicines. However, as this book was published in 2010, before the first Indian compulsory licence issued in 2012, Kuanporth was unable to compare the actual use of two countries.

In a similar vein, Sundaram has viewed India as a model for other developing countries to follow since the country has maximised all the freedom given by the TRIPS Agreement.<sup>121</sup> However, he expresses a concern that the re-introduction of the Indian product patent regime in 2005 might be counterproductive to the country's national interest and that of other developing countries relying on Indian generics supply. Sundaram fairly examines recent Indian compulsory licence applications and concludes that such applications do not affect pharmaceutical innovation in the country.

Turning to Brazil, Sundaram agrees with the view that the country's success in controlling the HIV/AIDS infection rate was attributed to its domestic manufacturing capacity and the credible threat of compulsory licensing.<sup>122</sup> The author of this thesis, nonetheless, disagrees with this conclusion as I view that Brazil's achievement lay in the single element of the threat only. The case study of Brazil will be dealt with in depth in Chapter 7.

Another important book in which compulsory licensing is the main theme is '*Compulsory licensing: Practical Experiences and Ways Forward*', edited by Reto M. Hilty and Kung-Chung Liu.<sup>123</sup> However, the author could not put this book into any theme listed above because it is a collection of 20 different conference papers written for the 2012 conference on European

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<sup>120</sup> Jennifer Sellin, *Access to Medicines: The interface between patents and human rights. Does one size fit all?* (Intersentia 2014) 459.

<sup>121</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) Chapter 7.

<sup>122</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 96.

<sup>123</sup> Reto M. Hilty and Kung-Chung Liu (eds), '*Compulsory licensing: Practical Experiences and Ways Forward*' (Springer 2015).

and Asian IP, with focus on compulsory licensing.<sup>124</sup> One particularly interesting aspect of this book is that it provides a comprehensive study of the compulsory licensing through the lenses of domestic laws and international legal frameworks. This book addresses a wide range of compulsory licensing activities made in India, Latin America (including Brazil), Thailand, Taiwan, Germany, and the EU in relation to both medical concerns and competition issues. Interestingly, Correa who examined the practice in Latin America suggests that local competition authorities should develop a better understanding of the relationship between IP and competition law to grant compulsory licensing in cases of anti-competitive practices for medicinal products.<sup>125</sup>

## 2.2 Empirical research on TRIPS compulsory licensing

It is essential to note that compulsory licence grants are subject to national law and the granting countries are not obliged to inform any international organization of their decisions. Therefore, this author has had to rely significantly on academic works. It is surprising that, although the topic of compulsory licensing for patented medicines has produced a heated global debate and copious academic literature, not many empirical studies have been conducted. Of these, only one is outstanding. It is: '*Trends in compulsory licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis*', written by Beall and Kuhn in 2012.<sup>126</sup> It is the first, and the most systematic empirical analysis of the subject.

In fact, there are other attempts which were made to survey the use of compulsory licences in the developing world, they are, nevertheless, unclear as to the source of data or lack critical evaluation. For example, 't Hoen referred to a report of an informal Advisory Group meeting at the WHO in 2017 to claim that, there may have been up to 30 compulsory licences in 26 countries.<sup>127</sup> However, the author of this thesis was unable to verify this data in the original

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<sup>124</sup> The Fifth Conference on European and Asian Intellectual Property: Compulsory Licensing was held on 3–5 December 2012 in Taipei under the auspices of the Max Planck Institute for Intellectual Property and Competition Law (Max Planck Institute for Innovation and Competition since 2014) and Institutum Iurisprudentiae, Academia Sinica, an event jointly sponsored by the National Science Council (Ministry of Science and Technology since March 2014), Fair Trade Commission, Institute of Law for Science & Technology, National Tsing Hua University, Institute for Information Industry, and National Taiwan University Law School in Taiwan.

<sup>125</sup> Carlos M. Correa, 'The Use of Compulsory Licences in Latin America' in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015) 59.

<sup>126</sup> Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis' (2012) 9 PLoS Medicine 1.

<sup>127</sup> Ellen FM 't Hoen *et al.*, 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 Bulletin WHO 185, 188, referring to The Informal Advisory Group meeting, 'Fair Pricing' (WHO 2017) <[http://www.who.int/medicines/access/fair\\_pricing/fpf\\_report/en/](http://www.who.int/medicines/access/fair_pricing/fpf_report/en/)> accessed 11 April 2018.

report as of this writing. Or another example is of James Love,<sup>128</sup> a very proactive health activist whose name will appear frequently in this work. He merely provided information about such licences without analysing them. As a consequence of the absence of international records and the scarcity of academic works, this section focuses strongly on Beall and Kuhn's article which has stood as a highly important empirical research in the post-TRIPS stage.

This study, carried out between 1 January 1995 and 6 June 2011, records 24 episodes<sup>129</sup> of actual occurrences of compulsory licensing in 17 countries issued by national governments during the said time. Such occurrences were initiated by the government (government use licences), no private party was found to be involved in. Apart from Canada and the US, which are high-income countries, the remaining granting countries are middle-income economies, of which Brazil and Thailand are the most active users.<sup>130</sup>

Beall and Kuhn report that only 50% of announcements of government use licensing led to actual grants, but more than 90% resulted in price reductions, either with voluntary or non-voluntary licences, or with price discounts. This thesis therefore argues that the real power of compulsory licensing derives not solely from its application in practice but also from its mere presence in a national legal system. Such a potential will be examined in the case of Brazil (Chapter 6) where the government had to make regulatory changes in order to strengthen its bargaining power. A coherent and comprehensive legal framework is therefore of significance to any country no matter whether compulsory licensing is in current use. As will be concluded in Chapter 10, an important finding of this thesis is to offer other countries a variety of choices, based on which policy-makers can create the best model for their own nations.

According to Beall and Kuhn, government use licences were not granted between 1995 and 2001. Nevertheless, after the adoption of the Doha Declaration in 2001, which reaffirmed the freedom of WTO members to use TRIPS flexibilities, compulsory licensing proliferated, particularly during the years 2003 – 2005. A substantial decline, however, took place from

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<sup>128</sup> James Packard Love, 'Recent examples of the use of compulsory licenses on patents' (KEI Research note 2007)

<<https://www.keionline.org/book/publications-and-research-notes/kei-rn-2007-2-recent-examples-of-compulsory-licensing-of-patents>> accessed 16 March 2018.

<sup>129</sup> An 'episode' refers to a situation where a compulsory licence was either publicly entertained by government officials or actually declared, subsequent to TRIPS. Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis' (2012) 9 PLoS Medicine 1.

<sup>130</sup> Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis' (2012) 9 PLoS Medicine 1, 3.

2006 onwards. The study also pointed out that, compulsory licences were used more frequently in upper middle-income countries than in least-developed and low-income nations. For example, while upper middle-income countries have granted 13 compulsory licences, least-developed and low-income nations together have issued eight licences in total. The remaining three licences were granted by high-income countries.

Beall and Kuhn further claimed that the majority of the 16 licences issued were related to drugs for the treatment of HIV/AIDS, whereas four licences were granted for other infectious diseases and six for non-communicable diseases. Such findings signify a fact that compulsory licensing is closely linked to acute conditions rather than chronic diseases. Nevertheless, with the shift from communicable diseases to non-communicable diseases as the leading causes of mortality, it remains to be seen whether there will be any similar shift in compulsory licensing. Chapter 7 will investigate Thailand as an example of a country which grants compulsory licences for medicines treating chronic diseases.

The research of Beall and Kuhn is significant, as the two authors did not only collect the data but also processed in an analytical manner. As a result, their studies went beyond a collection of compulsory licences, since TRIPS, so as to present the tendency of countries in using compulsory licences, analyse the actual outcomes and the target medicines. Their article has served as a starting point from which the three country case studies in this doctoral work are strategically taken for the examination. Despite these strengths, this thesis argues that Beall and Kuhn's study is less concerned with the regulatory framework and political process underpinning mandatory licences. There are these two issues which will be prominently treated in this thesis.

## **2.3 Individual studies of India, Brazil, and Thailand**

As noted in Section 1.5, India, Brazil and Thailand are no strangers to patent-based research in relation to the access to medicines. Therefore, it is necessary to analyse the relevant literature on each country.

### **2.3.1 India**

Amongst the three countries examined, India is the most accessible subject matter. There are several reasons for this. Firstly, Indian compulsory licensing laws and orders are written in English, which makes them more accessible. Secondly, as mentioned in Chapter 1, and as will

be seen in Chapter 5, the country's patenting regime is attractive to stakeholders, due to the significance of its market, and the crucial role which it plays as a generics supplier to the developing world.

Most of the studies of India have largely concentrated on its reintroduction of patents for medicines in 2005 and how such changes have affected the private sector and access to medicines in developing countries.<sup>131</sup> They all agree that, while India is one of very few developing countries which utilised all of the possible flexibilities under TRIPS, including compulsory licensing, there is a concern that the re-establishment of Indian patent drugs might increase prices, and hence exercise a negative effect on the right to health.

A few researchers have thoroughly and critically evaluated the Indian licence framework. Kapczynsky, Mueller, Basheer and Kochupillal, and Chaudhuri are examples of these.<sup>132</sup> In particular, Mueller's article titled '*The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*' and Basheer and Kochupillal's work titled '*The Compulsory Licence regime in India: Past, Present and Future*' offer very detailed and comprehensive analyses of almost every ground to issue a compulsory licence under the Indian Patents Act of 1970. Their opinions converge when they assert that, India adopted relatively broad grounds for the grant of non-voluntary licences, but that the grant procedure is complicated, bureaucratic, and troublesome. Notably Mueller firmly believes that India's compulsory licensing provisions are undoubtedly the broadest and most

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<sup>131</sup> Santanu Mukherjee, 'The Journey of Indian Patent Law towards TRIPS Compliance' (2004) 35 IIC 125; AD Damodaran, 'Indian Patent Law in the post-TRIPS decade: S&T Policy Appraisal' (2008) 13 Journal of Intellectual Property Rights 414; V.K. Unni, 'Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health' (2012) 25 Global Business and Development Law Journal 323; Mainak Mazumdar, *Performance of Pharmaceutical Companies in India: A Critical Analysis of Industrial Structure, Firm Specific Resources, and Emerging Strategies* (Springer 2013); William Greene, 'The Emergence of India's Pharmaceutical Industry and Impactions for the US Generic Drug Market' (US ITC, May 2007); Srividhya Ragavan, 'Of the Inequals of the Uruguay Round' (2005) 10 Intellectual Property L. Rev 273; Gopakumar K. M., 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' (2010) 3 The Law and Development Review 325; George T. Haley and Usha C.V. Haley, 'India: A study in patent-law effects' in Robert C. Bird and Subhash C. Jain (eds), *The Global Challenge of Intellectual Property Rights* (EE 2008); Sudip Chaudhuri, 'The pharmaceutical industry in India after TRIPS' in Hans Löfgren and Owain David Williams (eds), *The New Political Economy of Pharmaceuticals. Production, Innovation and TRIPS in the Global South* (Palgrave Macmillan 2013).

<sup>132</sup> Shamnad Basheer and Mrinalini Kochupillal, 'The Compulsory Licence regime in India: Past, Present and Future' (A Report for the JPO, 2005) <<https://ssrn.com/abstract=1685129>> accessed 19 March 2018; Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (OUP 2005); Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491; Amy Kapczynsky, 'Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 California Law Review 1571.

comprehensive of all the world's patent systems.<sup>133</sup> Although it might be a bold statement, compared with Brazil and Thailand, India indeed covers more situations upon which a compulsory licence can be sought, as will be clearly demonstrated in Chapter 8.

However, at the time these studies were conducted and published, no Indian compulsory licence had actually been issued. Actual grants of compulsory licences are therefore missing in these works. It was a book by Ali Feroz, '*The Access Regime: Patent Law Reforms for Affordable Medicines?*' (2016)<sup>134</sup> that provided a detailed and comprehensive assessment of Indian licensing with respect to the law and practice. While this book analysed the compulsory licences granted to Natco, it overlooked two other requests that were unsuccessful, namely *BDR vs. Bristol Myers Squibb* (Controller of Patents, 2013) and *Lee Pharma v. AstraZeneca* (Controller of Patents, 2016) (See Chapter 5, Sections 5.4.2 and 5.4.3 being applied).

### 2.3.2 Brazil

The study of Brazil in this thesis has met significant difficulties. The first challenge came from the language barrier, as the relevant Brazilian legislation is written in Portuguese. Secondly, very few books deeply explore the country's patent law or examine compulsory licensing from a purely legal perspective.<sup>135</sup> Most importantly, Kunisawa's book titled '*The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area*' has stood as an important source from which Chapter 6 on Brazil of this thesis is built upon. Kunisawa does not only examine the current Brazilian compulsory licensing regime but provides also revealing an insight into the country's patent legislation. For example, the author reveals that under previous laws, only two compulsory licences were recorded.<sup>136</sup>

Meanwhile, discussions about mandatory licences in relevant literature has been confined to the context of public health (HIV/AIDS campaigns) or political economy. For example, Loup *et al.*, Cassier and Correa, and Robine explore the scientific development of Brazil's

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<sup>133</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 580.

<sup>134</sup> Feroz Ali, *The Access Regime: Patent Law Reforms for Affordable Medicines?* (OUP 2016) 129.

<sup>135</sup> Maristela Basso and Edson Beas Rodrigues Junior, *Intellectual Property Law in Brazil* (Wolters Kluwer 2010); Hiroko Yamane, *Interpreting TRIPS Globalisation of Intellectual Property Rights and Access to Medicines* (Hart Publishing 2011); Viviane Yumy Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015).

<sup>136</sup> Viviane Yumy Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 129 – 130.

pharmaceutical capacity and how it helped Brazil to win the battle against HIV/AIDS.<sup>137</sup> Amy Nunn's book titled '*The Politics and History of AIDS Treatment in Brazil*' - a very well-known author in this regard – focuses on the interrelationship of politics and HIV/AIDS treatment in the country.<sup>138</sup> Shadlen also shed light on the political aspects of patents and medicines in Brazil.<sup>139</sup> Another strand of research is related to generics policies where Fonseca has stood as a prominent author.<sup>140</sup> Compulsory licensing, however, was a marginal topic in these works.

Of the others, the only research that deals solely with Brazil's compulsory licensing is that of Urias.<sup>141</sup> This work is original in a sense that this author investigates multiple factors which affected price negotiations between the government of Brazil and pharmaceutical companies. Urias developed a sophisticated approach to identify the drivers behind Brazil's credible threats to issue compulsory licences. They are: The Ministry of Health, the Ministry of Development, Industry and Trade, patent holding companies, the countries hosting these companies, international generics suppliers, and local companies.<sup>142</sup>

Urias expertly develops an integrative framework and captures the dynamics of price cuts and he found that the interaction between these factors will shape the outcome of the bargain. Ultimately, Urias arrives at an important conclusion which the author of this thesis also agrees with. That is, compulsory licensing is not a tool to promote long-term sustainable access to medicines.<sup>143</sup> While this research is very interesting and innovative, it should be noted that it is a PhD thesis of Economic and Social policies and therefore, the treatment of the legal aspect was insignificant.

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<sup>137</sup> Guillaume Le Loup *et al.*, 'The Brazilian Experience of 'Scaling-up': A Public Policy Approach' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008); Maurice Cassier and Marilena Correa, 'Scaling Up and Reverse Engineering: Acquisition of Industrial Knowledge by Copying Drugs in Brazil' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008); Amélie Robine, 'Technology Transfer Agreements and Access to HIV/AIDS Drugs: The Brazilian Case' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008).

<sup>138</sup> Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009).

<sup>139</sup> Kenneth C. Shadlen 'The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies' (2009) 42 *Comparative Politics* 41.

<sup>140</sup> ELize Massard da Fonseca, 'Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil' (PhD thesis, University of Edinburgh 2011).

<sup>141</sup> Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015).

<sup>142</sup> *Ibid.*, 108.

<sup>143</sup> *Ibid.*, 145.

### 2.3.3 Thailand

As stated in the first chapter, Thai compulsory licensing was highly controversial due to a number of reasons. Most importantly, these licences were issued by the post-coup government and they related to a broad range of medicines, including ones for the treatment of chronic diseases. Therefore, the case study of Thailand has deeply divided scholars. On the one hand, a number of writers, including Limpananont and Kijtiwatchakul, Krikorian, Flynn, and Ho, supported the Thai government's actions and argued that its policy was in conformity with international law.<sup>144</sup> Kuanporth, more cautiously, claimed that although the policy of Thailand was in line with TRIPS, the country's insufficient industrial development would undermine the effect of compulsory licensing.<sup>145</sup>

On the other hand, Cass, Bate, Lybecker and Folwer, Jamie and Skees took the view that the Thai government had abused its power and that compulsory licences should be confined to epidemics, i.e. HIV/AIDS, rather than for a wider range of circumstances.<sup>146</sup> They criticised such licences for disguising the country's financial constraints and the political crisis following the coup d'état. Occupying the middle ground was Tejavanija, who, while conceding that the Thai licensing was allowable under TRIPS, argued that the country should take into account the needs of strong IPRs and should explore other solutions.<sup>147</sup>

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<sup>144</sup> Gaëlle Krikorian, 'The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand' in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property Contestation Over the Ownership, Use, and Control of Knowledge and Information* (EE 2009); Cynthia M. Ho, 'Patent Breaking or Balancing? Separating Strands of Fact from Fiction under Trips' (2009) 34 N.C. J. of Int'l. L. & Com. Reg. 371; Jiraporn Limpananont and Kannikar Kijtiwatchakul, 'TRIPS Flexibilities in Thailand: Between Law and Politics' in Gaëlle Krikorian and Amy Kapczynski (eds), *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010); Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) Chapter 6.

<sup>145</sup> J. Kuanporth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (EE 2010).

<sup>146</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233; Ronald A. Cass, 'Compulsory licensing of Intellectual Property: The Exception that Ate the Rule?' (2007) Washington Legal Foundation, Working Paper Series No. 150 <[http://www.wlf.org/publishing/publication\\_detail.asp?id=1902](http://www.wlf.org/publishing/publication_detail.asp?id=1902)> accessed 7 March 2018; Roger Bate, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013; Feldman Jamie, 'Compulsory Licenses: The Dangers Behind the Current Practice' (2009) 8 Journal of International Business and Law 137; Kristina M. Lybecker and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 Journal of Law, Medicine and Ethics 222; Kristina Lybecker, 'Compulsory Licenses Won't Solve a Healthcare Crisis' (IP Watchdog, 1 April 2014) <<http://www.ipwatchdog.com/2014/04/01/compulsory-licenses-wont-solve-a-healthcare-crisis/id=48827/>> accessed 26 December 2017.

<sup>147</sup> Mingchanok Tejavanija, 'A New Kind of Drug War: Thailand's Taking on the Pharmaceutical Industry to improve access to HIV/AIDS drugs through the use of compulsory licensing' (2011) 28 Arizona Journal of International and Comparative Law 559.

As will be seen in Chapter 7, the Thai example is extremely controversial due to the alleged wide use of compulsory licensing and the involvement of the political element. Indeed, the entwinement of law and politics turned the Thai licensing issue into a blend of myth and fact. This thesis argues that because of the uniqueness of such a political environment, the fine line between rationality and legitimacy of Thailand's government use licences was very blurred. Therefore, it is worth revisiting the Thai example to filter the factual account from anecdotal stories.

## 2.4 For and against compulsory licensing

While comparative legal studies on compulsory licensing are scarce, there is copious research on its effects.<sup>148</sup> However, this section will discuss the studies which have examined the impact of compulsory licences on three aspects: medicine price, general innovation, and FDI attraction. These aspects have been frequently debated every time a compulsory licence is about to be granted.

### Medicine Price

As regards the price, an indisputable reason for supporting the notion of compulsory licensing is that it prompts the market entry of generics, which could have been delayed if patent monopolies had been in force.<sup>149</sup> Compelling the right holder to share his exclusivity with

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<sup>148</sup> Richard P. Rozek and Ruth Berkowitz, 'The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?' (1998) 1 The Journal of World Intellectual Property 180; Richard P. Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care' (2000) 3 The Journal of Intellectual Property 889; Richard P. Rozek and Renee L. Rainey, 'Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy' (2001) 4 The Journal of World Intellectual Property 463; Feldman Jamie, 'Compulsory Licenses: The Dangers Behind the Current Practice (2009) 8 Journal of International Business and Law 137; Kristina M. Lybecker and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 Journal of Law, Medicine and Ethics 222; Aileen M. McGill, 'Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis under The Doha Declaration' (2010) 10 Wake Forest Intellectual Property Law Journal 69; Richard A. Epstein and F. Scott Kieff, 'Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents' (2011) 78 The University of Chicago Law Review 72; Jon Matthews, 'Renewing healthy competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards Are Most Damaging to the United States Healthcare Industry' (2012) 4 The Journal of Business, Entrepreneurship and the Law 119. Kristina Lybecker, 'Compulsory Licenses Won't Solve a Healthcare Crisis' (IP Watchdog, 1 April 2014) <<http://www.ipwatchdog.com/2014/04/01/compulsory-licenses-wont-solve-a-healthcare-crisis/id=48827/>> accessed 26 December 2017.

<sup>149</sup> F. M. Scherer and Jayashree Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Countries' (2002) 5 Journal of International Economic Law 913; Susan K. Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 Wisconsin International Law Journal 481; UK Commission on IPRs, 'Integrating Intellectual Property Rights and Development Policy' (2002); Ellen F.M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 42; Amir

someone else enables competition between originators and imitators, thereby bringing about price reductions. Consequently, the consumers' access to pharmaceuticals is likely to be improved, as medicine prices will become more affordable.

Flynn *et al.* also viewed that compulsory licensing is more justifiable in countries with great inequalities of income, a bracket into which many developing countries fall.<sup>150</sup> In these markets, pharmaceutical companies could maximize their profits by charging high prices to the affluent sector of the society, rather than distributing the drug to the poor at an affordable price. For example, if a company sells a medicine at the price that only 550,000 patients in such a country can afford, the firm makes \$814.6 million in total revenue. On the other hand, if they reduce the price so that the drugs are accessible to 20% of the affected individuals, then only \$435.6 million is generated, less than half the profit previously cited.<sup>151</sup> In such situations, the issue of a compulsory licence might generate more benefits from greater access to medicines than the benefits from increased incentives for innovation through the exclusive right.

However, Beall *et al.* disagreed with the argument that compulsory licensing results in a cheaper medicine price. According to their findings, such a price is not lower than that gained by international procurement.<sup>152</sup> 't Hoen - a very proactive health activist, and Bermudez, argued that, in certain cases, international procurement did not give rise to lower prices.<sup>153</sup> To respond to this counterargument, Beall *et al.* suggested many flexibilities that could reduce prices without resorting to compulsory licences, such as voluntary licences, the non-enforcement of patents, or postponements of patentability compliance (which will be described

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H. Khoury, 'The "public health" of the Conventional International Patent Regime and the Ethics of "ethical": Access to Patented Medicines' (2008) 26 Cardozo Arts and Entertainment Law Journal 25; E. Richard Gold *et al.*, 'Are Patents Impeding Medical Care and Innovation?' (2009) 7 PLoS Medicine 1; Alexandra Cameron *et al.*, 'Medicine Prices, Availability and Affordability' in *The World Medicines Situation 2011* (3<sup>rd</sup> edn, WHO 2011) 1 <[http://www.who.int/medicines/areas/policy/world\\_medicines\\_situation/en/](http://www.who.int/medicines/areas/policy/world_medicines_situation/en/)> accessed 5 March 2018; Anand Grover *et al.*, 'Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability under the Right to Health' (2012) 40 Journal of Law, Medicines and Ethics 234; Ping Xiong, *An Interpretation of the TRIPS Agreement in Relation to the Right to Health* (Martinus nijhoff Publisher 2012); Saeed Ahmadiani and Shekoufeh Nikfar, 'Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective' (2016) 24 DARU Journal of Pharmaceutical Sciences 1.

<sup>150</sup> Sean Flynn *et al.*, 'An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries' (2009) 37 Journal of Law, Medicine and Ethics 184.

<sup>151</sup> *Ibid.*, 189.

<sup>152</sup> Reed F. Beall *et al.*, 'Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement' (2015) 34 Health Affairs 493.

<sup>153</sup> Ellen't Hoen and Jorge Bermudez, 'Compulsory Licenses for Medicines' (2015) 34 Health Affairs 1068.

in Section 3.4).<sup>154</sup> For Beall *et al.*, ‘calls for routine compulsory licensing when contrary to available pricing data would be neither wise nor evidence based’.<sup>155</sup>

In relation to price, Bird also pointed out another consequence of compulsory licensing, known as ‘shadow pricing’.<sup>156</sup> This practice happens when a compulsory licence drives a patent holder out of a particular market, thereby enabling the licensee to charge the generic price close to the price of the original drug. However, this thesis argues that the situation of ‘shadow pricing’ is unlikely to happen, as according to TRIPS Article 31, compulsory licensing must be granted on a non-exclusive basis (Section 4.2.4.4). This means that the right owner can voluntarily license his invention to others, while he himself preserves the right to exploit that particular patented invention. In any case, there is very little chance that a compulsory licence could lead to a market monopoly.

## General Innovation

In terms of the effect of compulsory licensing on general innovation, Ho and Outterson agree that patents have little impact in developing countries, because the latter are not the main markets for IPR owners, therefore developing countries are encouraged to grant compulsory licences.<sup>157</sup> According to these authors, the most substantial revenue is generated from financially wealthy countries, such as the US and some European countries, and not from developing countries. Ho maintained that, as long as the developed nations do not grant any compulsory licences for drugs, there should be no adverse impact on pharmaceutical innovations.<sup>158</sup> In the same vein, Outterson favours the copying of innovative medicines in low-income countries where the need is great, and the loss is small.<sup>159</sup>

Such reasoning is also supported by Stirner, who observed that while the practice of compulsory licensing in middle income countries like Brazil and Thailand poses a threat to

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<sup>154</sup> Reed F. Beall *et al.*, ‘Compulsory Licenses: The Authors Reply’ (2015) 34 *Health Affairs* 1068.

<sup>155</sup> *Ibid.*

<sup>156</sup> Robert C. Bird, ‘Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effect’ (2009) 37 *Journal of Law, Medicine and Ethics* 209, 214.

<sup>157</sup> Kevin Outterson, ‘Fair followers: Expanding access to generic pharmaceuticals for low and middle-income populations’ in Jillian Clare Cohen and others (eds), *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (Pluto 2006); Cynthia M. Ho, ‘Patent Breaking or Balancing? Separating Strands of Fact from Fiction under Trips’ (2009) 34 N.C. J. of Int’l. L. & Com. Reg. 371, 457.

<sup>158</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 153.

<sup>159</sup> Kevin Outterson, ‘Fair followers: Expanding access to generic pharmaceuticals for low and middle-income populations’ in Jillian Clare Cohen and others (eds), *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (Pluto 2006).

pharmaceutical companies and their host countries, the LDCs, such as Zimbabwe, Zambia, and Mozambique, have not provoked negative reactions from the patent holding companies or pharmaceutical industry associations.<sup>160</sup> This indicates a higher acceptance of compulsory licensing when used by countries with small markets and limited technological capacities than when practised in middle-income countries with substantial pharmaceutical markets and a significant pharmaceutical industry.<sup>161</sup> Such an observation lends support to the treatment of India, Brazil and Thailand in this thesis, as these markets are significant in the eyes of the patent holding companies, and therefore compulsory licensing has a considerably greater impact.

More recently, Moser and Voena,<sup>162</sup> and Baten *et al.*<sup>163</sup> tested the hypothesis that compulsory licensing discouraged innovations under the US Trading with the Enemy Act (1917). These authors reached a tentative conclusion that this legal measure encouraged innovation, as it increased the threat of competition for incumbent inventors and motivated them to invest more in R&D.<sup>164</sup> Nevertheless, this can only happen if the governments make a credible commitment to use compulsory licensing *only* in exceptional cases of emergency. Where compulsory licensing occurs repeatedly, companies may invest less in R&D. In other words, if this legal measure is used at random and unpredictably, it is likely to weaken innovation.

Critics of compulsory licensing assert that extensive use of this legal mechanism is synonymous with weak patent protection. One of the most vocal authors is Rozek who, in his series of articles, sharply criticises compulsory licensing for a variety of reasons while strongly supporting patent protection.<sup>165</sup> In '*The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?*' Rozek and Berkowitz examined medicine prices in nine developing

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<sup>160</sup> Beatrice Stirner, 'Learning from Practice: Compulsory Licensing Cases and Access to Medicines' (2012) 1 Pharmaceutical Patent Analyst 555, 566.

<sup>161</sup> *Ibid.*

<sup>162</sup> Petra Moser and Alessandra Voena, 'Compulsory Licensing: Evidence from the Trading with the Enemy Act' (2012) 102 American Economic Review 396.

<sup>163</sup> Joerg Baten *et al.*, 'Compulsory licensing and innovation - Historical evidence from German patents after WWI' (2017) 126 Journal of Development Economics 231.

<sup>164</sup> Petra Moser and Alessandra Voena, 'Compulsory Licensing: Evidence from the Trading with the Enemy Act' (2012) 102 American Economic Review 396; Joerg Baten *et al.*, 'Compulsory licensing and innovation - Historical evidence from German patents after WWI' (2017) 126 Journal of Development Economics 231.

<sup>165</sup> Richard P. Rozek and Ruth Berkowitz, 'The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?' (1998) 1 The Journal of World Intellectual Property 180; Richard P. Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care' (2000) 3 The Journal of Intellectual Property 889; Richard P. Rozek and Renee L. Rainey, 'Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy' (2001) 4 The Journal of World Intellectual Property 463.

countries and found that IP had little, if any, impact on price changes of all drugs.<sup>166</sup> In the next article, '*The Effects of Compulsory Licensing on Innovation and Access to Health Care*', Rozek established that while there was a growth in employment and R&D in countries that enacted patent law, the opposite occurred where a weak IP regime existed.<sup>167</sup> In '*Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy*', he found an enormous increase in R&D in the pharmaceuticals sector when the automatic compulsory licensing regime for medicines was revoked.<sup>168</sup> He also took the view that, in certain situations, generic prices were still higher than that of original medicines.<sup>169</sup> However, Ho and Stirner argue that compulsory licensing has neither a negative nor positive impact on the local sector where the market is insignificant.<sup>170</sup>

In general, opponents of compulsory licensing have insisted on the view that the reason for poor access to healthcare in developing countries is poverty and other factors, rather than patents. Attaran found that over 90% of the drugs included in the Essential Drugs List published by the WHO are not protected by US patents, but people in developing countries still cannot access these medicines.<sup>171</sup> Therefore, patents are not a barrier to access, as is commonly claimed. As will be seen in Section 9.3, even though the WHO backed away from the accusation that patents have implicated access to medicines.

## FDI Attraction

In terms of how compulsory licensing might reduce FDI attraction, Bird and Cahoy pointed out that when the Egyptian government decided to issue a compulsory licence for Viagra, the PhRMA withdrew their investment of \$300 million in Egypt's pharmaceutical sector.<sup>172</sup> Also, as will be seen in Chapter 6, a pharmaceutical company suspended a project worth \$27 million

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<sup>166</sup> Richard P. Rozek and Ruth Berkowitz, 'The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?' (1998) 1 *The Journal of World Intellectual Property* 180, 215.

<sup>167</sup> Richard P. Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care' (2000) 3 *The Journal of Intellectual Property* 889, 894 – 896.

<sup>168</sup> *Ibid.*, 895.

<sup>169</sup> Richard P. Rozek and Renee L. Rainey, 'Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy' (2001) 4 *The Journal of World Intellectual Property* 463, 468.

<sup>170</sup> Canada is such an example. See Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 153; Beatrice Stirner, 'Learning from Practice: Compulsory Licensing Cases and Access to Medicines' (2012) 1 *Pharmaceutical Patent Analyst*, 555.

<sup>171</sup> Amir Attaran, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in developing countries' (2004) 23 *Health Affairs* 155; Amir Attaran and Lee Gillespie, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa' (2001) 286 *the Journal of American Media Association* 1886.

<sup>172</sup> Robert C. Bird and Daniel R. Cahoy, 'The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargain Approach' (2008) 45 *American Business Law Journal* 283, 308.

in Brazil when the government was on the verge of granting a compulsory licence. In fact, as mentioned in Section 2.1, Sellin also observed that early compliance with TRIPS in Uganda was a trade-off for the attraction of FDI.

Reichman does not agree with the assertion that compulsory licensing reduces the flow of FDI into a country. He argues that strong IPR protection is not the only reason for attracting foreign investment, and that market opportunities and other conditions also have an influence.<sup>173</sup> He uses China as an example, although this country does not enact robust IP standards.<sup>174</sup> The author disagreed with Reichman because China is a bad example given its enormous population and other unique political and economic conditions. Therefore, it is not reasonable to compare China with other developing countries, particularly those which are not BRICs. In fact, Reichman had a significant change of heart back in 2003, when he was concerned about the ‘real risks’ of losing FDI and discouraging technology transfer if there was an excessive amount of compulsory licensing.<sup>175</sup>

It could be seen from the above analysis that the results of measuring the impacts of compulsory licences are inconclusive. While those studies are of particular relevance in any attempt to understand the possible long-term effects of the issue of compulsory licences, they did not in particular focus on any individual country. There are no discussions about the institutional process and the underlying rationale involved in a specific grant of a compulsory licence, an essential task which this thesis will fulfil. The author is of the view that only assessment of individual countries enables a successful discernment of how, and why compulsory licensing policies are shaped and the degree to which they satisfy a country’s particular needs.

## 2.5 Historical and interpretative studies of TRIPS Article 31

As will be seen in Section 4.2.1, the negotiation of Article 31 was complex, and compulsory licensing was one of the most controversial patent topics during the writing of TRIPS. Moreover, Article 31 is the longest provision of the patent section contained in TRIPS, the one

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<sup>173</sup> Jerome H. Reichman, ‘Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) 37 Journal of Law, Medicine and Ethics 247.

<sup>174</sup> *Ibid.*, 257.

<sup>175</sup> Jerome H. Reichman and Catherine Hasenzahl, ‘Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA’ (UNCTAD-ICTSD, June 2003) 24.

which was ‘misunderstood and mischaracterized’.<sup>176</sup> Accordingly, a review of the historical and interpretative studies of Article 31 is essential for the purpose of giving the most accurate exposition of it. Many of the leading authors in this area, such as Gervais,<sup>177</sup> Carvalho,<sup>178</sup> Gurry, Abbott and Cottier,<sup>179</sup> Correa and Yusuf,<sup>180</sup> have made substantial contributions. In addition, there was a UNCTAD book that supplements the understanding of Article 31.<sup>181</sup>

It should be noted that because of the length and the complexity of Article 31, it is impractical to present here how these authors interpret each and every single sub-section of Article 31. References to their views can be mainly found in Section 4.2.4, where an analysis of this Article is carried out. However, the author observes that the views of aforementioned authors are sometimes dissimilar, if not contradictory. In fact, they are the reflections of their connection to either the patentee community or the developing countries. For example, Carvalho – a former director of the IP and Competition Policy Division of WIPO, the organisation which supports patents and encourages countries to file more patents, advocates the right owners and thus opposes a broad use of compulsory licensing. (The viewpoint of WIPO is also assessed in Section 9.2) By contrast, the UNCTAD book reflects the view of developing countries because it was UNCTAD that helped these countries in drafting a TRIPS proposal during the Uruguay Round, as will be mentioned in Section 3.2.3.2.

Another book which is also important to fully understand Article 31 is Watal’s, *‘Intellectual Property Rights in the WTO and Developing Countries’*.<sup>182</sup> Watal is the Indian delegate who contributed to the drafting of this controversial Article. Accordingly, her study provides a uniquely personal insight into this provision. Similarly, in 2015, the WTO, also adopting an individual approach, published a book that, for the first time, presented diverse personal accounts of the negotiators of TRIPS.<sup>183</sup> Not only compulsory licensing but other IP matters were analysed in this publication from the perspectives of key participants in the Uruguay trade

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<sup>176</sup> Cynthia M. Ho, ‘Patent Breaking or Balancing? Separating Strands of Fact from Fiction Under Trips’ (2009) 34 N.C. J. of Int'l. L. & Com. Reg. 371, 462.

<sup>177</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012).

<sup>178</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018).

<sup>179</sup> Frederick M. Abbott *et al.*, *International Intellectual Property in an Integrated World Economy* (3<sup>rd</sup> edn, Wolters Kluwer 2015).

<sup>180</sup> Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade. The TRIPS Agreement* (3<sup>rd</sup> edn, Wolters Kluwer 2016).

<sup>181</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005).

<sup>182</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001).

<sup>183</sup> Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015).

Round. This work is of great value from the historical perspective but is not a legal interpretation.

Cynthia Ho's book also focuses particularly on patent and compulsory licensing from a TRIPS perspective without relying much on history.<sup>184</sup> Her work clarifies some misunderstandings of Article 31 and also sheds light on how different views of patents influenced public perceptions. Notably, she classifies the views on patents into two groups: patents as mere privilege (public health activists) and patents as an uber-right (the pharmaceuticals industry's view); thus, she accurately reflects the current dichotomy. Although she claims that neither represents her views, she seems to incline towards the first group.<sup>185</sup>

Ho has strongly criticised those who argue that compulsory licences should only be issued under circumstances of national emergency or extreme urgency. In her view, such an understanding is an intentional distortion that aims to change the meaning of Article 31 and the Doha Declaration in a way that is advantageous to the pharmaceutical companies. She stresses that national emergency, public non-commercial use or extreme urgency are not the conditions for issuing a non-voluntary licence listed by TRIPS, but the requirements for waiving prior negotiation. (There will be further discussion of this point in Section 4.2.4.2.) Ho therefore reiterates that the grounds to issue compulsory licences should remain as open as is stated in TRIPS.

These works greatly assisted the author of this thesis to understand and distil an unbiased reading of Article 31. As will be clearly demonstrated in Section 4.2, this article, one of the most contentious topics of TRIPS, is complex to understand and therefore is open to different interpretations. Certainly, these works deliver a compelling and detailed analysis of TRIPS compulsory licensing, but they concentrate more on the international dimension, and not the domestic aspects concerning developing countries, which is the main theme of this work.

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<sup>184</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011).

<sup>185</sup> *Ibid.*, 163 – 165.

## **2.6 Conclusions**

The literature review in Chapter 2 aims to place this thesis within a broader scope of compulsory licensing policies and to contextualise the practice of India, Brazil and Thailand. Despite significant research having been conducted on compulsory licensing, previous works have generally focused on the potential of compulsory licences for advancing the access to medicines without paying much attention to the domestic context of each country. The author therefore suggests that an individual assessment within each nation is critical if suitable policies are to be proposed.

The preceding studies have allowed the author to conclude that compulsory licensing has been and will be a highly debatable topic, in which contradictory viewpoints and opposing findings continually emerge. Scrutiny of existing literature reveals that no single viewpoint dominates the ongoing academic debate. We can also see that although negative effects associated with a non-voluntary licence occur periodically, it implies that this legal tool should be deliberately crafted. In order to fully understand how compulsory licensing is implemented domestically in each country case study, the two following Chapters will lay out the international background. Before exploring the compulsory licence provisions under international law in Chapter 4, it is necessary to analyse the revolution of the global patent system in Chapter 3 as compulsory licensing, as discussed in Chapter 1, was created to combat the defect in patent monopoly.

# CHAPTER 3: INTERNATIONAL PATENT LAW AND THE PHARMACEUTICAL INDUSTRY

*'The patent system added the fuel of interest to the fire of genius.'*<sup>186</sup>

*'Geniuses, just as the stars, must shine without pay.'*<sup>187</sup>

These two sayings are the accurate reflection of differing views about patent during the debates in the 19<sup>th</sup> century. The creation of TRIPS in the 20<sup>th</sup> century, which expanded patentability to medicines, has added fuel to that controversy. The purpose of Chapter 3 is to therefore survey the global patent system pre- and post-TRIPS, to examine the key characteristics of the pharmaceutical industry, and to highlight the benefits and disbenefits associated with patent innovation. As quickly sketched in Chapter 1 that the launch of TRIPS has dramatically reformed international IP-norm setting, this chapter will go into details of such reformation. In order to achieve the purpose, this chapter will answer the first research question, which consists of two parts: how has international patent law developed and to what extent do pharmaceuticals rely on the patent system?

Although Chapter 3 chiefly focuses on the TRIPS Agreement, it is equally necessary to consider the situation beforehand, mainly the Paris Convention, in order to critically evaluate the important changes brought about by the landmark 1995 Agreement. This historical aspect is also essential to comprehend the emergence and evolution of the political economy of pharmaceutical patents. The linkage between trade and IPRs, which was non-existent during the Paris Convention, was created at the end of the Tokyo Round of GATT and forged ahead with TRIPS during the Uruguay Round negotiations. Such interconnection was totally established and pushed by private industry, as will be demonstrated in this chapter.

The chronological assessment in Chapter 3 denotes that patent standards contained in TRIPS, compared with the Paris Convention, indeed, have entails a paradigm shift - a revolution. They strongly reflect the economic interest of the pharmaceutical sector where patent protection is deemed extremely vital. Therefore, Chapter 3 will further shed considerable light on medicine

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<sup>186</sup> US President Abraham Lincoln, Lecture on Discoveries and Inventions (Illinois College, 11 February 1859 <<http://www.abrahmlincolnonline.org/lincoln/speeches/discoveries.htm>> accessed 5 June 2018.

<sup>187</sup> Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 The Journal of Economic History 1, 17 quoting the disapproving citation made by Wilhelm Roscher, *System der Volkswirtschaft* (Nationalökonomik des Handels und Gewerbefleisses, Stuttgart, 1881) III, 758.

innovation: this is essential if an answer is to be given to the pivotal role of patents to the drug industry. Only by understanding the features of pharmaceutical R&D will the effect of compulsory licensing thereon be fully understood.

### 3.1 The international patent system prior to TRIPS

#### 3.1.1 Early history

The early history of patents can be traced back to the 6th Century B.C., in the Greek colony of Sybaris, where it took the form of granting exclusive rights to those who created a new dish.<sup>188</sup> The first recorded patent was granted by the Republic of Florence in 1421, and the earliest form of patent law – the Venetian Statute – was passed by the Republic of Venice in 1474.<sup>189</sup> These events credited Italy with being the homeland of the patent system. Although the Statute was a rudimentary form of legislation, it contained fundamental elements of patent law that have remained until today.<sup>190</sup>

The idea of granting privileges spread from Italy to other European countries, due to the emigration of Venetian artisans and craftsmen.<sup>191</sup> While Italian patents were granted occasionally, English patents developed strongly during the 15<sup>th</sup> and 16<sup>th</sup> centuries, particularly in the reign of Queen Elizabeth I. With England's agriculture lagging behind that of many European countries, Elizabeth liberally issued privileges to foreigners to import their craft to the country, as a means of introducing new technology to England.<sup>192</sup> A patent under Elizabeth I's reign, however, was more a royal prerogative than a 'right' pertaining to invented objects.

Her patriotic motives produced fruitful outcomes, with the arrival in the country of glass-manufacturing experts from Italy, Protestant skilled craftsman from France, weavers from the south of the Netherlands.<sup>193</sup> Moreover, Dutch farmers with drainage and intensive arable cultivation techniques, Jews from Spain and Portugal with business and finance management,

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<sup>188</sup> Craig Allen Nard, *The Law of Patents* (4<sup>th</sup> edn, Wolters Kluwer 2018) 6.

<sup>189</sup> Giulio Mandich, 'Venetian Patents (1450-1550)' (1948) 30 *Journal of the Patent Office Society* 166.

<sup>190</sup> The Statute, for example, set out the standards of patentability and disclosure of how to work a patent. It also granted a temporary monopoly to inventors for 10 years and provided compensation for patent owners in case of infringement. The Statue was reproduced in Giulio Mandich, 'Venetian Patents (1450-1550)' (1948) 30 *Journal of the Patent Office Society* 166, 177.

<sup>191</sup> Margo A. Bagley *et al.*, *International Patent Law and Policy* (West Academic Publishing 2013) 3.

<sup>192</sup> Craig Allen Nard, *The Law of Patents* (4<sup>th</sup> edn, Wolters Kluwer 2018) 12.

<sup>193</sup> Zhouying Jin, *Global Technological Change: From Hard Technology to Soft Technology* (University of Chicago Press 2005) 86.

all migrated to England and then contributed to the country's economic growth and technological development.<sup>194</sup>

However, Queen Elizabeth I's rules were later broken when some notorious patents were created.<sup>195</sup> A patent that was granted to Darcy in relation to playing cards marked the turning point of the English patent system, since it caused restrictions of trade and industry.<sup>196</sup> The public outcry over the case led to the adoption of the English Statute of Monopolies in 1623, which abolished all of the privileges, with one exception. Only 'the true and first' inventor of 'new manufactures' could still be granted a patent, provided that the exclusive rights were not used to break the law, nor used primarily to raise prices and obstruct trade.<sup>197</sup> The law also provided the inventors with 14 years of monopoly to exploit their creative objects.<sup>198</sup>

The 1623 Statute governed English patent law for more than 200 years, a longer period than any other in the world.<sup>199</sup> It is called the 'mother of our patent law'<sup>200</sup> or the Magna Carta of the rights of inventors as well as of the freedom of trade.<sup>201</sup> Maschlup and Penrose were of the view that such titles given to the Statute not because it originated patent protection for inventors but because it laid down the principle that only the 'true and first' inventors should be granted a monopoly patent.<sup>202</sup> Ladas praised the law for establishing, for the first time in history, the requirements for a patent grant: a limitation in time, and putting an end to arbitrary administrative action.<sup>203</sup>

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<sup>194</sup> Zhouying Jin, *Global Technological Change: From Hard Technology to Soft Technology* (University of Chicago Press 2005) 86.

<sup>195</sup> Craig Allen Nard, *The Law of Patents* (4<sup>th</sup> edn, Wolters Kluwer 2018) 13. Patents for vinegar, starch, and playing cards are such examples.

<sup>196</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 6.

<sup>197</sup> The English Statute of Monopolies in 1623, sec 6.

<sup>198</sup> The English Statute of Monopolies in 1623, sec 6.

<sup>199</sup> B. Zorina Khan, 'Intellectual Property and Economic Development: Lessons from American and European History' (UK Commission on IPRs, Study Paper 1a, 2002) 10

<[http://www.iprcommission.org/graphic/documents/study\\_papers.htm](http://www.iprcommission.org/graphic/documents/study_papers.htm)> accessed 19 March 2018.

<sup>200</sup> Margo A. Bagley *et al.*, *International Patent Law and Policy* (West Academic Publishing 2013) 10.

<sup>201</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 6 citing J. Kohler, *Handbuch des Deutschen Patentrechts* (1900) 19.

<sup>202</sup> Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 *The Journal of Economic History* 2.

<sup>203</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 6.

Nevertheless, it should be noted that under the Statute, trades and skills, as well as new discoveries, were ‘inventions’ and patentable if they were new to England.<sup>204</sup> The primary emphasis of English patent grants at that time was therefore on diffusion.<sup>205</sup> Patents, viewed as a public instrument, were aimed at promoting trades and skills on the island of Britain.<sup>206</sup>

After England, France became the second country in the world to legislate a patent regime.<sup>207</sup> In 1789, the outbreak of the French Revolution led to the adoption of the Declaration of the Rights of Man, on the basis of which the first French Patent Statute was enacted in 1791.<sup>208</sup>. Under this law, inventors’ rights were recognised as natural rights to the fruits of their creative endeavours.<sup>209</sup> Such recognition, however, was not found in the law of any other country, and even the French government backed away from this idea four years later.<sup>210</sup>

In America, the English Statute of Monopolies became a model for the American colonies.<sup>211</sup> It was not until 1790 that the US Congress enacted the first American Patent Act.<sup>212</sup> Following England and France, the US was the third country in the world to adopt a patent system. For this reason, these three countries are viewed as the three founding nations of the patent system.<sup>213</sup>

In addition, America, through its Patent Act of 1836, is credited with the creation of the first modern patent institution in the world: an official Patent Office for the examination of patent

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<sup>204</sup> Heinrich Kronstein and Irene Till, ‘A Re-evaluation of the International Patent Convention’ (1947) 12 Law and Contemporary Problems 765, 772 – 773.

<sup>205</sup> B. Zorina Khan, ‘Intellectual Property and Economic Development: Lessons from American and European History’ (UK Commission on IPRs, Study Paper 1a, 2002) 11  
<[http://www.iprcommission.org/graphic/documents/study\\_papers.htm](http://www.iprcommission.org/graphic/documents/study_papers.htm)> accessed 19 March 2018.

<sup>206</sup> Heinrich Kronstein and Irene Till, ‘A Re-evaluation of the International Patent Convention’ (1947) 12 Law and Contemporary Problems 765, 773.

<sup>207</sup> Gabriel Galvez-Behar, ‘The 1883 Convention and the Impossible Unification of Industrial Property’ (AHRC workshop, International Diversity in Patent Cultures – a historical perspective, Leeds, May 2014) 3.

<sup>208</sup> Thomas M. Méhbesher, ‘The Role of History in Comparative Patent Law’ (1996) 78 Patent and Trademark Office Society 592, 607.

<sup>209</sup> Margo A. Bagley *et al.*, *International Patent Law and Policy* (West Academic Publishing 2013) 5.

<sup>210</sup> Thomas M. Méhbesher, ‘The Role of History in Comparative Patent Law’ (1996) 78 Patent and Trademark Office Society 592, 607.

<sup>211</sup> A similar patent statute to the 1623 English Statute was enacted in Massachusetts in 1641, Connecticut in 1672, and South Carolina in 1691. See Margo A. Bagley *et al.*, *International Patent Law and Policy* (West Academic Publishing 2013) 4.

<sup>212</sup> US Patent Act of 1970.

<sup>213</sup> Gabriel Galvez-Behar, ‘The 1883 Convention and the Impossible Unification of Industrial Property’ (AHRC workshop, International Diversity in Patent Cultures – a historical perspective, Leeds, May 2014) 3.

applications.<sup>214</sup> In contrast to traditional European patent grants, which were subject to royal favour, American patents were granted after examinations.<sup>215</sup>

Patents, in the American view, were private property and should not be subjected to abuse, or any kind of governmental interference, and only international cooperation and mutual recognition of private property in patents could serve the final aim of the highest technological advance everywhere.<sup>216</sup> Such a viewpoint, as will be seen later in this chapter, has been a constant thread present in all US's policies aimed at creating a stronger patent system globally.

On the continent, under the influence of the French Revolution and the expansion of inter-European trade in the first half of the 19<sup>th</sup> century, the adoption of patent laws proliferated.<sup>217</sup> However, in the second half of the 19<sup>th</sup> century, a vibrant anti-patent movement started in England in response to the expensive, clumsy and uncertain procedure for obtaining an English patent.<sup>218</sup> From 1828 onwards, there was a call for dramatic patent reform which would be more favourable to inventors.<sup>219</sup> Ironically, the initial purpose of such a movement, which aimed to reshape the patent system, led to a counter effect: patent abolition.<sup>220</sup> In 1872, a Patent Reform Bill was passed by the House of Lords.<sup>221</sup>

Patent abolition was particularly strong in Germany, Switzerland, and Holland, for the reason that patent monopolies obstructed free trade.<sup>222</sup> Germany objected to the adoption of the patent system for the entire Reich in 1868, while Switzerland, which at that time had never adopted a

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<sup>214</sup> Craig Allen Nard, *The Law of Patents* (4<sup>th</sup> edn, Wolters Kluwer 2018) 22 – 23.

<sup>215</sup> B. Zorina Khan, 'Intellectual Property and Economic Development: Lessons from American and European History' (UK Commission on IPRs, Study Paper 1a, 2002) 12

<[http://www.iprcommission.org/graphic/documents/study\\_papers.htm](http://www.iprcommission.org/graphic/documents/study_papers.htm)> accessed 19 March 2018.

<sup>216</sup> Heinrich Kronstein and Irene Till, 'A Re-evaluation of the International Patent Convention' (1947) 12 Law and Contemporary Problems 765, 771 – 772.

<sup>217</sup> Patent laws were enacted in Austria in 1810, Russia in 1812, Prussia in 1815, Belgium and the Netherlands in 1817, Spain in 1820, Bavaria in 1825, Sardinia in 1826, the Vatican State in 1833, Sweden in 1834, Württemberg in 1836, Portugal in 1837, and Saxony in 1843. See Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 The Journal of Economic History 3.

<sup>218</sup> Charles Dickens, 'Poor Man's Tale of a Patent' (1850) 2 Household Words 73. It is a direct and satirical commentary on the burden of English patenting at that time. See further at Tanya Aplin and Jennifer Davis, *Intellectual Property Law. Text, Cases, and Materials* (3<sup>rd</sup> edn, OUP 2017) 605.

<sup>219</sup> Mark D. Janis, 'Patent Abolitionism' (2002) 17 Berkeley Technology Law Journal 899, 907.

<sup>220</sup> *Ibid.*, 922.

<sup>221</sup> Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 The Journal of Economic History 4.

<sup>222</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 12 – 16.

patent law, did not implement any patent system, despite several proposals asking for such in 1849, 1851, 1854, and early 1863.<sup>223</sup> Holland repealed her patent law in 1869.<sup>224</sup>

However, the opponents of patents did not enjoy their victory for long, and the advocates of patents regained their lost ground in 1873, when the arguments for free trade weakened in the wake of the severe economic depression of that same year.<sup>225</sup> In England, the Bill was withdrawn in the House of Commons.<sup>226</sup> In Germany, a uniform patent law for the entire Reich was passed in 1877.<sup>227</sup> Switzerland enacted the patent law in 1887, after a second referendum, and Holland finally re-adopted the patent legislation in 1910.<sup>228</sup>

### **3.1.2 Towards an internationalized patent system: the creation of the Paris Convention**

By the second half of the 19<sup>th</sup> century, most European countries and America had some kind of patent laws in their domestic legislation. However, the patent system had been adopted in a relatively *ad hoc* manner, depending on legal traditions rather than economic considerations.<sup>229</sup>

A wide diversity of patent subject matters, the conditions and formalities for a patent grant, administrative procedure, the term of protection, and obligations of the patentee... affected foreign patentees in many ways.<sup>230</sup> For example, what was patentable in one country might be unpatentable in another. Also, as patents have been territorial in nature, applications had to be made roughly at the same time in each individual country in order to avoid a publication in one country destroying the novelty of that invention in the other states. Furthermore, some countries imposed a requirement that a foreign patentee had to work his invention within a fixed period. Otherwise, the patent would be revoked. In many countries at that time, foreign patentees received a less sufficient protection than locals.

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<sup>223</sup> Fritz Machlup and Edith Penrose, ‘The Patent Controversy in the Nineteenth Century’ (1950) 10 *The Journal of Economic History* 5.

<sup>224</sup> *Ibid.*

<sup>225</sup> Mark D. Janis, ‘Patent Abolitionism’ (2002) 17 *Berkeley Technology Law Journal* 899, 924

<sup>226</sup> Fritz Machlup and Edith Penrose, ‘The Patent Controversy in the Nineteenth Century’ (1950) 10 *The Journal of Economic History* 6.

<sup>227</sup> *Ibid.*

<sup>228</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 12 – 16.

<sup>229</sup> Petra Moser, ‘How Do Patent Law Influence Innovation? Evidence from Nineteenth-Century World’s Fairs’ (2005) 95 *American Economic Association* 1214, 1216.

<sup>230</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 21 – 26.

The inadequacy became apparent in 1873 when the Government of the Empire of Austria-Hungary invited foreign inventors to attend an international exhibition of inventions at Vienna. However, many, particularly those from the US, expressed the doubt that their ideas would be stolen and exploited commercially in other countries since Austrian patent law did not provide sufficient protection.<sup>231</sup> Furthermore, the working provision, which required the patent to be worked within a year from the date of patent grant, was called the most vexatious rule and was strongly objected by the US.<sup>232</sup>

As a result, Austria had to pass a special law, which secured temporary protection for exhibited inventions, until the end of 1873.<sup>233</sup> Following the exhibition, the Congress of Vienna decided to meet in August that year for the patent reform purpose. This 1873 conference focused mainly on the nature of patent rights and set up a permanent execute committee to work on patent issues.

In 1878 and 1880, two international conferences, hold in Paris under the auspices of the French government, expanded the topics of patent discussions to other forms of industrial property. While the participants in the 1878 conference were mainly from European countries, the US and Russia, the 1880 conference had more representatives from less-developed countries such as Argentina, Brazil, Guatemala, Salvador, Turkey, Uruguay and Venezuela.<sup>234</sup> However, these countries did not make any significant contributions to the early debates on globalising the patent system.

During the negotiating process, the intention of unifying patent laws was proposed but vigorously contested by the participants because of the divergence of their countries' interests, legal structures, economic histories, aspirations and ideologies.<sup>235</sup> At the end of the 1880 conference, a draft convention was adopted. This thesis argues that even though the Convention failed to adopt a uniform patent law for all member states, it opened the era of patent internationalisation.

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<sup>231</sup> Midjohodo Franck Gloglo, ‘Legislative Comment: Pharmaceutical Patent Controversy Rises with Senator Bernard Sanders’s Proposed Bill’ (2013) 35 EIPR 527, 528.

<sup>232</sup> Fredrik Neumeyer, *Compulsory licensing of patents under some non-American systems* (US government printing office 1959) 6.

<sup>233</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 60.

<sup>234</sup> *Ibid.*, 61, 63.

<sup>235</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 53.

In 1883, a diplomatic conference was held in Paris to sign the Convention for the Creation of the Union for the protection of industrial property and the Final Protocol thereof. The 11 founding nations were: Belgium, Brazil, El Salvador, France, Guatemala, Italy, the Netherlands, Portugal, Serbia, Spain and Switzerland.<sup>236</sup> When the agreement came into effect on 7<sup>th</sup> July 1884, Great Britain, Tunisia and Ecuador joined, bringing the initial number of member countries to 14.<sup>237</sup>

It is interesting to highlight that the Paris Convention, which marked a start of internationalised patent, occurred at a crucial juncture where three opposing philosophies were competing: the anti-patent movement; the recognition of patents as private property; the recognition of patents as an instrument of public policy.<sup>238</sup> Germany, Switzerland, and Holland are notable representatives for the first group, the US is an evident example of the second one, whereas England and France are instances of the third viewpoint. The adoption of the Paris Convention was indeed a major victory of patent proponents. It is also the first international attempt to cooperate and mutually recognise patents within member states. The initial input and outcome of this agreement were solely made and shaped by European countries and America. Developing countries, despite their presence at the time of ratifying the Convention, were almost absent in the early, important discussions over the global patent regime.

In 1967, the Paris Convention was placed under the administration of WIPO, the UN's specialised agency, the role of which will be discussed in Section 9.2.

### 3.1.3 From Paris to GATT

One of the most important achievements of the Paris Convention was the inclusion of national treatment, a principle which prohibits the discriminatory treatment between foreign and local inventors. In fact, this principle is beneficial to foreigners when, and only when, patent protection has been implemented in a member state. In this way, international patentees can enjoy the same treatment given to domestic inventors. National treatment would have a zero impact if no patent regime existed in a particular market, because if a local invention was not protected by a patent, how could a foreign one claim the same treatment? Looking at the Paris

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<sup>236</sup> WIPO, *Intellectual Property Handbook: Policy, Law and Use* (2<sup>nd</sup> edn, WIPO 2004) 241.

<sup>237</sup> *Ibid.*

<sup>238</sup> Heinrich Kronstein and Irene Till, 'A Re-evaluation of the International Patent Convention' (1947) 12 Law and Contemporary Problems 765, 766.

Convention from this perspective, this treaty failed to create new substantive patent laws and instead recognised what had existed under the member states' domestic legislation.

Furthermore, the Convention did not provide the technology-based industries with adequate protection, neither did it impose minimum standards for levels of protection nor for patentable subject matter.<sup>239</sup> Indeed, the signatories retained significant room to carve out their own legal frameworks, with the result that patent regulations varied widely from one country to another. The compulsory licensing regime was also lax and did not set out the right to remuneration of the patent owners. In addition, the Convention was devoid of any effective enforcement machinery to punish a violation, which is considered another serious defect.<sup>240</sup>

For pharmaceuticals, the world's patent laws at that time were of a great diversity. With regard to subject matter patentability, for example, some countries (such as the US), protected both processes and products, some (for example India and Thailand) granted protection only on processes, and others, including Brazil, protected neither. As regards the term of protection, while the US allowed 17 years of patent life, Thailand gave 14 years, India only provided 7 years. Some nations treated compulsory licences as lawful, as was the case in Canada, while others, for example, the US, did not.<sup>241</sup> For this reason, the Paris Convention was by no means an overwhelming victory for those who desired a rigorous patent system.

This was particularly true of the US's pharmaceutical industry, which, after WW2, began to establish production units abroad.<sup>242</sup> Wide discrepancies of countries' patent law were to the detriment of the US's drug sector, which claimed huge trade losses linked to piracy and counterfeit.<sup>243</sup> One drug company, Merck, argued that global patent piracy cost the US pharmaceutical business about \$6 billion in 1986, possibly reducing the industry's R&D by between \$720 million and \$990 million.<sup>244</sup> In addition, Pfizer estimated that battles to defend its company's patents had cost over \$100 million between 1981 and 1991.<sup>245</sup> Nevertheless, as

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<sup>239</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 3.

<sup>240</sup> *Ibid.*

<sup>241</sup> Jerome H. Reichman and Catherine Hasenzahl, 'Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA' (UNCTAD-ICTSD, June 2003).

<sup>242</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 62.

<sup>243</sup> *Ibid.*

<sup>244</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 45.

<sup>245</sup> *Ibid.*

Scherer commented, using the term ‘piracy’ was a public relations ploy, since it was legal *not* to patent medicines in many countries at that time, hence there was no violation of international law.<sup>246</sup> The word ‘piracy’ was therefore chosen deliberately to provoke as much public impact as possible. Since the 1970s, the US’s pharmaceutical industry has been clamouring for stronger IP standards.

In the meanwhile, the generic drug industry took off in some developing countries. India, by the adoption of its Patent Act in 1970, which abolished patents on pharmaceutical products, developed a highly competitive generic sector, as will be seen in Chapter 5. (However, in order to comply with TRIPS, India reintroduced a product patent regime in 2005.) Brazil also got rid of patent protection for pharmaceutical products in 1945 and eliminated patent protection for medicine processes in 1969, as will be seen in Chapter 6. (Nevertheless, Brazil re-enacted the patent mechanism in 1996 on account of its TRIPS membership.)

Moreover, there was the emergence of other economic powers such as South Korea, Taiwan, and Singapore who had low IP standards. What is more, these countries, which were either not present at all or contributed only trivially to the adoption of the Paris Convention, now called for a revision of this treaty to further reduce patent standards.<sup>247</sup> From only six members in 1883, by the 1980s developing countries amounted to two-thirds of the membership.<sup>248</sup> As a result, such an increase made their voice heard.

The revisions of the Paris Convention effected between 1980 and 1984 became a battleground between the South and the North. While the requirement of flexible patents for the developing countries was rejected, the US’s effort of strengthening IP protection was equally unsuccessful.<sup>249</sup> The failure of the Paris process marked the start of a strong North-South division. It also marked the end of an era of lowering or weakening international IPR standards for developing countries. From this time, through to the end of the TRIPS negotiations, the developing world remained on the defensive with regard to IPRs.<sup>250</sup> At the other end of the spectrum, the developed countries quickly realised that the Paris Convention was no longer

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<sup>246</sup> Scherer’s comment was quoted in Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 46.

<sup>247</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 111.

<sup>248</sup> *Ibid.*, 99.

<sup>249</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 16 – 17.

<sup>250</sup> *Ibid.*, 17.

their exclusive ‘club’. They found themselves instead having to defend the existing IP standards.<sup>251</sup> It became clear to them that WIPO was not a proper platform for them to exercise their desired IP regime any more. They then turned to another forum: The GATT.

The status of GATT can be traced back to a meeting at Bretton Woods, New Hampshire, in 1944. In 1947, GATT was adopted, with the main objective of ensuring a freer, non-discriminatory trade in goods.<sup>252</sup> Under GATT, only a small number of IP provisions were adopted.<sup>253</sup> The first initiative to include IP within the GATT framework took place in the Tokyo Round. This was the seventh round of multilateral trade negotiations that happened between 1973 and 1979, where the US and the EC proposed a Counterfeit Code to deal with cross-border movement of counterfeit goods.<sup>254</sup> However, this effort, which started late in 1979 when the trade Round came to the end, failed to gain any support apart from the two aforementioned actors.<sup>255</sup> Despite such failure, the author views that the Tokyo Round marked a starting point for linking IP and trade within the multilateral framework. Such linkage was later manifested in the negotiation of TRIPS.

### 3.2 The TRIPS Agreement

The TRIPS Agreement, which is Annex 1C of the Marrakesh Agreement Establishing the WTO, entered into force on 1 January 1995. It is an integral part of the WTO Agreements, and is binding on each member country from the date TRIPS becomes effective for that country. TRIPS was a result of the Uruguay Round of the GATT, which started in September 1986 in Punta del Este, Uruguay and ended in 1994. This was the eighth round of trade negotiations after the Tokyo Round and by far the most comprehensive one.

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<sup>251</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 111.

<sup>252</sup> Mohammed El Said, *Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region*’ (WHO and ICTSD 2010) 27 – 28.

<sup>253</sup> Frederick M. Abbott, ‘Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework’ (1989) 22 Vanderbilt Journal of Transnational Law 689, 696.

<sup>254</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 8; Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 50; ‘The GATT years: from Havana to Marrakesh’ (WTO) <[https://www.wto.org/English/thewto\\_e/whatis\\_e/tif\\_e/fact4\\_e.htm](https://www.wto.org/English/thewto_e/whatis_e/tif_e/fact4_e.htm)> accessed 5 April 2017.

<sup>255</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 50.

Before the elaboration of how TRIPS came to life, it is necessary to understand TRIPS as a piece of the ‘mosaic’ that is the WTO. It is equally important to touch upon the US’s trade policies, as the US was the driver behind the formation of TRIPS in Punta Del Este.

### **3.2.1. The contextualization of the TRIPS Agreement within the Uruguay Round**

First of all, the negotiations to establish the WTO were based on the ‘single undertaking’ approach,<sup>256</sup> (i.e. nothing is agreed until everything is agreed), meaning that member states had to accept all the results of the Round as a single package without exception. The TRIPS Agreement is part of that package, and therefore applies to all WTO members.

Secondly, it should be noted that the Uruguay Round dealt with not only IPRs but also a number of trade issues. To many developing countries, from the very beginning of the Round, negotiating areas such as agriculture and textiles had systemic value for the whole exercise, not all the other areas, including IP, had the same intrinsic value.<sup>257</sup> Brazil and Thailand are such examples, as will be analysed in their individual chapter. Those countries entered the multilateral trading system with the main aim of eliminating export tariffs imposed by developed countries.

Finally, parties to TRIPS had to comply with the WTO dispute settlement system, regulated by the Dispute Settlement Understanding (DSU). If a member state’s legislation is found not to be in accordance with TRIPS (or any WTO Agreement), it is required to bring the law into conformity within a given period. Otherwise, that member might be subject to permissible trade retaliation. Therefore, the likelihood of enforcing TRIPS regulations is greater and stronger than the Paris Convention because the DSU, which is a part of the WTO single package, must be accepted by signatories as a whole.

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<sup>256</sup> Ministerial Declaration on the Uruguay Round (20 September 1986) MIN.DEC. See further at WTO, ‘How the negotiations are organized’ <[https://www.wto.org/english/tratop\\_e/dda\\_e/work\\_organ\\_e.htm](https://www.wto.org/english/tratop_e/dda_e/work_organ_e.htm)> accessed 5 March 2018 and ‘Frequently asked questions about TRIPS in the WTO. What is the place of the TRIPS Agreement in the multilateral trading system?’ <[https://www.wto.org/english/tratop\\_e/trips\\_e/tripfq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm)> accessed 5 March 2018.

<sup>257</sup> Antonio Gustavo Trombetta, ‘Negotiating for Argentina’ in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 262.

In short, that aforementioned factors influenced the dynamics and the whole gamut of the TRIPS negotiations, and further implied that losing in one sector can be compensated by winning in others.

### **3.2.2 The US's strategy leading up to the Uruguay Round**

As previously treated in Section 3.1.3, since the 1970s the US pharmaceutical industry had sought more stringent patent protection, but failed to achieve it at the multilateral level, through WIPO and the Tokyo Round of GATT. The country then unilaterally decided to establish IP norms through its trade law. In 1984, the US government amended the 1974 Trade Act to include IP in the GSP programme and in Section 301, which required its trading partners to raise the level of IP protection to American standards.<sup>258</sup> The new GSP programme demanded that a designated beneficiary country had to comply with US IP requirements if that country wished to enjoy duty-free exports to the US market.<sup>259</sup> Notably, Section 301 allowed the US president to withdraw trade benefits from a country or impose duties on its goods when that country failed to provide adequate and effective protection for US IP abroad.<sup>260</sup>

US efforts to link trade to IP bore fruit in the case of South Korea. In September 1985, the US launched its first investigation of South Korea under Section 301.<sup>261</sup> As a consequence, in July 1986, South Korea agreed to revise its patent law in a bilateral agreement with the US, which served as one of the two prototypes for the TRIPS Agreement.<sup>262</sup> The most significant revisions of Korean patent law were the patenting of pharmaceuticals, giving extension to pharmaceuticals, and providing retroactive protection for pharmaceutical inventions already in the public domain in the US, but new to the Korean market.<sup>263</sup>

Apart from revising South Korean patent law, an important subsidiary objective of the US, according to some, was to separate this country from joining developing countries to oppose

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<sup>258</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 18.

<sup>259</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 86 – 88.

<sup>260</sup> *Ibid.*, 88 – 89.

<sup>261</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 51.

<sup>262</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 61. The other prototype was the Basic Framework of GATT provisions on IP, representing the collective efforts of the business community in the US, Europe and Japan. It will be mentioned in section 3.3.3.1.

<sup>263</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 18 – 19.

IPRs in GATT.<sup>264</sup> The success with South Korea, just before Punta del Este, demonstrated US economic unilateralism in altering a country's patent policy in favour of US industry.<sup>265</sup> This thesis submits that seeing South Korea as an example, the developing world now faced a stark choice between bad and worse! Stated differently, developing countries faced the prospect of (A), either entering the multilateral trade talk within the GATT agenda, or (B) confronting a bilateral agreement with the US on their own.

In addition to unilaterally imposing economic sanction on developing countries, the US started building coalition with other like-minded countries. It realised that IP issues could not be settled at GATT without support from the Quad (the US, the EC, Japan, and Canada).<sup>266</sup> In March 1986, Opel and Pratt, the respective CEOs of IBM and Pfizer, formed the IPC to build an international consensus amongst their business counterparts from the Quad.<sup>267</sup> The IPC comprised 13 major US corporations from different industries. This group provided adequate funding and human resources to the IP effort, as well as persuading their business counterparts in the Quad to press their respective governments into introducing an IP code in the GATT talks. To the US, the EC was the key target, followed by Japan, while Canada, despite being a Quad member, was not really a player.<sup>268</sup> Therefore, the support from the EC and Japan added weight to the campaign. This thesis argues that the establishment of the IPC laid the foundation for private industry to lobby the US government to connect IP with trade issues during the Uruguay Round.

By the time the Uruguay Round was launched in September 1986, the US, the EC and Japan stood united in their common goal, which was to include IP in the GATT negotiation. This thesis submits that such coalition-building taking place prior to the Uruguay Round enabled them to enter the trade round with minimal disagreement. In addition, the US entered the

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<sup>264</sup> *Ibid.*, 18.

<sup>265</sup> *Ibid.*, 18 – 19.

<sup>266</sup> The Quadrilateral Group (Quad), formed in 1981, consisted of the US, the EC, Japan and Canada and aimed to develop a consensus for a new round of multilateral trade negotiations. Susan K. Sell, *Private Power, Public law. The Globalisation of Intellectual Property Rights* (CUP 1997) 104 – 105; Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 117-118.

<sup>267</sup> Susan K. Sell, *Private Power, Public law. The Globalisation of Intellectual Property Rights* (CUP 1997) 102 – 103.

<sup>268</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 118.

negotiations with the mantra ‘no IP, no trade round’.<sup>269</sup> On the other side of the negotiating table, the developing countries were totally unprepared, as will be examined next.

In 1988, while the TRIPS negotiations were ongoing, the US amended Section 301, which then became ‘Special 301’.<sup>270</sup> This amendment substantially enlarged the possibility for employing US trade pressure to countries which denied fair and equitable market access to US IPR holders. Special 301 permitted the USTR to submit an annual review to identify such countries and to retaliate quickly.<sup>271</sup> Under Special 301, US trading partners with IP deficiencies were listed under the following classifications: watch lists, priority watch lists, and priority foreign countries. The last one is the worst classification, and those countries on it are likely to face trade retaliation by the US. Although, as Drahos commented, Special 301 was much more about barking than biting, It was and still is instrumental in monitoring the IP policies of the nations having trade relationships with the US, as will be shown in Chapters 5 (India), 6 (Brazil) and 7 (Thailand).<sup>272</sup>

### **3.2.3 The writing of TRIPS**

The negotiating process of TRIPS can be split into three periods: September 1986 - April 1989, April 1989 – 1990, and the final phase, 1991 – 1994.<sup>273</sup>

#### **3.2.3.1 September 1986 - April 1989**

The first phase showed little progress, because the ten hard-line developing countries,<sup>274</sup> led by Brazil and India, vigorously objected to the inclusion of IP in GATT. They argued that WIPO, not GATT, was the proper forum to deal with such an issue.<sup>275</sup>

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<sup>269</sup> *Ibid.*, 72.

<sup>270</sup> *Ibid.*, 89.

<sup>271</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 61.

<sup>272</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (1<sup>st</sup> edn, Earthscan 2002) 99.

<sup>273</sup> Adrian Otten, ‘The TRIPS negotiations: An overview’ in Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015).

<sup>274</sup> Ten hard-line developing countries were India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania, and Yugoslavia. Susan K. Sell, *Private Power, Public law. The Globalisation of Intellectual Property Rights* (CUP 1997) 108; UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 3.

<sup>275</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 59; Charles Clift, ‘Why IPR issues were brought to GATT: A historical perspective on the origins of TRIPS’ in Carlos M. Correa (edn), *Research Handbook on the Protection of Intellectual Property under WTO Rules. Intellectual Property in the WTO Volume I* (EE 2010) 9 – 10; Adrian Otten, ‘The TRIPS

At the same time, the Quad, as the result of their pre-consensus, unanimously insisted on adequate protection and enforcement for IPRs.<sup>276</sup> In spite of having divergence on some issues, the group of developed countries maintained solidarity on the baseline issues of what had to be discussed in the negotiations. Notably, the text titled *Basic Framework of GATT Provisions in Intellectual Property: Statement of Views of the European, Japanese, and the United States Business Communities* became a blueprint for trade negotiators.<sup>277</sup> In addition to the bilateral agreement between South Korea and the US, this document served as a second prototype of TRIPS.<sup>278</sup>

The developing countries did not contribute any substantive written input. Their counter arguments were mostly put by way of oral presentations.<sup>279</sup> It was not until the end of 1988 that Thailand and Brazil submitted their statements. However, their submissions, unlike those of the developed countries, were uncoordinated.<sup>280</sup>

Outside the negotiating room, the US unilaterally imposed 100% tariffs on Brazil's imports in 1988<sup>281</sup> and dropped Thailand from the GSP list in 1989 and 1991.<sup>282</sup> (These situations will be touched upon in Chapters 6 and 7, which treat Brazil and Thailand respectively). The leaders of the opponents of IP - Brazil and India, were placed on the priority watch list. Other hardliners, namely Argentina, Egypt and Yugoslavia, also found themselves on the watch list.<sup>283</sup> For other countries, the US implemented the 'divide and rule' policy to separate them from the hard-core opponents. For example, the IPC specified to the ASEAN group that Brazil

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negotiations: an overview' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 61.

<sup>276</sup> Charles Clift, 'Why IPR issues were brought to GATT: A historical perspective on the origins of TRIPS' in Carlos M. Correa (edn), *Research Handbook on the Protection of Intellectual Property under WTO Rules. Intellectual Property in the WTO Volume I* (EE 2010) 11.

<sup>277</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 123.

<sup>278</sup> Charan Devereaux et al., *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 61.

<sup>279</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 23 – 26.

<sup>280</sup> Charles Clift, 'Why IPR issues were brought to GATT: A historical perspective on the origins of TRIPS' in Carlos M. Correa (edn), *Research Handbook on the Protection of Intellectual Property under WTO Rules. Intellectual Property in the WTO Volume I* (EE 2010) 11 – 12.

<sup>281</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 86; Charles Clift, 'Why IPR issues were brought to GATT: A historical perspective on the origins of TRIPS' in Carlos M. Correa (edn), *Research Handbook on the Protection of Intellectual Property under WTO Rules. Intellectual Property in the WTO Volume I* (EE 2010) 13.

<sup>282</sup> Jakkrit Kuanpooth, 'Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future' (EE 2010) 38.

<sup>283</sup> Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 52.

and India should not act as their representatives in the negotiations because these two countries did not pay as much attention as this group to the investment climate.<sup>284</sup>

In addition, since the middle 1980s, the US government won important victories, signing bilateral agreements with other developing countries. For example, the US - Israeli free trade agreement, which was launched in 1983 and concluded in 1985, was the first of this kind in terms of both scale and content.<sup>285</sup> Similarly, the US signed agreements with Indonesia and Taiwan, or made countries such as Saudi Arabia and Colombia to change their IP laws.<sup>286</sup> At the regional level, the US concluded the North American Free Trade Agreement (NAFTA) with Canada and Mexico in 1992, which entailed stringent IP requirements.<sup>287</sup> NAFTA became a landmark for future U.S. negotiations and a baseline for IP demands.<sup>288</sup> Towards the end of TRIPS, the US was negotiating some 20 bilateral agreements with developing countries that included regulations protecting IPRs.<sup>289</sup> This thesis argues that, although the US had not accomplished its goals through the multilateral system, they had succeeded at the bilateral and regional levels. Suppression of developing countries thus remained a matter of time.

### **3.2.3.2 April 1989 – 1990**

The negotiating parties could not reach consensus on the scope of GATT until April 1989, when, at the Trade Negotiating Committee meeting in Geneva, developing countries, with the exception of India, agreed to bring IP to the trade talks after two years of objection. It was the turning point of the negotiation process, which came as the outcome of the US's divisive policy. The ASEAN, after realising that they had different interests from other developing countries, moved the talks along.<sup>290</sup> While South Korea had long since given up confrontation with the

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<sup>284</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 129.

<sup>285</sup> Gaëlle Krikorian, ‘Free-Trade Agreements and Neoliberalism: How to Derail the Political Rationales that Impose Strong Intellectual Property Protection’ in Gaëlle Krikorian and Amy Kapczynski (eds), *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010) 297.

<sup>286</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 134.

<sup>287</sup> Susan K. Sell, *Private Power, Public law. The Globalisation of Intellectual Property Rights* (CUP 1997) 110.

<sup>288</sup> Gaëlle Krikorian, ‘Free-Trade Agreements and Neoliberalism: How to Derail the Political Rationales that Impose Strong Intellectual Property Protection’ in Gaëlle Krikorian and Amy Kapczynski (eds), *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010) 297.

<sup>289</sup> Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 50.

<sup>290</sup> Charan Devvereaux et al., *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 63.

US as a consequence of the bilateral agreement in 1985, Brazil, the victim subject to Special 301, relinquished its opposition due to a tariff imposed by the US in 1988.

Other developing countries also softened their stances, on account of trade sanctions from the US, or because of trade-offs in other areas. Some countries agreed to negotiate new standards in TRIPS in exchange for receiving important concessions in other negotiating areas, such as agriculture and textiles.<sup>291</sup> They came to believe that their interests in the agriculture sector should not be harmed by their intransigence on the TRIPS negotiating mandate.<sup>292</sup> India was left as the last country to hold out. In addition to isolation from its peers, the US's threat of trade sanctions against Indian exports forced the country's government to abandon its defensive mode. In September 1989, India announced that it had agreed to discuss IP in the Uruguay Round.<sup>293</sup>

Along with other IP forms, the framework of the patent area became clearer after April 1989. To the US and like-minded countries, the key objective was to ensure patent protection for pharmaceuticals (and agricultural chemicals).<sup>294</sup> In return, developing countries would be given a transitional period to implement such protection, and consideration given to their developmental and technological objectives.<sup>295</sup> As Watal commented, agreeing to the patenting of pharmaceuticals is one of the most crucial points that the developing countries gave up without trying to negotiate.<sup>296</sup>

Nevertheless, not only were the developing countries threatened by the stick of Special 301, they were also attracted by the carrot of market entry. The US gave Hong Kong, Singapore and South Korea preferential GSP benefits as rewards for the improvement of their IP policies.<sup>297</sup> Meanwhile, aware of what had happened to South Korea, India, and Brazil, other hardliners quickly realised that refusing IP in the multilateral trade round would not mean that the issues

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<sup>291</sup> Susan K. Sell, *Private Power, Public law. The Globalisation of Intellectual Property Rights* (CUP 1997) 110.

<sup>292</sup> A.V. Ganesan, 'Negotiating for India' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 220.

<sup>293</sup> Susan K. Sell, *Private Power, Public law. The Globalisation of Intellectual Property Rights* (CUP 1997) 109.

<sup>294</sup> Catherine Field, 'Negotiating for the United States' in Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 141.

<sup>295</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 27.

<sup>296</sup> *Ibid.*

<sup>297</sup> Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 55.

would go way; rather, they would have to face them in bilateral negotiations with the US where they would be in a more vulnerable bargaining position.

In addition to the overall dynamics of bargaining, the fall of Berlin Wall in the year 1989 had added uncertainty to the world's economy, and placed America at the centre of the new global order.<sup>298</sup> For developing countries, the possibility of the US turning away from the Uruguay Round was not in their interests.<sup>299</sup> Also the reunification of Germany and the dissolution of the Soviet Union signified the entry to a broader market, which appealed to less-developed countries.<sup>300</sup>

By 1989, the negotiation process had now started in earnest. In May 1990, five comprehensive draft legal texts were tabled, one from the EC, three from developed countries (the United States, Switzerland and Japan) and one from a group of 14 developing countries (Argentina, Brazil, China, Chile, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe) with the help from the UNCTAD, followed by an Australian text of geographical indications.<sup>301</sup> The proposals from the EC and the US having the same title and language implied that, they had consulted with each other before tabling the document.<sup>302</sup> While their approach was confined to a single Agreement, consisting of all the areas of negotiation and dealing with all seven categories of IP, the developing countries' proposals consisted of two parts, one on trade in counterfeit goods and another on the availability, scope and use of IPRs.<sup>303</sup>

Watal noted that developing countries, due to its lack of technical expertise, time and coordination, missed this crucial opportunity to present a more detailed text that reflected their interest and positions.<sup>304</sup> Their submissions were too general to counter the comprehensive text

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<sup>298</sup> Antonio Gustavo Trombetta, 'Negotiating for Argentina' in Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 261.

<sup>299</sup> Charan Devereaux et al., *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 64.

<sup>300</sup> Antonio Gustavo Trombetta, 'Negotiating for Argentina' in Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 261.

<sup>301</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 19 – 20.

<sup>302</sup> *Ibid.*, 20.

<sup>303</sup> *Ibid.*, 20 – 21.

<sup>304</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 31 – 32.

submitted by the developed nations.<sup>305</sup> As a result, the latter's input became the baseline for TRIPS negotiators in their drafting of the Agreement.

The text of the developing group nevertheless formed Articles 7 (Objectives), 8 (Principles), 27 (Exclusion from patentability), and 40 (Control of anti-competitive practices in contractual licences).<sup>306</sup> An important contribution made by India was the combination of government use and compulsory licences under Article 31, and this will be studied in more detail in the next chapter.

By the end of 1990, negotiations were advancing swiftly at the Brussels Ministerial meeting where the trade Round was near completion.<sup>307</sup> However, the meeting collapsed because the US and the EC could not reach an agreement on agriculture subsidies.<sup>308</sup>

### **3.2.3.3 The final phase: 1991 – 1994**

When the Uruguay Round resumed in March 1991, no significant progress was made, even though there were still a number of IP issues that needed to be debated. At the end of 1991, the Director General of the GATT, Mr. Dunkel, intended to conclude the negotiations by drafting a Final Act which included a proposal for an Agreement on TRIPS.<sup>309</sup> This draft, which provided strong IP protection, but delayed implementation for developing countries from five to 10 years, displeased the US pharmaceutical industry.<sup>310</sup> Despite the criticism, the Dunkel draft, with some minor modifications, became a part of the Uruguay Round Final Act. In April 1994, the text of TRIPS was formally adopted in Marrakesh, Morocco and came into effect on 1<sup>st</sup> January 1995.

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<sup>305</sup> *Ibid.*

<sup>306</sup> *Ibid.*

<sup>307</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 25.

<sup>308</sup> Charan Devreux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 68.

<sup>309</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 29.

<sup>310</sup> Charan Devreux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 70.

### **3.3 Principal pharmaceutical-related provisions under TRIPS**

This section will analyse the principal provisions of TRIPS in relation to pharmaceuticals which include:

- Exhaustion (Article 6)
- Patentable subject matter (Article 27.1)
- Other Use Without Authorization of the Right Holder (Article 31). It will be treated separately in the next chapter.
- Term of Protection (Article 33)
- Transitional arrangement and marketing exclusive rights (Article 65, Articles 70.8 and 70.9)

Except from Article 33, other provisions are regarded as important TRIPS flexibilities by which member states can circumvent patent monopoly to increase the access to medicines.<sup>311</sup>

However, before assessing those Articles in more depth, it is necessary to clarify the relationship between TRIPS and the Paris Convention, as this was one of the main concerns during the Uruguay negotiations. The adoption of TRIPS gave the Convention a new life.<sup>312</sup> Prior to TRIPS, accession to the Paris Convention was at the discretion of each country. However, as TRIPS incorporated this treaty, a member's agreement on joining TRIPS automatically bound it to the Paris Convention and comply with Articles 1 to 12, and Article 19 therein.<sup>313</sup> Such compliance creates a double-tiered effect, by which a member country's law is bound by TRIPS and the Paris Convention.

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<sup>311</sup> WIPO, 'Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels' (18 August 2010) CDIP/5/4REV; Jae Sundaram, 'Brazil's implementation of TRIPS flexibilities: ambitious missions, early implementation, and the plans for reform' (2014) 23 Information and Communications Technology Law 81; Jodie Liu, 'Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act' (2015) 56 Harvard International Law Journal 207; Mohammed K. El Said, 'TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries' (2016) 31 American University International Law Review 373, 399 – 401; Omar Serrano and Mira Burri, 'Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India' (2016) World Trade Institute Working Paper no. 1, <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2748447](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2748447)> accessed 7 March 2018; Ellen FM 't Hoen *et al.*, 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 Bulletin WHO 185.

<sup>312</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 3.  
<sup>313</sup> TRIPS, art 1.3 and art 2.1.

### **3.3.1 Exhaustion**

Article 6 of TRIPS addresses the exhaustion of IPRs, a practice which takes place when a product is placed on the market with the consent of the right owner. It should be noted that the right owner does not lose his IPRs embodied in that particular product but his control over its further movements. He cannot restrict, for example, the distribution, resale or re-import of such a product. This practice is also known as the ‘first sale doctrine’, as the right holder is considered to have ‘exhausted’ his rights over the good after its first sale.

There are national, regional or international exhaustion. Under the national exhaustion, the IP holder’s right to control finishes when a product is sold or marketed within the territory of a country. If a country follows regional exhaustion, such right ends when the first sale occurs in any country of a region. If a country adopts international exhaustion, the owner’s control is extinguished when the product is marketed anywhere in the world. International exhaustion gives rise to parallel importation which refers to goods produced and sold legally in a WTO member, and subsequently imported into another member.<sup>314</sup> Because TRIPS leaves member states to freely implement the exhaustion doctrine, this is a significant flexibility by which the access to medicines can be potentially increased. Countries can adopt international exhaustion, thereby ‘shopping around’ where international differential price exists.

### **3.3.2 Patentable subject matter**

Article 27.1, in defining the scope of a patent, is the biggest contribution of TRIPS towards rigorous patent protection. The first sentence of this Article establishes patentable inventions and conditions for patentability. Instead of relying on domestic law, as the Paris Convention had done, TRIPS imposes worldwide minimum standards of patent protection, as long as an invention is new, inventive and industrially applicable, and as long as the subject matter does not fall within a specific category (Article 27.2) or a specific class (Article 27.3).

Article 27.1 carries a significant implication for countries that had not previously provided patent protection for pharmaceutical products or processes. However, a flexibility is given here by the absence of a definition of the three criteria of patentability. What constitutes newness, inventiveness, and industrial application is left to each member state to decide, leaving them significant room for interpretation. WTO members can raise or lower the patent bar by setting

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<sup>314</sup> WHO, WIPO, and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections public health, intellectual property and trade* (WHO/WIPO/WTO 2013) 182.

these thresholds, depending on their own circumstances. Developing countries are advised to adopt strict standards to screen out substandard inventions.<sup>315</sup> India is an example where such bar is created to meet its national needs (Section 5.2.3).

Article 27.1 also executes a national treatment principle by forbidding discrimination against patents *and* patent rights as to the place of invention, the field of technology and whether products are imported or locally produced. The first element, which refers to the place where the invention was made, aims to prohibit the differential treatments of local and foreign inventors.<sup>316</sup> The second element addresses the practice of some countries of excluding pharmaceuticals from patenting prior to TRIPS. Such exclusion now becomes an unmitigated violation. The last element, which deals with the production of a patented article, is said to address the concern that compulsory licences might be issued for lack of local working.<sup>317</sup> However, according to some, equal treatment is limited to three factors: place of invention, the field of technology, and local production/importation.<sup>318</sup> Other forms of discrimination would not necessarily violate the TRIPS Agreement.<sup>319</sup>

It is very interesting to note that national treatment stipulated under Article 27.1 is an additional requirement because TRIPS imposes a general equal treatment for all IPR holders contained in Article 3. Apart from the patent section, this thesis submits that no other IP sections of TRIPS have a similar provision as Article 27.1. Such a peculiarity underlines the significance of patent protection for every kind of eligible inventions.

### 3.3.3 Term of protection

Article 33 provides the term of protection of 20 years after the date of filing of a patent. Before TRIPS, no patent laws in the world, even the US, had stipulated such a long period. However, during the writing of TRIPS, because the developed countries argued that 20 years was the emerging international consensus, it was accepted, while developing countries supporting a

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<sup>315</sup> Mohammed El Said and Amy Kapczynski, ‘Access to Medicines: the Role of Intellectual property Law and Policy’ (2012) Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law 5 <<https://hivlawcommission.org/report-resources/working-papers/>> accessed 5 July 2018.

<sup>316</sup> Justin Malbon *et al.*, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights. A Commentary* (EE 2014) 427.

<sup>317</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 353; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 432. This issue will be examined carefully in Section 4.2.3.

<sup>318</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 369.

<sup>319</sup> *Ibid.*

shorter period did not unite to propose any alternative.<sup>320</sup> All countries, including those of the industrialised world, had to amend their patent laws to comply with this standard. To the developing countries, 20 years was extremely high protection, if recalling the patent situation before TRIPS (Section 3.1.3). Nevertheless, as shall be seen in Section 3.4.3.4, the ‘effective’ or ‘commercial’ patent term is usually shorter than 20 years.

### 3.3.4 Transitional arrangement and marketing exclusive rights

As previously noted in Section 3.2.3.2, in return for patents on pharmaceutical (and agricultural) products, developing countries and LDCs were given a number of years to implement TRIPS while developed countries had one year, as per Article 65. Countries which did not patent medicines when TRIPS entered into force, i.e. 1 January 1995, would have a 10-year transitional period, i.e. until 1<sup>st</sup> January 2005, to fully comply with the patent requirements.

However, Article 70.8 and 70.9 overruled such an arrangement. From 1<sup>st</sup> January 1995, the transitional member states were obliged to introduce a facility (commonly called a ‘mail box’ provision) for the patentees to file their applications. Although those applications would not be examined for patenting until 2005, they would preserve their novelty and priority dates (Article 70.8).<sup>321</sup> In addition, these countries are required to grant Exclusive Marketing Rights<sup>322</sup> for pharmaceuticals for a period of five years until the grant or rejection of a product patent application, whichever is shorter (Article 70.9).<sup>323</sup>

As Watal observed, when Article 65 and Article 70.8 and 70.9 are read together, it becomes clear that the countries that had not had patent protection for medicines before were not given even a single transitional day, as they had to begin accepting patent applications from the date of their entry into the WTO Agreement.<sup>324</sup>

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<sup>320</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 114.

<sup>321</sup> TRIPS, art 70.8.

<sup>322</sup> There is no WTO definition of the term ‘Marketing Exclusive Rights’. The book of UNCTAD – ICTSD explains this term as followed: The holder of the patent application may not prevent third parties from producing the product within the territory of the Member, but may prevent third parties from advertising, offering or selling the product to a person other than the patent applicant. See UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 774.

<sup>323</sup> TRIPS, art 70.

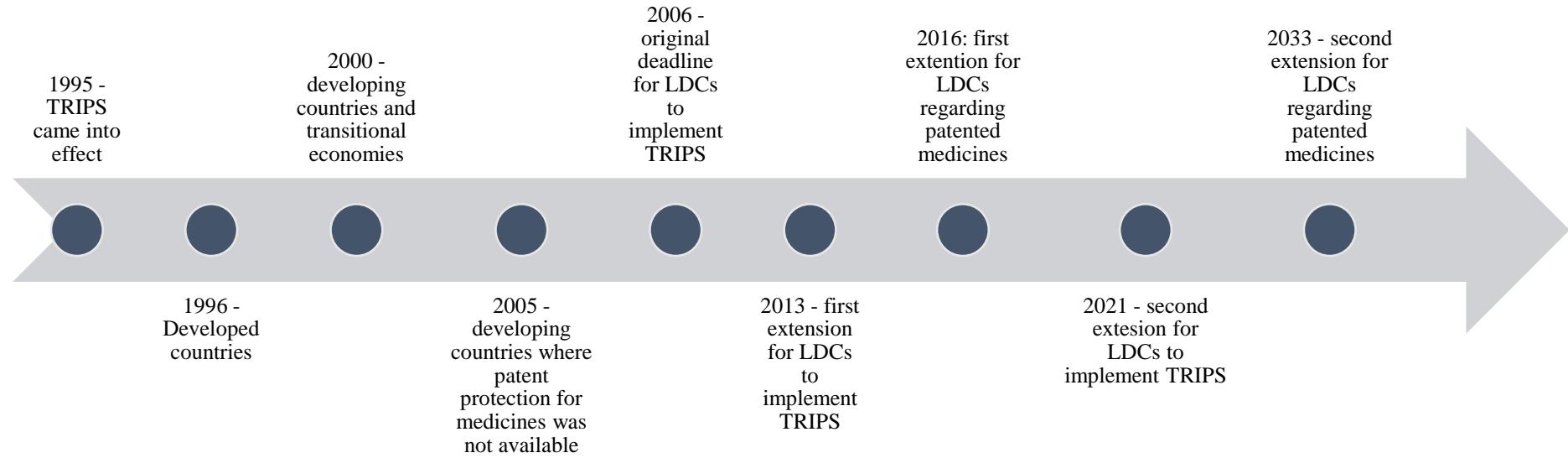
<sup>324</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 114.

For LDCs, full implementation of TRIPS can be delayed until 2033, following the most recent decision of the Council for TRIPS in November 2015.<sup>325</sup> Different deadline to implement TRIPS is depicted in the following figure.

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<sup>325</sup> Extension of the Transition Period under Article 66.1 for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products (6 November 2015) IP/C/73.

**Figure 1 Different deadlines to implement TRIPS<sup>326</sup>**



<sup>326</sup> The timelines are compiled by the author based on the following documents:

- TRIPS, art 65.1 – 65.4; art 66.1.
- The Doha Declaration
- Extension of the Transition Period under Article 66.1 for Least-Developed Country Members (30 November 2005) IP/C/40.
- Extension of the Transition Period under Article 66.1 for Least-Developed Country Members (11 June 2013) IP/C/64.
- Extension of the Transition Period under Article 66.1 for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products (27 June 2002) IP/C/25.
- Extension of the Transition Period under Article 66.1 for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products (6 November 2015) IP/C/73.

## **3.4 The pharmaceutical industry – one of a kind**

### **3.4.1 Medicine – a dual personality**

As stated in the introductory chapter, the pharmaceutical industry has a number of unusual characteristics that make it very different from others. Such a distinct nature has been underscored by Scherer as follows: ‘All industries are different, but some are more different than others. The pharmaceutical (or ethical drug) industry fits the latter category’.<sup>327</sup> The OECD group has also considered the pharmaceutical industry as an industry like no other.<sup>328</sup> Benoliel and Salama have described it as an ‘archetypical patent-sensitive industry’.<sup>329</sup>

The author views that what makes the pharmaceutical industry distinct of its kind can be found in three of its core characteristics. Firstly, medicine has a double personality, as a conventional commodity and as something to which human beings have a fundamental right.<sup>330</sup> Secondly, unlike other sectors, which follow a market-driven approach, the industry is often characterized as a ‘science- and technology-push’ model of innovation, meaning that scientific research is followed by product development and then marketing.<sup>331</sup> Lastly, based on patent data, the pharmaceutical industry is considered to have a discrete technology, which consists of a single patentable element, (or a relatively small number of them), for which patent ownership is more concentrated.<sup>332</sup> Accordingly, if an investor fails to patent that particular element, he will lose all. In contrast, in complex technologies such as smartphones, where many elements can be subject to patent applications, and so the input and the risk of the designing process is reduced.<sup>333</sup>

As a conventional product, medicine is driven by the rules of supply and demand. As a pivotal good in people’s lives, it requires more regulation than any other. It is the duality of pharmaceuticals which renders the industry replete with contradictions. Over a century, the

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<sup>327</sup> F. M. Scherer, *Industry Structure, Strategy, and Public Policy* (Harper Collins College Publishers 1996) 33.

<sup>328</sup> M.L. Burstall *et al.*, ‘An industry like no other: the pharmaceutical industry as seen by the OECD’ (OECD Paris 1981).

<sup>329</sup> Daniel Benoliel and Bruno Salama, ‘Towards an Intellectual Property Bargaining Theory: The Post-WTO Era’ (2010) 32 U.Pa.J. Int’l L. 265, 267.

<sup>330</sup> Min Ding, ‘The Pharmaceutical Industry: Specificity, Challenges, and What You Can Learn from this Book’ in Min Ding and others (eds), *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies* (Springer 2014) 5.

<sup>331</sup> Elina Petrova, ‘Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development’ in Min Ding and others (eds), *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies* (Springer 2014) 23.

<sup>332</sup> WIPO, ‘2012 World Intellectual Property Indicators’ (2012) 163 – 164

<<http://www.wipo.int/publications/en/details.jsp?id=273>> accessed 5 March 2018.

<sup>333</sup> *Ibid.*

medicine sector has consistently made great contributions to increase the quality of life and expand our life expectancy. At the same time, pharmaceuticals are identified in the public view as one of the least trusted industries.<sup>334</sup> 80% of the public believe that the pharmaceutical industry puts profits over people.<sup>335</sup> Marcia Angell's book '*The Truth About the Drug Companies*' portrayed the industry as being greedy, unethical, and corrupt, for making a hefty profit out of very few innovative drugs.<sup>336</sup> Sharing the same view, Hirsch heavily criticises pharmaceutical companies for paying attention only to composing medicines for diseases of affluence (heart disease, cancer, diabetes) and overlooking those of poverty (infectious diseases and infant mortality) and other neglected illnesses.<sup>337</sup>

A counterpoint to these viewpoints is Taylor's defence of the industry. He argues that it has been treated unfairly and has often been compared unfavourably to the nuclear industry.<sup>338</sup> In his view,

'it [the medicine sector] is one of the riskiest businesses but is perceived by the general public to be excessively profitable... Despite the acknowledged risks and costs associated with pharmaceutical development, many citizens still believe that pharmaceuticals should be being developed to meet all human needs and that when developed they should be given away to everyone on the basis of need'.<sup>339</sup>

The profit-making objective and the humanitarian aspect of medicines place the industry at the heart of the contemporary controversy over patent rights and patient rights. However, it is not the purpose of this chapter to address this matter, but rather to present the duality and to stress the complex nature of pharmaceuticals. The next two sections will elaborate on such complexity.

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<sup>334</sup> '2016 Edelman Trust Barometer, Global Healthcare Sector Trends' (Edelman, 4 May 2016) <<https://www.slideshare.net/EdelmanInsights/2016-edelman-trust-barometer-healthcare-sector-results>> accessed 28 October 16. In this survey, healthcare is near the bottom with a trust score of 61.

<sup>335</sup> 'Trust in Healthcare: Making Progress' (Edelman, 21 March 2017) <<https://www.edelman.com/post/trust-healthcare-making-progress>> accessed 5 March 2018.

<sup>336</sup> Marcia Angell, *The Truth About the drug Companies* (Random House New York 2004).

<sup>337</sup> Martin L. Hirsch, 'Side Effect of Corporate Greed: Pharmaceutical Companies Need a Dose of Corporate Social Responsibility' (2008) 9 Minnesota Journal of Law, Science and Technology 607, 607 – 611.

<sup>338</sup> David Taylor, 'The Pharmaceutical Industry and the Future of Drug Development' in RE Hester and RM Harrison (eds), *Pharmaceuticals in the Environment* (The Royal Society of Chemistry 2015) 1 – 2.

<sup>339</sup> *Ibid.*

### **3.4.2 New medicine: from genesis to commercialization**

Developing a medicine is a complex, laborious, lengthy, and costly process, with uncertain outcomes. The process includes a multitude of stages from pre-discovery, pre-clinical trials, clinical trials, regulatory approvals, all the way to marketing and running promotional campaigns.<sup>340</sup> In total, it takes from 10 to 15 years to place a safe and efficacious medicinal product on the market.<sup>341</sup>

**Pre-discovery** is the earliest stage of the process, where scientists carry out basic research into the disease. Then they will move to the stage of **drug discovery** to search for a ‘lead compound’ that can potentially become a medicine. From approximately 5,000 to 10,000 compounds at the beginning, now only between one and five molecules (candidate drugs) are left which will continue to be studied at the **pre-clinical** stage, before carrying out human trials. Drug discovery and the pre-clinical stage can take from three to six years.<sup>342</sup>

**The clinical** stage starts when sponsoring companies file a Clinical Trial Authorisation application, at the member state level in the EU, or an Investigational New Drug application in the US. This stage, which has 3 phases, aims to demonstrate the safety and efficacy of a candidate drug when used by humans. The clinical stage can take approximately 6 -7 years.

**Regulatory review and approval:** Upon the completion of the clinical trials, the sponsor can file a Licence Application (in the UK), a Marketing Authorisation Application (at the EU level) or a New Drug Application (in the US) to regulatory bodies, requesting approval to market the drug. The manufacturer must submit a marketing application in every country or territory where he wants to sell the new medicine. Upon receiving the application, the regulatory authority will assess the safety and efficacy of the candidate medicine before it reaches patients. This stage can last from half a year to two years.

**Post-marketing monitoring:** Successfully marketing a new drug does not mean putting an end to the research. To continue evaluating the safety and efficacy of the marketed drug, and for further development, clinical trials are still conducted to test for additional benefits that may

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<sup>340</sup> PhRMA, ‘2016 Profile’ 48 <<https://www.phrma.org/report/industry-profile-2016>> accessed 5 March 2018.

<sup>341</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 8.

<sup>342</sup> Elina Petrova, ‘Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development’ in Min Ding and others (eds), *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies* (Springer 2014) 28 – 29.

not have been studied in earlier phases. In some territories, such post-marketing clinical studies are mandatory.

### 3.4.3 Pharmaceutical innovation

The R&D process in the pharmaceutical industry has shaped its innovation in four key aspects: cost, uncertainty, return, and time.<sup>343</sup> The author will now elaborate on each of these four.

#### 3.4.3.1 Cost

Nowadays the question of how much money needs to make a new medicine is less of a mystery but more of a moot point. DiMasi from the Tufts Centre has been a leading author in this regard. Since 1991, he has conducted considerable research on R&D cost in the industry. His work has showed a tremendous increase in costs.<sup>344</sup> In 1991, the estimated out-of-pocket cost per approved new medicine was \$114 million.<sup>345</sup> In 2003, costs rose to \$802 million.<sup>346</sup> DiMasi claims that, by 2016, the cost of finding a new drug, *ab initio*, is \$1,395 billion.<sup>347</sup>

His works have been frequently cited by the business group as supporting evidence for the high cost of medicine R&D.<sup>348</sup> Nonetheless, there is plenty of room for disagreement. For example, Adam and Brantner conducted a reassessment, and concluded that the amount of \$802 was exaggerated.<sup>349</sup> Angell was also sceptical, and described that amount as imaginary, arguing that

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<sup>343</sup> Min Ding, ‘The Pharmaceutical Industry: Specificity, Challenges, and What You Can Learn from this Book’ in Min Ding and others (eds), *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies* (Springer 2014) 3.

<sup>344</sup> Joseph A. DiMasi *et al.*, ‘Cost of Innovation in the Pharmaceuticals Industry’ (1991) 10 Journal of Health Economics 107; Joseph A. DiMasi *et al.*, ‘Research and Development Costs for New Drugs by Therapeutic Category. A Study of the US Pharmaceutical Industry’ (1995) 7 Pharmacoeconomics 152; Joseph A. DiMasi *et al.*, ‘The Price of Innovation: New Estimates of Drug Development Costs’ (2003) 22 Journal of Health Economics 151; Joseph A. DiMasi *et al.*, ‘The Cost of Biopharmaceutical R&D: Is Biotech Different?’ (2007) 28 Managerial and Decision Economics 469; Joseph A. DiMasi *et al.*, ‘Innovation in the Pharmaceutical Industry: New Estimate of R&D cost’ (2016) 47 Journal of Health Economics 20.

<sup>345</sup> Joseph A. DiMasi *et al.*, ‘Cost of Innovation in the Pharmaceuticals Industry’ (1991) 10 Journal of Health Economics 107.

<sup>346</sup> Joseph A. DiMasi *et al.*, ‘The Price of Innovation: New Estimates of Drug Development Costs’ (2003) 22 Journal of Health Economics 151.

<sup>347</sup> Joseph A. DiMasi *et al.* ‘Innovation in the Pharmaceutical Industry: New Estimate of R&D cost’ (2016) 47 Journal of Health Economics 20, 26.

<sup>348</sup> European Federation of Pharmaceutical Industries and Associations (EFPIA), ‘The Pharmaceutical Industry in Figures 2017’ <<https://www.efpia.eu/publications/downloads/>> accessed 5 March 2018; PhRMA, ‘2016 Profile’ <<https://www.phrma.org/report/industry-profile-2016>> accessed 5 March 2018; International Federation of Pharmaceutical Manufacturers & Association (IFPMA), ‘The pharmaceutical industry and global health. Facts and Figures 2017’ <<https://www.ifpma.org/resource-centre/facts-and-figures-2014-the-pharmaceutical-industry-and-global-health/>> accessed 5 March 2018.

<sup>349</sup> Christopher P. Adam and Van V. Brantner, ‘Estimating the Cost of New Drug Development: Is it Really \$802 Million?’ (24) 2006 Health Affairs 420.

pharmaceutical companies spend more on marketing than on R&D.<sup>350</sup> Similarly, Collier questioned the transparency of this study, and questioned the manner in which the data was collected, as said data were not made available to other researchers.<sup>351</sup> Pharmaceutical companies normally refuse to publish their R&D costs. The US's Congressional Budget Office was likewise unconvinced, since they found that DiMasi's figures only include NME medicines, which are the costliest sub-group but amount to only about one third of the new drugs submitted to the FDA for approval.<sup>352</sup> Furthermore, the fact that the Tufts Centre is funded by the industry, and that DiMasi's group seemed to be the only one with access to the data, casts doubt on their works.<sup>353</sup>

This thesis submits that although it is impossible to verify the exact cost of producing a new medicine, it is widely accepted that the R&D budget of the pharmaceutical industry is certainly higher than others, and that many investments do not result in a return as a consequence of failure in clinical trials.<sup>353</sup>

Furthermore, majority of funding comes from the industry itself. The US pharmaceutical sector '[is] not dependent upon direct government contract support for its innovative activities'.<sup>354</sup> Sharing the same feature, the UK pharmaceutical industry funds healthcare-related research six times as much as the Department of Health, five times as much as medical charities, and eight times as much as the Medical Research Council.<sup>355</sup> Similarly, as the Commission observed, 90% of R&D is industry-financed.<sup>356</sup>

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<sup>350</sup> Marcia Angell, *The Truth About the Drug Companies* (Random House New York 2004) 39 – 46. However, Becker and Lillemark reject this argument by saying that pharmaceutical marketing consists of more than 'delivering the product to the customer'; for example, marketing and R&D integration as a response to market uncertainty. See Markus C. Becker and Morten Lillemark, 'Marketing/R&D integration in the pharmaceutical industry' (2006) 35 *Research Policy* 105.

<sup>351</sup> Roger Collier, 'Drug development cost estimates hard to swallow' (2009) 180 *Canadian Medical Association Journal* 279.

<sup>352</sup> Congressional Budget Office, 'Research and Development in the pharmaceutical industry' (Congress of the US, October 2006) 19 – 21 <<https://www.cbo.gov/publication/18176>> accessed 14 March 2018.

<sup>353</sup> Marcia Angell, *The Truth About the Drug Companies* (Random House New York 2004) 41; Roger Collier, 'Drug development cost estimates hard to swallow' (2009) 180 *Canadian Medical Association Journal* 279.

<sup>354</sup> F. M. Scherer, *Industry Structure, Strategy, and Public Policy* (Harper Collins College Publishers 1996) 336.

<sup>355</sup> Health Committee, *The influence of the pharmaceuticals industry* (HC 2004 – 2005, 42 – I) 11.

<sup>356</sup> Commission, 'The Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community' (Communication) COM (93) 718 final 5.

There are also controversies at this point, as some authors give the credit for R&D to universities and public sector – based scientists.<sup>357</sup> Schwartzman disputed this view by countering that academic scientists were only responsible for the underlying scientific principles and the basic chemistry and biology involved, and that the rest had to be done by the industry.<sup>358</sup>

This thesis argues that wherever the truth lies, discovering and developing a new medicine is painstaking, extremely expensive, and extremely risky when compared with the cost of other technological products, such as electronics and software. In these industries, since there are many elements for which patents can be applied, investors still have hope of offsetting their expenses in other parts of a product, if one part is unpatentable. Whereas, for pharmaceuticals, if an active ingredient is not granted the patent, the sponsor will lose all his investment.

### 3.4.3.2 Uncertainty

Despite the heavy costs of R&D activities, the outcome of pharmaceutical processes is uncertain. The sector bears an extremely high rate of failure, which can occur at any time during the development process. For example, the failure rate in taking cancer drugs to the market is around 95%.<sup>359</sup> In the 2016 study, DiMasi *et al.* indicated that the success rate (the likelihood that a drug that enters clinical testing will eventually be approved) is 11.83%, compared with 21.83% which is the figure for 2003.<sup>360</sup> Of every 5,000 (or 10,000) tested compounds for medical purposes, 250 will enter into pre-clinical testing, 10 into clinical development and only one will be granted marketing approval.<sup>361</sup> When reaching the market, only three out of ten approved medicines are profitable before patent expiry.<sup>362</sup>

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<sup>357</sup> Graham Dutfield, ‘The pharmaceuticals industry, the evolution of patent law and the public interest: A brief history’ in Guido Westkamp (ed), *Emerging Issues in Intellectual Property* (EE 2007) 110; Marcia Angell, *The Truth About the drug Companies* (Random House New York 2004).

<sup>358</sup> David Schwartzman, *The expected return from Pharmaceutical Research. Sources of new drugs and the profitability of R&D investment* (American Enterprise Institute for Public Policy Research 1975) 15.

<sup>359</sup> Health Committee, *The influence of the pharmaceuticals industry* (HC 2004 – 2005, 42 – I) 19.

<sup>360</sup> Joseph A. DiMasi *et al.*, ‘Innovation in the Pharmaceutical Industry: New Estimate of R&D cost’ (2016) 47 *Journal of Health Economics* 20, 23.

<sup>361</sup> Elina Petrova, ‘Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development’ in Min Ding and others (eds), *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies* (Springer 2014) 28 – 29.

<sup>362</sup> Nicoleta Tuominen, ‘An IP perspective on defensive patenting strategies of the EU pharmaceutical industry’ (2012) 34 EIPR 541, 542.

Such a low rate reflects the inherently risky nature of the pharmaceutical industry. The uncertainty can still remain even when the medicine is already on the market.<sup>363</sup> Undoubtedly, pharmaceutical R&D is an uncertain affair that can leave a company out of pocket in the end.

### 3.4.3.3 Returns

As a result of such risks, the pharmaceutical companies usually charge a price that will cover the cost of not only successful medicines but also those that failed at the testing/marketing stage. However, companies can only maximise the financial benefit for as long as the patent protection remains. It has been estimated that a new medicine requires 19 years to recoup R&D investment, whereas its effective patent life is much shorter, as will be explained in the next section.<sup>364</sup> Generally, the average price of the first generic entering the market is about 25% lower than that of the patented medicine.<sup>365</sup> Over time, and with increases in generic entry, generic prices remain at about 20% of the price of the original.<sup>366</sup> In some cases, prices sink even lower, by 90% or more of the price of the patented medicine, within a few weeks of the generic manufacturers entering the market.<sup>367</sup>

### 3.4.3.4 Time

It is a misinterpretation to say that a patented medicine monopolises a market throughout the *entire* 20 years of its term of protection. Here, it is important to bring the ‘theoretical’ patent term and the ‘effective’,<sup>368</sup> or ‘commercial’ patent term to light. The ‘theoretical’ patent term commences when a sponsor company files the patent application as soon as the lead compound is found. That usually happens at the discovery stage. To be patentable, the new compound needs to be new, inventive, and to have industrial application, regardless of whether it proves to work safely and efficaciously on patients or not. Nevertheless, if the company wishes to sell

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<sup>363</sup> This is the case with Vioxx®. It is a non-steroidal anti-inflammatory drug (NSAID) and a prescription painkiller marketed by Merck. It was approved for use by the FDA in 1999, but, in 2004, Merck withdrew the drug from the market, after a study revealed that it more than doubled the risk of heart attacks and death. See further discussion at Barbara Sibbald, ‘Rofecoxib (Vioxx) voluntarily withdrawn from market’ (2004) 171 CMAJ 1027.

<sup>364</sup> Henry Grabowski and John Vernon, ‘A sensitivity analysis of expected profitability of pharmaceutical research and development’ (1982) 3 Managerial and Decision Economics 36.

<sup>365</sup> Elina Petrova, ‘Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development’ in Min Ding and others (eds), *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies* (Springer 2014) 36.

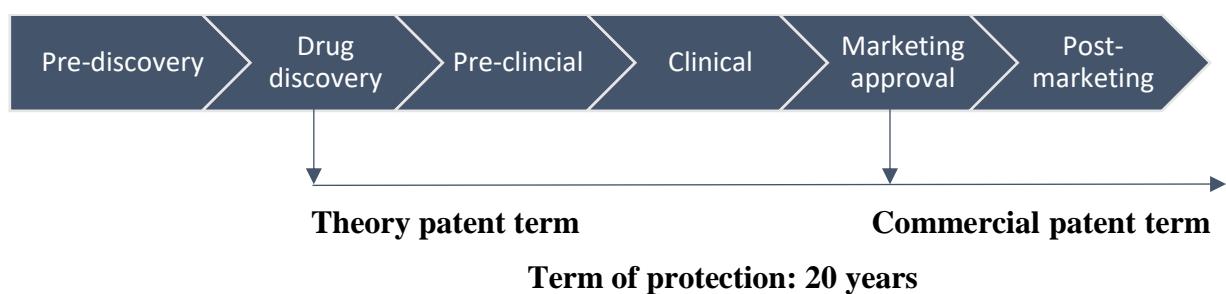
<sup>366</sup> *Ibid.*

<sup>367</sup> ‘About generics’ (British Generic Manufacturers Association) <<http://www.britishgenerics.co.uk/about-generics>> accessed 28 October 2016.

<sup>368</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 22 – 23.

that medicine, it has to demonstrate the efficacy and safety of the medicine at the later step - the marketing stage. The profit then can only be generated after the medicine is placed on the market. As a result of the overlap between these two stages, the ‘theoretical’ patent term starts much earlier than the ‘effective’ or ‘commercial’ term. By the time the approved drug reaches the market, the ‘commercial’ patent time may have less than half of its 20-year term left to run.<sup>369</sup>

**Figure 2 Theory patent term vs. Commercial patent term**



Such a market delay between patenting and marketing a new medicine erodes the effective patent life. In the UK, for example, it fell from 13 years in 1960 to less than 5 years in 1986.<sup>370</sup> In the US, a similar tendency was also found: the commercial patent term fell from 16 years in the early 1960s to below 8 years in the early 1980s.<sup>371</sup> In Germany, between 1960 and 1986, some patents had already expired by the time they received marketing approval.<sup>372</sup> With a tremendous investment in finding a new medicine, which could span more than a decade, the pharmaceutical companies rely on a mere handful of successful drugs to make sufficient profits during the relatively short commercial patent term. Moreover, they have to face the commercial participations by other companies when, for example, a compulsory licence is issued.

### 3.4.4 Generics and market entry

Compared to the development of an NME medicine, the making of a generic is shorter, simpler and cheaper. The imitators spend only \$2 million on producing a generic, and the process takes approximately 6 months.<sup>373</sup> Generic manufacturers focus on very limited types of clinical test

<sup>369</sup> *Ibid.*, 24.

<sup>370</sup> Aubrey Silberston, *Patent Policy: Is the Pharmaceutical Industry a Special Case?* (Scrip 1989) 29.

<sup>371</sup> *Ibid.*, 30.

<sup>372</sup> *Ibid.*, 31.

<sup>373</sup> Chidi Oguamana, ‘Patent and Pharmaceutical R&D: Consolidating Private – Public Partnership Approach to Global Public Health Crises’ (2010) 13 *The Journal of World Intellectual Property* 557.

to show the bioequivalence of the copied medicine and the patented drug. Bioequivalence means that the active ingredient of a generic must be the same as that of the originator, and typically with no more than 20% deviation in efficacy.<sup>374</sup> As these companies merely imitate what has been made by others, they can offer a much lower price than the originator, as previously noted in Section 3.4.3.3.

Despite the fact that the money and time invested in making generics are dramatically less than those of patented medicines; their market entry should not be taken for granted. Apart from facing the patent barrier, generic competition is hindered by other IP regimes, such as trademark, data exclusivity, and patent linkage embodied in a single pharmaceutical product.<sup>375</sup>

Most of the patented medicines use a trademark as the brand name. Hence, the generic manufacturers are not allowed to use such names, but have to register their products under different ones, which might not be familiar to prescribers. As a result, the late comers – the generics - cannot compete as well as the first movers – the original medicines.

Furthermore, generic manufacturers encounter data exclusivity, a form of protection against the use of test data submitted for regulatory approval by the patent holders. It is a distinct IP category for patents, which allows innovators to protect their clinical trials data for a few years (usually from 5 to 10 years) from the date of marketing approval, as a compensation for the time lost on the clinical stage. In the jurisdictions where data exclusivity exists, generic manufacturers are banned from relying on these data.<sup>376</sup> They must either wait until the exclusivity ends or carry out their own clinical testing. To the companies whose aim is to reverse-engineer initial medicines to sell at a much cheaper price, they do not have enough resources to perform such costly and lengthy testing. They simply have to wait.

Another form of IP which might obstruct the market entry of generics is patent linkage, which is the package of many patents embodied in a pharmaceutical product. Patent linkage will cover

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<sup>374</sup> Min Ding, ‘The Pharmaceutical Industry: Specificity, Challenges, and What You Can Learn from this Book’ in Min Ding and others (eds), *Innovation and Marketing in the Pharmaceutical Industry: Emerging Practices, Research, and Policies* (Springer 2014) 9.

<sup>375</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 20, 25, 30. In addition, delay in the market entry of generic products is also caused by the lawsuits filed by patent holding companies against generic companies. See Mohammed K. El Said, ‘TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries’ (2016) 31 American University International Law Review 373, 393.

<sup>376</sup> Further discussion can be found at WHO, WIPO, and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections public health, intellectual property and trade* (WHO/WIPO/WTO 2013) 63 – 67.

the patent of the active ingredient and one or more additional patents applying to the medicine, for example, the formulation. The imitators can only produce the IP protected medicine until the whole package expires, not merely when the term of protection of the active ingredient ends.<sup>377</sup>

Briefly stated, this thesis argues that the generic products can be only made where no legal barriers exist, or where patent rights are overridden by other legal tools, for example, compulsory licensing which will be discussed in-depth in the next chapter

### **3.4.5 The importance of patents in the pharmaceutical industry**

Since composing a new medicine is complicated and costly but duplicating it is easy and cheap, patents stand out as the strongest IP method of protecting drugs from being copied. Drug companies have maintained that where there is insufficient or no patent protection, free rides on the efforts of innovators would have been flourished. They argue that without patents, the incentive for pharmaceuticals innovations would be weakened, these companies would bear all the cost and run the risk of sharing profits with those whose main activities are reverse-engineering.

As Schwartzman highlights, ‘without patents, the return from investment in pharmaceutical research and development would fall to zero, and private companies would no longer engage in research and development’.<sup>378</sup> Silberston has further emphasised that an original medicine can be rapidly and simply reverse-engineered as soon as it enters the market, no matter whether the patent specification has been published or not.<sup>379</sup> With a person skilled in the art, the main ingredient of a medicine that was chemically synthesised can be quickly found and imitated.

Such easy imitation is highlighted when a comparison is made with another industry, for example the aircraft industry.<sup>380</sup> Scherer argues that, without patent protection, a company seeking to copy the Boeing 787 would have performed a massive amount of work, and by the time the developmental work was completed, Boeing would be a long way ahead in sales, and would have progressed far down its learning curve, enjoying a substantial production cost

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<sup>377</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 25.

<sup>378</sup> David Schwartzman, *Innovation in the pharmaceuticals industry* (Johns Hopkins University Press 1976).

<sup>379</sup> Aubrey Silberston, *Patent Policy: Is the Pharmaceutical Industry a Special Case?* (Scrip 1989) 9.

<sup>380</sup> F.M. Scherer, ‘Pharmaceutical Innovation’ in Bronwyn H. Hall and Nathan Rosenberg (eds), *Handbook of the Economics of Innovation, Vol. 1* (Elsevier 2010) 566.

advantage.<sup>381</sup> Obviously, this is not the same in the case of pharmaceuticals, where a generic company only needs few million dollars and few months to produce a generic version and then places it on the market.

Another corroborating argument of Scherer is that, unlike patents in other industries, patents in the pharmaceutical sector protect a clearly identified chemical molecule, around which the marketing of substitute variants is impossible without undergoing a complete new array of clinical trials.<sup>382</sup> Levin *et al.* further added that, in patenting a single molecule, it is easier to prove an allegedly infringing molecule; whereas it is more difficult to determine whether comparable components of two complex systems, such as an electrical or mechanical system ‘do the same work in substantially the same way’.<sup>383</sup>

Nevertheless, it should be noted that the patent system cannot create an absolute monopoly. The exclusivity is only granted to a lead compound - the active ingredient of a drug, not the whole class of it.<sup>384</sup> That is to say, having a patent for a specific drug is not necessarily synonymous with driving other competitors out of the market. A newly patented drug still has to compete with therapeutic classes, groups of drugs that are similar in their chemical structure, pharmacological effect, or clinical use, such as can be found in antidepressants or antibiotics.<sup>385</sup> Strictly speaking, not all patents can create the market power of making the owner the sole provider, because there are always visible substitutes.<sup>386</sup>

In contrast to the incentive theory stating that patents, generally, induce creative activities, the findings suggested by empirical studies varied from one industry to another. While there is little support for an affirmative response to whether the patent system incentivises creativity in other sectors, the pharmaceuticals industry is nonetheless one of a very few areas that show the greatest sensitivity to patents. A number of studies based on firm-level surveys show that the patent system has been regarded as the most important factor for R&D decisions and the

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<sup>381</sup> *Ibid.*, 567.

<sup>382</sup> F.M. Scherer, ‘The Pharmaceutical Industry’ in A.J. Culyer and J.P. Newhouse (eds) *Handbook of Health Economics*. Vol. 1 (Elsevier 2000) 1318.

<sup>383</sup> Richard C. Levin *et al.*, ‘Appropriating the Returns from Industrial Research and Development’ (1987) 3 Brookings Papers on Economic Activity 783, 798.

<sup>384</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 17.

<sup>385</sup> Congressional Budget Office, ‘Research and Development in the pharmaceuticals industry’ (Congress of the US, October 2006) 12 <<https://www.cbo.gov/publication/18176>> accessed 14 March 2018.

<sup>386</sup> Craig Allen Nard, *The Law of Patents* (4<sup>th</sup> edn, Wolters Kluwer 2018) 2.

development of new products. Taylor and Silberston's study in 1973 found a substantial impact of patent protection on R&D expenditure (64%) in the pharmaceuticals industry, whereas other sectors, such as basic chemicals; plant, machinery and equipment; components and materials were little affected or almost not at all affected.<sup>387</sup> In their findings, pharmaceuticals showed an extreme reaction to patent protection, that is, patent-based production occupied a significant share - 68% - of the total sales.<sup>388</sup>

Mansfield's study in 1986 arrived at similar conclusions.<sup>389</sup> That is, patent is of greater importance to the pharmaceuticals sector than to other of the selected industries that were examined.<sup>390</sup> Without a patent system, 60% of medical inventions could not have been developed and 65% could not have been commercially introduced. In contrast, figures for chemicals were 30% and 38% respectively, and 18% and 25% for petroleum, respectively.<sup>391</sup>

In the same vein, in 1987 Levin *et al.*, drawing a distinction between pharmaceuticals and other industries, confirmed that the former was the only one where product patents were considered by a majority of respondents as strictly more effective than other means of appropriation.<sup>392</sup> To them, substitutes for patents were not equally effective.<sup>393</sup> Other sectors, such as aircraft and computers, showed patents to be of little effect.<sup>394</sup>

Sharing the same finding, in 2000, Cohen *et al.* considered that patents for drugs (and medical equipment) accounted for more than 50% of product innovations.<sup>395</sup> The pharmaceutical industry applied for patents for more than two-thirds of their products and more than 40% of their processes.<sup>396</sup> These numbers are quite high in comparison to other industries, such as food,

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<sup>387</sup> C.T. Taylor and Z.A. Silberston, *The Economic Impact of the Patent System: A Study of the British Experience* (CUP 1973) 197 – 199.

<sup>388</sup> *Ibid.*, 201.

<sup>389</sup> The twelve industries are pharmaceuticals, chemicals, petroleum, machinery, fabricated metal products, primary metals, electrical equipment, instruments, office equipment, motor vehicles, rubber and textiles. Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32 Management Science 173.

<sup>390</sup> Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32 Management Science 173, 180.

<sup>391</sup> *Ibid.*, 174.

<sup>392</sup> Richard C. Levin *et al.*, 'Appropriating the Returns from Industrial Research and Development' (1987) 3 Brookings Papers on Economic Activity 783, 796.

<sup>393</sup> *Ibid.*, 818.

<sup>394</sup> *Ibid.*, 797.

<sup>395</sup> Wesley M. Cohen *et al.*, 'Protecting Their Intellectual Assets: Appropriability Conditions and Why the US Manufacturing Firms Patent (Or Not)' (2000) NBER Working Paper No. 7552, 9 <<http://www.nber.org/papers/w7552>> accessed 17 March 2018.

<sup>396</sup> *Ibid.*, 16.

textiles, glass, steel and other metals, where patents were applied for in the case of less than 15% of products<sup>397</sup>

To summarize, flowing from the above analysis, this thesis submits that while the patent system is not proven to be an incentive to innovation in certain industries, the case of the pharmaceutical industry is radically different. In this industry, the patent regime is therefore said not only to be maintained but also enhanced to ensure an expected return for the past investment and a guarantee for future inventions.

### 3.5 Conclusions

As critically evaluated in this chapter, the international patent system, from the Paris Convention to the TRIPS Agreement, has been significantly bolstered. Although the former is the first global agreement to regulate patents, the latter is the one which inaugurates worldwide patent protection. To the world's pharmaceutical industry, TRIPS is a giant leap in harmonising patentability because it not only eliminates discrepancies in patent laws across the countries but also creates the protection for the medicine inventions which were not patentable before. As a result, TRIPS is called 'the most ambitious international agreement on IPRs',<sup>398</sup> marking a watershed event in the IP norm-setting of our time.

Also, carefully analysed in Chapter 3, since the discussion of TRIPS, the attention to shaping international IPRs has been redirected from the legal view to the political economy lens. TRIPS contains a set of IP standards imposed by developed countries on developing countries through political influence and economic coercion. In particular, this Agreement is mainly the results of the relentless and strategic efforts of US business, the IPC, and notably Pfizer's CEO. 'If it had not been for the twelve American-based transitional corporations of the IPC, there would be no TRIPS today'.<sup>399</sup> 'No company was more influential in lobbying US trade negotiators

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<sup>397</sup> *Ibid.*

<sup>398</sup> Robert M. Sherwood, 'The TRIPS Agreement: Implications for Developing Countries' (1997) 37 *The Journal of Law and Technology* 491, 493.

<sup>399</sup> Susan K. Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 *Wisconsin International Law Journal* 481, 481.

than Pfizer and no CEO more committed to linking trade and intellectual property rights than Pfizer's CEO, Edmund Pratt'.<sup>400</sup>

These quotes accurately reflect the fact that, the TRIPS Agreement was the idea and the outcome of private players who were frustrated by the ineffective and discordant patent rules prior to TRIPS. Although the empirical studies that attempt to justify the role of patents in promoting inventions range from the sketchy to the non-existent in some industries, the medicines sector is a notable exception. For this reason, IP was the only issue in the Uruguay Round that was wholeheartedly promoted by the industry.<sup>401</sup> To pharmaceutical companies and developed countries, TRIPS was indeed a triumph. Apart from the 10-year transition for developing countries, the IPC got 95% of what it wanted.<sup>402</sup>

However, the conclusion of TRIPS was not the end of the story. In fact, it is the start of another, which is no less dramatic. The 'one size fits all' policy of TRIPS was completely unsuitable to the conditions of the developing world. These countries were no longer permissible to freely reproduce patent-protected drugs, instead they had to purchase them from the patent holders, who would charge a high price to compensate their outlay. It is not an exaggeration to say that the formation of TRIPS extinguishes the free-riding practice of imitators, particularly in developing countries, to copy and sell the generics at a fraction of initial medicines.

Needless to say, this situation has had an adverse impact on healthcare in the Third World. Patent exclusivity might lead to price gouging and scarcity of medicines, if compared to the situation in a competitive market. The expansion of drug patents has now put the policy makers in a dilemma: they must strike a delicate balance between providing incentives for future discoveries and ensuring affordable access to existing inventions. Such task can be viewed as trying to 'serve two masters'.<sup>403</sup> Against this backdrop, the developing countries have perceived compulsory licensing as a magic bullet.

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<sup>400</sup> Noah Benjamin Novogrodsky, 'Beyond TRIPS: the role of non-state actors and access to essential medicines' in Thomas Pogge and others (eds) *Incentives for Global Public Health. Patent Law and Access to Medicines* (CUP 2010) 347.

<sup>401</sup> Charan Devereaux et al., *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 76.

<sup>402</sup> Susan K. Sell, *Private Power, Public law. The Globalisation of Intellectual Property Rights* (CUP 1997) 115.

<sup>403</sup> Health Committee, *The influence of the pharmaceuticals industry* (HC 2004 – 2005, 42 – I) 9.

# **CHAPTER 4: THE DEVELOPMENT OF COMPULSORY LICENSING WITHIN INTERNATIONAL PATENT LAW**

Following Chapter 3 which deeply examined the development of international patent and the dependence of pharmaceuticals on the patent system, this chapter will critically evaluate compulsory licensing – a limitation to patent exclusivity. Chapter 4 attempts to answer the second research question: How has compulsory licensing developed within international patent law and to what extent has it affected pharmaceutical innovation? These are not new questions, but the answers are necessary for the purpose of setting out the background to this work. In this chapter, the author will examine compulsory licensing in the legal context of Article 5A of the Paris Convention, Article 31 of TRIPS, and the Doha Declaration which clarifies Article 31. As seen in Chapter 3 how the patent system has considerably changed from Paris to TRIPS, this Chapter also reveals a paradigm shift in the compulsory licensing regime.

However, a special attention will be paid to Article 31 because it contains important legal requirements in relation to the issue of a compulsory licence. While interpreting this Article, the author will particularly refer to the drafting history because Article 31 is a complicated provision that is hard to understand and open to competing interpretations, as will be demonstrated in Section 4.2 of this chapter. As Watal commented, the ambiguous language of Article 31 has permitted the parties to claw back what was lost in the negotiating battles in TRIPS.<sup>404</sup> Also, a heavy reference to the negotiating history is necessary as it will explain why Article 31 is said to deal with compulsory licensing even this term did not appear in both the title and the body text. For these reasons, a full comprehension of Article 31 cannot be achieved if we rely solely on the language of the treaty, and so a historical account will supplement that information.

In addition to understanding the compulsory licence in the eyes of the law, it is also significant to assess the degree to which this legal mechanism has affected pharmaceutical innovation. Whether non-voluntary licensing is a real danger to R&D activities as frequently claimed by patent holders, or does the industry simply overreact? As concluded in Chapter 3, the medicine

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<sup>404</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International, 2001) 9.

sector, compared with other sectors, has shown the greatest dependence on the patent system. This chapter will assess whether compulsory licensing, as a derogation to the exclusive rights, reveals the same tendency.

## 4.1 Compulsory licensing prior to TRIPS

### 4.1.1 The early history

Compulsory licensing was initially regulated in the English Statute of Monopolies of 1623 under the form of *compulsory working* of a patent within the country.<sup>405</sup> As discussed in the previous chapter, English patents in the 17<sup>th</sup> century were granted on the diffusion purpose, which could only be achieved by putting a patent into effect. Consequently, working the patent in a granting country became an obligation of the patent owner. Otherwise, it could be subject to cancellation. In this sense, patent revocation for failure to work was the only early remedy to patent monopoly at that time.

Originating from England, the concept of a local working patent spread throughout the world. Although England is the birthplace of the initial form of compulsory licensing, America is the first country which actually mentioned this term in an amendment to the first US patent law of 1790.<sup>406</sup> The House of Representatives, however, rejected the amendment, and the Senate then withdrew it.<sup>407</sup> In effect, America neither instituted compulsory licensing in its patent law nor imposed a sort of compulsory working requirement on the patentee.<sup>408</sup> Granting compulsory licences as a remedy under American anti-trust legislation, by contrast, has been popular.<sup>409</sup> By the 19<sup>th</sup> century, with the sole exception of the US, most of the countries adopted compulsory working in their patent laws in various forms.

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<sup>405</sup> N.S. Gopalakrishnan and Madhuri Anand, ‘Compulsory Licence Under Indian Patent Law’ in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory licensing: Practical Experiences and Ways Forward*’ (Springer 2015), 13. In the modern law context, compulsory working is also referred to as local working or national working.

<sup>406</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 165.

<sup>407</sup> Fredrik Neumeyer, *Compulsory licensing of patents under some non-American systems* (US government printing office 1959) 2.

<sup>408</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 26. However, it is important to stress here that although American patent law did not have a traditional compulsory licence system, it did contain a so-called government use which allowed the government to use the patent without the patent owner’s consent, with the royalty being settled in court. Such use has been made extensively. See further at Jerome H. Reichman and Catherine Hasenzahl, ‘Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA’ (UNCTAD-ICTSD, June 2003) 21 – 22.

<sup>409</sup> Jerome H. Reichman and Catherine Hasenzahl, ‘Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA’ (UNCTAD-ICTSD, June 2003) 19.

#### **4.1.2 To the Paris Convention**

Under the Paris Convention, compulsory licensing is contained in Article 5A. Although the Convention had been ratified in 1883, Article 5A was not inserted until the third amendment in The Hague in 1925. In fact, this provision has a turbulent history.<sup>410</sup> It, in a sense, is the history of the Paris Convention.<sup>411</sup> Therefore, it is necessary to sketch in the negotiation process of this Article. This thesis argues that such a description is not only fascinating from the historical lens but also significant from the economic point of view. As will be seen in this section, initial debates about compulsory licensing reflected its relationship with the economic growth of a country. Throughout the revision conferences, a member state's stance on this issue did not remain constant but changed with its industrial development.

As the internationalised patent system began with the Vienna Exhibition in 1873, so did compulsory licensing. As mentioned in Section 3.1.2, because the US participants opposed the working requirement of Austrian patent law, at the subsequent Vienna Congress, compulsory working was not endorsed.<sup>412</sup> However, as the majority of the participants came from Germany, the conference was dominated by the German view which prevailed over the American.<sup>413</sup> As a result, *compulsory licensing for the sake of public interest* was adopted, despite strong opposition from the US.<sup>414</sup>

At the 1878 conference in Paris, as the French comprised three-fifths of the delegates, many aspects of compulsory licensing, which reflected the French view were adopted.<sup>415</sup> That is, non-working of a patent in a country would lead to outright revocation, and even compulsory licensing as a substitute for such a sanction was not accepted.<sup>416</sup> M. Charles Lyon-Caen, a French lawyer, aggressively denounced compulsory licensing as 'a derogation of the right of property'. To him, the inventor subject to such licences were in a similar position as 'a man

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<sup>410</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 46.

<sup>411</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 519.

<sup>412</sup> Fredrik Neumeyer, *Compulsory licensing of patents under some non-American systems* (US government printing office 1959) 7.

<sup>413</sup> Heinrich Kronstein and Irene Till, 'A Re-evaluation of the International Patent Convention' (1947) 12 Law and Contemporary Problems 765, 769 – 770.

<sup>414</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 46.

<sup>415</sup> *Ibid.*, 48.

<sup>416</sup> *Ibid.*, 51.

who owned his house but was required to allow all who requested it, to live with him on the payment of a rental'.<sup>417</sup>

At the 1880 Conference, where the Convention was adopted and came into effect in 1883, the working requirement was described as follows:

Article 5: The introduction by the patentee into the country where the patent has been granted of objects manufactured in any one of the countries of the Union shall not entail forfeiture.

Nevertheless, the patentee is subject to the obligation to work his patent in accordance with the laws of the country into which he introduced the patented articles.<sup>418</sup>

The first paragraph remained virtually unchanged throughout all later revisions, as will be seen towards the end of this section. The second paragraph was adopted in face of the opposition of Belgium, Great Britain, Russia and Turkey which held that, it was inconsistent with the purpose of the Union to force the patentee to work his invention in every member country.<sup>419</sup> Switzerland, however, countered that the removal of compulsory working would be detrimental to Swiss industry, as this provision was the only weapon to reserve its rights in future patent legislation.<sup>420</sup>

At the Rome conference of 1886, the delegates debated Article 5. Both France and Belgium wanted to revise the Article but in contrary directions.<sup>421</sup> Eventually, the participants decided not to change the Article and to allow member states to interpret how a patent should be worked.<sup>422</sup> Such a compromise gave rise to different interpretations of one of the most important elements of the patent system, the working requirement. It has remained an

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<sup>417</sup> Lyon-Caen's opinion was quote by Enrico Bonadio, 'Compulsory Licensing of patents: the Bayer – Natco case' (2012) 34 EIPR 719, 720.

<sup>418</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 56.

<sup>419</sup> *Ibid.*, 79 – 80; Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 523 – 524.

<sup>420</sup> Ulf Anderfelt, *International patent-legislation and developing countries* (Martinus Nijhoff 1971) 69.

<sup>421</sup> France wanted to revise the first paragraph to allow patent revocation in case of importation, and to clarify the term 'to work' in the second paragraph by adding these words 'by manufacturing there the articles to which it applies'. Belgium, at the opposite side, not only desired to keep the first paragraph but also persisted in removing the second one See Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 73.

<sup>422</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 73 – 74.

extremely controversial issue, as will be seen in Section 5.4.1.2 (India) and Section 6.3.2 (Brazil).

In the subsequent revision conferences in Madrid (1890), Brussels (which was held in 1897 and 1900) and Washington (1911), continuing attempts to eliminate compulsory working were failed. Article 5 was retained as the *status quo*. It is interesting to note that at the conference in Washington, there was a striking change in the views of Germany and Great Britain concerning compulsory working, but in opposite directions to their initial stances. That is, while Germany joined the US to suppress compulsory working, Great Britain together with other countries opposed this proposal.<sup>423</sup>

The working clause, which had been maintained in German patent law since 1877, was abolished in 1911.<sup>424</sup> Germany's shift in position was a corollary of the bilateral agreements with other European countries and with the US, which assured that working a patent in one contracting country was equivalent to working it in another.<sup>425</sup> Meanwhile, since the late 19<sup>th</sup> century, Britain's position as the world's most industrialised country had been threatened by Germany and the US. Britain therefore enacted the duty to work in its 1907 Patents Act in the interest of retaining its industrial power.<sup>426</sup>

At the third revision conference in The Hague in 1925, expansion of the Union membership to 34 members made it impractical for a patent owner to work his invention in every country.<sup>427</sup> The local working requirement was about to be deleted entirely from the Convention. Nevertheless, Spain argued that such deletion only benefited the large, industrialised countries, while prejudicing less developed member states.<sup>428</sup> Another argument, put forward by Japan, Poland and Yugoslavia, was that compulsory licences were not always a reliable remedy, because of the difficulties of finding local licensees.<sup>429</sup> This thesis submits that these arguments, despite being made more than 100 years ago, still hold true today, even though the legal, social and economic contexts have changed so much. It is particularly compelling in the

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<sup>423</sup> Ulf Anderfelt, *International patent-legislation and developing countries* (Martinus Nijhoff 1971) 75.

<sup>424</sup> Richard Reik, 'Compulsory licensing of Patents' (1946) 36 *The American Economic Review* 813, 818.

<sup>425</sup> Fredrik Neumeyer, *Compulsory licensing of patents under some non-American systems* (US government printing office 1959) 8.

<sup>426</sup> Ulf Anderfelt, *International patent-legislation and developing countries* (Martinus Nijhoff 1971) 101.

<sup>427</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 82.

<sup>428</sup> Ulf Anderfelt, *International patent-legislation and developing countries* (Martinus Nijhoff 1971) 79.

<sup>429</sup> *Ibid.*

case of pharmaceuticals where only a handful of countries have the full capacity to produce the medicines.<sup>430</sup>

Since the members could not agree on whether to keep the working clause, revocation for non-working patents continued to apply, but at the same time, compulsory licensing was also incorporated as a substitution for patent forfeiture. According to Penrose, when the patentee does not exploit his invention, letting someone else do so by giving him a licence was a less extreme sanction than entirely depriving the patentee of his patent rights.<sup>431</sup> Such a reform at The Hague marked an important milestone in the history of the patent regime because compulsory licensing was, for the first time, explicitly recognised in an international agreement.

From this revision onwards, the issue of removing the working provision was raised, but opposed by others, using the same arguments that had previously been put forward.<sup>432</sup> Eventually, no change in substance was made to the text. In the latest amendment in 1979, the language was refined under Article 5A, but did not alter the patentee's manner of exploiting his invention, or the way in which compulsory licensing was stipulated.

With the revision in 1925, patent forfeiture in case of failure to work was abolished in the reality. Compulsory licensing, as a modified form of such sanction, was substituted and then become the most important limitation to patent rights. As a result of The Hague revision, some countries, for example, France and Italy, who had not previously instituted this legal mechanism, incorporated it into their patent systems.<sup>433</sup> By the beginning of the 1990s,

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<sup>430</sup> WHO, *The World Medicines Situation* (2<sup>nd</sup> edn, WHO 2004) 3–6 <<http://apps.who.int/medicinedocs/en/d/Js6160e/>> accessed 5 March 2018. According to this publication, over 90% of world pharmaceutical production located in a few high-income countries. Two-thirds of the value of medicines produced globally is accounted for by firms with headquarters in just five countries — the USA, Japan, Germany, France and the UK. Although there are 188 countries having some sort of medicines production capability, only ten countries are classed as having a 'sophisticated industry with significant research'. They are: the US, Japan, France, Germany, the UK, Switzerland, Sweden, Italy, Belgium and Netherlands. These ten countries, through the ten companies headquartered in them and, in some cases, through large amounts of publicly funded research, are the principal sources of new medicines discovery.

<sup>431</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) 84.

<sup>432</sup> *Ibid.*, 86; Ulf Anderfelt, *International patent-legislation and developing countries* (Martinus Nijhoff 1971) 85 – 89.

<sup>433</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 530 – 531.

compulsory licensing had become a widespread feature, recognised in the patent systems of around 100 countries.<sup>434</sup>

#### **4.1.3 Compulsory licensing under Article 5A**

According to Article 5A(2), a member state is reserved the right to grant compulsory licences to prevent patent abuses. Failure to work is just one of the examples of such abuses.<sup>435</sup> Even when a patent holder did not put his invention into practice, a country's government cannot immediately exercise the compulsory licence but has to follow certain conditions, as per Article 5A(4). They are:

- No compulsory licences shall be granted until the expiration of four years from the filing date or of three years from the granting date of the patent.
- Such licences will neither be granted if the patent owner can justify his non-exploitation.
- Compulsory licences shall be granted on a non-exclusive and non-transferable basis.

These sub-clauses imply that countries' governments are free to apply analogous or different measures in other situations which are not patent abuses, such as national defence, public interest, dependent patents, or in other kinds of patent abuses which are not failure to work.<sup>436</sup> In fact, aside from the prohibition of patent revocation in case of importation, which is the first minimum standard imposed on national law by the Paris Convention,<sup>437</sup> this treaty provided member states with significant leeway to govern compulsory licensing.

At the same time, national laws expanded the grounds upon which a compulsory licence can be sought from the original purpose of failure to work to include other situations, such as dependent patents, public interest, and government use. Canada, the UK, and India, for example, provided a special regime in relation to medicines, under which any person with an

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<sup>434</sup> Carlos M. Correa, 'Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries' (South Centre 1999) 4.

<sup>435</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection* (Harvard University Press 1975) 528; Thomas Cottier *et al.*, 'Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements' (2014) 17 *Journal of International Economic Law* 437, 444.

<sup>436</sup> G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as revised at Stockholm in 1967* (Geneva 1968) 70.

<sup>437</sup> Ulf Anderfelt, *International patent-legislation and developing countries* (Martinus Nijhoff 1971) 71.

interest in exploiting a relevant patent was automatically entitled to a compulsory licence after a period of time.<sup>438</sup>

As indicated in Section 3.1.3, patent provisions stipulated in the Paris Convention displeased either developed or developing countries. Compulsory licensing is a very good example as such. On the one hand, this regime was disadvantageous to the North, because it neither restricts the grounds to grant compulsory licensing nor establishes a right to remuneration. On the other hand, the South complained that the procedural grant was not straightforward, and that compulsory licensing was of little effect because the patent owner was not required to disclose the know-how. In addition, Article 5A is of no avail where there is no local licensee who can demand such a licence.<sup>439</sup>

For these reasons, at the revision conference in Nairobi in 1981, developing countries proposed two important changes. They demanded exclusive compulsory licensing, which inhibited the patent owner from using his own invention where it is subject to such a licence, and the automatic patent revocation in case of non-working.<sup>440</sup> It was not surprising that the US rejected this proposal. The revision conference in Geneva in 1982 broke down, in part because of the competing demands concerning compulsory licensing.<sup>441</sup>

Although Article 5A establishes a number of legal conditions, the author reemphasises that those obligations are applied in case of a non-working patent only. In other situations, the means of setting up a compulsory licensing regime or other legal remedies are left to the discretion of member states. However, the situation has drastically changed with the creation of the TRIPS Agreement, as will be seen in the next section.

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<sup>438</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 462.

<sup>439</sup> Ulf Anderfelt, *International patent-legislation and developing countries* (Martinus Nijhoff 1971) 148.

<sup>440</sup> William E. Schuyler, ‘Paris Convention for the Protection of Industrial Property - A View of the Proposed Revisions’ (1983) 8 North Carolina Journal of International Law and Commercial Regulation 155, 162.

<sup>441</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 463.

## 4.2 The compulsory licensing regime within the TRIPS context

### 4.2.1 The drafting history

At the Uruguay Round, compulsory licensing was no less contested than it had been in its earliest form, Article 5A. In fact, compulsory licensing was one of the most contested topics during the TRIPS negotiations.<sup>442</sup> As seen in Section 3.2.3, the TRIPS negotiating process was usually described as a North-South division. In the compulsory licensing context, however, it could also be characterised as having North-North and South-South differences.

The developed countries had a degree of divergence on this issue. The US in its proposal in 1987 took a very strict form. It proposed that the government should not generally grant compulsory licences.<sup>443</sup> The EC was less harsh, and stipulated four situations in which such a grant would be permitted: lack or insufficiency of exploitation; dependent patents; official licences; and public interest.<sup>444</sup> Canada, one of the ‘Quad’, was at that time operating a very open compulsory licensing regime for pharmaceuticals with a uniform royalty rate of 4%.<sup>445</sup> Other developed countries, such as Australia, New Zealand, Portugal and Spain occupied the ‘middle ground’.<sup>446</sup> In the face of such divergences, the developed countries had some convergences. They demanded a transparent process of decision-making on a compulsory licence grant, a judicial review of that grant, and the appropriate remuneration to the patent holder.<sup>447</sup>

Another objective of these countries was to eradicate the working requirement.<sup>448</sup> Interestingly, Switzerland, which had objected to such an eradication in 1880,<sup>449</sup> changed its view on this point during the writing of TRIPS. The Swiss delegate took the view that, because the country

<sup>442</sup> Sweden’s National Board of Trade, ‘The WTO Decision on Compulsory Licensing: Does it Enable Import of Medicines for Developing Countries with Grave Public Health Problems?’ (2008) 18 <<https://www.kommers.se/In-English/Publications/2010-and-older/The-WTO-decision-on-compulsory-licensing/>> accessed 14 March 2018; Antony Taubman, ‘Thematic review: Negotiating “trade-related aspects” of intellectual property rights’ in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 43.

<sup>443</sup> Holger Hestermeyer, *Human Rights and the WTO: The case of Patents and Access to Medicine* (OUP 2007) 239.

<sup>444</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 463.

<sup>445</sup> Jerome H. Reichman, ‘Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) 37 *Journal of Law, Medicine and Ethics* 247, 252.

<sup>446</sup> Thu-Lang Tran Wasescha, ‘Negotiating for Switzerland’ in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 161.

<sup>447</sup> Catherine Field, ‘Negotiating for the United States’ in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 143.

<sup>448</sup> *Ibid.*, 142.

<sup>449</sup> The view of Switzerland in the Paris Convention can be found at Section 4.1.2.

had a small market to guarantee local production, forcing a patent holder to work his invention was unnecessary.<sup>450</sup> Most importantly, by the time Switzerland entered the trade Round, it was (and still is) a developed country with a strong pharmaceutical industry which needed to be protected, and was at the forefront of the TRIPS negotiations.<sup>451</sup> In addition, as will be illustrated in Sections 7.4.3 and 9.1, Switzerland has put up strong opposition to compulsory licensing used by developing countries. The author is of the view that as in Great Britain's reversal of policy made in the Washington revision, Switzerland represents a fascinating example of how a change in a country's economy precipitates a U-turn in its stance on compulsory licensing.

While the North-North divide was limited to the scope of the grant, the South-South difference was portrayed in the context of local working. Brazil and India, the two major opponents of TRIPS, as well as being leaders of the developing world, began to drift apart. Brazil regarded compulsory licensing as a key clause in the TRIPS negotiations and insisted on retaining 'local working', since the country had a long history of using this legal mechanism to promote industrial development.<sup>452</sup> From the Brazilian perspective, it was imperative to preserve the government's power over such a regime.

India, nonetheless, was more relaxed. As will be shown in Chapter 5 (India), compulsory licensing was not a popular practice in its territory. At the time when India entered the multilateral trade talks in Uruguay, it already had a long-established generic industry which was the result of the exclusion of pharmaceutical products from patenting, and not because of the compulsory licensing regime. The Indian delegation thus believed that, from an economic perspective, the size and significance of the Indian market could hardly be overlooked by any patent owners, irrespective of the availability or otherwise of the working requirement.<sup>453</sup> They were also convinced that compelling a patent owner to work his invention in unfavourable conditions was undesirable, and inefficient for technological transfer.<sup>454</sup>

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<sup>450</sup> Thu-Lang Tran Wasescha, 'Negotiating for Switzerland' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 173.

<sup>451</sup> *Ibid.*, 162.

<sup>452</sup> Piragibe dos Santos Tarragô, 'Negotiating for Brazil' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 246.

<sup>453</sup> A.V. Ganesan, 'Negotiating for India' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 225.

<sup>454</sup> Jayashree Watal, 'Patents: An Indian perspective' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 307.

This thesis submits that in this respect, the Indian viewpoint had departed from that of Brazil and had come closer to that of developed countries. India's government was satisfied as long as it reserved the right to grant a compulsory licence on a case-by-case basis.<sup>455</sup> Other countries, for example Hong Kong, which did not have a developed pharmaceutical industry, did not push too hard on this issue, if it was of general application.<sup>456</sup>

Regardless of these intra-North and intra-South differences, the picture of TRIPS compulsory licensing could be still portrayed simply as the developed countries on one side and developing countries on the other. Such conflict would not have been reconciled had it not been for the drafting skills of an Indian delegate, Jayashree Watal. She found that while the US wished to restrict compulsory licences to national emergencies and situations of extreme urgency, it possessed a broad governmental power to seize patents and made extensive use of them.<sup>457</sup> She also identified a similar provision in one of the EU's submissions.<sup>458</sup> Watal decided to combine two separate provisions on compulsory licences and government use into one provision, entitled 'Use without authorization of the right holder'.<sup>459</sup> This article was later refined and emerged as Article 31, 'Other uses without authorization of the right holder'.

In effect, the drafting history of Article 31 is of a great help in addressing the concerns raised at the beginning of Chapter 4. Firstly, it explains why this Article has been referred to as 'compulsory licensing', even this term is nowhere used therein. Article 31 was, in fact, made to regulate this practice. Secondly, it is also clear that the current concept of compulsory licensing is not strictly defined in its real sense, as noted at section 1.2.2, but is expanded to cover the government use. Thirdly, because of such expansion, there is no restriction on the grounds to issue a compulsory licence because keeping the potential grounds open reflected the US's interest – the main driver behind TRIPS.

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<sup>455</sup> A.V. Ganesan, 'Negotiating for India' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 224.

<sup>456</sup> David Fitzpatrick, 'Negotiating for Hong Kong' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 287.

<sup>457</sup> Jayashree Watal 'Patents: An Indian perspective' in Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 302.

<sup>458</sup> *Ibid.*, 304.

<sup>459</sup> *Ibid.*, 306.

#### **4.2.2 Possible grounds to grant a compulsory licence**

As previously discussed, although Article 31 does not limit the situations to issue a non-voluntary licence, Carvalho, Rozek and Rainey insists that TRIPS is not completely silent on this matter.<sup>460</sup> They are, nonetheless, mistaken in their views that compulsory licences can be granted in only four particular cases. To Carvalho, the four cases are: anti-competitive practices, dependent patents, patent abuses and lack of or insufficient working of a patent.<sup>461</sup> To Rozek and Rainey, they are: national emergency or other conditions of extreme urgency, public non-commercial use, possible remedy for anti-competitive practices, and dependent patents.<sup>462</sup>

This thesis argues that such a restrictive interpretation not only twists the law but also erroneously reflects the law-makers' intention, as noted in the previous section. Furthermore, if Article 31 was intended to restrict the potential grounds, it could have done so explicitly. Later, the Doha Declaration also confirmed that each member is free to determine the grounds to grant a compulsory licence, as will be discussed in Section 4.3. Stated succinctly, under Article 31, the situations that can result in the use of compulsory licences should be deemed non-exhaustive.

According to Julian-Arnold's survey in 1993, compulsory licensing is most frequently used when a dependent patent is being blocked, or where a patent is not being exploited, or when an invention relates to food or medicine.<sup>463</sup> Deere's research in 2009, which examined the implementation of TRIPS in domestic laws during the period 1995 – 2007, indicated different findings. 'Failure to work' or a 'non-working patent' was the most popular ground for a grant, and had been adopted in 39 countries' laws, followed by 'public non-commercial use' (33 countries), and thirdly 'dependent patents' (adopted by 29 countries).<sup>464</sup> 'To remedy anti-competitive practices' occupied fourth place (24 countries) while both 'national/health emergency' and 'refusal to license' shared fifth position (22 countries).<sup>465</sup> Such findings

<sup>460</sup> Richard P. Rozek and Renee L. Rainey, 'Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy' (2001) 4 *The Journal of World Intellectual Property* 463, 468; Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 383.

<sup>461</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 383.

<sup>462</sup> Richard P. Rozek and Renee L. Rainey, 'Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy' (2001) 4 *The Journal of World Intellectual Property* 463, 468.

<sup>463</sup> Gianna Julian-Arnold, 'International Compulsory Licensing: The Rationales and the Reality' (1993) 22 *The Journal of Law and Technology* 349, 349 – 350.

<sup>464</sup> Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 83.

<sup>465</sup> *Ibid.*

indicate that WTO member states have placed a great emphasis on the importance of a local working patent. As previously examined in Section 4.1.1, in the early history, working a patented invention in the country where it was granted was a principal method to transfer new technology to that country. At the international level, how to regulate a ‘working’ patent was a highly contentious topic during the negotiations of the Paris Convention and TRIPS. For these reasons, a brief examination of this issue is essential.

### **4.2.3 A local working patent**

It is an area of contention whether working a patent can be understood as either commercial use (through importation) or industrial use (through local manufacture). In the international law context, the definition of a local working patent is significantly ambiguous. Since the Rome Conference of 1886 of the Paris Convention, the Union decided to allow members to determine for themselves the meaning of the term ‘work’. Bodenhausen, the director of BIRPI<sup>466</sup> - the precursor of WIPO, held that, this term normally referred to the manufacture of a patented product or to the industrial application of a patented process, not to the importation or sale of the patented article.<sup>467</sup> But, as the law was silent on this matter, and as the Convention failed to address this issue in all the revision conferences, the author of this thesis tends to assume that, determining how a patent is worked falls within the competence of national law.

The issue is made no clearer by the provisions of TRIPS. In order to consider if lack of local working is a sufficient ground to issue a compulsory licence under TRIPS, a reference to the last sentence of Article 27.1 is necessary.<sup>468</sup> It reads as follow: ‘[...] patents shall be available and patent rights enjoyable without discrimination as to [...] whether products are imported or locally produced’.

This sentence has been the cause of controversy and confusion. Some have reasoned that, in the absence of local exploitation of a patent, a compulsory licence may be a remedy.<sup>469</sup> In

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<sup>466</sup> BIRPI is the French term of the United International Bureaux for the Protection of Intellectual Property (Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle). It was set up in 1893 to administer the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. The BIRPI is the predecessor of the (WIPO).

<sup>467</sup> G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as revised at Stockholm in 1967* (Geneva 1968) 71.

<sup>468</sup> A detailed analysis of Article 27.1 can be found in Section 3.3.2.

<sup>469</sup> Michael Halewood, ‘Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law’ 35 (1997) Osgoode Hall Law Journal 243, 252 – 253; Paul Champ and Amir Attaran, ‘Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.–Brazil Patent Dispute’ 27 (2002) Yale Journal of International Law 365; Bryan Mercurio and Mitali Tyagi, ‘Treaty Interpretation in

contrast, Carvalho, UNCTAD, and Gervais claimed that Article 27 bars member states from granting a compulsory licence on the ground of the non-use of the patent.<sup>470</sup> Ho and Carvalho assert that Article 27.1 does not deal with working a patent, but with the origin of the invention: irrespective of whether those inventions are locally manufactured or imported, they should be entitled to an equal treatment.<sup>471</sup>

Interestingly, Ho and Carvalho have differing opinions on the issue of whether non-exploitation of a patent can lead to a compulsory licence. Ho claims that Article 31, and also Article 5A(2) of the Paris Convention clearly indicates that lack of local working is a ground for granting a compulsory licence,<sup>472</sup> Carvalho criticised Article 5A(2) as being conceptually flawed because it does not distinguish between ‘failure to work’ and ‘abusive failure to work’.<sup>473</sup> This thesis argues that, because the Convention was unable to express the proper meaning of a local working patent, it would be a mistake to intentionally tie local working to local manufacturing within the meaning of the Paris Convention.

Adding the complexity to the issue is the lack of precedents. At the international level, despite more than 500 disputes brought before the WTO, not even a single one addressed the working requirement.<sup>474</sup> Only one time the US filed a complaint against Brazil in relation to Article 68 of the Brazilian Patents Act (1996) which maintained the duty to exploit of the patent owner.<sup>475</sup> However, the two parties agreed to settle the dispute through a bilateral mechanism, leaving the matter unresolved.<sup>476</sup> Within the domestic law context, local working was addressed in the

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WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements’ 19 (2010) Minnesota Journal of International Law 275; Carlos M. Correa, ‘Patent rights’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade. The TRIPS Agreement* (3<sup>rd</sup> edn, Wolters Kluwer 2016) 285.

<sup>470</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 353; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 433; Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 277 – 278.

<sup>471</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 131; Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 277 – 278.

<sup>472</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 132.

<sup>473</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 276.

<sup>474</sup> WTO, ‘Chronological list of disputes cases’

<[https://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_status\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm)> accessed 20 April 2018.

<sup>475</sup> WTO, *Brazil: Measure Affecting Patent Protection. Request for Consultations by the United States* (8 June 2000) WT/DS199/1.

<sup>476</sup> This case will be analysed in more details in Section 6.3.2.

2012 Indian compulsory licence.<sup>477</sup> Nevertheless, the approach of Indian competent authorities are also nuanced which has provided plenty room for disagreement.<sup>478</sup>

The author is of the view that most countries still maintain local working in their patent laws as a remnant of the old practice. In addition, they felt that ‘they should not be tributary to foreign industry and must encourage the development of national industry by requiring a foreign patentee to work his invention directly or through a licensee’.<sup>479</sup> A compulsory licence would thus act like a safety valve in response to a ‘flood’ of foreign manufactured goods issuing from foreign patent holders.

In fact, such a concern is not groundless. Federico, in his 1948 study, indicated that, during the period 1930 – 1937, there were countries in which more patents had been granted to foreigners than to local inventors.<sup>480</sup> The US, had had a low proportion of patent grants to foreigners (12.5%), but the figure was 25% in Japan and Germany, relatively high in France and England with 50%, and extremely high in the Netherlands and Canada, with 80% and 90%, respectively.<sup>481</sup> In developing countries, such as India, there was disparity between the number of patents granted to Indians and to foreigners: a ratio of 1:9.<sup>482</sup> At the same time, more than 90% of patents granted were not worked within the territory of India.<sup>483</sup>

There are two main justifications for the existence of the working clause. Firstly, it is considered as an exchange for the patent granted. Ladas, nonetheless, countered that the exclusivity given to the patentee was not in exchange for working his invention, but rather for his disclosure of the patent.<sup>484</sup> Secondly, the obligation to exploit was considered as a duty toward the State, therefore a non-working patent might deprive the community of an important cultural benefit.<sup>485</sup> Carvalho disagrees with this and asserts that a patent that gives the owner

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<sup>477</sup> *Natco v. Bayer* (Controller of Patents, 2012).

<sup>478</sup> This case will be explored deeply in Section 5.4.1.

<sup>479</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights – National and International Protection* (Harvard University Press 1975) 523.

<sup>480</sup> P.J. Federico, ‘Compulsory Licensing in other countries’ (1948) 13 Law and Contemporary Problems 195, footnote 4.

<sup>481</sup> *Ibid.*

<sup>482</sup> N. Rajagopala Ayyangar, *Report on the revision of the Patents Law* (India, September 1959) 14.

<sup>483</sup> Shamnad Basheer and Mrinalini Kochupillal, ‘The Compulsory Licence regime in India: Past, Present and Future’ (A Report for the JPO, 2005) 4 <<https://ssrn.com/abstract=1685129>> accessed 19 March 2018.

<sup>484</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights – National and International Protection* (Harvard University Press 1975) 521.

<sup>485</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights – National and International Protection* (Harvard University Press 1975) 521 cited Hohler, *Deutsches Patentrecht* (1901) 613, 618.

the rights to exclude others from exploiting his invention does not give him the rights to its use.<sup>486</sup>

Logically, the patentee himself, as an owner, would desire more than anyone to exploit the invention, so as to maximise the return and compensate for past investment. Why should a patentee overlook a market if it is favourable for production? Forcing the right owner himself to work the patent where it was inappropriate might do harm to the consumers, as the costs might increase due to the lack of labour, or high tariffs, or the expense of building an initial infrastructure.

From the economic point of view, the working requirement was also considered ineffective. Penrose, a prominent economist, in the first half of the 20<sup>th</sup> century, made an emphatic refutation.<sup>487</sup> She claimed that maintaining the duty to work is of value in the industrialisation of undeveloped countries *only* under very special conditions.<sup>488</sup> Therefore, in her view, compulsory licensing as a sanction for a non-working patent was based upon a false approach to the treatment of foreign patents.<sup>489</sup>

Ladas also strongly argued that many inventions cannot be worked out on a business basis and brought into commercial use until a practical ‘know-how’ has developed.<sup>490</sup> Compelling the patentee to exploit his invention in an unfavourable climate might encourage him to keep the invention secret rather than to share it with the public.<sup>491</sup> In this way, mandatory working of a patent is of no benefit to society.

In the modern economy, Julian-Arnold suggests that accepting importation as equal to a local working patent reflects the free movement of goods throughout the global market, provided that public access to that (imported) product is available.<sup>492</sup> This thesis also submits that issuing compulsory licences for the sole reason that no local manufacture occurs in a country is contrary to economic realities, especially in the biotechnology industry. As Kevin M. McCabe

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<sup>486</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 276.

<sup>487</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (Johns Hopkins Press 1951) chapter VII.

<sup>488</sup> *Ibid.*, 150.

<sup>489</sup> *Ibid.*, 161.

<sup>490</sup> Stephen P. Ladas, *Patents, Trademarks, and Related Rights – National and International Protection* (Harvard University Press 1975) 521.

<sup>491</sup> *Ibid.*

<sup>492</sup> Gianna Julian-Arnold, ‘International Compulsory Licensing: The Rationales and the Reality’ (1993) 22 *The Journal of Law and Technology* 349, 367.

has explained, it would be very difficult for the patent holding companies in industrialized countries ‘to set up a manufacturing facility in every country having such requirements in order to maintain patent rights. Such action would be too burdensome for any company.’<sup>493</sup>

In contemporary globalisation, the right holder will take into account a number of factors, for example, available human resources, lower tariffs, policies and legal frameworks, or investment incentives offered by a government... to decide whether or not he wants to set up production units. The working requirement is not among those factors. Being the owner, the right holder would be in the best position to decide what would be the ideal location to maximize his return by minimizing production costs. The author maintains that from the customers’ perspective, they are best served if the price provided is minimal, no matter where the article was made. In many cases, making a product domestically costs more than importing it from abroad, as will be seen in the case of Brazil’s compulsory licensing for Efavrenz.<sup>494</sup>

It could be, therefore, argued that the working requirement has become redundant in the present global economy. In medieval times, when technological development was at a low level, the chief aim of compulsory working was to transfer technology and promote national industries. At that time, movement of goods and services was more arduous than as it is today. Shipping and transportation was a huge expense, and so working a patent in a granting country was a sensible method. Nowadays, most of the technical barriers to the rapid circulation of products have been removed. Furthermore, with highly complex technology that is involved in current production, it would be unrealistic to expect that with the help of the working requirement, a country might create a new trade or establish an industry.

Shortly stated, Article 5A of the Paris Convention shies away from determining whether working a patent means local manufacturing or importation. Under TRIPS, it remains controversial whether a compulsory licence could be granted on the basis of non-working. As the law did not restrict the grounds to issue the mandatory licence, WTO member states are rendered the authorisation to regulate this. However, when the matter is examined under an economic lens, the working clause seems less feasible. This thesis therefore maintains that the mere absence of local working should not constitute a ground for the compulsory licensing of

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<sup>493</sup> Kevin W. McCabe, ‘The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries toward the Patentability of Biotechnology’ (1998) 6 Journal of Intellectual Property Law 41, 62. footnote. 95.

<sup>494</sup> See Section 6.4.4 of this thesis.

a patent. Only when such absence hampers the public interest should this legal mechanism then be applied.

#### **4.2.4 Compulsory licensing under Article 31**

Article 31 contains thirteen sub-clauses and occupies 40% of the text of the TRIPS patent section.<sup>495</sup> It is the most lengthy and complex patent provision, thereby, being interpreted differently, as previously noted. This section will therefore provide a comprehensive analysis of Article 31 in order to suggest a right interpretation thereof and to show revolutionary changes in the compulsory licensing regime from Paris to TRIPS. The following sub-sections will study 11 sub-clauses from (a) to (j). The remaining provisions are excluded because they address the anti-competitive practices (k) and dependent patents (l), which are not the focus of this thesis.

As Ho indicates, although TRIPS permits compulsory licensing, it does not require member states to implement that legal measure.<sup>496</sup> This thesis argues that such understanding is correct theoretically, but in fact the majority of countries (apart from the US) incorporate this provision in their patent laws, as previously emphasised. In the absence of patent revocation as an outright reprimand for patent abuse, compulsory licensing has become the most effective safeguard. It can be used to combat various situations where the government's intervention is deemed necessary to strike the balance between the private rights and public interest.

##### **4.2.4.1 Individual merits**

Article 31 a) requires each application for a compulsory licence to be considered on its individual merits, meaning that WTO members cannot screen out medicines to a pre-established compulsory licensing scheme, as was done by, for example, Canada, India, and the UK prior to TRIPS. Under TRIPS, such a blanket authorisation is prohibited, whereas the Paris Convention does not have a similar provision.

According to Ho, individual merits require the member states to evaluate *individual* patents to decide whether the licence is appropriate, as well as whether the remuneration is proper.<sup>497</sup>

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<sup>495</sup> Mogens Peter Carl, 'Evaluating the TRIPS negotiations: a plea for a substantial review of the Agreement' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 111.

<sup>496</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 128.

<sup>497</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 130.

Nevertheless, Watal suggests that sub-clause (a) does not require a patent-by-patent consideration, but should be read in the light of substantial national laws.<sup>498</sup> In cases of government use, UNCTAD suggests that Article 31(a) can be read in the light of the US practice where the consideration of individual merits can take place after the licence is granted, and relates only to the question of compensation.<sup>499</sup>

#### 4.2.4.2 Prior negotiations

Article 31(b) mandates the prospective licensee to consult first with the patentee on the acquisition of a voluntary licence ‘on reasonable commercial terms and conditions’. When such an effort made ‘within a reasonable period’ is fruitless, the licensee can proceed to the compulsory licence. The main idea behind this provision is to protect the legitimate interests of the patent holder whose rights should not be subject to a surprise challenge.<sup>500</sup> However, the requirement of prior negotiation could be used as a tactic by the right holder to prolong the process, as will be seen in the chapter on India (Section 5.4.2).

However, the law does not define what constitutes ‘reasonableness’. This thesis submits that it is an elastic concept, which is subject to change and could be perceived differently by the patent holder and the licensee. What is reasonable to one might be unreasonable to another. For example, in the Indian compulsory licence in 2012, while the patent owner requested the royalty of 15%, the licensee’s proposed offer was only 6%.<sup>501</sup> Or, in Germany in 2016, Merck offered to pay \$10 million as a one-off payment for the global licence for an HIV medicine, but the respective patent owner (Shionogi) demanded a much higher offer: 10% of the turnovers.<sup>502</sup>

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<sup>498</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 322.

<sup>499</sup> UNCTAD- ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 468.

<sup>500</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 385.

<sup>501</sup> Maricel Estavillo, ‘India Grants First Compulsory Licence, For Bayer Cancer Drug’ (IP Watch, 12 March 2012) <<https://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/>> accessed 6 March 2018.

<sup>502</sup> Rudolf Teschemacher, ‘Patent Law’ (IP reports, Bardehle, 23 October 2017) <<https://www.bardehle.com/ip-news-knowledge/ip-news/news-detail/german-federal-court-of-justice-confirms-the-compulsory-license-granted-by-way-of-a-preliminary-inju.html>> accessed 6 March 2018. On 21 November 2017, German’s Federal Court of Patent set up a license fee of 4% on the sales of the drug. See ‘Festsetzung der Lizenzgebühr für Zwangslizenz für HIV-/AIDS-Medikament’ (Federal Patent Court, Press Releases, 22 November 2017) <[https://www.bundespatentgericht.de/cms/index.php?option=com\\_content&view=article&id=153%3A2017-11-22-14-40-14&catid=9%3Apressmitteilungen&Itemid=79&lang=de](https://www.bundespatentgericht.de/cms/index.php?option=com_content&view=article&id=153%3A2017-11-22-14-40-14&catid=9%3Apressmitteilungen&Itemid=79&lang=de)> accessed 6 March 2018.

In specific circumstances, the duty of holding talks with the patent holder can be waived. ‘National emergency’, ‘other circumstances of extreme urgency’ or ‘public non-commercial uses’ are given in Article 31(b) as examples of such situations. It should be noted that TRIPS does not require a member state to make a formal declaration of these situations, meaning that a government can simply indicate in their grant the circumstance leading to it.<sup>503</sup> The three situations mentioned only permit the rule of prior negotiation to be bypassed. Other legal obligations are still applied.

TRIPS does not determine the nature of these circumstances. So far, there have been no WTO panel or Appellate Body reports that address this matter, which leaves the three aforementioned notions undefined. Ordinarily, a ‘national emergency’ could refer to a situation where the nation is in danger or is in need of immediate remedial actions. Similarly, ‘extreme urgency’ implies a dire situation, requiring swift action. In effect, while ‘national emergency’ emphasises the geographical spread of the event, ‘extreme urgency’ is justified by the gravity of the situation itself.

Although it is hardly possible to distinguish between these two situations as they point towards a catastrophe, pandemic or epidemic, it is not difficult to gauge if such a situation is prevailing in a country. By contrast, ‘public non-commercial use’ is much harder to judge. This term which comprises two operative words ‘public’ and ‘non-commercial’, concerns the people or the government for not-for-profit purposes. This thesis argues that amongst the three listed situations in Article 31(b), ‘public non-commercial use’ is the most controversial concept, open to different interpretations.

Some authors believe that public non-commercial use is a permissive ground. UNCTAD emphasises that it is a flexible concept, leaving governments with considerable flexibility in granting compulsory licences without requiring commercial negotiations in advance.<sup>504</sup> Ho concurs, and is of the opinion that the term potentially opens up a wide range of situations where compulsory licenses could be imposed without prior negotiation.<sup>505</sup> Gold and Lam support a liberal interpretation of the term in national laws, so that member states could

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<sup>503</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 471; Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 135.

<sup>504</sup> *Ibid.*

<sup>505</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 135.

interpret it arbitrarily, subject only to respecting the rights and obligations contained in the Agreement.<sup>506</sup>

According to UNCTAD and Ho, the term ‘public’ could refer to the user, which is the government, or to the purpose of the use.<sup>507</sup> Therefore, even when a licence is issued to a private entity, it can be considered for the public if the main aim is to bring benefit to the latter. UNCTAD took the view that this term might relate, either to the nature of the transaction, where it may be understood as ‘not-for-profit’ use, or to the purpose of the use, which is to supply public institutions that are not functioning as commercial enterprises.<sup>508</sup>

At the opposite extreme, others view the term ‘public non-commercial uses’ as well as the whole of Article 31, through a narrower lens. Yang asserted this concept as ‘a superfluous, open-ended term with no internationally standardized definition’, which allows any country to declare a government use when there are insufficient grounds to make the situation ‘a national emergency’.<sup>509</sup> A significant attempt to bring about a better understanding of this concept is credited to Pier DeRoo.<sup>510</sup> He declares that the term is best defined approximately as ‘use by the government’ or ‘government use’, given the fact that the term was built upon the concept of ‘government use’ under the 28 USC Section 1498(a).<sup>511</sup>

The historical review of this Article, as referred to Section 3.1.3, tends to support this interpretation. Gorlin, an American involved in the TRIPS negotiations also shared the same view.<sup>512</sup> The US, while attempting to limit the commercial use of compulsory licences in developing countries, found itself in a dilemma, since it needed to reserve for its own government the right of use for non-commercial purposes. Consequently, the term ‘public non-

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<sup>506</sup> E. Richard Gold and Danial K. Lam, ‘Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing’ (2003) 6 *The Journal of World Intellectual Property* 5, 25 – 26.

<sup>507</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 471; Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 135.

<sup>508</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 471.

<sup>509</sup> Deli Yang, ‘Compulsory Licensing: for Better or For Worse, the Done Deal Lies in the Balance’ (2012) 17 *Journal of Intellectual Property Rights* 76, 79.

<sup>510</sup> Pier DeRoo, “Public Non – commercial Use” compulsory licensing for pharmaceutical drugs in government health care programs’ (2011) 32 *Michigan Journal of International Law* 347, 365.

<sup>511</sup> *Ibid.*, 390.

<sup>512</sup> Jacques J. Gorlin, *An Analysis of The Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement* (IP Institute 1999) 33 – 35.

commercial use’, instead of ‘government use’, was chosen to avoid use by governments for the purpose of generating profits.

In addition, as can be seen from the negotiations of TRIPS (Section 3.2.3), this thesis argues that this Agreement is aimed at reinforcing IP protection, not weakening it. The compulsory licensing regime is a case in point: all the requirements, such as individual merits, prior-negotiation and others to come, have the purpose of protecting, not eroding, the patent owner’s rights. ‘Public non-commercial use’ therefore should fall in line with this approach. The situation of ‘public non-commercial use’ will be revisited in Chapter 7 on Thailand where the government issued compulsory licensing on this ground.

In general, while this thesis supports Carvalho’s view that Article 31 should be considered as an alleviation of the adverse consequences of compulsory licensing to patent owners, and not as facilitating the grant of such licences,<sup>513</sup> it should not take away the fact that, ‘public non-commercial use, ‘national emergency’, and ‘extreme urgency’ are *not* the sole grounds to issue a compulsory licence. They instead merely allow the waiver of only the prior negotiation.

#### 4.2.4.3 Scope and duration

Sub-clause (c) states that the scope and duration of the compulsory licence ‘shall be limited to the purpose for which it was authorised’. On the one hand, Carvalho<sup>514</sup> agrees with other authors<sup>515</sup> that such a scope is limited to the field where the application for the compulsory licence is made. On the other hand, he goes further by linking the scope of the limitation to geography, so that the criterion is whether the licence meets the needs of a certain region or part of a particular market.<sup>516</sup>

As regards duration, other authors take a view more favourable to the licensee that, while a compulsory licence might likely end when the situation leading to it ceases to exist, the licensee’s legitimate interests should be taken into account.<sup>517</sup> If the compulsory licence had to

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<sup>513</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 397.

<sup>514</sup> *Ibid.*

<sup>515</sup> Jacques J. Gorlin, *An Analysis of The Pharmaceutical-Related Provisions of the WTO TRIPS (Intellectual Property) Agreement* (IP Institute 1999) 36; UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 472; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 495; Carlos M. Correa, ‘Patent rights’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade. The TRIPS Agreement* (3<sup>rd</sup> edn, Wolters Kluwer 2016) 298.

<sup>516</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 397.

<sup>517</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 472; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 495.

expire before the licensee could recover the reasonable investment put into the manufacture or import of the patented article, people would be discouraged from seeking such licences. By contrast, Carvalho believed compulsory licensing should end whenever the purpose has been fulfilled, no matter how harmful such an ending could be to the applicant.<sup>518</sup>

#### **4.2.4.4 Non-exclusive**

According to sub-clause (d), compulsory licences must be non-exclusive, meaning that the patent owner is free to grant more licences to other entities to make and sell the products, and he himself can conduct his own exploitation.<sup>519</sup> Consequently, a prospective licensee might face competition from other licensees and the patent holder. This requirement negated the developing countries' proposal in Nairobi in 1961, where they asked for exclusive compulsory licensing, as mentioned in Section 4.2.1. By comparison, the governing scope of Article 31(d) is broader than that of Article 5A. As summarised at the end of Section 4.1.3, under the Paris Convention, a non-exclusive licence is applied to a patent which is failed to work in the granting country. Under TRIPS, this requirement must be followed in all cases.

#### **4.2.4.5 Non-assignable**

Under sub-clause (e), a compulsory licence must be non-assignable, meaning that the licensee cannot sell this licence to a third party. However, as UNCTAD interpreted, it is permitted if the licensee sells or transfers his business, the assets of which are largely comprised of that licence.<sup>520</sup> This provision, having its roots in Article 5A, tends 'to prevent a grantee [...] from obtaining a stronger position than is warranted by the purpose of the licence [...]'<sup>521</sup>. In this way, Article 31(e) is designed so as to discourage more people from seeking such licences.<sup>522</sup>

Like sub-clause (d), sub-clause (e) is to be applied to all compulsory licences, no matter on which grounds they were granted.

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<sup>518</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 397.

<sup>519</sup> *Ibid.*, 399.

<sup>520</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 473.

<sup>521</sup> G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as revised at Stockholm in 1967* (Geneva 1968) 73.

<sup>522</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 136.

#### **4.2.4.6 Domestic market supply**

According to Article 31(f), TRIPS requires that the patented article that is manufactured under the compulsory licence must be predominantly supplied within the domestic market. As UNCTAD suggests, the word ‘predominantly’ implies that more than 50% of the product is to be distributed nationally.<sup>523</sup> This lead to a further implication, which is that up to 49.9% of the production can be exported.<sup>524</sup> However, Carvalho disagrees and argues that ‘predominant’ should be read in conjunction with the business goal of the manufacturer, and not with the output figure.<sup>525</sup> He asserts that the main purpose of a compulsory licence is to supply the national market, not the foreign market, and that only unintended (or unavoidable) surpluses should be exported.<sup>526</sup> Reading this provision in line with others of Article 31, the author views that they all clearly point to a more restricted compulsory licensing regime. Accordingly, the interpretation of Article 31(f) should not be made on the figure but on the purpose of the compulsory licence instead.

No matter how the provision is read, it does not alter the fact that it restricts the export of a patented article under a compulsory licence. Such a restriction has posed a serious problem to countries that have insufficient pharmaceutical manufacturing capacities or none at all. In fact, for the majority of the developing world, the only realistic sourcing mechanism is importation. However, Article 31(f) prevents countries with manufacturing capability from supplying medicines to others in need. Nevertheless, a new compulsory licensing provision was inserted to remove this obstacle. Details regarding this new mechanism will be discussed in Section 4.3.3

#### **4.2.4.7 Termination**

Article 31(g) requires the compulsory licence be terminated if the events that led to it ‘cease[s] to exist and are unlikely to recur’.<sup>527</sup> The termination, however, needs to take the legitimate interest of the licensee into account, since, if unreasonably applied, potential applicants would be discouraged by an awareness that the licence could be revoked at any time.<sup>528</sup> Moreover,

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<sup>523</sup> TRIPS, art 31 (f).

<sup>524</sup> WTO, *Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Joint Communication from the African Group in the WTO* (Geneva 24 June 2002) IP/C/W/351.

<sup>525</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 402.

<sup>526</sup> *Ibid.*, 402.

<sup>527</sup> TRIPS, art 31 (g).

<sup>528</sup> Carlos M. Correa, ‘Patent rights’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade. The TRIPS Agreement* (3<sup>rd</sup> edn, Wolters Kluwer 2016) 299.

the more efficient the licensee is, the sooner the situation leading to the compulsory licence will cease, and the sooner the licensee will lose his right to use the invention.<sup>529</sup>

#### 4.2.4.8 Remuneration

Article 31(h) provides the patent owner with the right to an ‘adequate remuneration’ that takes into account the ‘economic value of the authorisation’ without providing criteria for determining a royalty payment. In Gervais’s view, this provision refers to the normal cost of a licence when it is obtained voluntarily from the patent owner.<sup>530</sup> Carvalho goes further by arguing that the compensation must be calculated on the basis of the amount of actual or potential financial gain that the licences may extract from the market.<sup>531</sup>

Some international organisations have proposed different methods. UNCTAD suggested that the ‘adequacy’ can be based on the ordinary course of trade, on the patent owners’ justification for their request, on the benchmark established by an independent international organization or on the percentage of its income from sales of the licensed product.<sup>532</sup> UNDP recommended that the normal rates could be set at 4% and adjusted within the range of 2%, i.e. from 2-6%.<sup>533</sup> By way of comparison, the previous practice in Canada set up a royalty rates of 4% of the sales price of the medicines under the licence, while India limited the payments to a maximum of 4% of net sales.<sup>534</sup> The 1998 Japan Patent Office Guidelines (for government-owned drug patents) specify royalties that amount to 2%–4% of the generic product price; this amount can vary by as much as 2%, in a range of 0%–6%.<sup>535</sup>

The practice of remuneration varies from one country to another. For instance, Zambia fixed a maximum royalties rate at 2.5% of the turnover of the product, and Thailand and Indonesia paid only 0.5%.<sup>536</sup> In prominent pharmaceuticals countries, however, the royalties are much

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<sup>529</sup> Carlos M. Correa, ‘Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries’ (South Centre 1999) 8.

<sup>530</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 496.

<sup>531</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 405.

<sup>532</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 476.

<sup>533</sup> James Love, ‘Remuneration Guidelines for non-voluntary use of a patent on medical technologies’ (WHO 2005) 7.

<sup>534</sup> Tsai-Yu Lin, ‘Compulsory Licenses for Access to Medicines, Expropriation and Investor-state Arbitration under Bilateral Investment Agreements - Are There Issues beyond the TRIPS Agreement?’ (2009) 40 IIC 123, 128.

<sup>535</sup> James Love, ‘Remuneration Guidelines for non-voluntary use of a patent on medical technologies’ (WHO 2005) 7.

<sup>536</sup> James Packard Love, ‘Recent examples of the use of compulsory licenses on patents’ (KEI Research note 2007) 12 – 13, 18

higher. For example, the average range for pharmaceuticals in the US is 5%. In Germany, this amount could be as high as 10%.<sup>537</sup>

#### 4.2.4.9 Review

Sub-clauses (i) and (j) demand that the decisions in relation to a compulsory licence grant and the remuneration thereof must be subject either to judicial review or to any independent review by a higher authority. It relies upon member states to make provision for this in their national laws. However, WTO developing members are advised to elect the administrative review to hasten the grant procedure and minimize the burdens, compared with the courts.<sup>538</sup> Sub-clause (i) should be read in conjunction with Article 44.2 where the use by governments or third parties assigned by the government can be challenged in terms of remuneration only.<sup>539</sup>

#### 4.2.5 Summing up

Flowing from the above analysis, this thesis submits that, along with patent requirements, there has been a paradigm shift in the compulsory licensing regime from the Paris Convention to TRIPS. Article 5A, despite being supposedly too rigorous for developing countries, still gave member states substantial room to shape their legal policies. In fact, the Convention governs the compulsory licence only in case of failure to work. It did not extend the influence of international obligations to other situations. In a sharp contrast with Article 5A, Article 31 of TRIPS has expanded the governing scope, leaving member states with minimal freedom to regulate compulsory licensing whilst increasing the protection of the patent holder's interests. These charts below are clear demonstrations of how compulsory licensing has evolved from Paris to TRIPS towards a more stringent legal framework.

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<<https://www.keionline.org/book/publications-and-research-notes/kei-rn-2007-2-recent-examples-of-compulsory-licensing-of-patents>> accessed 16 March 2018.

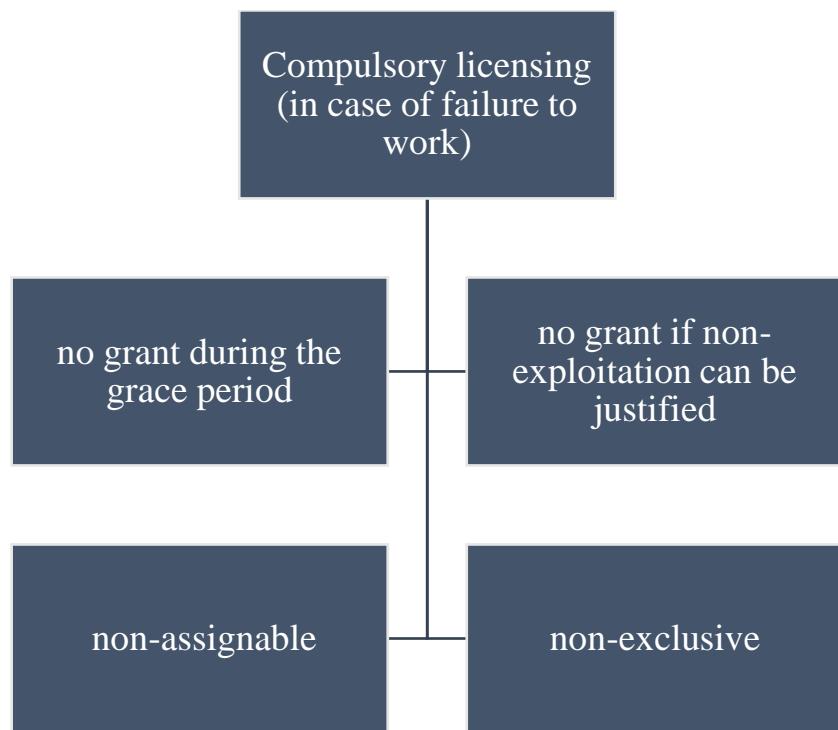
<sup>537</sup> Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (OUP 2007) 248.

<sup>538</sup> WHO, 'The TRIPS Agreement and Pharmaceuticals. Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals' (WHO, Jakarta, 2-4 May 2000) 33

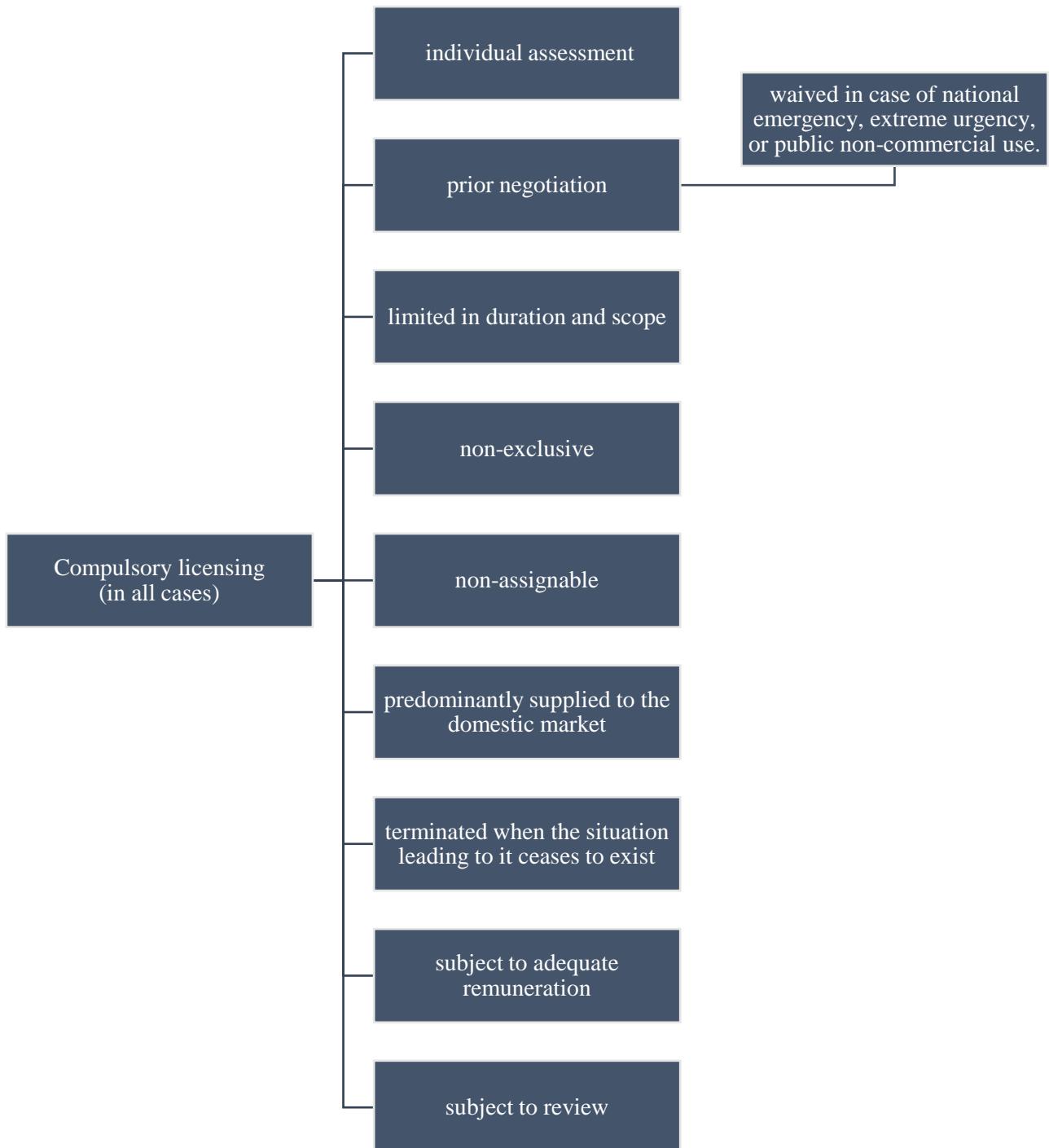
<<http://apps.who.int/medicinedocs/en/d/Jh1459e/5.3.html>> accessed 13 February 2018.

<sup>539</sup> TRIPS, art 44.2.

**Figure 3 Compulsory licensing under Article 5A of the Paris Convention**



**Figure 4 Compulsory licensing under Article 31 of TRIPS**



As stated in Section 3.3 that TRIPS incorporated the Paris Convention, any grant of a compulsory licence must now comply with two Articles: 5A and 31, signifying that WTO member states' freedom has been curtailed substantially.

## 4.3 The Doha Declaration – has the balance been achieved?

### 4.3.1 The path to Doha

Not long after TRIPS came into force in 1995, its impacts on access to medicines started to show. In 1997, the South African government, in response to the HIV/AIDS crisis in the region, adopted the Medicines and Related Substances Control Amendment Act. This Act permitted the Minister of Health to override patent rights by using compulsory licences when there was a threat to public health. Unsurprisingly, the South African government became the subject of a ‘multi-pronged attack’ from the pharmaceuticals industry and from the US government.<sup>540</sup>

In addition to being placed on the US’s Special 301 Watch List and facing the threat of US commercial sanctions, South Africa’s cabinet was sued by 39 pharmaceutical firms on the ground that the Act violated TRIPS.<sup>541</sup> The attack evolved into ‘a public-relations nightmare’ led by NGOs. (The role of NGOs in this event will be analysed separately in Section 9.4.) Bowing to public pressure, the international pharmaceutical companies dropped the case in 2001.<sup>542</sup>

Subsequently, the US challenged Brazil before the WTO regarding the working provision of Brazil’s patent law. However, the case was withdrawn, and the two countries opted for a private bilateral negotiation.<sup>543</sup> This dispute will be touched upon in Section 6.3.2. Notably, the agreement between two countries resulted in the compromise text of Doha,<sup>544</sup> as will be seen next.

These cases are merely the tip of the iceberg of the effects of TRIPS on public health in developing countries. Even though those concerns were expressed in many fora; the path to the Doha Declaration was not built until Zimbabwe, on behalf of the Africa Group, in a coalition

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<sup>540</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 175 – 176.

<sup>541</sup> Olasupo Owoeye, ‘International patents law and public health: revisiting the TRIPS compulsory licensing regime and the Doha Paragraph 6 System’ (2015) 37 EIPR 782, 783.

<sup>542</sup> Robert C. Bird, ‘Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effect’ (2009) 37 Journal of Law, Medicine and Ethics 209, 213.

<sup>543</sup> WTO, *Brazil: Measure Affecting Patent Protection. Notification of Mutually Agreed Solution* (19 July 2001) WT/DS199/4.

<sup>544</sup> Ellen F.M.‘t Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’ in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 52.

with the NGOs, requested a special TRIPS Council session on access to medicines in 2001.<sup>545</sup> Zimbabwe proposed that ‘Members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health’.<sup>546</sup> The adoption of the Doha Declaration did not go through easily once competing interests were aroused. While the countries with the leading pharmaceutical industries, the US, Switzerland, the UK, Germany, and Japan fought energetically to limit mandatory licences to medicines that treated just a few diseases, the developing countries insisted on a broader range of illnesses to be covered.<sup>547</sup>

At the same time, the UN General Assembly adopted a Declaration of Commitment on HIV/AIDS, and a number of African leaders adopted the Abuja Declaration on HIV/AIDS and other related diseases.<sup>548</sup> But the turning point on the path to Doha was the bio-terror attack using the anthrax virus in the US, which occurred shortly after the tragedy of 11 September 2001.<sup>549</sup> The number of serious illnesses and deaths that ensued forced the US government to threaten to issue a compulsory licence for Bayer’s patent on ciprofloxacin. As a consequence of this event, the US found itself in a quandary. How could they refuse the right of developing countries to grant such licences while they themselves were using it? Eventually, the US attitude switched from rejecting to (reluctantly) accepting non-restricted compulsory licences.<sup>550</sup>

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<sup>545</sup> Susan K. Sell, ‘TRIPS and the Access to Medicines Campaign’ (2002) 20 Wisconsin International Law Journal 481, 512.

<sup>546</sup> WTO, *Council for Trade-Related Aspects of Intellectual Property Rights. Special Discussion on Intellectual Property and Access to Medicines* 4 (10 July 2001) IP/C/M/31 (Restricted).

<sup>547</sup> Frederick M. Abbott, ‘The Doha Declaration of the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’ (2002) 5 Journal of International Economic Law 469, 482.

<sup>548</sup> Jennifer Sellin, *Access to Medicines: The interface between patents and human rights. Does one size fit all?* (Intersentia 2014) 260.

<sup>549</sup> Holger Hestermeyer, *Human Rights and the WTO: The case of Patents and Access to Medicine* (OUP 2007) 16.

<sup>550</sup> Jason D. Ferrone, ‘Compulsory Licensing during Public Health Crises: Bioterrorism’s Mark on Global Pharmaceutical Patent Protection’ 26 (2003) Suffolk Transnational Law Review 385, 403 – 406.

### **4.3.2 The legal status of the Doha Declaration and its effects**

The Doha Declaration on the TRIPS agreement and public health, adopted in 2001, contains 7 paragraphs.

The first paragraph recognises the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, TB, malaria and other epidemics. Then, at paragraphs 2 and 3, the Declaration affirms the role of TRIPS in the national and international actions in addressing these problems and documents the importance of IP protection for new medicines as well as its effects on price. The interpretation of TRIPS and its implementation, therefore, should serve the purpose of promoting access to medicines for all. It does not and should not prevent the parties from protecting public health, as stated at paragraph 4.

The fifth paragraph is the most substantive provision. It affirms the rights of WTO members to decide the grounds upon which a licence is granted and to determine what constitutes a national emergency, or other circumstances of extreme urgency. Although this paragraph does not override the TRIPS obligations, it eliminates the uncertainty of Article 31, as well as refuting a restrictive interpretation of this Article. Paragraph 6 recognises the difficulties of WTO members with insufficient or no manufacturing capacities in the pharmaceuticals sector, which hinder them from making effective use of TRIPS compulsory licensing. The last paragraph allows the LDCs to extend the transition period with respect to pharmaceutical products to 2016.<sup>551</sup>

The legal status of the Doha Declaration is open to contrasting interpretations because in a very strict sense, this document does not form part of the TRIPS Agreement. O'Farrell observes that the document serves as an interpretative tool to reaffirm the freedom of developing countries in using the compulsory licences, putting an end to the argument that those licences are granted only in cases of emergency.<sup>552</sup> Murthy, with a more positive view, claimed that the Declaration is essential as a primary source for the WTO Panel seeking guidance on the settlement of disputes.<sup>553</sup> Reichman, a leading expert in the debate on access to medicines, viewed this

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<sup>551</sup> However, as mentioned in Figure 1, this deadline is now extended until 2033. See page 89.

<sup>552</sup> Gemma O'Farrell, 'One small step or one giant leap towards access to medicines for all?' (2008) 30 EIPR 211, 212.

<sup>553</sup> Divya Murthy, 'The Future of compulsory licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health' (2002) 17 American University International Law Review 1299, 1328.

document as having a political value rather than a strictly legal character.<sup>554</sup> It becomes clear that compulsory licensing has closely interrelated with politics. Such interrelation is also featured in country case-studies, as will be shown in Chapters 6 (Brazil) and 7 (Thailand).

McGill has called for a definition of ‘public health crisis’, cited in paragraph 5, because, in her view, member nations might invoke compulsory licensing for a range of conditions that go beyond the original concept.<sup>555</sup> The terms of the Doha Declaration favoured the position taken by developing countries with pharmaceutical production capabilities, such as India and Brazil.<sup>556</sup> McGill worries that a broad interpretation of Doha would not serve those countries most in need of inexpensive medication, especially the LDCs (such as those in Africa) with high rates of HIV/AIDS.<sup>557</sup> She claims that lack of clarification and excessive flexibility has caused the Declaration to exceed the scope of the WTO’s intended criteria of use.<sup>558</sup>

Carvalho is particularly critical of the Doha Declaration, arguing that its sole purpose was to appease the entirely unreal fears of developing countries, fears that stemmed essentially from an overall misunderstanding of the international patent system.<sup>559</sup> Sherman and Oakley conceded that Doha neither materially changed TRIPS, nor international patent protection, nor weakened compulsory licensing.<sup>560</sup> Sharing the same view, the pharmaceutical industry viewed it as a merely political statement rather than a legally binding text.<sup>561</sup> As a result, it had zero impact on them.<sup>562</sup> For this reason, both of the parties, the patent advocates and the health activists, claimed Doha as their own victory.<sup>563</sup>

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<sup>554</sup> Jerome H. Reichman and Catherine Hasenzahl, ‘Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA’ (UNCTAD – ICTSD, June 2003) 18.

<sup>555</sup> Aileen M. McGill, ‘Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis under The Doha Declaration’ (2010) 10 Wake Forest Intellectual Property Law Journal 69, 74.

<sup>556</sup> *Ibid.*, 97.

<sup>557</sup> *Ibid.*, 89.

<sup>558</sup> *Ibid.*, 87 – 92.

<sup>559</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 197.

<sup>560</sup> Peggy B. Sherman and Ellwood F. Oakley, ‘Pandemics and Panaceas: The World Trade Organization’s Effort to Balance Pharmaceutical Patents and Access to AIDS Drugs’ (2004) 41 American Business Law Journal 353, 381.

<sup>561</sup> Susan K. Sell, ‘TRIPS and the Access to Medicines Campaign’ (2002) 20 Wisconsin International Law Journal 481, 518.

<sup>562</sup> Charan Devvereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 104.

<sup>563</sup> Drahos took the view that the Doha Declaration of 2001 was a victory for Developing Countries, coming right after the victory of the US by the conclusion of TRIPS in 1995. See Peter Drahos, ‘Four lessons for developing countries from the trade negotiations over access to medicines’ (2007) 28 Liverpool Law Review 11, 14. Kenneth

This thesis submits that while the legal status of the Doha Declaration is unclear, its effects are far-reaching. It firstly dispels the popular myth of Article 31 by restating that WTO members are reserved the right to capitalise on TRIPS flexibilities and have complete freedom to determine the grounds upon which a compulsory licence can be granted. In the author's view, the Declaration creates legal certainty which led to a result that, more compulsory licences were granted by developing countries during the years 2003 – 2005, as indicated in Chapter 2.<sup>564</sup>

Secondly, as Paragraph 6 of the Declaration instructs the Council to find solutions for countries with insufficient or no pharmaceutical manufacturing capacities, the Council adopted a decision in 2003.<sup>565</sup> This decision led in 2005 to the amendment of Article 31,<sup>566</sup> which came into effect on 23 January 2017.<sup>567</sup> In short, it is the Doha Declaration which paved the way for the amendment of TRIPS – the first WTO Agreement amended since the organisation formation in 1995. It is not the intention of this thesis to determine the exact legal character of this document, but there is no doubt that Doha is a strongly political statement and has exerted significant effects on TRIPS as well as access to medicines. For these reasons, the author accepts the view of Correa that the Declaration can be regarded as a ‘subsequent agreement’ between the parties.<sup>568</sup>

### 4.3.3 The new compulsory licensing regime

Along with the conventional compulsory licence governed by Article 31, an additional form of compulsory licensing is created and incorporated in TRIPS under Article 31bis. The newly inserted regime, was sometimes termed the ‘paragraph 6 system’, from its origin in the Doha Declaration. The provision is essentially comprised of three waivers from Article 31 in respect of medicines. It waives (i) the obligation in Article 31(f) that, compulsory licences shall be predominantly for the supply of the domestic market; (ii) the obligation in Article 31(h) for the

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C. Shadlen, ‘Patents and Pills, Power and Procedure: The North-South Politics of Public Health in the WTO’ (2004) 39 *Studies in Comparative International Development* 76, 95 quoted the comments of Alan F. Holmer, president of the PhRMA, and Harvey Bale, director general of the IFPMA, in “Drug Makers Now Say Doha TRIPs Pact Does Not Diminish Protection of IP Rights,” (*International Trade Daily*, 16 November 2001). They state that there is “nothing in [the Doha] declaration that undermines or diminishes the intellectual property rights that pharmaceutical companies have”.

<sup>564</sup> See Section 2.2.

<sup>565</sup> WTO General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health* (Decision of 30 August 2003) WT/L/540.

<sup>566</sup> WTO General Council, *Amendment of the TRIPS Agreement* (Decision of 6 December 2005) WT/L/641.

<sup>567</sup> ‘WTO IP rules amended to ease poor countries’ access to affordable medicines’ (23 January 2017) <[https://www.wto.org/english/news\\_e/news17\\_e/trip\\_23jan17\\_e.htm](https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm)> accessed 22 May 2017.

<sup>568</sup> Carlos M. Correa, ‘Implications of the Doha Declaration on the TRIPS Agreement and Public Health (WHO 2002) 45 <<http://apps.who.int/medicinedocs/en/d/Js2301e/>> accessed 19 March 2018.

importing country to pay remuneration to the right holder; and (iii) the obligation in Article 31(f), to the extent that re-export of the imported pharmaceuticals is allowed among members of a regional trade agreement where at least 50% of the members are LDCs.<sup>569</sup>

All LDCs are automatically entitled to use the compulsory licensing system. Developing country members are eligible if they have insufficient manufacturing capacity or none at all, provided that they notify their intention to the TRIPS Council. Any member may be an exporter. However, the developed states opted out of using the system as importers, while some high-income developing nations declared that they would only use it in situations of national emergency or extreme urgency.<sup>570</sup> The compulsory licensing mechanism under Article 31bis, however, falls beyond the scope of this thesis, as stated and explained in Section 1.4.2 of Chapter 1.

In general, the new compulsory licensing regime, which removes the export barrier, is expected to increase the access to generics in LDCs. This practice has been welcomed by the pharmaceutical industries. Its effectiveness however, remains to be seen. In 2007, Rwanda announced its use of the new system, but it was found to be cumbersome, costly and time-consuming, whereas it needed to be simple, fast and automatic.<sup>571</sup> In addition, many developing countries have not adopted the new system in their patent laws yet, for example Brazil (Chapter 6) and Thailand (Chapter 7).

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<sup>569</sup> WTO General Council, *Amendment of the TRIPS Agreement* (Decision of 6 December 2005) WT/L/641.

<sup>570</sup> WTO, ‘Obligations and exceptions’ (Fact Sheet: TRIPS and Pharmaceutical Patents, September 2006) <[https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm)> accessed 6 March 2018. All WTO member countries are eligible to import under this decision, but 23 developed countries have announced voluntarily that they will not use the system to import: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the UK and the US. After joining the EU in 2004, another 10 countries have been added to the list: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia. And 11 more said they would only use the system to import in national emergencies or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

<sup>571</sup> Katri Paas, ‘Compulsory licensing under the TRIPS Agreement – a cruel taunt for developing countries?’ 2009 (31) EIPR 609, 612 – 613.

## 4.4 The effects of compulsory licensing on the pharmaceutical industry

As repeatedly stressed, a common criticism of compulsory licences is that they have a deleterious effect on innovative activities. As analysed in Chapter 3, the drug sector is one of the industries where patent ownership is more concentrated than others, and as a consequence, a compulsory licence, theoretically, has a more drastic effect on medicines than on the products of other industries.

A number of economic studies were conducted to test this hypothesis. In 1973, Taylor and Silberston, while evaluating the effect of the British patent system, concluded that a thoroughgoing compulsory licensing regime could lead, in the long term, to a reduction of two-thirds in patented medicines of UK pharmaceutical companies.<sup>572</sup> The reason given was that these companies would face uncertainties as to the share and revenue of the UK market, since they cannot know how many compulsory licences would be made and how far sales would be affected.<sup>573</sup> Such a decline in research-based products might prompt an increase in incrementally innovated medicines, such as second line products and diversification through packaging, dosage forms, or other non-research based goods, such as beverages and health foods.<sup>574</sup> If such a tendency developed, the pharmaceutical industry, arguably, would fail one of its central missions, which is to make medicines for the treatment of life-threatening diseases.

By contrast, a research carried out by Scherer in 1977 arrived at a different conclusion.<sup>575</sup> He claimed that compulsory licensing had not forced firms to invest in R&D at a level below the norms in their industries.<sup>576</sup> This thesis nevertheless argues that Scherer's examination was made within the context of US antitrust decrees, while Taylor and Silberston's exploration was carried out under the patent law. Since the situations leading to a compulsory licence differ between the two laws, Scherer's findings in antitrust law might not, arguably, be applied in the case of patent law.

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<sup>572</sup> C.T. Taylor and Z.A. Silberston, *The Economic Impact of the Patent System: A Study of the British Experience* (CUP 1973) 263.

<sup>573</sup> *Ibid.*, 254.

<sup>574</sup> *Ibid.*, 263 – 264.

<sup>575</sup> F.M. Scherer, *The Economic Effects of Compulsory Patent Licensing* (New York University 1977).

<sup>576</sup> *Ibid.*, 67 – 68.

In 2003, Chien assessed the impacts of compulsory licensing on pharmaceutical innovation during the period between 1980 and 1997.<sup>577</sup> Her study, however, drew tentative conclusions. On the one hand, she observed no decline in pharmaceutical investment after compulsory licensing and found that this legal mechanism has very little impact on innovation, especially when such licences are granted in a small and insignificant market.<sup>578</sup> On the other hand, she confessed that where a compulsory licence is predictable, and the market is significant to the company, and where the companies' profit is largely generated from patent-based products, compulsory licensing might provoke negative impacts.<sup>579</sup> However, because the markets of developing countries are small and the incentive to innovate drugs majorly comes from the developed world, Chien tends to favour the use of compulsory licences in developing countries.<sup>580</sup>

In essence, the empirical studies have failed to give a definitive answer that to which extent compulsory licensing has affected pharmaceutical R&D. Despite the lack of conclusive findings, the industry has, nonetheless, displayed extreme sensitivity towards the compulsory licence.

## 4.5 Conclusions

As critically analysed in this chapter, compulsory licensing, from the Paris Convention to the TRIPS Agreement, has always provoked vigorous debates among the contracting parties. Since the grant of a compulsory licence curtails the monopoly right embodied in a patent, it is described as an antidote to the perceived ills of the patent system.<sup>581</sup> In effect, a compulsory licence touches directly on the core value of a patent, which is the exclusivity by which a patent holder can prohibit others from using his invention, and which enables him to be the only beneficiary from it. A compulsory licence, once issued, although it does not take the patent holder's rights away entirely, turns his exclusivity into a shared privilege.

In other words, once a compulsory licence is granted, the patentee does not lose his rights but instead the exclusivity encapsulated therein. From a legal viewpoint, such a licence does not

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<sup>577</sup> Colleen Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation' (2003) 18 Berkeley Technology Law Journal 1.

<sup>578</sup> Colleen Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation' (2003) 18 Berkeley Technology Law Journal 1, 40 – 41.

<sup>579</sup> *Ibid.*, 41.

<sup>580</sup> *Ibid.*, 43.

<sup>581</sup> *Ibid.*, 3.

adversely affect the right owner as the patent is still in his possession. He can still preclude other parties (apart from the licensee) from using his invention. However, from the economic aspect, a compulsory licence modifies his rights negatively, because when a licensee enters the market where the patent owner was previously dominant, his profits will shrink. It is interesting to note that, while Nard maintains that patent monopoly should be viewed through a legal lens, not an economic one because there are always substitutions on the market,<sup>582</sup> the compulsory licence shows that it has more economic effects than legal consequences.

On the one hand, the negotiation history of Article 31 suggested that it is an actual compromise. It turned away from addressing important terms, and thus leaving the Article open to various (mis)understandings. Local working is such an example. Article 31 is an accurate reflection of the ‘constructive ambiguity’<sup>583</sup> of international accords which permit discretionary explanation according to each party’s own interests.

On the other hand, as concluded in Chapter 3 that TRIPS reflected the economic interest of private industry who demands a stricter patent regime, that is also the case of the compulsory licensing system. From the Paris Convention to the TRIPS Agreement, the liberty of member states has been considerably eroded. While Article 5A has merely 4 sub-clauses, Article 31 has 13. Not only do the requirements increase in quantity, but also in quality. The freedom, which was considered insufficient for developing countries following the Paris Convention, has diminished in the wake of TRIPS.

In the pharmaceutical sector where the R&D investment is enormous, but the risk is substantially high, compulsory licensing is therefore a real threat to returns. For this reason, when patented medicines are mandatorily licensed in developing countries, the practice has not been as smooth as it would seem, if judged according to the letter of the law. Given that so little leeway is provided by TRIPS, the question which needs to ask is how WTO member states can implement a compulsory licensing regime to meet their national needs. The three chapters that follow will endeavour to provide an answer to that question.

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<sup>582</sup> Craig Allen Nard, *The Law of Patents* (4<sup>th</sup> edn, Wolters Kluwer 2018) 2.

<sup>583</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 7.

## CHAPTER 5: INDIA

In contrast with Chapters 3 and 4 which analyse in depth drug patents and compulsory licensing in an international law context, this chapter will now critically evaluate the aforementioned elements but, through the lens of Indian domestic law. This chapter, along with Chapters 6 (Brazil) and 7 (Thailand) will answer the third research question, namely: how have developing countries adopted a compulsory licence regime which caters for their own interests?

The reasons for choosing India as one of the three country case-studies are multi fold. Firstly, India is distinct from many countries of the South. It has a very well developed pharmaceutical sector which has earned the reputation of ‘the pharmacy of the developing world’.<sup>584</sup> Any changes in India patent law have, therefore, important implications for other developing countries and LDCs.<sup>585</sup> Secondly, the Indian compulsory licence granted to Natco in 2012 is of significant importance.<sup>586</sup> As stressed by the Controller of Patents<sup>587</sup> in the order, it is the first Indian compulsory licence of its kind,<sup>588</sup> or to be more precise, the first one since the country re-enacted drug patents in 2005. More importantly, to the entire world, it also served as the first, post-TRIPS compulsory licence in a conventional sense of this word, as noted in section 1.2.2. Remarkably, the decision threw the spotlight on one of the most irreconcilable issues of the patent system: the working requirement, as discussed in Section 4.2.3. For these reasons, Natco’s licence marked a watershed event and went well beyond an ordinary ruling. It is a historical and important decision for all developing countries and it also tests India’s compliance with TRIPS.<sup>589</sup>

Finally, while the 2012 historic decision seemed herald a new era of compulsory licensing in the region, the reality is pointing to the opposite. The Controller, unexpectedly, turn down two

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<sup>584</sup> MSF, ‘Save the pharmacy of the developing world!’ (2007) <<http://www.msfaccess.org/content/2007-save-pharmacy-developing-world>> accessed 5 May 2016; Jeremiah Norris, ‘India’s role as a pharmacy to the developing world’ (Financial Times, 18 September 2015) <<https://www.ft.com/content/d4951900-5aea-11e5-9846-de406ccb37f2>> accessed 16 February 2018.

<sup>585</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 144.

<sup>586</sup> *Natco v. Bayer* (Controller of Patents, 2012).

<sup>587</sup> The patent system in India is administered under the direction of the Controller General of Patents, Designs and Trade Marks, hereinafter referred to as the Controller of Patents. This is a subordinate office under the Department of Industrial Policy and Promotion (DIPP), the Ministry of Commerce and Industry.

<sup>588</sup> *Natco v. Bayer* (Controller of Patents, 2012) 4.

<sup>589</sup> KD Raju, ‘Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries’ (2017) 22 Journal of Intellectual Property Rights 1, 26.

subsequent applications made by private companies, in late 2013 and early 2016.<sup>590</sup> All of these moves have signified that India has developed a complex ideology towards compulsory licensing which merits further examination. It is interesting to note that while *Natco* has received significant attention from the international pharmaceutical industry, these other two cases did not come under the same spotlight.<sup>591</sup>

Three applications filed by national companies have signalled the enthusiasm and interests of private industry in contesting medicine patentability and indicated that, market-driven licences entirely dominate the Indian practice. Government use licences, meanwhile, have never been granted in the country. In 2013, the Ministry of Health recommended such licences for three medicines but none of them was ever granted for a variety of reasons.<sup>592</sup> This issue will be dealt with in Section 5.5 of this chapter. Stated succinctly, market-initiated mandatory licensing is a characteristic which distinguishes India from this thesis's other case studies - Brazil and Thailand - where government use licensing is the main method. Accordingly, it is given considerable attention in this chapter. Because of far-reaching implications of the 2012 compulsory licence, this chapter will focus particularly on it.

## 5.1 An introduction to India

Located in South Asia, India is the world's second largest country in terms of population and the world's eighth biggest country in terms of land area. In 2016, India's GDP of \$2,264 million was ranked as the world's seventh largest.<sup>593</sup> With the GNI per capital of \$1,670, it is classified as a lower-middle income country.<sup>594</sup> India is the world's fastest growing major economy,<sup>595</sup> having its largest and youngest ever workforce, and in a decade's time, set to become the

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<sup>590</sup> *BDR vs. Bristol Myers Squibb* (Controller of Patents, 2013); *Lee Pharma. vs. AstraZeneca* (Controller of Patents, 2016).

<sup>591</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 151.

<sup>592</sup> India's Ministry of Commerce and Industry, 'Compulsory licensing on patented drugs' (Press Information Bureau, 19 December 2014) <<http://pib.nic.in/newsite/PrintRelease.aspx?relid=113719>> accessed 27 February 2018.

<sup>593</sup> WB, 'Gross Domestic Product 2016' (World Development Indicators, 15 December 2017) <<http://databank.worldbank.org/data/download/GDP.pdf>> accessed 5 March 2018.

<sup>594</sup> WB, 'India' (Databank) <<https://data.worldbank.org/country/india>> accessed 19 February 2018.

<sup>595</sup> Manoj Kumar 'India regains status as fastest growing major economy' (Reuters, 28 February 2018) <<https://www.reuters.com/article/us-india-economy-gdp/india-regains-status-as-fastest-growing-major-economy-idUSKCN1GC1UD>> accessed 6 March 2018.

world's most populous country.<sup>596</sup> With these impressive indicators, the country has been viewed as a rising economic power house.

For almost a century, India was under British rule. The relationship between the two countries started in the 16<sup>th</sup> century with the physical and economic presence of the East India Company in Surat.<sup>597</sup> Such a trading partnership subsequently turned into military power in South India and rapidly extended northward.<sup>598</sup> In 1858, the British Crown took control of the Company, initiating an era of colonization that lasted until 1947. Since independence, India, has arguably, built on its democratic credentials to become the world's largest democracy.

For the past decade, the Indian government has taken radical steps to boost the manufacturing sector of the economy, to strengthen the purchasing power of Indian consumers, thereby spurring the economic development. Between 2014 and 2015, Modi's cabinet has launched various economic initiatives such as Make in India, Digital India, Smart Cities, Skill India, and Start Up India... with the vision to transform the country into a global manufacturing hub.<sup>599</sup> This thesis therefore argues that such vibrant campaigns will create positive synergies with India's IP policies, which will likely distinguish the nation from its peers, Brazil, for example, as will be seen in chapter 6.

## 5.2 India's patent law and the pharmaceutical industry

As briefly stated at the beginning of Chapter 5, Indian companies are the main generics suppliers to the world's poor. Although India is being viewed as a developing country, its pharmaceutical manufacturing capacity has outpaced many other in the South. As Halliburton commented, Indian companies are not confined to India but span the globe and they are not simply small, generic producers, nor are they mere victims of large multinational firms.<sup>600</sup> India's highly successful pharmaceutical sector is largely owed to its 1970 Patents Act which was principally built on a report of Justice N. Ayyangar.<sup>601</sup> This work is important to a degree

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<sup>596</sup> WB, 'The World Bank in India' (11 October 2017) <<http://www.worldbank.org/en/country/india/overview>> accessed 5 March 2018.

<sup>597</sup> Peter Marshall, 'The British Presence in India in the 18th Century' (BBC 2011) <[http://www.bbc.co.uk/history/british/empire\\_seapower/east\\_india\\_01.shtml](http://www.bbc.co.uk/history/british/empire_seapower/east_india_01.shtml)> accessed 27 October 2014.

<sup>598</sup> *Ibid.*

<sup>599</sup> India's DIPP, 'Government of Indian initiatives' <<http://www.makeinindia.com/goi-initiatives>> accessed 24 July 2017.

<sup>600</sup> Murphy Halliburton, *India and the Patent Wars. Pharmaceuticals in the New Intellectual Property Regime* (Cornell University Press 2017) 116 - 117.

<sup>601</sup> N. Rajagopala Ayyangar, *Report on the revision of the Patents Law* (India, September 1959).

that it is used as a guide for the Indian patent office to establish and develop the reasoning in *Natco*.<sup>602</sup> Accordingly, critical evaluations of Ayyangar's report and the 1970 Patents Act are essential if a comprehensive understanding of the Indian practice is going to be achieved.

### 5.2.1 The era of colonization

With almost a century of British rule in India, British legislation exerted a profound influence on the Indian legal system. Amongst others, patent law is such concrete evidence. The first Indian patent legislation was the Act VI of 1856, which was originally based on the British Patent Law of 1852.<sup>603</sup> India at that time became the first country outside the Western world to have a patent law.<sup>604</sup> Along with the introduction of the patent system, other technological industries, for example, textiles, food processing, and metals, besides pharmaceuticals, started developing in India from the 1880s onward.<sup>605</sup>

In 1911, the Indian Patents & Designs Act was enacted and this Act, similar to its precursors, allowed the patenting of pharmaceuticals.<sup>606</sup> Under the new law, India's patent system was exploited by foreign companies with the sole purpose of achieving the monopoly in the Indian market. The foreign companies did not establish production units in India but instead exported raw materials from the country, transformed them into finished products, and imported them back.<sup>607</sup> India, despite being one of the poorest countries in the world, had some of the world's highest drug prices.<sup>608</sup> The 1911 Act was described as 'a tremendous set-back', as it did not encourage either investment in R&D or the transfer of technology, and no medicines were manufactured in the country.<sup>609</sup>

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<sup>602</sup> For example, the IP Appellate Board in the case stated as follow: 'It is true that this report [Ayyangar's report] was before TRIPS Agreement, but it has not lost in its significance a whit. Whenever a question arises in regard to patents we will learn much if we read it'. See *Bayer v. Union of India and Ors.*, Order no 45 of 2013 (IPAB) 12

<sup>603</sup> N.S. Gopalakrishnan and Madhuri Anand, 'Compulsory Licence Under Indian Patent Law' in Reto M. Hilty and Kung-Chung Liu (eds), '*Compulsory licensing: Practical Experiences and Ways Forward*' (Springer 2015) 14.

<sup>604</sup> A D Damodaran, 'Indian Patent Law in the post-TRIPS decade: S&T Policy Appraisal' (2008) 13 Journal of Intellectual Property Rights 414, 415.

<sup>605</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 507.

<sup>606</sup> V.K. Unni, 'Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Contest of Public Policy and Health' (2012) 25 Global Business and Development Law Journal 323, 325.

<sup>607</sup> Mainak Mazumdar, *Performance of Pharmaceutical Companies in India: A Critical Analysis of Industrial Structure, Firm Specific Resources, and Emerging Strategies* (Springer 2013) 18.

<sup>608</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 66.

<sup>609</sup> Santanu Mukherjee, 'The Journey of Indian Patent Law towards TRIPS Compliance' (2004) 35 IIC 125, 127.

## 5.2.2 Post-Independence

The 1911 Act remained in force until India gained independence from Britain in 1947. However, no significant change occurred in the pharmaceutical industry after independence. By that time, Western companies controlled from 80% to 90% of the Indian market through importation, which made medicine prices unreasonably high in comparison with Indian living standards.<sup>610</sup> Such a grave situation was a direct consequence of the colonisation, where patent rules were merely a tool helping foreign firms to suppress competition from local companies.

In order to examine the country's pharmaceutical situation, the newly independent Indian government set about a task. In 1948, it appointed the Tek Chand Committee to undertake the investigation behind the unaffordability of medicine prices.<sup>611</sup> The Committee reviewed Indian patent law and established that there were loopholes which might encourage misuse or abuse of patent monopolies and which needed to be counteracted by a compulsory licensing regime.<sup>612</sup>

Although the Tek Chand report was important, it was the second work, under the chairmanship of Justice N. Ayyangar, that set the tenor of India's current patent law.<sup>613</sup> In 1957, the Ayyangar committee was formed to undertake a further investigation of Indian patents. Ayyangar concluded that the Indian patent system neither stimulated inventions among Indians nor encouraged the development and exploitation of new inventions to secure the benefits thereof for the public.<sup>614</sup> Ayyangar identified patent monopolies as the greatest 'evil' of the patent mechanism. He, however conceded that, there were no alternative methods for achieving better results, and that patent remained as the most desirable method of encouraging inventions and rewarding them.<sup>615</sup> Furthermore, as the patent system had been operational in India for over a century, he could not recommend an abolition of the system.<sup>616</sup>

In order to eliminate 'handicaps' created by patent monopolies, Ayyangar recommended some changes to Indian patent law. The key recommendations were: an exclusion from patentability

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<sup>610</sup> Srividhya Ragavan, 'Of the Inequals of the Uruguay Round' (2005) 10 Intellectual Property L. Rev 273, 280.  
<sup>611</sup> *Ibid.*, 279.

<sup>612</sup> Shamnad Basheer and Mrinalini Kochupillal, 'The Compulsory Licence regime in India: Past, Present and Future' (A Report for the JPO, 2005) 3 – 4 <<https://ssrn.com/abstract=1685129>> accessed 19 March 2018.

<sup>613</sup> V.K. Unni, 'Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Contest of Public Policy and Health' (2012) 25 Global Business and Development Law Journal 323, 327.

<sup>614</sup> N. Rajagopala Ayyangar, *Report on the revision of the Patents Law* (India, September 1959) 13.

<sup>615</sup> *Ibid.*, 19-20.

<sup>616</sup> *Ibid.*, 19-20.

of pharmaceutical products (and food), an expansion of the grounds for compulsory licences, and an obligation to exploit inventions as soon as possible after patents were granted.<sup>617</sup> In addition, Ayyangar objected to the idea of joining the Paris Convention because the country would suffer rather than gain any advantage.<sup>618</sup> Accordingly, India remained an outsider of the Convention until 1998.

Ayyangar's work led to an extensive debate in the Indian Parliament. Although the process of patent reform had been initiated in India immediately after the independence, it took the government more than two decades to enact a new patent law, which was largely built on Ayyangar's report. It was not until 1970 that the Indian Patents Act was adopted, and came into force in 1972.<sup>619</sup> Chaudhuri observed that even though the process of TRIPS compliance took India a substantial amount of time, it took even longer to introduce the 1970 Patents Act.<sup>620</sup>

According to some leading scholars, Ayyangar's report formed the backbone of the Indian patent system by recommending revolutionary changes to the country's existing patent law.<sup>621</sup> Under this Act, Indian patents are not a medium to enable patentees to enjoy a monopoly for the importation of patented articles. It provided weak patent protection, particularly with respect to pharmaceuticals. Patents on medicine products were excluded and only process patents were allowed. Moreover, the Act shortened the term of protection for pharmaceutical processes to 5 years from the date of sealing, or 7 years from the filing date of the complete specification, whichever period was *shorter*.<sup>622</sup> For other inventions, patent term was granted for 14 years.<sup>623</sup> Moreover, the 1970 Patents Act expanded the grounds for compulsory licensing, which will be discussed in Section 5.3. Patent rules under this legislation shaped an overt policy of favouring domestic industries over foreign companies and halted the non-exploitation of Indian patents. In essence, this work was in support of utilising the patent system

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<sup>617</sup> *Ibid.*, 38 – 39, 68.

<sup>618</sup> *Ibid.*, 107.

<sup>619</sup> Indian Patents Act of 1970.

<sup>620</sup> Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (OUP 2005) 65, footnote 9.

<sup>621</sup> Srividhya Ragavan, 'Of the Inequals of the Uruguay Round' (2005) 10 Intellectual Property L. Rev 273, 281 footnote 53; Gopakumar K. M. 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' (2010) 3 The Law and Development Review 325, 329; V.K. Unni, 'Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Contest of Public Policy and Health' (2012) 25 Global Business and Development Law Journal 323, 327.

<sup>622</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 513

<sup>623</sup> *Ibid.*

as a protectionist tool, to encourage domestic industries in countries having low-level technology like India.

Barnes has commented that this Act was a copy of the English Patent Act 1949, but with weaker patent protection.<sup>624</sup> To a certain extent, this statement is true because some parts of the 1970 Patents Act, for example, compulsory licensing, were derived from the English patent law. In fact, in the report, Ayyangar heavily referred to UK patent law.<sup>625</sup> After a century of British rule, the influence of colonization inevitably lingered on. The key point is that, India adopted a pragmatic approach by transplanting legal concepts of English law, which had one of the most advanced patent systems in the world, into its national law. For this reason, India has a well-developed patent law, compared with Brazil and Thailand, as will be highlighted in Chapter 8.

### 5.2.3 The TRIPS scenario

However, free-riding in Indian pharmaceuticals appeared to be over with the advent of WTO membership. The Indian government took the lead in opposing the expansion of IPRs to medicines during the Uruguay Round, as analysed in Section 3.2.3. One of the main reasons behind India's resistance to joining the WTO was the commercial interest of its indigenous generic sector.<sup>626</sup> The country's patent law had been completely overhauled in 1970 after more than two decades of extensive debates, and the Indian industry was decidedly against further changes.

Nevertheless, due to globalisation and external pressure, coupled with being isolated from other developing countries, India agreed to include IP topics in the GATT agenda in late 1989. Together with a liberalized industrial policy of a new Indian government taking office in June 1991, India eventually yielded to the demand of patenting medicine products.<sup>627</sup> Nonetheless, India's concession did not please the patent proponents as it successfully obtained crucial flexibilities: a ten-year transitional period and the compulsory licence regime.<sup>628</sup> Such

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<sup>624</sup> Stephen Barnes, 'Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa' (2002-2003) 91 Kentucky Law Journal 911, 920.

<sup>625</sup> N. Rajagopala Ayyangar, *Report on the revision of the Patents Law* (India, September 1959).

<sup>626</sup> Jayashree Watal, 'Patents: An Indian perspective' in Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 296.

<sup>627</sup> A.V. Ganesan, 'Negotiating for India' in Jayashree Watal and Antony Taubman (eds) *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 223.

<sup>628</sup> Jerome H. Reichman, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 Journal of Law, Medicine and Ethics 247, 248; Amy Kapczynsky, 'Harmonization and Its

flexibilities restrained patent monopoly in a manner that other developing countries could also benefit from.

Like the way India was the last holdout against TRIPS, its TRIPS compliance was also made at the slowest pace possible.<sup>629</sup> Instead of transposing all international legal obligations into domestic law at once, the Indian government amended the 1970 Patents Act in a piecemeal manner in 1999, 2002, and 2005 with the most resistance.<sup>630</sup> The first amendment was actually initiated in 1994 but was not implemented until 1999<sup>631</sup> following a lawsuit of the US against India within the WTO.<sup>632</sup> The second amendment was made in 2002, so as to comply with most of TRIPS obligations.<sup>633</sup> This stage also witnessed the openness of India to the world's IPRs when it decided to join the Paris Convention and the PCT in 1998, marking the shift in the country after the long decades of refusal to be a member of these treaties. Notably, the final amendment in 2005 welcomed the return of an 'old acquaintance' – patents on pharmaceutical products after a three-decade absence from the country's patent system. By 2005, India wholly incorporated TRIPS into its Patents Act.

While other developing countries, for example Brazil and Thailand, were susceptible to TRIPS, India represents a successful case of maximizing TRIPS flexibilities to adapt its own situation. Firstly, the country utilised the 10-year transition to slowly implement international law. Such a 'delay cycle'<sup>634</sup> permits its indigenous generic sector to gradually catch up with TRIPS patent standards as well as building a capable capacity before stepping into the world's level playing field. Secondly, India made full use of the undefined patentable criteria given by Article 27.1 to protect the national interest. India has one of the strictest patentability criteria that could be

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Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 California Law Review 1571, 1581.

<sup>629</sup> Robert C. Bird, 'Defending Intellectual Property Rights in the BRIC Economies' (2006) 43 American Business Law Journal 317, 343.

<sup>630</sup> V.K. Unni, 'Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Contest of Public Policy and Health' (2012) 25 Global Business and Development Law Journal 323, 330 – 335.

<sup>631</sup> Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (OUP 2005) 65 – 66.

<sup>632</sup> WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products - Report of the Panel* (5 September 1997) WT/DS50/R.

<sup>633</sup> Jeffrey Colin, 'Coming into Compliance with TRIPS: A discussion of India's New Patents Law' (2007) 25 Cardozo Arts and Ent LJ 877, 887.

<sup>634</sup> Robert C. Bird, 'Defending Intellectual Property Rights in the BRIC Economies' (2006) 43 American Business Law Journal 317, 343.

found anywhere in the world.<sup>635</sup> Section 3(d) of the 1970 Patents Act is such an example where ‘a new form of a known substance’ or ‘[a] new property or a new use for a known substance’ is unpatentable.<sup>636</sup> This section is new since new forms or new uses of known substances are commonly patented in the US and EU today.<sup>637</sup> This thesis further submits that Section 3(d) is an effective means to prevent the phenomenon of ‘ever-greening’ - a practice which pharmaceutical companies use to prolong the patent life of a product based on incremental modifications.<sup>638</sup> On the basis of Section 3(d), the Indian Patent Office rejected many patent applications. One case, extensively covered by the media, related to Glivec.<sup>639</sup>

India’s intention to counter the effect of patent monopoly is also reflected in the high threshold of the ‘inventive step’ requirement. The current Indian Patents Act defines the ‘inventive step’ as ‘a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art’.<sup>640</sup> This requirement is seen as ‘unique’ in the history of worldwide patent legislation.<sup>641</sup> India does not enforce the principle of data exclusivity, a distinct IP category which prevents the imitators from using the data of the clinical trial for a period of time. In addition to these flexibilities, the 1970 Patents Act operates parallel importation, a practice which is not governed by TRIPS, as analysed in Section 3.3.1.<sup>642</sup>

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<sup>635</sup> Mohammed K. El Said, ‘TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries’ (2016) 31 American University International Law Review 373, 405.

<sup>636</sup> Indian Patents Act 1970, sec 3(d).

<sup>637</sup> Amy Kapczynsky, “Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector” (2009) 97 California Law Review 1571, 1590 – 1591.

<sup>638</sup> Some interesting ideas on the notion of evergreening are held by Reji K Joseph. ‘The term “evergreening” is used in the literature dealing with patents to indicate the strategy of the patent holder to extend the life of patent by making minor modifications to the product. As a result, there are a number of patents, obtained at different periods, on the same product. This results in a situation where the product is protected even when the initial patent is expired. Evergreening is a strategy widely adopted by pharmaceutical MNCs to prevent the generic firms from the manufacture and supply of the generic drugs when the patent expires.’ Reji K Joseph, ‘The R&D Scenario in Indian Pharmaceutical Industry’ (RIS Discussion Paper No. 176, 2011) 52 <<http://www.ris.org.in/rd-scenario-indian-pharmaceutical-industry>> accessed 19 March 2018. See also Mohammed El Said, ‘The Morning After: TRIPS-Plus, FTAs and Wikileaks - Fresh Insights on the Implementation and Enforcement of IP Protection in Developing Countries’ (2012) 28 American University International Law Review 71, 90.

<sup>639</sup> *Novartis AG and another v. Union of India and others*, W.P. Nos 24759 and 24760 of 2006.

<sup>640</sup> Indian Patents Act 1970, sec 2.1 (ja).

<sup>641</sup> Janice M. Mueller, ‘The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation’ (2007) 38 University of Pittsburgh Law Review 491, 550 – 551; Amy Kapczynsky, ‘Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector’ (2009) 97 California Law Review 1571, 1593.

<sup>642</sup> Indian Patents Act 1970, sec 107 (A) (b).

This thesis submits that unlike Brazil and Thailand as will be examined in Chapters 6 and 7, India exploited all possible flexibilities to carve out its own patent policy. The Indian government took advantage of such latitude to safeguard the national robust generic industry against multinational corporations and, thereby alleviating much the impacts of TRIPS on it. In fact, rather reluctantly complying with TRIPS, via the 2005 Amendment, India has created a new model. The country has demonstrated how the TRIPS Agreement, which is deemed to enrich wealthy nations, was transformed into a potent weapon that can legitimately protect the interests of a less developed country.

### **5.2.4 The Indian pharmaceutical industry - A sunrise sector**

Over the last 30 years or so, the world has witnessed the rapid growth and transformation of the Indian pharmaceutical industry. Beginning as an insignificant player, India is now recognised as a world leader in the production of high quality generic drugs. From the vantage point of the present, this thesis argues that such an impressive transformation was marked with a defining moment: the adoption of the 1970 Patents Act. It was a key element in transforming the Indian industry from import-dependency to self-reliance. By recognising patents only on processes and not on products, this Act allowed local firms to legally replicate medicines patented elsewhere. India's flexible approach has provided the impetus for its pharmaceutical sector to become a rising global star. Briefly stated, the 1970 Patents Act has been an important milestone and served as a substantial driver of the industry.

However, the re-introduction of drug patents in India, in 2005, has caused substantial changes. A concern raised is that the post-TRIPS scenario would invite multinational companies to exert their influence further on the generic market, which historically is the 'playing field' of Indian manufacturers only.<sup>643</sup> Mueller, nevertheless, argued that this view is considered 'extreme'.<sup>644</sup> There have been positive indications. After 2005, R&D profile of Indian firms has shifted from reverse-engineering innovative medicines to developing NME drugs. In 1973, national firms spent only 1.1% of their sales turn over on R&D.<sup>645</sup> When the country implemented TRIPS,

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<sup>643</sup> Sudip Chaudhuri, 'The pharmaceutical industry in India after TRPS' in Hans Löfgren and Owain David Williams (eds), *The New Political Economy of Pharmaceuticals. Production, Innovation and TRIPS in the Global South* (Palgrave Macmillan 2013) 112.

<sup>644</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 495.

<sup>645</sup> Reji K Joseph, 'The R&D Scenario in Indian Pharmaceutical Industry' (RIS Discussion Paper No. 176, 2011) 7 <<http://www.ris.org.in/rd-scenario-indian-pharmaceutical-industry>> accessed 19 March 2018.

the intensity of R&D started to increase from 2000/2001, and reached its peak in 2005/2006, at 5%.<sup>646</sup>

Until 1970, almost the entire Indian market was in the hands of multinational companies. After the new law came into effect, the position was reversed. By the beginning of the 1990s, India was an internationally recognised powerhouse in reverse engineering.<sup>647</sup> The country's sector today is one of the most successful stories in India. It is ranked 3<sup>rd</sup> in volume and ranked 14<sup>th</sup> in values in the world's pharmaceutical market.<sup>648</sup> The Indian industry is highly fragmented with 20,000 registered units,<sup>649</sup> meeting 70% of the market demand.<sup>650</sup> At the heart of the sector is the generics segment, which dominates 72% of the national market (in terms of revenue).<sup>651</sup>

India, a country which used to rely heavily on imported medicines, is now one of the greatest exporters of pharmaceuticals – particularly to Africa, Asia and Latin America with a great concentration on vaccines and ARVs for treating HIV. India now has a 20% share of the global generic market<sup>652</sup> and more than 65%-70% of medicines in the WHO Prequalified List of Medicinal Products are manufactured by Indian manufacturers.<sup>653</sup> Once a country had highest drug prices in the world, today India offers the lowest.<sup>654</sup> Not only does India export to the developing world but also captures a substantial market share in developed nations. The top five exporting destination countries are the US, Russia, Germany, Austria and the UK, with the US alone accounting for almost 20% of total export.<sup>655</sup> In 2015, India is ranked in the US's top

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<sup>646</sup> *Ibid.*, 7 – 8.

<sup>647</sup> *Ibid.*, 5.

<sup>648</sup> Makhan Saikia, 'Impact of the TRIPs Agreement on the Indian pharmaceutical industry: an assessment from 1995 to 2011-12' (2015) 37 EIPR 515, 519.

<sup>649</sup> Murali Kallummal and Kavita Bugalya, 'Trends in India's trade in pharmaceutical sector: Some insights' (August 2012, Indian Institute for Foreign) 4 <<http://wtocentre.iift.ac.in/workingpaper.asp>> accessed 19 March 2018.

<sup>650</sup> *Ibid.*, 9.

<sup>651</sup> IBEF, 'Indian Pharmaceuticals Industry Analysis' (January 2018) 9 <<https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentationx>> accessed 20 February 2018.

<sup>652</sup> India's Planning commission, 'Drugs and pharmaceuticals' (Working Groups. The file was last updated/modified on 3 November 2014) 10

<<http://planningcommission.gov.in/aboutus/committee/index.php?about=12strindx.htm>> accessed 28 February 2018.

<sup>653</sup> Gopakumar K. M. 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' (2010) 3 The Law and Development Review 325, 329.

<sup>654</sup> Yaeko Mitsumori, 'India's First Compulsory License: Its Impact on the Indian Pharmaceutical Market as well as the World Market' (Proceedings of PICMET '14 Conference, Portland 27 – 31 July 2014) 1437, 1437.

<sup>655</sup> India's Planning commission, 'Drugs and pharmaceuticals' (Government of India, Working Groups. The file was last updated/modified on 3 November 2014) 9

<<http://planningcommission.gov.in/aboutus/committee/index.php?about=12strindx.htm>> accessed 28 February 2018.

five sources of imports of pharmaceuticals.<sup>656</sup> It is therefore safe to argue that the pharmaceutical industry of India which has been dubbed as a ‘sunrise sector’, compared with those in many other countries in the developing world, is advanced and nearly self-sufficient.

### 5.3 India’s compulsory licence provisions

India’s compulsory licence regime has a long history and develops with time. The very first provisions which were stipulated in the Invention and Design Act of 1883 allowed a compulsory licence when the inventions were not worked in India or when the reasonable requirements of the public were not met.<sup>657</sup> Under the Patents & Designs Act of 1911, compulsory licences were issued in case of misuse or abuse of patent rights. However, the procedural grants proved to be ineffective in reality. The major hindrance is the lack of a fixed prior-negotiation period between the patent holder and the prospective licensee for a voluntary licence.<sup>658</sup> The former, therefore could prolong the negotiations for years. During the life of the 1911 Act, only 18 applications were filed, of which three licences were granted, the remainder were either withdrawn, dismissed, or unknown.<sup>659</sup>

Under the 1970 Patents Act, the grounds for compulsory licensing were expanded to ‘public interest’, going beyond the previous Acts where this legal measure was a remedy to patent abuse only.<sup>660</sup> The number of applications was also extremely low. Only five applications were made, of which two were granted, one was refused and the remaining two were withdrawn.<sup>661</sup> There are several reasons accounting for such a low grant rate. Firstly, the cumbersome procedure allowed patentees to oppose the grant indefinitely.<sup>662</sup> Secondly, it is difficult to assess whether the ‘public interest’ had not been met.<sup>663</sup> Finally, this thesis submits that because India did not protect pharmaceutical products under patents, domestic companies found it

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<sup>656</sup> US Department of Commerce, ‘2016 Top Markets Report Pharmaceuticals. A Market Assessment Tool for U.S. Exporters’ (May 2016) 8 <<https://www.trade.gov/topmarkets/pharmaceuticals.asp>> accessed 28 February 2018.

<sup>657</sup> N.S. Gopalakrishnan and Madhuri Anand, ‘Compulsory Licence under Indian Patent Law’ in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015) 14.

<sup>658</sup> *Ibid.*, 15.

<sup>659</sup> N. Rajagopala Ayyangar, *Report on the revision of the Patents Law* (India, September 1959) 275 – 276.

<sup>660</sup> Shamnad Basheer and Mrinalini Kochupillal, ‘The Compulsory Licence regime in India: Past, Present and Future’ (A Report for the JPO, 2005) 4 <<https://ssrn.com/abstract=1685129>> accessed 19 March 2018.

<sup>661</sup> Sudip Chaudhuri, *The WTO and India’s Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (OUP 2005) 93.

<sup>662</sup> *Ibid.*

<sup>663</sup> N.S. Gopalakrishnan and Madhuri Anand, ‘Compulsory Licence under Indian Patent Law’ in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015) 18.

unnecessary to request the compulsory licence while they still could duplicate patented medicines.

Currently, India's compulsory licensing regime is governed by Sections 82 to 89 of Chapter XVI of the Patents Act, 1970. There are four avenues leading to the award of a compulsory licence:

- Market-initiated situations (Section 84)
- Related (or dependent) patents (Section 91)
- Government use (Section 92)
- Export of patented pharmaceutical products in certain exceptional circumstances (Section 92A). This section is aimed to implement Article 31bis of TRIPS.

As being bound by the research scope (Section 1.4.2), this section will only focus on two situations in which Indian compulsory licences for medicines have been and possibly will be sought. They are Section 84 and 92 where the former was used by Indian private companies while the later was recommended by the Ministry of Health.

### **5.3.1 Section 84: market-initiated compulsory licensing**

Any time after the expiration of three years from the date of the grant of a patent, any 'interested person' can file a compulsory licence request to the Controller of Patents. Section 2(t) explains that an 'interested person' is anyone who has engaged in, or promoted research in the same field as that to which the invention relates.<sup>664</sup> The Act also allows those who might already hold a voluntary licence with the patent holder to apply for a compulsory licence, as long as the possible grounds are satisfied.<sup>665</sup> This provision is also similar to that found in the English Patents Act of 1977.<sup>666</sup>

Section 84 establishes three possible grounds upon which a non-voluntary licence might be sought. These are: that the reasonable requirements of the public have not been satisfied (unavailability), or that the invention is not available at a reasonably affordable price (unaffordability), or that the invention is not worked in India (lack of local working).<sup>667</sup> These

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<sup>664</sup> Indian Patents Act 1970, sec 2 (t).

<sup>665</sup> Indian Patents Act 1970, sec 84 (2).

<sup>666</sup> English Patents Act 1977, sec 48 (8).

<sup>667</sup> Indian Patents Act 1970, sec 84 (1).

grounds will be examined thoroughly in Section 5.4.1, in particular, with reference to Natco's licence.

With respect to the unavailability, Section 84(7) carries almost a dozen sub-clauses to describe situations where the reasonable requirements are not satisfied. It could be that, the demand has not been met to an adequate extent or on reasonable terms, or that an export market of the patented article manufactured in India is not being supplied, or that the establishment or development of commercial activities in India is prejudiced...<sup>668</sup> It is interesting to note that this section was also construed similarly to sections 48A and 48B of the English Patents Act 1977.

Overall, the author asserts that Indian law makers have borrowed many ideas from Britain, where the foundations of the modern patent system were laid. This may explain why India has very comprehensive and broad grounds upon which a compulsory licence can be granted, compared with the systems in Brazil (Chapter 6) and Thailand (Chapter 7).

While assessing the compulsory licence application, the Controller will consider whether a *prima facie* case has been established, meanings that the applicant must satisfy the Controller why he is entitled for such a licence.<sup>669</sup> As Khader commented, 'to establish a *prima facie* case, the applicant is only required to produce sufficient evidence to substantiate his case and it is immaterial whether such evidence is the best evidence'.<sup>670</sup> The Controller also must consider, for example, the nature of the invention,<sup>671</sup> whether three years have passed since the grant of the patent,<sup>672</sup> the ability of the applicant to work the invention to the public advantage,<sup>673</sup> and his capacity to undertake the risk.<sup>674</sup>

In particular, it is mandatory for the Controller to assess whether the applicant has made plausible efforts to obtain a voluntary licence, and why such efforts have not been successful within a reasonable period.<sup>675</sup> In fact, as will be analysed in *BDR*, the Indian Controller adopted

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<sup>668</sup> Indian Patents Act 1970, sec 84 (7).

<sup>669</sup> Tamali Sen Gupta, *Intellectual Property Law in India* (Wolters Kluwer 2011) 66.

<sup>670</sup> Feroz Ali Khader, *The Law of Patents with a special focus on pharmaceuticals in India* (LexisNexis 2007) 713.

<sup>671</sup> Indian Patents Act 1970, sec 84 (6) (i).

<sup>672</sup> Indian Patents Act 1970, sec 84 (6) (i).

<sup>673</sup> Indian Patents Act 1970, sec 84 (6) (ii).

<sup>674</sup> Indian Patents Act 1970, sec 84 (6) (iii).

<sup>675</sup> Indian Patents Act 1970, sec 84 (6) (iv).

a very strict view on prior-negotiation, that is, it must be fully complied. India is innovative here in imposing the reasonable period ‘not ordinarily exceeding [...] six months’.<sup>676</sup> The six-month cap aims to prevent substantial delay on the part of the patentee, in cases where he is not willing to grant the voluntary licence on reasonable terms and conditions. Otherwise, the patentee could lengthen the process, which would be frustrating for the applicant. This thesis submits that it is a distinct feature of Indian patent law, which appears not to exist elsewhere.

Upon agreeing that a *prima facie* case has been established, a copy of the application will be sent to the patentee and *any* other person interested.<sup>677</sup> The application will then be published in the official journal of patents.<sup>678</sup> Within two months of publication, the patentee or that person, may file a notice of opposition.<sup>679</sup> A copy of the notice is provided to the applicant, and a hearing is conducted, during which both parties will have the right to be heard.<sup>680</sup> The Controller will then make a final decision.

If a *prima facie* case is not made out, the Controller will notify the applicant accordingly.<sup>681</sup> The applicant may request a hearing within one month from the date of the notification.<sup>682</sup> If the applicant opts not to do so, the application will be refused. If the applicant files the request, a hearing will be conducted and then, the Controller will determine whether that request will be granted or refused.<sup>683</sup> If the Controller’s decision is affirmative, the procedure described above will be followed.

Any appeal from the Controller’s decision will be reviewed by the IP Appellate Board.<sup>684</sup>

This thesis submits that the procedural grant via Section 84 is unduly complicated, longer, and more tortuous than that required by TRIPS. It permits the patentee to prolong the procedure and it might take years before a compulsory licence is granted. The law does not only permit the patentee to file the opposition against the application unlimitedly, but also allows indirectly

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<sup>676</sup> Indian Patents Act 1970, sec 84 (6) (iv).

<sup>677</sup> Indian Patents Act 1970, sec 87 (1).

<sup>678</sup> Indian Patents Act 1970, sec 87 (1).

<sup>679</sup> Indian Patents Act 1970, sec 87 (2); Indian Patent Rules 2003, sec 98 (1).

<sup>680</sup> Indian Patents Act 1970, sec 87 (4); Indian Patent Rules 2003, sec 98 (5).

<sup>681</sup> Indian Patent Rules 2003, sec 97 (1).

<sup>682</sup> Indian Patent Rules 2003, sec 97 (1).

<sup>683</sup> Indian Patent Rules 2003, sec 97 (2).

<sup>684</sup> Indian Patents Act 1970, sec 117 (A).

relevant parties to be involved in the process. Such complication might discourage compulsory licence seekers who might lack the resources to pursue the long-running legal battles.

By contrast, the patentees - multinational corporations - by means of their wealth and power, readily fight for their patents. Even when the Controller agrees to grant the compulsory licence, that decision can still be challenged at the Appellate Board before a compulsory licence is ultimately permitted.<sup>685</sup> Such complications, without any doubt, severely hamper the applicants, who wish for faster and more straightforward legal proceedings. These assumptions are not groundless but are exemplified in *Natco* where a grant was tested in reality.

### **5.3.2 Section 92: government use licensing**

Under this Section, a compulsory licence can be granted, upon the declaration of the Central Government in the Official Gazette, in one of the following situations: a national emergency, extreme urgency, or public non-commercial use.<sup>686</sup> It should be noted that such a declaration is not mandatory in TRIPS Article 31, as highlighted in section 4.2.4.2.

Following the Declaration of the Government, any ‘person interested’ can file the request to the Controller.<sup>687</sup> In line with Article 31(b) of TRIPS, the potential licensee who is waved from the obligation of prior-negotiation can apply for the compulsory licence any time, after the sealing of the patent, without waiting for the three-year period lapse.<sup>688</sup> It is stressed here that the Indian Controller, not the Government is responsible for issuing a compulsory licence. Upon receiving the application, the Controller will grant the licence on the terms and conditions as he thinks fit.<sup>689</sup> He has to ensure that, the product manufactured under the patent will be available at the *lowest* prices but must be consistent with the patentees’ rights.<sup>690</sup> Implicit in the word ‘lowest’ is the assumption that the purpose of a government use licence is not to generate profit but to serve the public interest.

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<sup>685</sup> Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (OUP 2005) 91 – 92.

<sup>686</sup> Indian Patents Act 1970, sec 92 (1).

<sup>687</sup> Indian Patents Act 1970, sec 92 (1) (i).

<sup>688</sup> Indian Patents Act 1970, sec 92 (1) and (3).

<sup>689</sup> Indian Patents Act 1970, sec 92 (1) (i).

<sup>690</sup> Indian Patents Act 1970, sec 92 (1) (ii).

Any appeal arising from the Controller's decisions will be referred to the Appellate Board.<sup>691</sup> However, the law is ambiguous regarding how the decisions are appealed. On the one hand, Mueller opines that only the terms and conditions, not the grounds of such grants, are appealable.<sup>692</sup> This view is in line with Article 44.2 of TRIPS, as noted in Section 4.2.4.9. On the other hand, Section 117A(2) of the 1970 Patents Act, states that *any* decision, order or direction of the Controller or Central Government under Section 92 can be reconsidered.<sup>693</sup> Reading from language of the Act, it would seem that not only the terms and conditions but also the legal validity of a compulsory licence grant can be reviewed by the Appellate Board.

Despite being called the 'government route', this thesis argues that the role of the Indian government under Section 92 is negligible, if compared with its counterparts in Brazil or Thailand, as will be demonstrated in the two following chapters. The declaration of the government under the Patents Act mainly serves as an invitation for the compulsory licence applications from private entities. In addition, terms and conditions of the licences issued are not determined by the government but by the Controller. In effect, the Indian Patents Act leaves the right owners significant room to challenge the decisions and the patentees, beyond doubt, will not miss this opportunity to oppose the compulsory licence, or at least, to make it difficult to be granted. To date, the Controller of Patents has not granted any compulsory licence under Section 92, though the Ministry of Health recommended it on one occasion.<sup>694</sup> This practice will be touched upon in section 5.5.

## 5.4 The practice of Indian market-initiated compulsory licences

In spite of providing potentially wide grounds for compulsory licensing, this legal tool has rarely been relied on in India. Until 2005 there was no patent regime for medicine products in the country, leading to the fact that the access to affordable drugs in India was not under critical conditions. As a result, Indian companies did not rush to file any compulsory licences to copy original medicines while the existing patent law permitted them to do so without applying for

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<sup>691</sup> Indian Patents Act 1970, sec 117A.

<sup>692</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 586.

<sup>693</sup> Indian Patents Act 1970, sec 117A (2).

<sup>694</sup> India's Ministry of Commerce and Industry, 'Compulsory licensing on patented drugs' (Press Information Bureau, 19 December 2014) <<http://pib.nic.in/newsite/PrintRelease.aspx?relid=113719>> accessed 27 February 2018.

such licences. Since the reintroduction of the Indian patent regime in 2005, there have been only three applications under Section 84. The three cases are:

- *Natco v. Bayer* (Controller of Patents, 2012), ‘*Natco v. Bayer*’.
- *BDR vs. Bristol Myers Squibb* (Controller of Patents, 2013), ‘*BDR v. BMS*’.
- *Lee Pharma v. AstraZeneca* (Controller of Patents, 2016), ‘*Lee Pharma v. AstraZeneca*’.

The author will now proceed to analyse these cases in chronological order.

Natco’s licence has carried the most significant implications, as it provided the first test case for Indian competent authorities, which might set an important precedent for future cases. It also shed substantial light on the working provision which was left unresolved in international agreements, as thoroughly investigated in Section 4.2.3. Moreover, *Natco* is the only case which was examined at all judicial levels, from the Controller to the IP Appellate Board, then the High Court and the Supreme Court of India. It is, therefore, a demonstration of how a patent holder exhausted all pre-emptive legal actions to obstruct a compulsory licence grant.

## **5.4.1 Natco v. Bayer**

### **5.4.1.1 Facts**

Bayer is a patent holder of Sorafenib, the active ingredient for the treatment of liver and kidney cancers, which was marketed under the trade name Nexavar. On 6 December 2010, Natco approached Bayer seeking a voluntary licence but was rejected. On 29 July 2011, Natco filed the application for a compulsory licence under three grounds of Section 84 of the 1970 Patents Act. Natco stated that the medicine was neither available nor affordable to the Indian public; moreover, the patentee did not manufacture the medicine in the country. The Controller, in the order dated 9 March 2012,<sup>695</sup> agreed to the applicant’s request. The order set up the royalty rate at 6% of Natco’s net sales to Bayer.

Being displeased with the Controller, Bayer appealed the case to the IP Appellate Board. The Board’s decision delivered in March 2013 upheld the original decision with some

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<sup>695</sup> *Natco v. Bayer* (Controller of Patents, 2012), hereinafter: *Natco v. Bayer*’

modifications.<sup>696</sup> The only notable victory for Bayer was the increase of the royalty rate from 6% to 7%.

The judgment of the Appellate Board did not put an end to the legal battle. Bayer, which again was not satisfied with the Board's decision, appealed the case to the High Court. Unfortunately for Bayer, in July 2014, the High Court held that there was no reason to overturn the compulsory licence originally granted by the Controller and later upheld by the Board.<sup>697</sup>

Undaunted, Bayer moved the case to the Supreme Court in the hope of getting the decision overturned. However, in a two-sentence order dated 12 December 2014, the Supreme Court rejected Bayer's petition for special leave to appeal against the compulsory licence.<sup>698</sup>

Since Natco's licence was justified on three grounds under Section 84 (unavailability, non-affordability and lack of local working), the author will analyse the case for each justification.

#### **5.4.1.2 Justifications for Natco's licence**

##### **Unavailability**

Regarding this ground, Natco submitted that Bayer did not satisfy the reasonable requirements of the Indian public. While Indian patients needed around 23,000 bottles of medicine per month, Bayer imported only 200 in 2009, none in 2008, and unknown quantities in 2010.<sup>699</sup> Responding to this allegation, Bayer used the data of its sales and of Cipla, a patent infringer sued by Bayer itself, to prove that the public's requirements were being fulfilled by both.<sup>700</sup>

However, this argument was rejected by both the Controller and Appellate Board on the grounds of its 'two-facedness'. In their views, Bayer had treated Cipla as their licensee, and at the same time as an alleged infringer for the same violation. The Controller reasoned that the drug demand had to be fulfilled by the right owner only and not by third parties. The Board also upheld that Cipla's sales could not be used as a justification for Bayer's supply.<sup>701</sup>

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<sup>696</sup> *Bayer v. Union of India and Ors.*, Order no 45 of 2013 (IPAB), 'Bayer (IPAB)'.

<sup>697</sup> *Bayer v. Union of India and Ors.*, Writ Petition No.1323 of 2013, 'Bayer (High Court)'.

<sup>698</sup> *Bayer Corporation v. Union of India and Ors.*, Special Leave to Appeal (C) NO(S). 30145/2014.

<sup>699</sup> *Natco v. Bayer*, 13.

<sup>700</sup> Cipla is another Indian company which had been selling the generic version of Sorafenib in India since 2010, without Bayer's consent. Bayer therefore filed an infringement suit against Cipla, which was pending at the time the compulsory licence application made.

<sup>701</sup> *Bayer (IPAB)* 19 – 23.

While Natco gave evidence to prove that Bayer did not meet the public demand, Bayer failed to specify exactly how many patients were covered by the drug. As a result, the Controller held that Nexavar was made available to less than 2% of patients, which clearly indicated an insufficient quantity.<sup>702</sup> For this reason, it was concluded that the reasonable requirements of the public had not been satisfied.

However, some authors disagreed with this approach.<sup>703</sup> Parthasarathy and Ramanujan argued that the law requires consideration of the ‘demand for the patented product’ and not the entire market to which the product caters.<sup>704</sup> Sharing the same reasoning, Anand and Gupta asserted that this was clearly an issue of demand and supply, and not of the number of patents, which did not reflect the actual demand for a specific drug.<sup>705</sup> These authors explained that Nexavar, being a prescription drug, may not be recommended by a prescriber to a certain class of patients, since the drug might not prove effective for that class. In addition, there could have been the presence of substitutes or alternatives, which the Controller failed to take into account.<sup>706</sup> Accordingly, these authors concluded that the Controller erred in representing the ‘reasonable requirements of the public’ as being equivalent to the number of patients.<sup>707</sup> However, this thesis argues that it is not the responsibility of the Controller to consider the facts and evidence that were not submitted by the two parties.

Both the Appellate Board and the High Court did not rule differently in this regard. Moreover, the High Court substantiated the concept of ‘the reasonable requirements’ by placing this term in the context of the number of patients requiring the patented drug.<sup>708</sup> According to the High Court, this number was not based on mathematical calculation, but on the evidence submitted by the parties.<sup>709</sup> The Court referred to Section 84(7), where it is written that such requirements

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<sup>702</sup> *Bayer* (IPAB) 22.

<sup>703</sup> R. Parthasarathy and Adarsh Ramanujan, ‘The Limited Lessons of Natco’s Compulsory License’ (2012) 219 Managing Intellectual Property 28; Pravin Anand and Aditya Gupta, ‘Do India’s Compulsory Licenses Violate TRIPS’ (2012-2013) 225 Managing Intellectual Property 47.

<sup>704</sup> R. Parthasarathy and Adarsh Ramanujan, ‘The Limited Lessons of Natco’s Compulsory License’ (2012) 219 Managing Intellectual Property 28, 29.

<sup>705</sup> Pravin Anand and Aditya Gupta, ‘Do India’s Compulsory Licenses Violate TRIPS’ (2012-2013) 225 Managing Intellectual Property 47, 49.

<sup>706</sup> *Ibid.*

<sup>707</sup> R. Parthasarathy and Adarsh Ramanujan, ‘The Limited Lessons of Natco’s Compulsory License’ (2012) 219 Managing Intellectual Property 28; Pravin Anand and Aditya Gupta, ‘Do India’s Compulsory Licenses Violate TRIPS’ (2012-2013) 225 Managing Intellectual Property 47.

<sup>708</sup> *Bayer v. Union of India and Ors.*, Writ Petition No.1323 of 2013, hereinafter referred to as *Bayer v. Union of India* (High Court) 34.

<sup>709</sup> *Bayer* (High Court) 34.

are not satisfied if the demand for a patented article is not met to an adequate extent.<sup>710</sup> The concept of ‘adequate extent’ differs from one article to another, but with respect to medicines, in the Court’s view, it meant to the fullest extent, meaning that a medicine had to be made available for every patient.<sup>711</sup>

### **Unaffordability**

Regarding this ground, Natco argued that the price charged by Bayer (Rs.2, 80,428 - approx. \$5,500) for one month’s therapy was exorbitant in terms of Indian living standards. The applicant proposed to sell the drug at a price of Rs.8800 (approx. \$170) at the time the application was made. Bayer took the view that, the phrase ‘available to the public at a reasonably affordable price’ applies only to a particular class/section of the public. They stated that, ‘What may be affordable for one class/section may not be affordable to another class/section’.<sup>712</sup> Although the Controller accepted this argument, he questioned why Bayer did not launch a differential pricing policy in India, charging a lower price for Indian patients.<sup>713</sup> In fact, the company set a global price for the drug, charging a similar amount of money in both high and low-income markets. Bayer’s submission that ‘reasonableness’ referred to both patients and the patent holder failed to convince the Controller. He was of the view that reasonable affordability had to be judged in relation to the public only.<sup>714</sup> Therefore, he held that the drug was not made available at a reasonably affordable price.

The Controller’s view was supported by the Appellate Board, which confirmed that, the concept of ‘reasonably affordable’ did not lie in the price charged by the company, but in the purchasing power of the public.<sup>715</sup> The question was not whether Bayer could afford to sell the medicine at price X, but whether the public could reasonably afford to buy it at that price.<sup>716</sup> It was therefore the patentee’s responsibility to ensure that the price was affordable with reference to the public.<sup>717</sup>

The High Court also viewed the medicine price through the public interest lens. It held that a reasonable price is not determined by the authorities but established on the basis of both parties’

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<sup>710</sup> *Bayer* (High Court) 38.

<sup>711</sup> *Bayer* (High Court) 39.

<sup>712</sup> *Natco v. Bayer*, 31.

<sup>713</sup> *Natco v. Bayer*, 35.

<sup>714</sup> *Natco v. Bayer*, 36.

<sup>715</sup> *Bayer* (IPAB), 19, 34.

<sup>716</sup> *Bayer* (IPAB), 13.

<sup>717</sup> *Bayer* (IPAB), 19, 34.

submissions.<sup>718</sup> Natco's price (approx. \$170 per month) was undoubtedly far more reasonable than that of Bayer (approx. \$5,500 per month) with regard to the Indian public. Bayer's classic argument that its high price was caused by the large investment in R&D was not accepted by the Court. The Court claimed that the R&D cost could be factored into the price and that the burden of proof was on the Patentee to justify his charge.<sup>719</sup> However, as Bayer did not produce any evidence, the Court could not consider its price as reasonable.

In terms of medicine price, it is clear that the competent Indian authorities have put the public interest over private rights and that 'reasonable affordability' is to be defined from a public perspective.<sup>720</sup> However, Wang has ironically commented that the generic price of Natco is still far too expensive for the general public in India.<sup>721</sup> From the economic perspective, this thesis submits that Natco's decision has created a knock-on effect. Right after the decision, Cipla further reduced its generic version to Rs.6, 840 (approx. \$130) per month, which is even lower than the proposed price of Natco.<sup>722</sup> In addition to Cipla, other international companies also reduced their medicine prices in the wake of this 2012 historic decision.<sup>723</sup> In other words, this thesis submits that the compulsory licence granted to Natco benefitted a larger number of Indian patients, not only the ones using Nexavar but also those suffering from other diseases.

### **Lack of local working**

The last ground – 'local working' – is the most controversial ground, on which international IP treaties, including the Paris Convention and the TRIPS Agreement, have all remained unclear. In addition to the absence of global consensus, there is a divergence of opinions on this matter amongst legal scholars, as illustrated in Section 4.2.3. Although this contentious issue was finally addressed within the context of India Patents Act, both the Controller and IP Appellate Board's interpretations are relatively nuanced, which has also provoked controversy.

Natco contended that Bayer did not set up any production unit to manufacture the medicine in India but imported it from abroad. Bayer's counter argument was that India's demand was

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<sup>718</sup> *Bayer* (High Court), 40.

<sup>719</sup> *Bayer* (High Court), 41 – 42.

<sup>720</sup> Mansi Sood, 'Natco Pharma Ltd v. Bayer Corporation and the Compulsory Licensing Regime in India' (2013) 6 NUJS Law Review 99, 109.

<sup>721</sup> Mei-Hsin Wang, 'Trends and case analyses regarding compulsory licensing in Asia' in Randall R. Rader and others (eds), *Law, Politics and Revenue Extraction on Intellectual Property* (Cambridge Scholars Publishing 2015) 105.

<sup>722</sup> Feroz Ali, *The Access Regime: Patent Law Reforms for Affordable Medicines?* (OUP 2016) 148.

<sup>723</sup> *Ibid.*

insufficient to warrant production in the country, and so it had to import the medicine from Germany. The company argued that the drug had been worked in India on a commercial scale through importation. The Controller, however, disagreed with this argument on the basis of Section 83 of the Patents Act, which states that patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.<sup>724</sup> He therefore established that mere importation could not amount to a local working patent.<sup>725</sup> It was Bayer's obligation to exploit the patent within the country, either by manufacturing the drug or by licensing another to do so. In this case, the requirement of a local working patent was not fulfilled.

The Controller's reasoning clearly divided the academic writers. On the one hand, some authors supported the Controller because they maintained that as there is no international definition of 'non-working', issuing a compulsory licence for a non-use patent is allowed under the Indian Patents Act.<sup>726</sup> On the other hand, others criticised the Controller for relying on Section 83 (national law) to interpret the duty to work, while disregarding Article 27.1 of TRIPS (international law), which prohibited the discrimination between imported and locally made products.<sup>727</sup> According to these authors, such a narrow interpretation of the working clause sets a dangerous precedent, where the availability of a patented product solely by imports cannot prevent a compulsory licence, even if it meets the reasonable requirements of the public at a reasonable price.<sup>728</sup> This thesis argues that the Controller's strict approach in *Natco*, if upheld by the higher authority, might possibly have a negative effect on FDI of the Indian pharmaceutical industry, the 5<sup>th</sup> largest FDI-attracting sector in India in 2013.<sup>729</sup>

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<sup>724</sup> *Natco v. Bayer*, 43.

<sup>725</sup> *Natco v. Bayer*, 43.

<sup>726</sup> V.K. Unni, 'Compulsory Licensing of Pharmaceutical Patents in India: Whether the Natco Decision Will Meet the Global Benchmarks?' (2015) 37 EIPR 296, 303; Emmanuel Kolawole Oke, 'Exploring the flexibilities in TRIPS: lessons from India's pharmaceutical patent law' (2015) 41 Commonwealth Law Bulletin 82, 98; K.D. Raju, 'The First Compulsory Licencing Case in India under the TRIPS Agreement: An Analysis of Bayer Versus Natco Pharma Ltd' (2016) 1 Journal of Development Policy and Practice 71, 83 – 84.

<sup>727</sup> Enrico Bonadio, 'Compulsory Licensing of Patents: The Bayer - Natco Case' (2012) 10 EIPR 719, 722 – 723; Levon Barsoumian, 'India's Use It or Lose It: Time to Revisit TRIPS' (2012) 11 The John Marshall Review of Intellectual Property Law 797, 810; R. Parthasarathy and Adarsh Ramanujan, 'The Limited Lessons of Natco's Compulsory License' (2012) 219 Managing Intellectual Property 28; Pravin Anand and Aditya Gupta, 'Do India's Compulsory Licenses Violate TRIPS' (2012-2013) 225 Managing Intellectual Property 47, 49; Javier Esparza, 'Indian Patent Law: Working within the Trips Agreement Flexibilities to Provide Pharmaceutical Patent Protection While Protecting Public Health' (2014 – 2015) 24 J. Transnat'l L. and Pol'y 205, 219.

<sup>728</sup> Naval Satarawala Chopra and Dino Muthappa, 'The Curious Case of Compulsory Licensing in India' (2012) 8 Competition Law International 34, 35.

<sup>729</sup> Mansi Sood, 'Natco Pharma Ltd v. Bayer Corporation and the Compulsory Licensing Regime in India' (2013) 6 NUJS Law Review 99, 107.

Nevertheless, the concept of ‘local working’ was diluted at the Appellate Board, which held that, in the absence of a definition in international agreements, this requirement was to be interpreted on a case-by-case basis.<sup>730</sup> Whether ‘working’ means entirely local manufacture or only importation depends on the facts and evidence particular to each occasion.<sup>731</sup> However, the Board emphasised that the patentee must show why the invention could not be manufactured locally. A mere statement without supporting evidence was not sufficient. In this case, Bayer failed to give reasons to this effect.

Still some scholars viewed such a flexible approach as problematic. Liu<sup>732</sup> and Esparza<sup>733</sup> maintained that the term ‘working’ was very ill-defined by the Appellate Board, and that Section 84 of the Indian Patents Act might be found to be in violation of Article 27. In this regard, it is very interesting to note that, although Oke disagreed with the Board’s conclusion, he had a very different reason for disagreement.<sup>734</sup> Oke claimed that the Board failed to distinguish two separate legal issues. They are: the ‘legitimate reasons’ for the non-exploitation of a patent (contained in Article 5A(4) of the Paris Convention) on the one hand; and on the other hand, whether importation could also satisfy the local working requirements.<sup>735</sup> To Oke, whether or not the patent holder has ‘legitimate reasons’ for not working the patent in India does not mean that importation constitutes ‘working’ that patent.<sup>736</sup> It merely acknowledges the fact that there are some technical, legal barriers which prevent the exploitation of the patent. In short, Oke has in his mind that the term ‘working’ under Indian patent law points towards local manufacture, and he therefore wants to assess the legitimacy of a non-working patent before moving on to consider the importation.

The IP Appellate Board’s approach to the working provision was upheld by the High Court. That is, the right holder had to demonstrate that it worked the patent in India, by manufacture or otherwise, when facing the application for a compulsory licence. Even when the non-

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<sup>730</sup> *Bayer* (IPAB), 43.

<sup>731</sup> *Bayer* (IPAB), 44.

<sup>732</sup> Jodie Liu, ‘Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act’ (2015) 56 Harvard International Law Journal 207, 218.

<sup>733</sup> Javier Esparza, ‘Indian Patent Law: Working within the Trips Agreement Flexibilities to Provide Pharmaceutical Patent Protection While Protecting Public Health’ (2014 – 2015) 24 J. Transnat'l L. and Pol'y 205, 218.

<sup>734</sup> Emmanuel Kolawole Oke, ‘Can Importation Satisfy Local Working Requirements?’ (2015) 37 EIPR 278, 282 – 283.

<sup>735</sup> *Ibid.*, 282.

<sup>736</sup> *Ibid.*

exploitation of the patent was justifiable due to certain reasons, the patent owner has to establish that the patent is commercially exploited in the country through import.<sup>737</sup>

#### **5.4.1.3 Further development and case comments**

It is very interesting to note that the final decision of the Supreme Court did not put an end to the legal battle between Bayer and Natco. It has, in fact, created another one related to the potential grey market for exports created by a compulsory licence. While a medicine manufactured under such a licence cannot be exported outside the granting country, as per Article 31(f) of TRIPS, Natco has sold the generic version of Nexavar to China for the purpose of development clinical studies and trials there.<sup>738</sup> Since 2014, Bayer has fought fiercely to prevent such export.<sup>739</sup> Although exploratory use is a well-established and recognised exception to patent rights under Article 30 of TRIPS,<sup>740</sup> this article does not spell out whether or not such use can take place outside the country that grants a compulsory licence. On March 2017, the Indian High Court ruled that Natco's export for such an experiment purpose is allowable under Section 107A (known as the Bolar exemption) of the Indian Patents Act.<sup>741</sup> This thesis argues that this ruling is a demonstration of what are possible associated consequences resulting from a compulsory licence.

It is also very interesting to note that Natco did not earn the expected return from the compulsory licence.<sup>742</sup> As Wang explained, firstly, India has a tiny patient pool with the rate for liver and kidney cancers which is considered the world lowest, i.e. 0.002% for men and 0.0009 for women.<sup>743</sup> Secondly, cancer medicine is classified as prescription drug, commercial advertisement is not allowed and media exposure will not change a doctor's prescription habit.<sup>744</sup> Wang therefore claims that it is 'naïve' to issue the compulsory licence for Nexavar

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<sup>737</sup> *Bayer* (High Court), 48 – 49.

<sup>738</sup> Devika Agarwal and Radhika Agarwal, 'Delhi High Court broadly interprets the Bolar exemption in India' (2017) 12 *Journal of Intellectual Property Law and Practice* 623, 623 – 624.

<sup>739</sup> Ari Altstedter and Upmanyu Trivedi, 'Generic Firms Can Export Bayer Drugs for RandD in India Ruling' (Bloomberg, 8 March 2017) <<https://www.bloomberg.com/news/articles/2017-03-08/indian-court-allows-generic-firms-to-export-bayer-drugs-for-r-d>> accessed 21 February 2018.

<sup>740</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 437; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 472 – 473.

<sup>741</sup> *Bayer Corporation vs Union of India and Ors.*, Writ Petition No.1971 of 2014.

<sup>742</sup> Mei-Hsin Wang, 'Trends and case analyses regarding compulsory licensing in Asia' in Randall R. Rader and others (eds), *Law, Politics and Revenue Extraction on Intellectual Property* (Cambridge Scholars Publishing 2015) 105.

<sup>743</sup> *Ibid.*, 105.

<sup>744</sup> *Ibid.*, 105.

because the medicine dissatisfied the public demand (of less than 1%) and that the price is unaffordable as rich Indian patients would prefer branded medicine, i.e. Bayer's Nexavar.<sup>745</sup>

Although the compulsory licence was granted to Natco, this case demonstrates the legal impediments facing applicants in the Indian patent system.

**Table 1 Natco v. Bayer timelines**

Date	Events
<b>6/12/2010</b>	Natco approached Bayer to seek a voluntary licence case
<b>27/12/2010</b>	Bayer rejected Natco's proposal
<b>29/7/2011</b>	Natco filed the application to the Controller
<b>9/8/2011</b>	The prior-negotiation requirement was satisfied. The Controller issued an order which directed Natco to supply the copy of the application to Bayer
<b>12/8/2011</b>	The application was published in the official patent journal
<b>23/8/2011</b>	Bayer's request of a one-month extension was accepted
<b>7/10/2011</b>	Bayer filed an 'interlocutory petition' stay of proceedings
<b>27/10/2011</b>	Bayer's petition was refused
<b>18/11/2011</b>	Bayer filed a notice of opposition. In the meanwhile, Bayer filed two petitions.
<b>21/12/2011</b>	Both petitions were refused
At the same time, Bayer twice challenged the order dated 9/8/2011 but failed.	
<b>13/1/2012</b>	The hearing between both parties took place.
<b>27-28/2/2012</b>	The hearing continued.
<b>9/3/2012</b>	The Controller decided to grant the compulsory licence
<b>4/3/2013</b>	The IPAB upheld the Controller's order
<b>15/7/2014</b>	The High Court upheld the IPAB's decision
<b>12/12/2014</b>	The Supreme Court rejected Bayer's petition for special leave to appeal

As can be seen from the table, it took several years to settle this case. Undue complication of Indian patent law, as discussed previously, was not merely a theoretical possibility, but materialised in this order. *Natco* exemplifies how a patent holder can exploit all the possible

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<sup>745</sup> *Ibid.*, 106.

loopholes to stop a grant. Bayer's endless efforts has also proved the extreme sensitivity of patent protection in pharmaceuticals, where patents are deemed to play an irreplaceable role, as examined in Section 3.4.5. The Indian compulsory licence regime, as Chaudhuri commented, is excessively legalistic and provides patentees with the opportunity to buy time through litigation.<sup>746</sup>

It is clear from *Natco* that the 'local working' requirement has stood out as the most compelling issue. The author views that no matter how this provision is interpreted, it has been and will be a continuing controversy. However, even though this ground was not established in *Natco*, the Controller retains the right to grant the compulsory licence on the other two grounds under Section 84: insufficient quantity and unaffordable price. If medicine prices are justified by numbers, the generics will always win out, as they do not share the R&D cost incurred by others, as noted in section 3.4.4. In order to defend the high charge, the patent holder might consider submitting a breakdown of such cost. Pharmaceutical companies, however, rarely make these costs public, and it is less likely that they will do so in future.

Since India re-established the patent system for medicines, not a single application for a compulsory licence was made, until the one granted to Natco. This was hence a landmark decision which set an example for those sharing the same interests as Natco. In the second application which will be examined next, the applicant also referred to this case. Furthermore, for a common law country such as India, this thesis argues that the judgment had an important implication, is that it set a precedent for similar future cases. Natco's order has been used as a benchmark to settle the third request which will be examined separately in Section 5.4.3. In short, the compulsory licence granted to Natco was a breakthrough ruling and marked an important milestone in the history of the Indian patent system.

#### **5.4.1.4 Reactions to *Natco*'s licence**

On the one hand, *Natco* undoubtedly pleased the international healthcare community, which has always supported a flexible IP protection, particularly in relation to medicines. Since the return of patent protection to India in 2005, there is concern that India will no longer be 'the pharmacy of the developing world'.<sup>747</sup> The 2012 compulsory licence was hailed as a 'silver

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<sup>746</sup> Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (OUP 2005) 91 – 92.

<sup>747</sup> Murphy Halliburton, *India and the Patent Wars. Pharmaceuticals in the New Intellectual Property Regime* (Cornell University Press 2017) 36.

lining,<sup>748</sup> and expected to be a watershed event that would open the floodgates for more compulsory licence applications.<sup>749</sup> The reasoning behind the licence was applauded for being ‘very elaborate and comprehensive’.<sup>750</sup> Some have advised the Controller of Patents not to hesitate invoking compulsory licensing whenever the drugs required by the poor remain out of reach.<sup>751</sup> An author even suggested that *Natco* should be seen as a model by all developing countries in issuing compulsory licences in the future.<sup>752</sup>

On the other hand, there was no surprise that the licence granted to *Natco* has provoked a strong reaction from pharmaceutical industry and the countries where transnational companies are headquartered. Bayer CEO Marijn Dekkers angrily described that licence as ‘essentially theft’.<sup>753</sup> The Japan Pharmaceutical Manufacturers Association commented as follow: ‘Compulsory license may solve drug access problems of the poor in India in a short term; however, in a long term, compulsory license may discourage investment into pharmaceutical market in India and eventually may deteriorate Indian people’s access to medicine.’<sup>754</sup>

Immediately after the order, in March 2012, the US Commerce Secretary, John Bryson, in a visit to India, raised concerns over the decision, calling it a ‘dilution of the international patent regime’.<sup>755</sup> In August 2013, after the Indian government hinted that another drug was facing the threat of compulsory licensing, the patent holder – Roche - withdrew a drug patent from

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<sup>748</sup> V. Lakshmi Kumaran, ‘India: The Silver Lining in India’s latest Compulsory Licensing Decision’ (*Managing Intellectual Property*, 1 September 2014) <<http://www.managingip.com/Article/3375729/India-The-silver-lining-in-Indias-latest-CL-decision.html>> accessed 20 November 2014.

<sup>749</sup> ‘India Grants First Compulsory License to Generic Drug Producer’ (2012) 16 Bridges Weekly Trade News Digest 1, 6; MSF, ‘India: Landmark victory for generic drugs’ (Press release, 4 March 2013) <<https://www.msf.org.uk/article/india-landmark-victory-generic-drugs>> accessed 25 February 2018.

<sup>750</sup> V.K. Unni, ‘Compulsory Licensing of Pharmaceutical Patents in India: Whether the *Natco* Decision Will Meet the Global Benchmarks?’ (2015) 37 EIPR 296, 302.

<sup>751</sup> Shinu Vig and Teena Bagga, ‘Compulsory licensing of Patents in India’ in Rashmi Aggarwal and Rajinder Kaur (eds), *Patent Law and Intellectual Property in the Medical Field* (IGI Global 2017) 131.

<sup>752</sup> K.D. Raju, ‘The First Compulsory Licencing Case in India under the TRIPS Agreement: An Analysis of Bayer Versus *Natco* Pharma Ltd’ (2016) 1 Journal of Development Policy and Practice 71, 85.

<sup>753</sup> Transcript of Bayer’s CEO Marjin Dekkers quote at an event hosted by the Financial Times event dated at the 3 December 2013, regarding India’s compulsory licence of Nexavar <<https://www.keionline.org/node/1924>> accessed 27 September 2017.

<sup>754</sup> The comment of the Japan Pharmaceutical Manufacturers Association was quoted in Yaeko Mitsumori, ‘India’s First Compulsory License: Its Impact on the Indian Pharmaceutical Market as well as the World Market’ (*Proceedings of PICMET ’14 Conference*, Portland 27 – 31 July 2014) 1437, 1441.

<sup>755</sup> Amiti Sen, ‘US protests patent issuance to *Natco* to sell copied versions of Nexaver’ *The Economic Times* (New Delhi, 27 March 2012)

<[http://articles.economictimes.indiatimes.com/2012-03-27/news/31245102\\_1\\_compulsory-licence-patent-owner-indian-patent-office](http://articles.economictimes.indiatimes.com/2012-03-27/news/31245102_1_compulsory-licence-patent-owner-indian-patent-office)> accessed 29 August 2016.

India.<sup>756</sup> In September 2013, the US ITC launched an investigation against India's trade and investment policies and released a report in December 2014.<sup>757</sup> The report found that, the pharmaceutical sector was affected the most by Indian IP policies, and that Natco's licence had alarmed the loss in the pharmaceutical and biotechnology industries.<sup>758</sup> At the same time, the PhRMA urged the USTR to prioritise actions against the country due to its unfriendly IP environment.<sup>759</sup> Consequently, the USTR named India on the Priority Watch List of the 2014 Special 301 report, with a specific concern regarding the compulsory licence.<sup>760</sup>

Although the report recorded that no new compulsory licences were issued after Natco and that the Indian government had taken a 'measured and cautious approach', the US still called for greater clarity on how decisions would be made in the future in India.<sup>761</sup> As a result, in 2015, India was placed on the Priority Watch List partly because the US identified that India might apply compulsory licensing as a tool of industrial policy for green technologies in other sectors.<sup>762</sup> In 2016<sup>763</sup> and 2017,<sup>764</sup> India remained on the Priority Watch List due to its IP deficiencies including the use of compulsory licences.

In February 2016, the US-India Business Council revealed that the Indian government had 'privately reassured' it that India would not use compulsory licences for commercial purposes.<sup>765</sup> Although India denied such a reassurance, two Indian generic companies, BDR and Lee Pharma, blamed the lack of government support for compulsory licences and decided

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<sup>756</sup> Sally Pipes, 'India's War On Intellectual Property Rights May Bring With It A Body Count' (Forbes, 16 September 2013) <<https://www.forbes.com/sites/sallypipes/2013/09/16/indias-war-on-intellectual-property-rights-may-bring-with-it-a-body-count/#49ecc8987c25>> accessed 27 September 2017.

<sup>757</sup> US ITC, 'Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy' (2014)<[https://www.usitc.gov/publications/industry\\_econ\\_analysis\\_332/2014/trade\\_investment\\_and\\_industrial\\_policies\\_india.htm](https://www.usitc.gov/publications/industry_econ_analysis_332/2014/trade_investment_and_industrial_policies_india.htm)> accessed 21 March 2018.

<sup>758</sup> Ibid., 5, 24.

<sup>759</sup> Sumeet Chatterjee and Ben Hirschler, 'Big Pharma pushes for U.S. action against India over patent worries' (Reuters, 6 February 2014) <<http://www.reuters.com/article/us-india-usa-pharma/big-pharma-pushes-for-u-s-action-against-india-over-patent-worries-idUSBRE150H320140206>> accessed 27 September 2017.

<sup>760</sup> USTR, 'Special 301 Report' (Reports and Publications, 2014) 8, 40 – 41

<<https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/2014>> accessed 7 March 2018.

<sup>761</sup> Ibid., 41.

<sup>762</sup> USTR, 'Special 301 Report' (Reports and Publications, 2015) 50

<<https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/2015>> accessed 7 March 2018.

<sup>763</sup> USTR, 'Special 301 Report' (Reports and Publications, 2016) 43 <<https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/2016/special-301-report>> accessed 7 March 2018.

<sup>764</sup> USTR, 'Special 301 Report' (Reports and Publications, 2017) 42 <<https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/2017>> accessed 7 March 2018.

<sup>765</sup> Zeba Siddiqui, 'U.S. industry body says India agreed to not issue 'compulsory' drug licences' (Reuters, 8 March 2016) <<https://www.reuters.com/article/india-patents-usa/u-s-industry-body-says-india-agreed-to-not-issue-compulsory-drug-licences-idUSKCN0WA18Q>> accessed 5 March 2018.

not to appeal the Controller's decisions.<sup>766</sup> (These two cases will be examined next.) As deeply explored in Chapter 3, Special 301 is not an empty threat but an instrumental tool to change IP policies of US trading partners. In the past, many countries such as South Korea, Brazil, and Thailand adapted their IP laws to avoid sanctions from Special 301. This thesis, therefore, argues that the private reassurance between the Indian government and the US business is not unfounded.

## 5.4.2 BDR v. Bristol Myers Squibb (BMS)

### 5.4.2.1 Facts

BMS is the patent holder of Dasatinib, the active ingredient for the treatment of chronic myeloid leukaemia. Dasatinib was launched on the market under the trade name Sprycel.<sup>767</sup> In February 2012, BDR approached BMS to request a voluntary licence. One month later, in March 2012, the patentee replied to this request by raising some queries. For example, BMS asked how BDR could consistently supply the medicine to the market. The patent holding company also asked about the applicant's litigation history and other factors which might jeopardize BMS's market position. The right holder was also concerned about the compliance with local standards, quality and quality assurance systems, and many other aspects.<sup>768</sup>

Instead of responding to these queries, BDR took this letter as a rejection of the request for the voluntary licence and did not pursue the negotiation further. In March 2013- one year passed since the last communication between the two parties, BDR filed the compulsory licence under Section 84. In May 2013, the Controller noticed that a *prima facie* case had not been made out. Six days after the notice and two months after filing the application, on 10 May 2013, the applicant replied to the right holder's questions raised in March 2012. However, in the order in October 2013, the Controller rejected the application on the grounds that BDR had not made credible efforts to negotiate with the right owner.

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<sup>766</sup> Zeba Siddiqui, 'Two Indian generics makers end battle to copy drugs amid patent debate' (Reuters, 12 April 2016) <<https://www.reuters.com/article/india-medicine-patents/rpt-two-indian-generics-makers-end-battle-to-copy-drugs-amid-patent-debate-idUSL3N17F3AW>> accessed 3 March 2018.

<sup>767</sup> *BDR v. Bristol Myers Squibb* (Controller of Patents, 2013), hereinafter: *BDR v. BMS*.

<sup>768</sup> *BDR v. BMS*, 6.

#### **5.4.2.2 Justification for the refusal of BDR's request**

BDR, in its application, condemned BMS's reply as delaying tactics aimed at keeping the voluntary licence in abeyance.<sup>769</sup> Moreover, BDR regarded BMS's questions as extracting information against BDR itself in ongoing patent infringements in other courts.<sup>770</sup> Such arguments, however, failed to convince the Controller who viewed that BDR did not specify the questions that would jeopardize its position either before the Controller or before the courts.<sup>771</sup>

BDR further argued that in an issue of the 'Indian Business Law Journal', BMS's attorney publicly declared that the company's strategy was 'to keep the potential licensee of the compulsory licence engaged without a clear outright rejection'.<sup>772</sup> It thus appeared to BDR that BMS had no intention of holding talks on the voluntary licence at all. This view was later reinforced when BDR received a similar reply from BMS to another voluntary licence for another drug. BDR reached the conclusion that BMS's queries were no more than a well-planned strategy to frustrate the applicant. Consequently, BDR decided not to respond to BMS but applied for a compulsory licence.

The Controller, nevertheless, strongly disagreed with BDR's submission. Although not all the queries raised by BMS were reasonable, the company did have the right to seek additional information.<sup>773</sup> The Controller took the view that even when the attorney's opinion reflected the right owner's true intention, the compulsory licence seeker was still bound to follow the prior-negotiation procedure. The Controller emphasised that, even if BDR was under the impression that BMS was engaging in delaying tactics, the applicant had to respect the spirit of prior-negotiation.<sup>774</sup> According to the Controller, compulsory licences are the last resort where all the previous mutual deliberations had failed to produce fruitful outcomes.<sup>775</sup> In fact, after receiving BMS's letter, BDR did not engage in any kind of dialogue with the patentee, but waited for one year to file the compulsory licence. The Controller stated that BDR failed

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<sup>769</sup> *BDR v. BMS*, 7.

<sup>770</sup> *BDR v. BMS*, 7.

<sup>771</sup> *BDR v. BMS*, 8.

<sup>772</sup> *BDR v. BMS*, 8.

<sup>773</sup> *BDR v. BMS*, 9.

<sup>774</sup> *BDR v. BMS*, 10.

<sup>775</sup> *BDR v. BMS*, 10.

to demonstrate any plausible attempts since it did not even bother to reply to the patentee's queries.

To counter, BDR argued that it tried to consult with the patent holder which was demonstrated by the reply on 10 May 2013 to BMS's questions raised on 13 March 2012. The Controller, nonetheless, refuted this argument as this effort was made after the application. BDR counterargued by referring to *Natco*, where it was interpreted that only the attempts that were made by the patent holder, (*not* by the applicant), after filing the compulsory licence request must not be considered.<sup>776</sup> The Controller dismissed this submission for two reasons. Firstly, that interpretation was applied to the facts of the case of *Natco* only and was not exhaustive. Secondly, to the Controller in this case, any attempt made after a compulsory licence application, no matter whether it was made by the patentee or the applicant, must not be used to consider the merit of the case. Otherwise, the applicant always has an undue advantage and the right owner will always be prejudiced, which is against the underlying intent of Indian patent law.<sup>777</sup>

#### 5.4.2.3 Case comments

In this much-awaited decision, which could have led to a second Indian compulsory licence, the Controller rejected the request on a *prima facie* case. While substantive law formed the central discussions in *Natco*'s licence, BDR's decision shed substantial light on the procedural provisions – prior negotiation. For this reason, the author asserts that the Controller in *BDR* developed his own interpretation and reasoning and was not greatly influenced by *Natco*. This view is also shared by Sundaram who observes that the Indian authorities interpreted the law in light of true purport and compulsory licences will not be granted on all applications.<sup>778</sup> The rejection of BDR's application is a clear indication that, prior negotiation under the Indian Patents Act is not a mere cosmetic framework but has to be satisfied in terms of quantity (time) and quality (sincere efforts). Otherwise, those seeking the compulsory licence might simply send requests of voluntary licensing to merely comply with the law but do not genuinely engage in the consultation with the right holder. To this extent, this thesis submits the Controller took an even-handed approach in this case.

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<sup>776</sup> *BDR v. BMS*, 10 – 11.

<sup>777</sup> *BDR v. BMS*, 10 – 11.

<sup>778</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 151.

Raju, nonetheless, implied that the rejection to BDR's request resulted from external pressure from the US,<sup>779</sup> even though he agreed that genuinely getting a voluntary licence before requesting a compulsory licence is mandatory under Indian patent law.<sup>780</sup> Carvalho concurred with the decision because he claimed that BDR just made 'frivolous or mock-up attempts'.<sup>781</sup> Oke considered prior negotiation as an essential safeguard to protect the right owner's interests before the compulsory licence can be requested for lack of local working.<sup>782</sup> In fact, a consultation with the patent holder is a prerequisite condition which must be respected in all cases of compulsory licensing, except from government use licensing under Section 92 of Indian Patents Act.

As Oke observed, the failure of BDR to respond to the queries raised by BMS proved to be fatal to BDR's application for a compulsory licence.<sup>783</sup> The refusal also pacified the fear of the pharmaceutical industry which was under constant threat of Indian compulsory licensing after Natco's licence.<sup>784</sup> As Banerjee claimed, just because compulsory licences for medicines are inherently linked to public health, the patentee's interests cannot be arbitrarily sacrificed and compulsory licences are not available on demand.<sup>785</sup>

It can also be demonstrated in this case that the patent holder's interests were protected to a very large extent. That is, even when the patentee intentionally uses delaying tactics to hinder the voluntary licence, the applicant is obliged to make an effort to reach an agreement. This thesis submits that BMS developed a more sophisticated strategy than Bayer had done. Bayer, in an exchange with Natco, expressed a clear rejection.<sup>786</sup> As a result, the Controller in *Natco* accepted that prior negotiation had occurred but had been unproductive. Whereas in *BDR*, BMS had left the negotiation unfinished by not explicitly rejecting or accepting the request. The right owner acted wisely by showing its engagement in the negotiation but at the same time,

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<sup>779</sup> KD Raju, 'The First Compulsory Licencing Case in India under the TRIPS Agreement: An Analysis of Bayer Versus Natco Pharma Ltd' (2016) 1 Journal of Development Policy and Practice 71, 85.

<sup>780</sup> KD Raju, 'Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries' (2017) 22 Journal of Intellectual Property Rights 1, 28.

<sup>781</sup> Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5<sup>th</sup> edn, Wolters Kluwer 2018) 387.

<sup>782</sup> Emmanuel Kolawole Oke, 'Exploring the flexibilities in TRIPS: lessons from India's pharmaceutical patent law' (2015) 41 Commonwealth Law Bulletin 82, 103.

<sup>783</sup> *Ibid.*

<sup>784</sup> Someshwar Banerjee, 'Compulsory licences: you don't just ask and get one' (2014) 9 Journal of Intellectual Property Law and Practice 2, 3.

<sup>785</sup> Someshwar Banerjee, 'Compulsory licences: you don't just ask and get one' (2014) 9 Journal of Intellectual Property Law and Practice 2, 3.

<sup>786</sup> *Natco v. Bayer*, 10. 'In view of what has been stated above, our client does *not* consider it appropriate to grant a voluntary licence to manufacture and market the product, Nexavar, to Natco'.

circumvented a refusal to the voluntary licence and did not address the terms for its grant. From the applicant's perspective, it is not groundless that BMS's questions might risk BDR's positions in ongoing disputes in other forums, given the complex environment of patent infringements in India where two parties can sue each other in different lawsuits.

It is important to note that compulsory licences in the present order, are regarded as a last resort when two parties cannot come to a mutual settlement.<sup>787</sup> However, the author argues that the consultation on a voluntary licence can only be reached if both sides have a genuine intention to do so. BMS's sincerity, however, was open to doubt. This thesis therefore submits that if such a strict approach is followed in future cases, it is likely that the patentees will adopt a strategy of frustration to dissuade the applicant, rather than sincerely engaging in the negotiation. This is no longer a possibility, since it became a harsh reality in the following case.

### **5.4.3 Lee Pharma v. AstraZeneca**

#### **5.4.3.1 Facts**

AstraZeneca is a patent holder of Saxagliptin, an active ingredient for the treatment of Type-II diabetes. Saxagliptin was launched on the market under the trade name Onglyza. Apart from Saxagliptin, three other medicines having the same function are also available on the Indian market.

In May 2014, Lee Pharma approached Astra for a voluntary licence. One month later, the patent holder replied, asking for more information. However, this reply, sent via email, did not reach the applicant.<sup>788</sup> In October 2014, Lee Pharma sent a reminder and received a reply from Astra on 7 November 2014, which sought the applicant's manufacturing and marketing details, R&D costs and other relevant details. Lee Pharma again replied on 22 November 2014 but received little cooperation from Astra after that day.<sup>789</sup>

Lee Pharma made the last request on 2 March 2015 and Astra still remained silent.<sup>790</sup> On 29 June 2015, Lee Pharma filed the compulsory licence under Section 84. Although the Controller

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<sup>787</sup> Someshwar Banerjee, 'Compulsory licences: you don't just ask and get one' (2014) 9 Journal of Intellectual Property Law and Practice 2, 3.

<sup>788</sup> *Lee Pharma v. AstraZeneca* (Controller of Patents, 2016), 6. Hereinafter: *Lee Pharma v. AstraZeneca*.

<sup>789</sup> *Lee Pharma v. AstraZeneca*, 6.

<sup>790</sup> *Lee Pharma v. AstraZeneca*, 6.

was satisfied that the applicant had made plausible efforts to obtain the voluntary licence, the application was rejected as the applicant failed to justify its request on any of three grounds.

#### **5.4.3.2 Justification for the refusal of Lee Pharma's request**

Regarding the availability of the drug, Lee Pharma submitted that, the patent holder just imported 823,855 tablets in 2013, about 0.23% of the required tablets per year for India. Thus, there was a 99% shortage of the medicine in the Indian market.<sup>791</sup> This argument failed to convince the Controller for two reasons. Firstly, the number of Indian patients submitted by Lee Pharma was taken from a report of the International Diabetes Federation, a non-government agency, which the Controller did not consider an authentic source.<sup>792</sup> Secondly, referring to Natco's licence where the patentee's argument was rejected as it failed to stipulate the number of patients covered by his medicine, the Controller applied the same reasoning to Lee Pharma in this case.

Due to the presence of medicines that were interchangeable with Saxagliptin, the Controller needed specific data as to how many patients needed the drug, and how many of them were deprived of it because of the non-availability.<sup>793</sup> The applicant, however, could not produce any satisfactory evidence in response to these questions. In addition, Lee Pharma failed to explain why Saxagliptin was the best option for the compulsory licence compared to the other three.<sup>794</sup> The Controller therefore concluded that the Applicant had failed to justify the non-availability of the medicine in question.

Regarding affordability, the Controller again relied on the High Court's Natco ruling, in which the Court stated that the 'reasonably affordable' was proven by two parties, not by the competent authority.<sup>795</sup> The Controller found that the candidate medicine was sold from Rs. 41 to 49 per tablet (approx. \$0.60 - \$0.72), and that the others were also sold at similar prices, i.e. Rs. 42 to 58 (approx. \$0.61 - \$0.85).<sup>796</sup> It was therefore hard to conclude that while others having the same range of prices were affordable, the price of Saxagliptin was not.<sup>797</sup>

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<sup>791</sup> *Lee Pharma v. AstraZeneca*, 7.

<sup>792</sup> *Lee Pharma v. AstraZeneca*, 13.

<sup>793</sup> *Lee Pharma v. AstraZeneca*, 9.

<sup>794</sup> *Lee Pharma v. AstraZeneca*, 10.

<sup>795</sup> *Lee Pharma v. AstraZeneca*, 10 -11.

<sup>796</sup> *Lee Pharma v. AstraZeneca*, 11.

<sup>797</sup> *Lee Pharma v. AstraZeneca*, 11.

As regards the ‘local working’ requirement, Lee Pharma argued that Astra had not manufactured the medicine in India for eight years after the date of the patent grant. Once again, the Controller referred to *Natco*, in which local manufacturing was held to be not always necessary. In the present case, as Lee Pharma neither submitted the number of patients in need of the medicine nor proved its unreasonably high price, the Controller could not specify whether or not local manufacture was needed.<sup>798</sup> Although each ground under Section 84 is independently assessed, whether or not the first two grounds can be established has a consequential implication as to whether or not the last ground was required.<sup>799</sup>

As Lee Pharma failed to prove its application on one of the three grounds under Section 84, the compulsory licence request was refused.

#### 5.4.3.3 Case comments

This thesis submits that *Lee Pharma* exemplified the way that both the applicant and the patent holder had learned from the previous case. To avoid rejection for the same reason that BDR’s request was rejected, Lee Pharma devoted a significant amount of time to negotiate with the patent holder for the voluntary licence. The applicant took a proactive approach, as evidenced by its sending replies and reminders to the right owner. In other words, the applicant in this case fulfilled the prior negotiation requirement in terms of both quantity and quality. On the other hand, Astra applied the same strategy used by BMS by either delaying or not responding to the applicant’s request to hinder the voluntary licence.

*Lee Pharma* adds clarity to the three grounds under Section 84 and the burden of proof related to each of them.<sup>800</sup> That is, the applicant should provide the required evidence which must be extracted from any official data or governmental reports and submit comparative data concerning other relevant drugs, when needed.<sup>801</sup> This thesis submits that future applicants are being put at a disadvantage, as the Controller required authentic sources of data without substantiating further. And the implications of said non-substantiation is to increase the likelihood of inadmissibility of the evidence. Notably, the Controller shifted the burden of proof of quantifying the number of patients and establishing the reasonable demand from the

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<sup>798</sup> *Lee Pharma v. AstraZeneca*, 14.

<sup>799</sup> *Lee Pharma v. AstraZeneca*, 14.

<sup>800</sup> Devika Agarwal and Radhika Agarwal, ‘Indian Patent Office rejects Saxagliptin compulsory license application’ (2016) 11 Journal of Intellectual Property Law and Practice 565, 566.

<sup>801</sup> *Ibid.*

patent holder in *Natco* to the applicant in *Lee Pharma*.<sup>802</sup> As a result, where there are alternatives on the market, the compulsory licence seeker must account for why a patented medicine but not others, should be subject to a compulsory licence.<sup>803</sup> *Lee Pharma* was viewed as elucidating Indian compulsory licence provisions and strengthening the evolving jurisprudence in the region.<sup>804</sup> Most importantly, the second rejection of the Indian patent office signifies the fact that the likelihood of obtaining a compulsory licence in India remains low.<sup>805</sup>

## 5.5 The practice of Indian government use licences

In Jan 2013, the Indian Ministry of Health approached the DIPP to propose compulsory licences on three anti-cancer drugs. They were the breast cancer treatment Herceptin (Trastuzumab), leukaemia medicine Sprycel (Dasatinib), and the chemotherapy drug Ixempra (Ixabepilone).<sup>806</sup> The Ministry of Health inclined to grant the compulsory licence in accordance with Section 92, which refers to the presence of one of the following conditions: national emergency, extreme urgency, or public non-commercial use (Section 5.3.2).

Nevertheless, as the patent on Herceptin expired, and Ixempra was considered unsafe, the compulsory licence requests of these two medicines were revoked.<sup>807</sup> Sprycel was left as the only target medicine for the government use licence. Immediately, two Indian private companies approached the DIPP with applications to manufacture Sprycel.<sup>808</sup> It should be

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<sup>802</sup> Kameshwari Sridhar, ‘Indian Patent Office’s recent decision on Saxagliptin Compulsory License – a step towards more coherent interpretation of Indian patent law’s compulsory licensing provisions? (9 February 2016) 7 <<https://ssrn.com/abstract=2729778>> accessed 4 March 2018.

<sup>803</sup> Interestingly, the reasoning behind the Controller’s rejection in this case is found similar to that of the German Federal Court of Justice in the case *Polyferon* in 1998. The Court of Justice overturned a provisional compulsory licence, which was first granted on the ground of public interest by the Federal Patent Court, because of the Court of Justice observed that the public interest was satisfied with other, more or less equivalent, alternative products. See further at David Perkins, ‘Compulsory Licensing in Europe’ (ICC and AIPLA Joint Conference: The Future of TRIPS: Impact of the Doha Public Health Declaration, Paris 13 September 2002) and Philipp Maume, ‘Compulsory Licensing in Germany’ in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015) 98.

<sup>804</sup> Kameshwari Sridhar, ‘Indian Patent Office’s recent decision on Saxagliptin Compulsory License – a step towards more coherent interpretation of Indian patent law’s compulsory licensing provisions? (9 February 2016) 10 <<https://ssrn.com/abstract=2729778>> accessed 4 March 2018.

<sup>805</sup> Devika Agarwal and Radhika Agarwal, ‘Indian Patent Office rejects Saxagliptin compulsory license application’ (2016) 11 Journal of Intellectual Property Law and Practice 565, 566.

<sup>806</sup> India’s Ministry of Commerce and Industry, ‘Compulsory licensing on patented drugs’ (Press Information Bureau, 19 December 2014) <<http://pib.nic.in/newsite/PrintRelease.aspx?relid=113719>> accessed 27 February 2018.

<sup>807</sup> *Ibid.*

<sup>808</sup> Vidya Krishnan, ‘Panel backs compulsory licence on cancer drug’ (Livemint, 11 September 2013) <<http://www.livemint.com/Industry/j4wMuxxqIyYnQZ5HwLHhMP/Panel-backs-compulsory-licence-on-cancer-drug.html>> accessed 2 May 2016.

noted that this medicine, at the same time, was also under the shadow of the compulsory licence applied by BDR under Section 84.

If being approved, Sprycel would become the first government use licence in India. However, the DIPP took a cautious and prudent course of action when they requested the Ministry of Health to justify why the compulsory licence was essential. The DIPP expressed concern over the impacts of the medicine, the number of patients prescribed, and the total cost on procurement...<sup>809</sup> In particular, the DIPP noted that the probability of occurrence of the disease was 0.0001% and that there had been no alarming trend. Could such a situation, therefore, be categorized as a national emergency or a matter of extreme urgency? While the Ministry of Health suggested the compulsory licence under public non-commercial use, the DIPP tended towards a national emergency or extreme urgency which did not prevail in the country at the time of the request.<sup>810</sup> By the time of this writing, no more records on this issue can be found, so it can be assumed that the request for government use licensing of Sprycel was not accepted eventually.

As no compulsory licence has been granted under Section 92, the DIPP's corresponding concerns were understandable. In addition, in the absence of clarity of these said situations, the Indian patent office appeared to meet difficulties to act accordingly. This thesis argues that India wants to ensure that all the procedural steps need to be fully complied, in order to avoid being challenged, like what happened with other countries which applied government use licences. That will be illustrated in the coming Chapters (6 and 7) which examine how similar practice in Brazil and Thailand created an angry backlash from the patent holding companies and their host countries.

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<sup>809</sup> The list of 9 questions can be found at Shahnad Basheer, 'The Dasatinib Dance Continues: Compulsorily Licensing and Public Non Commercial Use' (Spicy IP, 11 November 14) <<http://spicyip.com/2014/11/the-dasatinib-dance-continues-compulsorily-licensing-and-public-non-commercial-use.html>> accessed 30 March 2015.

<sup>810</sup> Dilasha Seth and Soma Das, 'DIPP defers decision on issuance of compulsory licence for cancer drug Dasatinib' *The Economic Times* (New Delhi, 16 October 2014) <[http://articles.economictimes.indiatimes.com/2014-10-16/news/55106950\\_1\\_cancer-drug-dasatinib-health-ministry-compulsory-licence](http://articles.economictimes.indiatimes.com/2014-10-16/news/55106950_1_cancer-drug-dasatinib-health-ministry-compulsory-licence)> accessed 29 August 2016.

## 5.6 Conclusions

Three key conclusions emerge from this chapter.

Firstly, Indian law-makers have developed a very sophisticated and broad compulsory licensing system, which is clearly demonstrated by Section 84 of the 1970 Patents Act. Such a system significantly protects the Indian generic industry and the public interest. However, the Indian framework is not entirely problem – free. The system, which was put to the test in 2012 in the context of India’s compulsory licence granted to Natco, has a number of deficiencies. Indeed, Bayer has in many ways sought tirelessly to overturn the compulsory licence grant, or at least, to soften the effect when the licensee performed its rights under the licence. In contrast to Bayer’s sheer determination, other compulsory licence applicants gave up after losing at their first attempt - the Controller stage. Implicit in their discontinuity could be their limited resources to pursue the cases further.

Secondly, the private sector has played a pro-active role in the Indian practice, compared with insignificant performance of the public authority. Such enthusiasm has demonstrated the high interest of the country’s generic industry in challenging the validity of the patented medicines, as well as its enormous capacity to reverse engineer the drugs once compulsory licences are issued. The patent owners should therefore take into account some potential pitfalls when facing a compulsory licensing request. They should note that the Controller of Patents has adopted a strict approach towards the admissibility of proof. For example, a patent holding company must prove that it satisfies the market demand by itself, not in association with another party. In cases where the company does not manufacture the medicine nationally, it is advisable to provide as much detail as possible to explain why there is no production and that importation works on a commercial scale, satisfying the reasonable requirements of the Indian public. This is a critical condition, given the context of the flourishing Indian industry. Demonstrating ‘local working of a patent’ should, therefore, be taken with particular attention and extra care.

Thirdly, contrary to the common criticism that India has adopted flexible patent protection, the rejection of the Controller of all compulsory licence applications after *Natco*, has shown the opposite. It is unclear whether such a strict approach comes from the commercial interests of market-initiated compulsory licences or from the external pressure of the US. Given the US’s well-known trade policies to modify the IPRs of other countries, it can be assumed that the

degree to which India has been affected by the US is substantially high. Whatever the scenario is, the fact remains that patentee rights are not taken lightly by the Indian patent office. It could be too soon to say, but, judging solely on the issue of compulsory licensing, India's stance has slowly shifted towards stronger IP protection.

India's excessive caution is demonstrated by the Controller's stringent examination of the prior negotiation requirement. It is true that a straight rejection by the patentee of the applicant's request for a voluntary licence is unjustifiable. But it is equally true that a disregard for the patentee's appropriate questions is also unacceptable. Another example of India's cautious approach can be found in the liberal interpretation of the local working requirement. That is, local manufacture is not mandatory, and importation can be considered as such if the patentee can defend the lack of local working of his invention. Such a flexible interpretation could be viewed as a trivial victory for the right owners. However, the matter of local working has to be judged on the merits of each case, and the same approach cannot be adopted for all patented products.

## CHAPTER 6: BRAZIL

While Chapter 5 focused on India's compulsory licensing regime, Chapter 6 will examine such a regime in the context of Brazil – the second country case study in this thesis. This chapter will answer the third research question, how developing countries have implemented the compulsory licence to meet its specific needs. Brazil is present in this work because it is a 'poster child'<sup>811</sup> for the threat to issue compulsory licences in price negotiations with the pharmaceutical companies. Starting in 2001, the country's strategy resulted in desired outcomes as patent holders relented and reduced prices drastically. Such a tactic was successful because Brazil's national laboratories, albeit with difficulty, could produce the medicines under such licences. Local production has thus increased the government's bargaining power. Only in 2007, when Brazil failed to settle a further price discount on Efavirenz – a HIV/AIDS drug did it actually issue a compulsory licence.<sup>812</sup> The grant for Efavirenz stands as the only example of Brazilian compulsory licensing.

Unlike India's 2012 ruling, which was the outcome of a market-driven demand, Brazil's application of compulsory licences, characterised as government use, served in the treatment of HIV/AIDS. For this reason, it is necessary to look into the right to health in Brazil as it was the main reason which shaped the government's hard-line position in the use of compulsory licensing. The success of the Brazilian programme, including the threats to issue mandatory licences, has been termed 'the Brazilian model' and strongly recommended in other countries.<sup>813</sup> This chapter, however, argues that this statement should be treated with caution. Brazil rallied its manufacturing capacity, political willingness and international influence behind its strategy. These factors might not be present in the case of other countries. Therefore,

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<sup>811</sup> Peter K. Yu, 'Access to Medicines, BRICS Alliances, and Collective Action' (2008) 34 American Journal of Law and Medicines' 345, 349.

<sup>812</sup> Brazil's Decree No. 6.108, of 4<sup>th</sup> May 2007 in relation to compulsory licensing for Efavirenz, for non-commercial public use.

<sup>813</sup> UNAIDS, 'Brazil and UNAIDS Join Forces in the Global Fight against AIDS' (Press release, 1 September 2004); Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009); Jillian Clare Cohen and Kristina M. Lybecker, 'AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health' (2005) 28 The World Economy 211; Alan Berkman *et al.*, 'A Critical Analysis of the Brazilian Response to HIV/AIDS: Lessons Learned for Controlling and Mitigating the Epidemic in Developing Countries' (2005) 95 American Journal of Public Health 1162; Patrice M. Jones, 'Brazil AIDS Program Touted as Model for World', Chicago Tribune (Rio De Janeiro, 8 June 2003); Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015).

close scrutiny of Brazil's model might benefit policy makers to decide if they want to follow in Brazil's footsteps. And if that is the case, which aspects they should factor in?

Apart from Brazil, a number of countries - Indonesia, India, Vietnam, and South Korea used the same strategy in the period 2003-2006 (i.e. threatening to issue compulsory licences), when their people were being endangered by Asian influenza.<sup>814</sup> As a result, Roche, the patent holder of Tamiflu, the medicine which could prevent the epidemic, had to enter into partnership with those countries to ensure sufficient supplies.<sup>815</sup> Nevertheless, none of them made such threats as frequently and strategically as Brazil.

## 6.1 An introduction to Brazil

Brazil is a largest country in Latin America, and the world's fifth largest country in land area, as well as in population. In 2016, its GDP was \$1,796 trillion, the world's ninth largest.<sup>816</sup> With a GNI per capital of \$5,640, the WB categorises Brazil as an upper middle-income country, making it the richest country in both South and Latin America.<sup>817</sup>

For more than 3 centuries, from 1500 until 1822, Brazil was under the dominion of the Portuguese crown. Since independence, the country has experienced different political systems, having been a monarchy, a republic, and a military dictatorship.<sup>818</sup> Brazil was hurled into political turmoil before the re-establishment of democracy, which has been maintained since 1985.<sup>819</sup> Nonetheless, the economic crisis starting in late 2015, coupled with the political crisis in 2016, has jeopardized Brazil's sustainable development.

Brazil has been an emerging power at the forefront of global relationships. It is a founding member of MERCOSUR, a South American economic association. Moreover, the country is one of the pioneering voices advocating a move towards free and open source software.<sup>820</sup> In

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<sup>814</sup> Jerome H. Reichman, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 Journal of Law, Medicine and Ethics, 247, 250.

<sup>815</sup> Jerome H. Reichman, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 Journal of Law, Medicine and Ethics 247, 250.

<sup>816</sup> WB, 'Gross Domestic Product 2016' (World Development Indicators, 15 December 2017) <<http://databank.worldbank.org/data/download/GDP.pdf>> accessed 5 March 2018

<sup>817</sup> WB, 'Brazil' (Databank) <<https://data.worldbank.org/country/brazil>> accessed 19 February 2018.

<sup>818</sup> Maristela Basso and Edson Beas Rodrigues Junior, *Intellectual Property Law in Brazil* (Wolters Kluwer 2010) 19.

<sup>819</sup> *Ibid.*

<sup>820</sup> Brian Fitzgerald and Nic Suzor, 'Legal Issues for the Use of Free and Open Source Software in Government' (2005) 29 MELB. U. L. Rev 412, 422; Lawrence A. Kogran, 'Commercial High Technology Innovations Face

other areas, such as climate change, the Brazilian government is also a leader. It played a key role in formulating the climate framework for the 2015 COP 21 and has ratified the Paris Agreement.<sup>821</sup>

In the public health sphere, Brazil has been a strong and active actor. As seen in Section 4.3, the path leading to the Doha Declaration was in part a result of the dispute between the US and Brazil regarding the working provision. (This will be discussed again in Section 6.3.2) In 2004, Brazil, (with Argentina), submitted the first proposal for the establishment of a Development Agenda for WIPO.<sup>822</sup> This move was characterised as ‘ground-breaking’, and as the first reshaping since the inception of WIPO of its policies towards developing countries. The role of WIPO and its mission will be subject to a detailed discussion in Chapter 9.

## **6.2 Brazil’s patent law, the right to health and the pharmaceutical industry**

### **6.2.1 The Brazilian perspective on patent law**

It is very interesting to note that Brazil’s patent system has developed with complication. Despite the fact that the country has long created a culture of disrespecting patents and has been criticised as ‘a prominent member of the axis of IP evil,’<sup>823</sup> it is little known that Brazil has a long established contemporary patent system. Its first patent law, which was enacted in 1809, made Brazil the fourth state in the world, after England (the Statute of Monopolies, 1623), the US (the Patent Act of 1790), and France (Law on the Privilege for Inventions, 1791) to institute a patent mechanism.<sup>824</sup> Far from being in its infancy, therefore, patent law is one of

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Uncertain Future Amid Emerging “BRICS” Compulsory Licensing and IP Interoperability Frameworks’ (2011) 13 San Diego International Law Journal 1, 33.

<sup>821</sup> ‘The World Bank in Brazil’ <<http://www.worldbank.org/en/country/brazil/overview>> accessed 5 March 2018.

<sup>822</sup> WIPO, Proposal by Argentina and Brazil the Establishment of a Development Agenda for WIPO (27 August 2004) WO/GA/31/11.

<sup>823</sup> Kenneth Adelman, former U.S. Ambassador to the United Nations, wrote a scathing critique of the Brazilian government in the Miami Herald (11/3/2005). “Brazil is a prominent member of the axis of intellectual property evil”. This quote was mentioned in ‘The Two Faces of Intellectual Property in Brazil’ (University of Pennsylvania, 1 March 2006) <<http://knowledge.wharton.upenn.edu/article/the-two-faces-of-intellectual-property-in-brazil-2/>> accessed 18 July 2017.

<sup>824</sup> On 28<sup>th</sup> April 1809, the Portuguese Crown enacted the *Alvara* (‘Decree’ in Portuguese) in Brazil to promote international trade. The Decree established a patent system following the English Statute of Monopolies. Nuno Pires de Carvalho, *The TRIPS Regime of Trademarks and Designs* (2<sup>nd</sup> edn, Wolters Kluwer 2011) 77.

the oldest laws of the Brazilian legal system.<sup>825</sup> In addition, Brazil adopted the French Civil Code, enacted by Napoleon in 1804, as the foundation of its own IP laws.<sup>826</sup>

After independence from Portugal in 1822, Brazil adopted a new patent law in 1830, which was amended in 1882 to conform to the Paris Convention.<sup>827</sup> The amended law granted patents for 15 years, with the state retaining power over patent monopoly to protect public interest.<sup>828</sup> Until WW2, Brazil generally maintained an adequate patent protection for both pharmaceutical products and processes. Nevertheless, as the patent system did not further the progress of technology in the country, after WW2, Brazil began a process of industrialisation, based on the economic model of Import Substitution Industrialisation (ISI).<sup>829</sup> Lying at the core of this approach was an increase in the barriers to imports so as to boost domestic production. Since multinational companies could not bring their products into the region due to the ISI policy, they had to establish subsidiaries and produce drugs locally.<sup>830</sup>

However, this economic model failed to lift the domestic industry up to the expected level, and Brazil's pharmaceutical industry was largely taken over by foreigners.<sup>831</sup> The Brazilian government therefore decided to remove patent protection for pharmaceutical products and processes, in 1945 and 1969 respectively.<sup>832</sup> Both decisions were reaffirmed in the Code of Industrial Property No. 5.722/1971.<sup>833</sup> In spite of such endeavours, multinational companies still retained a dominant position in the Brazilian market between 1980 and 1994.<sup>834</sup>

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<sup>825</sup> Viviane Yumi Mitsuuchi Kunisawa, *The TRIPS Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 29.

<sup>826</sup> Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 35.

<sup>827</sup> Thiago Caliari et al., 'Innovations in the Brazilian Pharmaceutical Industry in Post-TRIPS' in Sunil Mani and Richard R. Nelson (eds), *TRIPS Compliance, National Patent Regimes and Innovation Evidence and Experience from Developing Countries* (EE 2013) 17.

<sup>828</sup> Jae Sundaram, 'Brazil's implementation of TRIPS flexibilities: ambitious missions, early implementation, and the plans for reform' (2014) 23 Information and Communications Technology Law 81, 94.

<sup>829</sup> Bruno Salama and Daniel Benoliel, 'Pharmaceutical Patent Bargains: The Brazilian Experience' (2010) 18 Cardozo J. of Int'l and Comp. Law 633, 639.

<sup>830</sup> The Brazilian Chamber of Deputies – Center for Strategic Studies and Debates, *Brazil's Patent Reform: Innovation towards national competitiveness* (2013) 27 – 28.

<sup>831</sup> Jillian Clare Cohen, 'Expanding Drug Access in Brazil' (2006) 97 Canadian Journal of Public Health 15, 16

<sup>832</sup> Jae Sundaram, 'Brazil's implementation of TRIPS flexibilities: ambitious missions, early implementation, and the plans for reform' (2014) 23 Information and Communications Technology Law 81, 95.

<sup>833</sup> Law No. 5.722/1971 (Code of Industrial Property).

<sup>834</sup> Hiroko Yamane, *Interpreting TRIPS Globalisation of Intellectual Property Rights and Access to Medicines* (Hart Publishing 2011) 358.

In the international IP regime, Brazil engaged in the globalised patent system at an early stage. It was one of the 16 founding members of the Paris Convention in 1883, as noted in section 3.2.2, and the only developing country to have remained in the Convention since its establishment. Additionally, Brazil was the first and the only country of South America to join the PCT in 1978.

However, since the 1960s, there has been a paradigm shift in the country's patent policy. In 1961, Brazil kick-started the debate on patents and developing countries, in a nationalist resolution at the UN.<sup>835</sup> The document, titled *The Role of Patents in the Transfer of Technology to Underdeveloped Countries*, challenged the international patent system for the whole developing world, and demanded a revision of the Paris Convention to meet the needs of non-industrialised countries.<sup>836</sup> From the Brazilian standpoint, the patent was a barrier, not a passage, to smooth technological transfer to these nations. This has created in Brazil a culture of patent infringement.<sup>837</sup> This thesis submits that Brazil's local-centred perspective affected its overall policies towards patents until the multilateral trade negotiations in Uruguay.

Since patents were not viewed by Brazil as an important component of industrial development, its government entered the Uruguay Round with a negative attitude towards IP issues. Together with India, Brazil was the most vocal opponent of the expansion of patentability to medicines during the trade talks. It is worth repeating that the entire absence of Brazilian patent protection on drugs caused the US sanction on the country's products. In October 1988, for the first time in the IP arena, the US Reagan administration imposed 100% tariff on \$39 million dollars' worth of Brazilian imports. Only when Brazil announced that it would draft legislation protecting pharmaceuticals and that it would ensure a Bill would be presented to the National Congress by 20<sup>th</sup> March 1991, did the US government remove the economic coercion.<sup>838</sup>

As a result, on 14 May 1996, Brazil legislated Law No. 9.279 (Law on Industrial Property) which came into effect in 1997 (and is henceforth referred to as Brazil's Patents Act). In order to comply with TRIPS, both medicine products and processes were fully protected by patents

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<sup>835</sup> Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 42.

<sup>836</sup> Ulf Anderfelt, *International Patent-legislation and developing countries* (Martinus Nijhoff 1971) 172.

<sup>837</sup> Vivian Yumy Mitsuuchi Kunisawa, 'The Brazilian Patent System: challenges for future' in Ryo Shimanami (ed), *The Future of the Patent System* (EE Publishing Limited 2012) 283.

<sup>838</sup> Robert C. Bird and Daniel R. Cahoy, 'The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement' (2007) 3 North-western Journal of Technology and Intellectual Property 400, 404.

under the new IP law. In effect, the country made a grave mistake in missing out on the 10-year transition provided by TRIPS Article 65. This thesis argues that technically, the high patent standards of TRIPS were incorporated entirely and immediately into Brazil's domestic system, without giving the country a single day to adjust.

In addition to the foreign pressure, which came at a time when Brazil was vulnerable to trade retaliation, there were two other factors that contributed to such a rushed implementation. The first was Fernando Henrique Cardoso's 1994 electoral victory.<sup>839</sup> His presidency marked the high point of democracy in Brazil, initiating the country's economic reform and integrating Brazil into global trade. The adoption of the 1996 patent law was regarded as a new step towards globalisation under Cardoso's administration. The second one was Brazil's negotiating priority in the Uruguay Round, which was to promote the liberalization of trade in agriculture.<sup>840</sup> Brazil is widely known as a major exporter of agricultural goods. Its main goal at the negotiations was therefore to eliminate barriers to the entry to high income markets, such as the US and the EC. Given all these reasons, this thesis submits that to Brazil, IP in the trade Round was a marginal topic compared with agriculture.<sup>841</sup> Therefore, loss in the former area could be compensated by a win in the latter.

This thesis also submits that not only did the Brazilian government rush to establish an IP regime that was inappropriate for its local needs; it also went beyond the minimum requirements. Firstly, Brazil disallowed parallel importation by adopting the national exhaustion doctrine<sup>842</sup> rather than the international exhaustion, whereas WTO member states are allowed considerable latitude in legislating this in their domestic laws, as stipulated at TRIPS Article 6. Such a regulation obstructed Brazil's opportunities to look around when there were differential international prices. Secondly, Brazil voluntarily implemented pipeline protection which is not mandated by TRIPS. The pipeline mechanism allows an invention to be patented automatically in Brazil without being examined under the country's own

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<sup>839</sup> Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009) 95.

<sup>840</sup> Pedro da Motta Veiga, 'Brazil and the G-20 Group of Developing Countries' in Peter Gallagher and others (eds), *Managing the Challenges of WTO Participation: 45 Case Studies* (CUP 2005).

<sup>841</sup> Brazil's huge interest in agriculture is sharply demonstrated by its landmark victory in the trade battle against the US cotton subsidies before the WTO. See WTO, *United States: Subsidies on Upland Cotton – Report of the Panel* (8 September 2004) WT/DS267/R; WTO, *United States: Subsidies on Upland Cotton – Report of the Appellate Body* (21 March 2005) WT/DS267/AB/R. In contrast, Brazil withdrew a complaint against the US in relation to the US Patent Code (Section 6.3.2). See WTO, *Brazil: Measure Affecting Patent Protection. Request for Consultations by the United States* (8 June 2000) WT/DS199/1.

<sup>842</sup> Brazil's Patents Act 1996, art (IV).

patentability criteria, as long as it had already been patented abroad.<sup>843</sup> This provision carries a latent danger to public interest, since the patent may be subjected to flexible standards or may be unsuited to Brazil's public health requirements. As a result of Brazil's Patents Act, within one year from its enactment, 1,182 pipeline applications were filed, 63% of which concerned medicines, including those for AIDS treatment, cancer, Alzheimer's, Parkinson's and schizophrenia.<sup>844</sup>

Additionally, Brazil did not raise the threshold of a patentable invention, but merely adopted general requirements: novelty, inventive steps, and industrial application.<sup>845</sup> This could ease the filing process for the (mostly foreign) patent holders to the detriment of the country's public health policies. Overall, this thesis argues that Brazil's quick and excessive implementation of TRIPS has placed the country at a considerable disadvantage. Brazil rushed to extend patents over medicines as early as 1996 whereas, as a developing country, it could have delayed such protection until 2005, as depicted in Figure 1. Moreover, failure to optimise other flexibilities (parallel importation and strict patentability) while exercising a non-TRIPS requirement (pipeline patents) has risked the country's national interest. Brazil had very few options left to retrieve its lost opportunities, and one of these options was compulsory licensing, as will be seen in Section 6.3. The country's disadvantage regarding the implementation of TRIPS was magnified in its national healthcare.<sup>846</sup>

## 6.2.2 The right to health

The 'right to health' movement in Brazil started with its anti-HIV/AIDS campaigns. Brazil once had a grave AIDS problem, and in 2006 it was the home of more than one third of the total population of infected people living in Latin America.<sup>847</sup> The first AIDS case was found in the region in 1980 and subsequently, the epidemic spread rapidly throughout the country, and by the beginning of 1990 there were more than 10,000 infected persons.<sup>848</sup> A report of the WB in 1993 projected that, Brazil's infection rate would rise to 1.2 million by the year 2000 if

<sup>843</sup> Piergiuseppe Pusceddu, 'Access to medicines and TRIPS compliance in India and Brazil' (2014) 36 EIPR 790, 797.

<sup>844</sup> The Brazilian Chamber of Deputies – Center for Strategic Studies and Debates, *Brazil's Patent Reform: Innovation towards national competitiveness* (2013) 103.

<sup>845</sup> Brazil's Patents Act 1996, art 8.

<sup>846</sup> Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 91 - 92

<sup>847</sup> UNAIDS, 'Fact Sheet: Latin America' (May 2006) <[http://www.who.int/hiv/mediacentre/200605-FS\\_LatinAmerica\\_en.pdf?ua=1](http://www.who.int/hiv/mediacentre/200605-FS_LatinAmerica_en.pdf?ua=1)> accessed 3 October 2017.

<sup>848</sup> Viviane Yumi Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 158.

no intervention occurred.<sup>849</sup> In addition to this prediction, the WB recommended that, Brazil should prioritise preventive methods over treatment programmes, for cost-saving reasons.<sup>850</sup>

In 1986, Brazil established the National STD/AIDS program in response to the epidemic and demanded that AIDS be treated as a public health priority.<sup>851</sup> Since 1990s, the Brazilian government has run nationwide HIV education and prevention campaigns. A key player in Brazil's reaction to the HIV/AIDS epidemic was the 'sanitary movement' (sanitarista in Portuguese), a collection of different social classes who demanded a public health system.<sup>852</sup> The movement led to the recognition of the universal right to healthcare under the Constitution of 1988, which stated that 'healthcare is the right of all citizens and the duty of the State'.<sup>853</sup> In the same year, Brazil's Unified Health System (SUS - Sistema Único de Saúde in Portuguese) was formed and is charged with providing a healthcare service to the entire population.<sup>854</sup>

In November 1996, 5 months after the adoption of the Patents Act, Brazil enacted Law 9.319 – Sarney's Law, under which, the government is legally bound to provide universal free medicines for HIV/AIDS patients. With Law 9.319/1996, Brazil was the first and only emerging country at that time to implement large-scale healthcare treatment for its citizens.<sup>855</sup> Sarney's Law has only four articles and did not set a cap on the amount of money that the government could spend on treatments. As Nunn commented, this law gave Brazil's government 'a blank check for AIDS treatment'.<sup>856</sup>

The aim of providing ARVs free-of-charge, particularly in a developing nation, seemed to be unachievable. However, Brazil turned an ambitious policy into an attainable goal, thanks to two primary vehicles. First, there was a series of large loan from the World Bank in 1994 (\$160

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<sup>849</sup> WB, *Brazil: AIDS and STD Control Project* (8 October 1993) 11734-BR 68.

<sup>850</sup> WB, *Brazil: AIDS and STD Control Project* (8 October 1993) 11734-BR.

<sup>851</sup> Viviane Yumy Mitsuuchi Kunisawa, *The TRIPS Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft, 2015) 157.

<sup>852</sup> Guillaume Le Loup *et al.*, 'The Brazilian Experience of 'Scaling-up': A Public Policy Approach' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 108.

<sup>853</sup> Constitution of the Federative Republic of Brazil (1988) art 196.

<sup>854</sup> Michele Gragnolati *et al.*, *Twenty Years of Health System Reform in Brazil. An Assessment of the Sistema Único de Saúde* (WB 2013) 16 – 17.

<sup>855</sup> Guillaume Le Loup *et al.*, 'The Brazilian Experience of 'Scaling-up': A Public Policy Approach' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 105; Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 89.

<sup>856</sup> Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009) 89.

million), 1998 (\$165 million) and 2003 (\$100 million).<sup>857</sup> The second was Brazil's local production of ARV medicines, starting in the early 1990s, helped the government to make significant savings.<sup>858</sup>

Brazil entered the year 2000 with positive outcomes, and almost all infected individuals have been placed under treatment.<sup>859</sup> In 2016, Brazil's HIV prevalence was 0.6%,<sup>860</sup> which is lower than the global rate, i.e. 0.8%<sup>861</sup> and much lower than other affected regions, such as South Africa, which has an infection rate of 19%.<sup>862</sup> In addition, the establishment of the SUS has brought about a profound change in Brazil. In 1981, only half of the population had public health coverage, whereas, by 2003 almost 90% of Brazilians relied on SUS.<sup>863</sup>

### 6.2.3 Brazil's pharmaceutical capacity

In 2014, Brazil had the world's eighth largest pharmaceutical market, with total sales of \$24.8 billion.<sup>864</sup> Together with China, Brazil is one of only two developing countries listed in top 10 pharmaceutical markets world-wide.<sup>865</sup> Closer scrutiny, however, reveals that Brazil's pharmaceutical market, like many in the developing world, is dominated by foreign companies, which account for about 70% of the market share.<sup>866</sup> The country has 18 state-owned

<sup>857</sup> Guillaume Le Loup *et al.*, 'The Brazilian Experience of 'Scaling-up': A Public Policy Approach' in Benjamin Coriat (ed) *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 110.

<sup>858</sup> Ellen F.M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 45; Gabriela Costa Chaves *et al.* and Barney Whiteoak (tr), 'Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society' (2008) 5 International Journal on Human Rights 163, 166.

<sup>859</sup> Zita Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil' (2003) 6 Yale Human Rights and Development Law Journal 103, 128 – 129; Dirceu B. Greco and Mariangela Simão, 'Brazilian policy of universal access to AIDS treatment: Sustainability challenges and perspectives' (2007) 21 AIDS 37, 40; Amy Stewart Nunn *et al.*, 'AIDS Treatment in Brazil: Impacts and Challenges' (2009) 28 Health Aff (Milwood) 1103, 1104; Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law. The Unresolved Problem of Access to Medicines* (Routledge 2018) 89.

<sup>860</sup> UNAIDS, 'Brazil' (2016) <<http://www.unaids.org/en/regionscountries/countries/brazil/>> accessed 3 October 2017.

<sup>861</sup> WHO, 'Global Health Observatory (GHO) data. HIV/AIDS' (2017) <<http://www.who.int/gho/hiv/en/>> accessed 3 October 2017.

<sup>862</sup> UNAIDS, 'South Africa' (2016) <<http://www.unaids.org/en/regionscountries/countries/southafrica>> accessed 3 October 2017

<sup>863</sup> Michele Gragnolati *et al.*, *Twenty Years of Health System Reform in Brazil. An Assessment of the Sistema Único de Saúde* (WB 2013) 58.

<sup>864</sup> IMS Health, 'Top 10 Pharmaceutical Markets Worldwide' (IMS Health, 2014) <[https://www.imshealth.com/files/imshealth/Global/North%20America/Canada/Home%20Page%20Content/Pharma%20Trends/Top10WorldwideSales\\_EN\\_14.pdf](https://www.imshealth.com/files/imshealth/Global/North%20America/Canada/Home%20Page%20Content/Pharma%20Trends/Top10WorldwideSales_EN_14.pdf)> accessed 3 October 2017.

<sup>865</sup> *Ibid.*

<sup>866</sup> Matthew Flynn, 'Corporate Power and State Resistance: Brazil's Use of TRIPS Flexibilities for Its National AIDS Program' in Kenneth C Shadlen and others (eds), *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries* (EE 2011) 160.

laboratories, which occupy less than 5% of the market, but are the main suppliers to the public health system.<sup>867</sup> For example, 80% of the vaccines and 30% of the medicines acquired by the SUS are provided by these laboratories.<sup>868</sup> The biggest and the most important pharmaceutical laboratory is Farmanguinhos, which provides medicines to those covered by the SUS and responds to emergency situations in Brazil and abroad. Brazil also has domestic private firms that produce generic formulations, and one local company that produces raw materials and active ingredients.<sup>869</sup> Reflecting the trend in Third World countries, Brazil's pharmaceutical activities largely concentrate on copying patented medicines which amount to almost 90% of registered generics in the domestic market.<sup>870</sup>

The country's local production of ARVs was first launched in 1993, as a strategic partnership between the public and private sectors to reduce treatment costs, which had increased due to the growing number of HIV patients.<sup>871</sup> Nevertheless, the government failed to recognise this 'springboard' to the enhancement of the country's industrial capacity. Instead of investing in the development of raw materials necessary for the production of ARVs, Brazil, owing to its public procurement system, continued buying these materials from India and China and turning them into finished dosage forms.<sup>872</sup> Failing to compete with these cheap sources, Brazil's laboratories halted their scientific processes. As a result, the capacities of Brazilian state laboratories were too limited to complete the entire drug manufacturing process. They continue purchasing active ingredients, primarily from Asian-sources and, to a lesser extent, from domestic private companies.<sup>873</sup>

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<sup>867</sup> *Ibid.*

<sup>868</sup> Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015) 70

<sup>869</sup> Matthew Flynn, 'Corporate Power and State Resistance: Brazil's Use of TRIPS Flexibilities for Its National AIDS Program' in Kenneth C Shadlen and others (eds), *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries* (EE 2011) 160.

<sup>870</sup> Cassandra M. Sweet, 'The Pharmaceutical Production in Brazil' in Hans Löfgren and Owain David Williams (eds), *The New Political Economy of Pharmaceuticals. Production, Innovation and TRIPS in the Global South* (Palgrave Macmillan 2013) 40.

<sup>871</sup> Maurice Cassier and Marilena Correa, 'Scaling Up and Reverse Engineering: Acquisition of Industrial Knowledge by Copying Drugs in Brazil' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 130.

<sup>872</sup> Maurice Cassier and Marilena Correa, 'Scaling Up and Reverse Engineering: Acquisition of Industrial Knowledge by Copying Drugs in Brazil' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 134.

<sup>873</sup> Maurice Cassier and Marilena Correa, 'Patents, Innovation and Public Health: Brazilian Public-Sector Laboratories' Experience in Copying AIDS Drugs' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 94.

With the introduction of the Patents Act and Sarney's Law, each infected individual in the 1990's cost the government more than \$10,000 per year, which challenged the fiscal health of the State.<sup>874</sup> To combat rising costs, in 1999 under the leadership of the Minister of Health – Mr. Jose Serra, Brazil enacted the Law 9.787 (Generics Act) which created a new category of medicines – the generics. It is worth emphasising here that prior to such law, generics did not exist in Brazil in the technical sense, because there was no demonstration of bioequivalence of 'similar pharmaceutical products'.<sup>875</sup> The new law has established a more competitive market and better regulated off-patent medicines and also required that the prices of generics should be at least 33% lower than those of patented equivalents.<sup>876</sup> In addition to the establishment of the generic industry, Brazil created the Health Surveillance Agency (ANVISA) to add another layer of examination to the patent grants for pharmaceuticals.<sup>877</sup>

Thanks to a wide range of price control policies, the HIV/AIDS treatment was driven down to \$2,500 in 2001.<sup>878</sup> Brazil saved \$1.2 billion from 2001 to 2005, because of the substitution of patented medicines for generics in the list of ARVs under the universal access program.<sup>879</sup> Furthermore, the law added impetus to the national generic industry. By 2007, the local laboratories could supply eight out of the 17 ARV drugs.<sup>880</sup>

In summary, this thesis submits that, compared with its peers in the developing world, Brazil's pharmaceutical capacity is more developed insofar as it can produce some generics to meet national needs. Strategically, such a manufacturing ability was sufficient to strengthen the government's compulsory licence threats, as will be seen later. Scientifically, Brazil's technology development is relatively weak to complete the whole manufacturing process. In

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<sup>874</sup> Amy Stewart Nunn *et al.*, 'AIDS Treatment in Brazil: Impacts and Challenges' (2009) 28 *Health Aff* (Milwood) 1103; Amy S. Nunn *et al.*, 'Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment' (2007) 4 *PLoS Medicine* 1804.

<sup>875</sup> Fabienne Orsi *et al.*, 'Intellectual Property Rights, Anti-AIDS Policy and Generic Drugs. Lessons from the Brazilian Public Health Program' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 119.

<sup>876</sup> Cassandra M. Sweet, 'The Political Economy of Pharmaceutical Production in Brazil' in Hans Löfgren and Owain David Williams (eds), *The New Political Economy of Pharmaceuticals. Production, Innovation and TRIPS in the Global South* (Palgrave Macmillan 2013) 38.

<sup>877</sup> The Brazilian Chamber of Deputies – Center for Strategic Studies and Debates, *Brazil's Patent Reform: Innovation towards national competitiveness* (2013) 130.

<sup>878</sup> The speech was given by the new Director of the Department of STDs, AIDS and Viral Hepatitis - Fábio Mesquita at the Workshop on Compulsory Licensing of Antiretroviral 14 August 2015, Rio de Janeiro.

<sup>879</sup> Amy S. Nunn *et al.*, 'Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment' (2007) 4 *PLoS Medicine* 1804.

<sup>880</sup> Nathan Ford *et al.*, 'Sustaining Access to Antiretroviral Therapy in Developing Countries: Lessons from Brazil and Thailand' (2007) 21 *AIDS* 21, 22.

the long term, where patented medicines are more complex and thus require advanced technology to duplicate, the country's limitations will be exposed.

### 6.2.4 Summing up

It can be said that Brazil's policies on patent and healthcare are replete with contradictions. The country has one of the world's oldest patent laws, and yet has developed an unfriendly environment for the patent system. It is the founding member of the Paris Convention, but at the same time, it is the first member to question the value of patents for developing countries. Moreover, Brazil relinquished patentable protection for medicines in 1971. In 1996, however, the country made an about turn by promptly and unduly exercising TRIPS and by protecting pharmaceuticals under patents before the transitional period had passed. In the same year, Brazil enacted Sarney's Law, which provided universal treatment for the HIV/AIDS patients. This thesis therefore argues that Brazil's pharmaceutical capacity is as paradoxical as its national policies. The fact that Brazil can produce the medicines *to a limited extent* has characterised the country as a high-bargaining model,<sup>881</sup> and one that is liable to issue compulsory licences, as will be seen next.

## 6.3 Brazil's compulsory licence provisions

Overall, the working requirement has been the focus of Brazil's compulsory licensing policy. This legal measure, first enacted in the country's 1945 patent law, was to be imposed when a patent holder did not exploit the invention for 2 years from the granting date, or when the holder interrupted its exploitation for more than 2 years.<sup>882</sup> National interest could also result in expropriation of a patent.<sup>883</sup> Later legislation contained similar provisions.<sup>884</sup>

Nonetheless, compulsory licensing has not been widely used in Brazil. Under previous legislation, only two compulsory licences were recorded. One was issued on the ground of public interest in relation to a vaccine, and another was the result of a non-use patented process.<sup>885</sup>

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<sup>881</sup> Daniel Benoliel and Bruno Salama, 'Towards an Intellectual Property Bargaining Theory: The Post-WTO Era' (2010) 32 U.Pa.J. Int'l L. 265, 313.

<sup>882</sup> Viviane Yumy Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 129 – 130.

<sup>883</sup> *Ibid.*

<sup>884</sup> *Ibid.*

<sup>885</sup> *Ibid.*

Under the current Patents Act adopted in 1996, compulsory licences are stipulated from articles 68 – 74 in cases of:

- Abusive exercise of rights or abuse of economic power (or anti-competitive behaviours, *caput* of Article 68)
- Market-initiated situations (Article 68)
- Dependent patent (Article 70)
- Government use (Article 71)

Given the scope of this thesis, as set out in Chapter 1, this chapter will address market-initiated compulsory licensing (Article 68) and government use licensing (Article 71), since they are potential venues where a compulsory licence for patented pharmaceuticals has been and is likely to be sought.

It is noted that Brazil has not yet incorporated TRIPS Article 31bis, which allows import of the generics from countries with sufficient capacities to those having little or no pharmaceutical production. The author strongly recommends such incorporation for the strengthening of the Brazilian pharmaceutical industry because Brazil could then act as both the exporter and importer.

### **6.3.1 Article 68: market-initiated compulsory licensing**

A market-initiated compulsory licence can be granted in two situations. They are:

- that a patented product is not exploited, or incompletely exploited, or that a patented process is not put into full use (lack of local working), or
- that the commercialization does not satisfy the needs of the market (unaffordability and unavailability).<sup>886</sup>

However, it should be highlighted that only where a patent is not locally exploited as a result of economic unfeasibility, importation is to be permitted.<sup>887</sup> Implicit in such an approach was the assumption that other non-economic obstacles might not allow the owner to import the patented article. In line with Article 5A of the Paris Convention and Article 31 of TRIPS, a compulsory licence shall not be proceeded, if the right owner can justify the non-exploitation or insufficient exploitation; or if he shows serious and effective preparations for exploitation;

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<sup>886</sup> Brazil's Patents Act, art 68 (1).

<sup>887</sup> Brazil's Patents Act, art 68 (1) I.

or if he can defend the non-fulfilment of the market based on legal obstacles.<sup>888</sup> No compulsory licence must be instituted until three years after the granting date of the patent.<sup>889</sup>

According to Kunisawa, Brazil has adopted a narrow interpretation to Article 68, which is that the right holder must use *all* the patent claims in the country.<sup>890</sup> On the contrary, the working obligation imposed on the licensee is milder. The invention is considered to work as long as the licensee exploits it in an efficient way.<sup>891</sup> This thesis submits that such an interpretation gives an undue advantage to the licensee and significantly prejudices the patent owner. It remains to be seen how the National Institute of Industrial Property (or Instituto Nacional da Propriedade Industrial in Portuguese – INPI) will interpret Article 68, but there is no doubt that Brazil historically has adopted a defensive stance on the working clause. It is one of very few countries that insisted on the retention of this requirement in the Paris Convention, as shown in Chapter 4.

While the Paris Convention was under revision, Brazil was also the country that criticised the substitution of compulsory licensing for patent revocation because of the low possibility of finding a local licensee.<sup>892</sup> For this reason, Brazil decided to stay with the 1925 Hague version, since subsequent versions of the Convention increasingly restricted the compulsory licence grant. Such a restriction, however, contradicted Brazil's viewpoint on this matter.<sup>893</sup> The country did not adhere to the 1967 Stockholm amendment until 1992, when TRIPS was on the verge of completion.<sup>894</sup>

Nevertheless, market-initiated compulsory licences were not a popular practice in Brazil, because patent protection for medicines was not available from 1945 until 1996. It should be stressed that compulsory licensing can only be granted where there is a patent. Without patents, compulsory licences are of no use. On its journey to patent reform, Brazil has considered adopting a more aggressive approach. In 2013, the Centre for Strategic Studies and Debates of

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<sup>888</sup> Brazil's Patents Act, art 69.

<sup>889</sup> Brazil's Patents Act, art 68 (5).

<sup>890</sup> Viviane Yumy Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 138 – 139.

<sup>891</sup> Brazil's Patents Act, art 68 (2); Viviane Yumy Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 138 – 139.

<sup>892</sup> Ulf Anderfelt, *International Patent-legislation and developing countries* (Martinus Nijhoff 1971) 85 - 86.

<sup>893</sup> Cícero Gontijo and Andrea Carina Ceschi (tr), 'Changing the patent system from the Paris Convention to the TRIPS Agreement. The position of Brazil' (Global Issue Papers, Heinrich Böll Foundation, 2005) 18.

<sup>894</sup> *Ibid.*

the Brazilian Chamber of Deputies published a report on the national patent system.<sup>895</sup> The report proposed legislative changes to the 1996 Patents Act to empower the country's innovative capacity. Nevertheless, at the time of writing, a Bill containing that proposal remains with the Brazilian Chamber under the number H.R. 5402/2013.<sup>896</sup> The Bill aimed to reinforce the working requirement, notably in cases where there is an absence of local working in the territory, regardless of the presence of economic unfeasibility.<sup>897</sup> The author argues that such a hard-line position is unlikely to be accepted.

According to Article 73 of Brazil's Patents Act, a potential licensee must file the application to the INPI. He must demonstrate his legitimate interest, and also demonstrate the technical and economic capacity to effectively manufacture the patented article, which should be predominantly supplied to the domestic market.<sup>898</sup> If the patent holder disagrees with the request, as usually happens, he has 60 days to submit the grounds of his opposition.<sup>899</sup> Otherwise, the licence will be issued under the conditions indicated by the applicant.

In cases where a compulsory licence is filed on the basis of non-working, the burden of proof is on the right owner.<sup>900</sup> After gathering all necessary evidence, the INPI will make a decision within 60 days.<sup>901</sup> The decision can be appealed to the President of the INPI within 60 days, but the appeal has no suspensive effect.<sup>902</sup>

In the case of the compulsory licence being granted, the licensee must exploit the patent within one year from the granting date and is entitled to an interruption for the same period of time.<sup>903</sup> If he does not start the exploitation during the said time, the patent holder can request a cancellation of the licence.<sup>904</sup>

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<sup>895</sup> The Brazilian Chamber of Deputies – Center for Strategic Studies and Debates, *Brazil's Patent Reform: Innovation towards national competitiveness* (2013).

<sup>896</sup> As of this writing, the Bill is still pending.

<sup>897</sup> The Brazilian Chamber of Deputies – Center for Strategic Studies and Debates, *Brazil's Patent Reform: Innovation towards national competitiveness* (2013) 167.

<sup>898</sup> Brazil's Patents Act, art 68 (2).

<sup>899</sup> Brazil's Patents Act, art 73 (1).

<sup>900</sup> Brazil's Patents Act, art (3).

<sup>901</sup> Brazil's Patents Act, art (7).

<sup>902</sup> Brazil's Patents Act, art 73 (8), art 212.

<sup>903</sup> Brazil's Patents Act, art 74.

<sup>904</sup> Brazil's Patents Act, art (1).

Nonetheless, this thesis submits that Brazil's patent law does not oblige the applicant to attempt to obtain the voluntary licence from the patent owner before proceeding with a compulsory licence application, whereas the requirement of prior-negotiation is mandated by TRIPS. This thesis argues that such ignorance deprives the patent holder of his legitimate rights to be consulted about reasonable terms and conditions of a voluntary licence contract. It also shows an inconsistency between Brazil's national law and international obligations.

In general, the current patent law provides a vague timescale for a compulsory licence grant, because it does not cap the time permissible for the evidence collection process. It can take a long time for the INPI to make a decision. Records show that the INPI took 39 months to determine a compulsory licence request that had been filed in October 2003 and denied in January 2007.<sup>905</sup> The ambiguity of the language as well as the backlog of Brazil's patent office can undermine the efficiency of the compulsory licensing regime.

### **6.3.2 The US - Brazil dispute concerning Article 68**

Article 68 was a source of conflict between Brazil and the US in 2000. In June of that year, the US filed a complaint with the WTO, raising concerns about the legitimacy of Article 68.<sup>906</sup> The US alleged that the provision, which discriminates against foreign patentees, violated Articles 27 and 28 of TRIPS. Brazil counter-argued that Article 68 was in conformity with TRIPS, which allows compulsory licensing if there is a failure to work a patent domestically.<sup>907</sup>

In defence, in January 2001, Brazil questioned the validity of the US Patent Code. Brazil legally challenged Articles 204 and 209 of Title 35 of the Code for failing to respect the principle of non-discrimination contained in Article 27 and 28 of TRIPS.<sup>908</sup> It was the first time that a developing country had brought an IP-related case to the WTO against a developed member, i.e. the US. The dispute gained political momentum when India joined the dispute, claiming that it had a 'systemic interest' in the proceedings.<sup>909</sup>

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<sup>905</sup> Maristela Basso and Edson Beas Rodrigues Junior, *Intellectual Property Law in Brazil* (Wolters Kluwer 2010) 92.

<sup>906</sup> WTO, *Brazil: Measure Affecting Patent Protection. Request for Consultations by the United States* (8 June 2000) WT/DS199/1.

<sup>907</sup> Duncan Matthews, *Intellectual Property, Human Rights and Development. The Role of NGOs and Social Movements* (IE 2011) 133.

<sup>908</sup> WTO, *US: US Patents Code. Request for Consultations by Brazil* (31 January 2001) WT/DS224/1.

<sup>909</sup> WTO, *US: US Patents Code. Request to Join Consultations by Communication from India* (19 February 2001) WT/DS224/2.

Instead of quietly resolving the conflict before the WTO, Brazil stated publicly that a US victory in the case would be detrimental to Brazil's ARV access programme. Using the South Africa dispute<sup>910</sup> taking place at the same time, as a point of comparison, Brazil put the US under intense international pressure.<sup>911</sup> Interestingly, the government of Brazil wisely shaped the dispute as a North-South division between the developed and developing worlds while Brazil was the only country involved.<sup>912</sup> It also held an NGO global meeting which led to a demonstration outside the US Embassy in Sao Paulo.<sup>913</sup> Other forms of protest were organised, both nationally and globally.<sup>914</sup>

In fact, the US complaint over 'local working' referred to general goods without direct reference to pharmaceuticals, Brazil, however, manipulatively tied the dispute to the controversial AIDS debate, which deeply separated developing countries and pharmaceutical companies at that time.<sup>915</sup> Here is the defending argument of the USTR:

'Brazil has asserted that the U.S. case will threaten Brazil's widely-praised anti-AIDS program, and will prevent Brazil from addressing its national health crisis. Nothing could be further from the truth. For example, should Brazil choose to compulsory [sic] license anti-retroviral AIDS drugs, it could do so under Article 71 of its patent law, which authorizes compulsory licensing to address a national health emergency, consistent with TRIPS, and which the United States is not challenging. In contrast, Article 68 - the provision under dispute - may require the compulsory licensing of any patented product, from bicycles to automobile components to golf clubs. Article 68 is unrelated to health or access to drugs, but instead is discriminating against all imported products in favour of locally produced products. In short, Article 68 is a protectionist measure intended to create jobs for Brazilian nationals.'<sup>916</sup>

Brazil retaliated against the US, not only on the legal front but also in other fora. In May 2001, Brazil successfully introduced to the UN Human Rights Commission a resolution entitled

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<sup>910</sup> The South Africa case was briefly noted in Section 4.3.1 and will be touched upon in Section 9.4.

<sup>911</sup> Ellen F.M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 45; Robert C. Bird and Daniel R. Cahoy, 'The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement' (2007) 3 North Western Journal of Technology and Intellectual Property 400, 407.

<sup>912</sup> Robert C. Bird, 'Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effect' (2009) 37 Journal of Law, Medicine and Ethics 209, 215.

<sup>913</sup> *Ibid.*

<sup>914</sup> Duncan Matthews, *Intellectual Property, Human Rights and Development. The Role of NGOs and Social Movements* (EE 2011) 134.

<sup>915</sup> Robert C. Bird and Daniel R. Cahoy, 'The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement' (2007) 3 Northwestern journal of Technology and Intellectual Property 400, 407.

<sup>916</sup> USTR, 'Special 301 Report' (Reports and Publications, 2001) 10 <<https://ustr.gov/issue-areas/intellectual-property/special-301/previous-special-301-reports>> accessed 7 March 2018.

*Access to Medication in the Context of Pandemics such as HIV/AIDS*, which affirmed that access to AIDS treatment was a human right.<sup>917</sup> It gained the support of 52 countries present except for the US.<sup>918</sup> At the same time, Brazil introduced another resolution at the WHO's Assembly in Geneva, proposing legislative protection for countries wishing to produce generic versions of the ARV drugs.<sup>919</sup> Although the resolution was not adopted, it had a huge impact on the world's health policies. As a result of the attempted resolution and new evidence of the need for treatment in developing countries, in 2002, ARVs were included in the WHO Model List of Essential Medicines for the first time.<sup>920</sup>

Meanwhile, the Brazilian government also used HIV/AIDS NGOs as the channels to circulate their opposition to the US challenge of Article 68.<sup>921</sup> The US's complaint, which provoked negative publicity and international protests, was withdrawn in June 2001, and Brazil, in turn, agreed to provide a prior notice to the US if it were to issue a compulsory licence.<sup>922</sup> The two countries agreed to resolve any disputes through a special 'consultative mechanism'.<sup>923</sup> Brazil also dropped the case challenging the US Patent Code.

The dispute between the US and Brazil is of significance, as it concerned one of the most controversial topics of the patent mechanism: the working requirement. In fact, as related in Chapter 4, local working was subject to endless debates since the 19<sup>th</sup> century. Many attempts were made, albeit unsuccessfully, to remove this requirement from the Paris Convention, as well as later revisions thereof. During the negotiation of TRIPS, 'local working' once again was placed on the agenda. All the parties, however, failed to reach consensus on the matter. It is also the legal issue which attracted significant attention in *Natco* (Section 5.4.1.2). The working clause could have been settled by a ruling of the WTO, but the agreement between the US and Brazil left the legal issue open. The author therefore asserted that the dispute concerning compulsory licences was more political than legal. This case is also a demonstration

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<sup>917</sup> Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009) 129.

<sup>918</sup> Robert C. Bird, 'Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effect' (2009) 37 *Journal of Law, Medicine and Ethics* 209, 215.

<sup>919</sup> Mark S. Langevin, 'The Brazilian Model to Fight HIV/AIDS: Why do Brazil's HIV/AIDS policies have many drug companies worried?' (*The Globalist*, 28 June 2005) <<http://www.theglobalist.com/the-brazilian-model-to-fight-hivaids/>> accessed 19 November 2015.

<sup>920</sup> Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009) 132.

<sup>921</sup> Duncan Matthews, *Intellectual Property, Human Rights and Development. The Role of NGOs and Social Movements* (IE 2011) 135.

<sup>922</sup> WTO, *Brazil: Measure Affecting Patent Protection. Notification of Mutually Agreed Solution* (19 July 2001) WT/DS199/4.

<sup>923</sup> *Ibid.*

that if not well-handled, such a dispute could have turned into a political tragedy and had a counter effect on the initiator.

It is correct to say that Article 68 brings anxiety for the patent owner about his duty to exploit the invention in Brazil. However, since the adoption of the 1996 Patent law, only two requests for a compulsory licence have been filed, and there are no records of a compulsory licence having been granted due to lack of local working.<sup>924</sup> In summary, this thesis argues that compulsory licensing for a non-working patent under Article 68 is less likely to happen.

### **6.3.3 Article 71: government use licensing**

Another important legal vehicle by which the Brazilian government can retain their power over patent rights is Article 71.<sup>925</sup> The granting, *ex officio*, of a compulsory licence can be instituted in case of national emergency or public interest, if the patent holder fails to meet ‘such need’. The law does not stipulate what the need could be but leaves the government to act at its own discretion. ‘Such need’ could refer to the non-availability of a patented product, or its unaffordability or insufficiency, in accordance with different situations. The author observes that the term ‘public non-commercial use’ used by TRIPS is replaced by the word ‘public interest’ under Brazil’s Patents Act. However, ‘public non-commercial use’ is present in the Act with regard to the protection of integrated circuit topography.<sup>926</sup>

Article 71 was mandated through Decree 3.201/1999,<sup>927</sup> which was later amended by Decree 4.830/2003.<sup>928</sup> According to current law, a ‘national emergency’ is defined as a condition of impending danger to the public, whereas ‘public interest’ is described in an open list, covering a wide range of areas from public health, nutrition, protection of environment, to technological or social and economic development of the country.<sup>929</sup> This thesis submits that such broad

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<sup>924</sup> In the exchange letter of the US to Brazil, the US also noted that ‘while we had real concerns regarding the potential use of Article 68 of Brazil’s Industrial Property Law, we note that this provision has never been used to grant a compulsory license’ in WTO, *Brazil: Measure Affecting Patent Protection. Notification of Mutually Agreed Solution* (19 July 2001) WT/DS199/4. See also at Fabio Albergaria Dias, ‘Brazil: Getting to Work’ (Mondaq, 14 November 2015) <<http://www.mondaq.com/brazil/x/434478/Patent/Getting+to+Work>> accessed 16 July 2017.

<sup>925</sup> Brazil’s Patents Act, art 71.

<sup>926</sup> Law No. 11.484 of May 31, 2007 (Integrated Circuit Topographies), art 47.

<sup>927</sup> Decree No. 3.201/1999 of 6 October 1999.

<sup>928</sup> Decree No. 4.830/2003 of 4 September 2003. It amended articles 1, 2, 5, 9, 10 of Decree No. 3.201/1999

<sup>929</sup> Decree No. 3.201/1999 of 6 October 1999, art 2(1) (2).

definitions give the government the discretion to determine when the safety of the country is at stake.

Any situation, whether a national emergency or a matter of public interest, that leads to the grant of an *ex officio* compulsory licence must be declared by the government and published in the Official Gazette.<sup>930</sup> These measures are not required by TRIPS. Moreover, the law also requires verification that the patent owner (the owner himself or his licensees) has failed to take steps to deal with the situation in question.<sup>931</sup> Some commentators have argued that this requirement forces the government to negotiate with the patent holders prior to the grant.<sup>932</sup> In the case of an *ex officio* compulsory licence, the public authority must specify the term, the possible extension, and the remuneration.<sup>933</sup> However, if national emergency or public interest turns into a matter of extreme urgency, the compulsory licence may be implemented irrespective of the said stipulations (i.e., publication in the Gazette and the other conditions).<sup>934</sup>

Notably, the patent holder is obliged to transfer ‘necessary and sufficient information’ for the effective production of the patented article.<sup>935</sup> This thesis submits that by this provision, the law-makers wish to ensure the effective exploitation of the invention that is subject to government use. Therefore, that said obligation is to prevent the patent holder from keeping the scientific information which can hinder the effectiveness of such use.

In line with TRIPS, the Brazilian government’s use of patent is non-exclusive, and terminates when the situation leading to it stops.<sup>936</sup> In addition, prior negotiation with the patent holder is also waived to speed up the granting process. However, it is not clear under the current law whether Article 71 can be appealed.

Two important changes were made by the 2003 Decree to increase the leverage of Brazil’s government use. Firstly, the amended Decree, while limiting compulsory licences in case of public interest to non-commercial use, extended such licences to commercial purposes when a

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<sup>930</sup> Decree No. 3.201/1999 of 6 October 1999, art 3.

<sup>931</sup> Decree No. 4.830/2003 of 4 September 2003, art 2.

<sup>932</sup> Maristela Basso and Edson Beas Rodrigues Junior, *Intellectual Property Law in Brazil* (Wolters Kluwer 2010) 95.

<sup>933</sup> Decree No. 4.830/2003 of 4 September 2003, art 5.

<sup>934</sup> Decree No. 3.201/1999 of 6 October 1999, art 7.

<sup>935</sup> Decree No. 4.830/2003 of 4 September 2003, art 5 (1).

<sup>936</sup> Brazil’s Patents Act, art 71.

national emergency arises.<sup>937</sup> By this provision, not only public-run organisations but also profit-making enterprises can exploit the medicines in emergency.

Secondly, and most importantly, the amended Decree eases the importation of the patented article from anywhere in the world,<sup>938</sup> whereas the 1996 Patents Act did not allow such imports, and the 1999 Decree only permitted the importation of the product from where it is placed on the market with the patent owner's consent.<sup>939</sup> These provisions prior to the amendment blocked Brazil's possibilities for purchasing medicines or active ingredients from countries where patent protection for pharmaceuticals has not yet been implemented, for example India.<sup>940</sup> However, the 2003 Decree gives preference to the product that is marketed with the authorisation of the right owner, as long as it does not hamper the purpose of the licence.<sup>941</sup>

This regulatory change was of significance to Brazil at that time, because the country was in price negotiations with the pharmaceutical companies, and the previous legislation had curtailed the government's bargaining power. As will be seen in Section 6.4, the new Decree strengthened the Brazilian government's leverage to obtain much better outcomes.

Article 71 is criticised as being complicated and stricter than TRIPS requires.<sup>942</sup> Therefore, the Bill 5402/2013 proposed a new article (Article 43A) to simplify the government use of patented products. It should be noted that Article 43A does not intend to replace Article 71 but will exist side-by-side.<sup>943</sup> Therefore, if adopted, Brazil's government use licensing can be granted under two separate provisions. However, while Article 71 implemented TRIPS Article 31, Article 43A appears to address exceptions to patent rights contained in TRIPS Article 30.<sup>944</sup> For this reason, Article 43A is found not to necessarily comply with Article 31.<sup>945</sup> This thesis submits that Brazilian policy-makers are allowed to creatively propose a new regime so as to broaden

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<sup>937</sup> Decree No. 4.830/2003 of 4 September 2003, art 1.

<sup>938</sup> Decree No. 4.830/2003 of 4 September 2003, art 10.

<sup>939</sup> Brazil's Patents Act, art 43 (IV); Decree No. 3.201/1999 of 6 October 1999, art 9.

<sup>940</sup> See Chapter 5. India only enacted patent protection for medicines in 2005.

<sup>941</sup> Decree No. 4.830/2003 of 4 September 2003, art 10, sole paragraph.

<sup>942</sup> Roberto Romandini, 'Flexibilities under TRIPS: An Analysis of the Proposal for Reforming Brazilian Patent Law' (2016) 15 *The John Marshall Review of Intellectual Property Law* 150, 188.

<sup>943</sup> The Brazilian Chamber of Deputies – Center for Strategic Studies and Debates, *Brazil's Patent Reform: Innovation towards national competitiveness* (2013) 98 - 99.

<sup>944</sup> Under TRIPS Article 30, members may provide limited exceptions to patent rights. Using a patent for an experimental purpose or a preparatory work are such exceptions.

<sup>945</sup> Roberto Romandini, 'Flexibilities under TRIPS: An Analysis of the Proposal for Reforming Brazilian Patent Law' (2016) 15 *The John Marshall Review of Intellectual Property Law* 150, 190.

the government's controls over patents while circumventing the conditions set out by TRIPS Article 31.

## **6.4 The practice of Brazilian government use licensing**

It can be seen from the previous sections that adequate funding is the key to Brazil's accomplishment of a universal access programme of AIDS treatment. Nevertheless, this achievement has been hampered by Brazil's premature enactment of TRIPS in association with the inclusion of pipeline patents and exclusion of parallel importation in the Patents Act. This thesis therefore argues that Brazil was left with the sole option of compulsory licensing to reduce treatment costs and to maintain the national health programme.

Because increasing expenditure outpaced the government's budget, since early 2001 Brazil has directly entered into price cut negotiations with the patent holders. Its bargaining position, reinforced by threats to use compulsory licences, yielded good returns. The prices of medicines that were subject to such threats fell significantly, as did the prices of other medicines.

**Table 2 Brazil's price negotiations of AVRs drugs<sup>946</sup>**

Year	Medicine	Company	Compulsory licensing threats	Result
2001	Efavirenz	Merck	YES	59% discount
	Indinavir	Merck	NO	65% discount
	Nelfinavir	Roche	YES	40% discount
2003	Atazanavir	BMS	NO	76% discount
	Efavirenz	Merck	YES	25% discount
	Nelfinavir	Roche	YES	10% discount
	Lopinavir/ritonavir (Kaletra)	Abbott	YES	13% discount
2005	Lopinavir/ritonavir (Kaletra)	Abbott	YES	46% discount
	Tenofovir	Gilead	YES	51% discount
2007	Efavirenz	Merck	YES - Compulsory licence issued	75% price reduction
2008	Tenofovir	Gilead	YES	14.5% discount
	Tenofovir	Gilead	Potential rejection of patent claim	22% discount
2010	Raltegravir	Merck	Voluntary licensing	32% discount
	Atazanavir	BMS	Voluntary licensing	5.7% (200 mg) and 5% discount (300 mg)

As indicated in the table above, not every episode of Brazil's negotiations involved the threat of compulsory licensing. The sub-sections will therefore discuss the ones where such a threat was made.

<sup>946</sup> This table is compiled based on the following sources:

- Jennry Wetzler, 'Timeline on Brazil's compulsory licensing' (American University, Program on Information Justice and Intellectual Property, 2008).
- Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015).

See also Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009) and Elize Massard da Fonseca, 'Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil' (PhD thesis, University of Edinburgh 2011).

#### **6.4.1 2001: Efavirenz and Nelfinaviz**

The first two targeted medicines were Nelfinavir and Efavirenz. At that time, they were the only two drugs supplied under the universal access programme that were protected by patents, and they represented about 36% of the expenditure on ARVs.<sup>947</sup> Therefore, the Minister of Health at that time, Mr Jose Serra, warned the patent holders that Brazil would consider compulsory licensing of these drugs if no discount was offered.

Actually, Merck, the patent owner of Efavirenz, supplied the medicine at a significantly lower price in Brazil's market, compared with its price in the US.<sup>948</sup> However, the price was still unaffordable for Brazil. In March 2001, Farmanguinhos, the state-owned laboratory, which is also the main distributor of medicines for Brazil's SUS announced that, it could produce Efavirenz at a price 49% cheaper than that of the patentee.<sup>949</sup> Brazil's threat was deemed to be credible. As a result, Merck offered a 59% discount in return for Brazil not issuing a compulsory licence.<sup>950</sup> In addition, the company also offered Indinavir at 65% discount.<sup>951</sup>

In 2001, Brazil began a similar negotiating process with Roche, the patent owner of Nelfinaviz. After nine months of negotiation, Roche's best offer was a 13% reduction.<sup>952</sup> Brazil, however, rejected this price, because Farmanguinhos was able to make a generic version of Nelfinaviz that was 40% cheaper and would be available by December 2001.<sup>953</sup>

Roche was aware of Brazil's manufacturing capacity and feared that it would lose the market to domestic producers if compulsory licensing was granted. Thus, the company agreed, in August 2001, to discount the medicine by 40%, as long as Brazil did not issue such a licence for Nelfinavir.<sup>954</sup> Although Brazil's decision to hold off the compulsory licence reassured the

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<sup>947</sup> Eduardo Muniz Pereira Urias, ‘Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?’ (PhD thesis, University of Maastricht 2015) 84.

<sup>948</sup> Peggy B. Sherman and Ellwood F. Oakley, ‘Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs’ (2004) 41 American Business Law Journal 353, 389.

<sup>949</sup> Eduardo Muniz Pereira Urias, ‘Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?’ (PhD thesis, University of Maastricht 2015) 85.

<sup>950</sup> Jennryn Wetzler, ‘Timeline on Brazil's compulsory licensing’ (American University, Program on Information Justice and Intellectual Property, 2008).

<sup>951</sup> *Ibid.*

<sup>952</sup> Eduardo Muniz Pereira Urias, ‘Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?’ (PhD thesis, University of Maastricht 2015) 86.

<sup>953</sup> *Ibid.*

<sup>954</sup> Peggy B. Sherman and Ellwood F. Oakley, ‘Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs’ (2004) 41 American Business Law Journal 353, 357.

pharmaceutical industry, it disappointed the health activists. They took the view that if granted, compulsory licensing not only saved the country money, but also encouraged other developing countries in the region to follow Brazil's example.<sup>955</sup>

It should be borne in mind that Minister Serra's threats took place during his 2002 presidential campaign.<sup>956</sup> There is no doubt that that strategy saved Brazil a substantial amount of money, and also that his policy gained him public support. However, he did not win a sufficient number of votes to become the president.

#### **6.4.2 2003: Kaletra, Efavirenz and Nelfinavir**

In July 2003, the Brazilian Ministry of Health established the 'Negotiation Group for Acquisitions and Production of ARV medicines' to negotiate with Abbott, Merck, and Roche, which were the patent owners of Kaletra, Efavirenz and Nelfinavir, respectively. The negotiation not only aimed to reduce the price but also to obtain the voluntary licences, so as to allow local production of these medicines in Brazil's public laboratories.<sup>957</sup> The Minister of Health asked for a 40% discount on each drug, but none of the companies accepted the request.

The negotiations did not bear fruit until 2003, when Brazil made a critical move by amending the 1999 compulsory licence Decree, as noted in Section 6.3.3. At that time, either Brazil's local laboratories were not capable of making the generics or the country was not allowed to import them from abroad. The amended Decree in 2003, which permitted such imports, thus changed the dynamics of the negotiations and augmented the Brazilian government's bargaining power. On 18 November 2003, the Minister of Health reached an agreement with Merck to buy Efavirenz at a discount of 25%.<sup>958</sup> On 8 December 2003, Abbot and Roche came up with new offers of 13.3% and 10% for each medicine, and these offers were accepted by Brazil.<sup>959</sup>

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<sup>955</sup> Jennifer L. Rich, 'Roche Reaches Accord on Drug with Brazil' (New York Times, 1 September 2001) <<http://www.nytimes.com/2001/09/01/business/roche-reaches-accord-on-drug-with-brazil.html>> accessed 26 November 2015.

<sup>956</sup> Jillian Clare Cohen and Kristina M. Lybecker, 'AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health' (2005) 28 The World Economy 211, 220.

<sup>957</sup> Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015) 88.

<sup>958</sup> Jennryn Wetzler, 'Timeline on Brazil's compulsory licensing' (American University, Program on Information Justice and Intellectual Property, 2008).

<sup>959</sup> Jennryn Wetzler, 'Timeline on Brazil's compulsory licensing' (American University, Program on Information Justice and Intellectual Property, 2008).

Nevertheless, this thesis argues that these concessionary offers were very modest compared to the initial Brazilian requests. The question here is: Why did the Minister of Health agree? The answer lies in the limited capabilities of Brazil's domestic production. At that time, Brazil's laboratories were incapable of reverse-engineering the medicines that had been subject to the threats of compulsory licensing. Farmanguinhos which could only make the generic versions at the laboratory scale, was not prepared for the mass production of the medicine if the compulsory licence was issued.<sup>960</sup>

In addition to the absence of local production, the quality of international supply was also a big concern. By that time, generic versions of these medicines were not approved either by WHO or the regulatory authorities from developed countries such as the US FDA or the European Medicines Agency.<sup>961</sup> In such a situation, Brazil's limited pharmaceutical capacity weakened its bargaining strength, undermining the credibility of the threats. For this reason, the Minister of Health had no better option than to accept the modest offers.

#### **6.4.3 2005: The 'Kaletra deal'<sup>962</sup>**

In 2005, three ARV drugs - Efavirenz (Merck), Kaletra (Abbott), and Tenofovir (Gilead) represented more than 60% of Brazil's ARVs budget, but none of these was domestically produced in Brazil,<sup>963</sup> and the government therefore considered issuing compulsory licences for them. However, after intense debates, Brazil's President and Minister of Health decided to focus on Kaletra only. There were two reasons for this decision. Firstly, the international reaction would be extreme if the government were to issue many compulsory licences at once.<sup>964</sup> Secondly, Kaletra was the most expensive of the three drugs, accounting for 30% of

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<sup>960</sup> Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015) 89.

<sup>961</sup> *Ibid.*, 110 – 111.

<sup>962</sup> As presented in Table No.2, in 2007 Brazil made two threats of compulsory licensing. However, this part will only deal with Kaletra as this case is significant in many facets. Another threat was targeted at Tenofovir, owned by Gilead. The company agreed to offer a discount of approximately 50%, beginning in May 2006. Jennryn Wetzler, 'Timeline on Brazil's compulsory licensing' (American University, Program on Information Justice and Intellectual Property, 2008)

<sup>963</sup> Ellen F.M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers 2009) 46.

<sup>964</sup> Cristina de Albuquerque Possas, 'Compulsory Licensing in the Real World: The Case of ARV Drugs in Brazil' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 156.

the ARVs budget.<sup>965</sup> At that time, Abbot was selling the medicine at \$3,200 per patient per year in Brazil but made it for only \$400 in other developing countries.<sup>966</sup>

Subsequent to deliberations, the Minister of Health threatened to mandatorily license the patent of Kaletra unless the owner either drastically reduced the price or voluntarily licensed the drug.<sup>967</sup> After Abbot offered a 26% reduction, which did not meet Brazil's expectations, on 24 June 2005, the government enacted Ordinance 985/2005, announcing that Kaletra was a 'public interest medicine'.<sup>968</sup> The company had ten days to make a counter offer.<sup>969</sup> The declaration was the first step on the way to compulsory licensing under Brazil's Patents Act, as noted in Section 6.3.3. It was the closest that Brazil had ever come to issuing a compulsory licence as a bargaining strategy. While waiting for Abbot's reply, Farmanguinhos announced that a generic version of Kaletra would be made available for \$0.68 a pill, 42% less than the cost of the brand-name product (\$1.17).<sup>970</sup> However, it would be ten months subsequent to the issue of the compulsory licence before the laboratory would be able to produce the medicine.<sup>971</sup>

While the negotiation was ongoing, the National Health Council issued Resolution No.352/2005, which stated that the negotiations with the patent holders had failed and that compulsory licences were required for Efavirenz (Merck), Kaletra (Abbott), and Tenofovir (Gilead).<sup>972</sup> Furthermore, the resolution recommended the local production of these medicines.<sup>973</sup>

Despite social pressure, the Minister of Health, Mr. Saraiva Felipe signed a deal with Abbott in October 2005. The deal included several provisions. Firstly, Abbott agreed to lower the price

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<sup>965</sup> Veriano Terto Jr. *et al.*, 'The fight goes on: advances and setbacks for access to antiretroviral drugs in Brazil' in Angelica Basthi and others (eds) *Myth vs. Reality: Evaluating the Brazilian Response to HIV in 2016* (ABIA – The Brazilian Interdisciplinary AIDS Association 2016) 43.

<sup>966</sup> *Ibid.*

<sup>967</sup> Jennifer Bjornberg, 'Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?' (2006) 27 Northwestern Journal of International Law and Business 199, 212.

<sup>968</sup> Viviane Yumy Mitsuuchi Kunisawa, *The TRIPS Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 160.

<sup>969</sup> Ernest V. Linek and John P. Iwanicki, 'Brazil's Agreement with Abbott: A New Perspective on Patent Prosecution as a Business Process' (2005) 17 Intellectual Property and Technology Law Journal 26, 26.

<sup>970</sup> Christopher Bowe and Raymond Colitt, 'Brazil to break patent on Abbott Aids drug (Financial Times, 25 June 2005) <<https://www.ft.com/content/816699fe-e50a-11d9-95f3-00000e2511c8>> accessed 7 March 2018.

<sup>971</sup> Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015).

<sup>972</sup> Brazil's National Health Council, Resolution No. 352 of 11 August 2005.

<sup>973</sup> *Ibid.*

to \$0.63 per pill, which was 46% cheaper than the previous price.<sup>974</sup> That price, which was expected to save Brazil \$339 million, would not change until 2011.<sup>975</sup> Abbott also agreed to donate \$3 million worth of other pharmaceuticals to Brazil.<sup>976</sup> Secondly, the company would transfer the technology to Farmanguinhos when the patent expired in 2015, thereby enabling it to manufacture Kaletra domestically.<sup>977</sup> Finally, the agreement also guaranteed that Brazilian AIDS patients would have access to a new heat-stable-version of Kaletra at a 10% price increase once it gained marketing approval in the US.<sup>978</sup> In return, Brazil agreed not to issue the compulsory licence.

The Brazilian Minister's last-minute action, which rebuffed the health activists, also contradicted Brazil's previous commitment to the WHA in Geneva, where he had made a speech in favour of compulsory licensing of Kaletra.<sup>979</sup> The deal was regarded by public health advocates as 'unacceptable'. In their view, the price, which was going to be fixed over a period of six years, was disadvantageous to Brazil, regardless of the changes in the number of patients or international prices.<sup>980</sup> Moreover, the price that Brazil was to pay was not the lowest in the world. South Africa, for example, paid less.<sup>981</sup>

This thesis, however, argues that comparison with South Africa is misleading, since the latter has a much greater prevalence of HIV, i.e. 18.9%, compared with the Brazilian figure of 0.6%, (as noted in Section 6.2.2). In addition, South Africa's GDP (\$294,891 billion) is also much lower than that of Brazil (\$1.796 trillion). Therefore, it would be difficult for Brazil to achieve

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<sup>974</sup> Paulo Prada 'Brazil Near Deal With Abbott for Price Cut on AIDS Drug (The New York Times, 5 October 2005) <<http://www.nytimes.com/2005/10/05/business/worldbusiness/brazil-near-deal-with-abott-for-price-cut-on-aids.html>> accessed 17 October 2017.

<sup>975</sup> Cristina de Albuquerque Possas, 'Compulsory Licensing in the Real World: The Case of ARV Drugs in Brazil' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 157.

<sup>976</sup> Paulo Prada, 'Brazil Near Deal With Abbott for Price Cut on AIDS Drug (New York Times, 5 October 2005) <<http://www.nytimes.com/2005/10/05/business/worldbusiness/brazil-near-deal-with-abott-for-price-cut-on-aids.html>> accessed 17 October 2017.

<sup>977</sup> Ernest V. Linek and John P. Iwanicki, 'Brazil's Agreement with Abbott: A New Perspective on Patent Prosecution as a Business Process' (2005) 17 Intellectual Property and Technology Law Journal 26, 26.

<sup>978</sup> Viviane Yumi Mitsuuchi Kunisawa, *The Trips Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 161.

<sup>979</sup> Cristina de Albuquerque Possas, 'Compulsory Licensing in the Real World: The Case of ARV Drugs in Brazil' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 157.

<sup>980</sup> Jennifer Chan, *Politics in the Corridor of Dying: AIDS Activism and Global Health Governance* (Johns Hopkins University Press 2015) 99.

<sup>981</sup> Frederick M. Abbott, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 19 Journal of International Economic Law 921, 951 – 952.

the same price as South Africa. Furthermore, the monetary aid offered by Abbott enticed the Brazilian government away from the compulsory licence.

The agreement between Abbott and the government of Brazil generated so much public objection that the Minister of Health had to issue a technical note to explain why it did not pursue compulsory licences.<sup>982</sup> He argued that the existing situation did not justify the use of compulsory licences under Article 71. Moreover, the AIDS situation in Brazil did not qualify as a ‘national emergency’ because of the low prevalence of HIV infection and the country’s control over the epidemic.<sup>983</sup> As for the argument that the compulsory licence of Kaletra was in the public interest, the Minister claimed that given the price Abbott had offered, the factor of excessive cost no longer existed, and therefore such a measure could not be justified.<sup>984</sup>

In relation to local manufacture, the Minister confessed that Brazilian laboratories did not yet meet the standards required of the product, and that until that standard was met, Brazil would have to continue to purchase the generic version of Kaletra on the international market. The best offer that they had received was for \$0.72 per pill from an Indian company, which was still higher than the offer from Abbott. In fact, as said by the Minister of Health, Abbott’s discount was the most generous pricing agreement of any country outside Africa, and therefore constituted a ‘significant price reduction’.<sup>985</sup>

However, this was not the end of the story. On 1 December 2005, the Brazilian Federal Prosecuting Authority and NGOs filed a case against the Kaletra deal, seeking the grant of a compulsory licence.<sup>986</sup> This request was rejected on the ground that the Brazilian government had acted in accordance with its best judgement and that the use of compulsory licensing could provoke the US’s Special 301.<sup>987</sup> This again re-affirmed that Special 301 is a truly potent

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<sup>982</sup> Brazil’s Minister of Health, ‘Technical Note of 10 November 2005’ <<http://www.aids.gov.br/noticia/no-inicio-do-mes-de-agosto-o-conselho-nacional-de-saude-emitiu-resolucao-352-leia-abaixo-rec>> accessed 10 December 2015.

<sup>983</sup> *Ibid.*

<sup>984</sup> *Ibid.*

<sup>985</sup> *Ibid.*

<sup>986</sup> Duncan Matthews, *Intellectual Property, Human Rights and Development the Role of NGOs and Social Movements* (EE 2011) 141.

<sup>987</sup> Veriano Terto Jr. *et al.*, ‘The fight goes on: advances and setbacks for access to antiretroviral drugs in Brazil’ in Angelica Basthi and others (eds), *Myth vs. Reality: Evaluating the Brazilian Response to HIV in 2016* (ABIA – The Brazilian Interdisciplinary AIDS Association 2016) 44.

weapon. As a victim of this economic punishment in 1988, Brazil knew that it could not afford to make the same mistake again.

At the same time, there was also an increasing pressure on Brazil not to issue the compulsory licence. For example, Abbott decided to delay plans to invest \$27 million in a manufacturing facility in Rio de Janeiro while the discussion on the compulsory licence over Kaletra was ongoing.<sup>988</sup> This provides an example of how the intention of issuing a compulsory licence could affect FDI flowing into a developing country. In parallel with pressure from Abbott, there was a threat from the US that it would withdraw Brazil's trade privileges from the US GSP.<sup>989</sup> The US's economic coercion in effect carried weight in Brazil: the threat of trade sanctions was largely plausible, since Brazil is one of the world's biggest exporters of agricultural products.

It remains unclear if Abbott lobbied the US government to increase pressure on Brazil. The US's stance on pharmaceutical patent protection, however, is always a defensive one, as has been seen so far. It is little known that such a possibility of economic damage generated an internal conflict between two of Brazil's Ministries, the Ministry of Health and the Ministry of Development, Industry and Trade. In the middle of price negotiations, the former was no longer coordinating the discussions and the latter took the lead.<sup>990</sup>

Furthermore, the US retaliation did not stop at trade measures. A US diplomat threatened to terminate all Brazilian scientific projects and studies at US universities if Brazil were to use the compulsory licence.<sup>991</sup> It is uncertain how credible the threat was, but the fact is that Brazil was unable to stand firm under the multi-pronged attack.

As clearly seen in the Kaletra deal, the pharmaceutical companies would rather lose in the price war than in the patent battle. They are willing to lend support through monetary aid and offer other alternatives, as long as their patent monopoly remains intact. The great sensitivity of the

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<sup>988</sup> Eduardo Muniz Pereira Urias, 'Improving Access to HIV/AIDS Treatment in Brazil. When Are Compulsory Licenses Effective in Price Negotiations?' (PhD thesis, University of Maastricht 2015) 92.

<sup>989</sup> Jennifer Bjornberg, 'Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?' (2006) 27 Northwestern Journal of International Law and Business 199, 221.

<sup>990</sup> Jennifer Chan, *Politics in the Corridor of Dying: AIDS Activism and Global Health Governance* (Johns Hopkins University Press 2015) 99.

<sup>991</sup> Matthew Flynn, 'Corporate Power and State Resistance: Brazil's Use of TRIPS Flexibilities for Its National AIDS Program' in Kenneth C Shadlen and others (eds), *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries* (EE 2011) 168.

pharmaceutical industry to the patent issue is once again demonstrated. The heavy dependence of pharmaceuticals on patent protection is what most distinguishes it from other industries, as discussed in Section 3.4.5.

Given the unfavourable climate concerning price and international generic sources at that time, this thesis argues that the agreement reached with Abbott was the best option available to the Brazilian government, and the adverse reaction of civil campaign groups was therefore excessive. This deal was, in fact, a win-win solution for both the patent holder and Brazil. From Abbott's perspective, it is a pure business decision.<sup>992</sup> The company preserved its patent exclusivity, still selling Kaletra profitably and filing future drug patents. To a lucrative market like Brazil which has a large population coupled with a public insurance system, price discounts can be compensated by large sales volumes. Such reductions would not constitute a major loss. Abbott itself considered the price cuts as 'volume discount'.<sup>993</sup> At the same time, the Brazilian government also benefited from the deal. It obtained a price cut to fund the national health programme whilst reinforcing the IP environment. Brazil, by entering the agreement with Abbott, conveyed a clear message to patentee community that it truly respected IPRs and only under a drastic situation can a patent be seized.<sup>994</sup>

#### **6.4.4 2007: The compulsory licence for Efavirenz**

Efavirenz is one of the drugs included in Brazil's free HIV/AIDS treatment programme and was used by nearly 50% of patients in 2007.<sup>995</sup> As described above, Brazil had had a history of price negotiations with Merck reaching back to 2001, and the company had several times reduced the price of Efavirenz accordingly. Notwithstanding, more patients were put into treatment in 2003 and 2004, and the demand thus increased. Although the drug price in Brazil was lower than in other middle-income countries with similar HIV prevalence rates, it was still higher than the price of available generics.<sup>996</sup>

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<sup>992</sup> Ernest V. Linek and John P. Iwanicki, 'Brazil's Agreement with Abbott: A New Perspective on Patent Prosecution as a Business Process' (2005) 17 Intellectual Property and Technology Law Journal 26, 27.

<sup>993</sup> 'Compromise Averts Compulsory AIDS Drug License in Brazil' (2005) 9 Bridges Weekly Trade News Digest 15.

<sup>994</sup> Ernest V. Linek and John P. Iwanicki, 'Brazil's Agreement with Abbott: A New Perspective on Patent Prosecution as a Business Process' (2005) 17 Intellectual Property and Technology Law Journal 26, 27.

<sup>995</sup> Carlos M. Correa, 'The Use of Compulsory Licences in Latin America' in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015) 31.

<sup>996</sup> Gabriela Costa Chaves *et al.*, 'Access to medicines and intellectual property in Brazil: reflections and strategies of civil society' (2008) 8 International Journal on Human Rights 163, 171.

In 2006, the Brazilian government opened another round of negotiations with Merck, asking for a cheaper price, one that was in line with that of countries like Thailand, which had the same Human Development Index (HDI) as Brazil, but with less demand.<sup>997</sup> The Ministry of Health requested the price of \$0.65, which Thailand was paying at that time, after its issuance of the compulsory licence on Efavirenz in January 2007, as will be seen in the next chapter. Brazil also claimed that while only 17,000 Thai citizens were entitled to the treatment, there were 75,000 infected individuals in Brazil, and the latter had to pay more than the former.<sup>998</sup>

Merck argued that the price that had been offered to Brazil had been decided after consultations with the WB, the WHO and other UN agencies, and was based on Brazil's HDI.<sup>999</sup> The company also argued that the prevalence of HIV/AIDS in Brazil was three times lower than in Thailand, and that therefore the Thai price could not be used as a benchmark in the context of Brazil.<sup>1000</sup> On 4 April 2007, Merck offered a price reduction from \$1.65 to \$1.10 and promised to transfer Efavirenz technology to Brazil by 2010 (2 years before its patent expired).<sup>1001</sup> Brazil rejected the discount on the basis that it was not a price that they could afford.

Eventually, on 4 May 2007, the Brazilian President - Da Silva, signed Decree No. 6.108 which issued a compulsory licence for Efavirenz on the ground of public interest.<sup>1002</sup> In his speech, President Da Silva argued as follows:

‘It doesn't matter if the firm is German, Brazilian, French or Argentinean. The concrete fact is that Brazil cannot be treated as a country that does not deserve respect. That is, we paid US\$1.60 while the same medicine is sold to another country at US\$0.60. This is rough, not just from an ethical perspective but from a political and economic point of view. It is disrespectful. It's like the Brazilian patient is inferior to a patient in Malaysia.’<sup>1003</sup>

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<sup>997</sup> Viviane Yumi Mitsuuchi Kunisawa, *The TRIPS Agreement Implementation in Brazil: Patents in the Pharmaceutical Area* (Nomos Verlagsgesellschaft 2015) 162.

<sup>998</sup> *Ibid.*

<sup>999</sup> Elize Massard da Fonseca, ‘Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil’ (PhD thesis, University of Edinburgh 2011) 231.

<sup>1000</sup> Matthew Flynn, ‘Corporate Power and State Resistance: Brazil's Use of TRIPS Flexibilities for Its National AIDS Program’ in Kenneth C Shadlen and others (eds) *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries* (EE 2011) 165.

<sup>1001</sup> *Ibid.*

<sup>1002</sup> Decree No. 6.108 of 4 May 2007.

<sup>1003</sup> Elize Massard da Fonseca, ‘Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil’ (PhD thesis, University of Edinburgh 2011) 232.

It should be noted that this announcement was broadcasted on television before Brazil's presidential election in 2008.<sup>1004</sup> This thesis views that President Da Silva's speech explicitly articulated nationalist sentiments, as when he said, for example, 'Brazil cannot be treated as a country that does not deserve respect' or 'It's like the Brazilian patient is inferior to a patient in Malaysia'. Brazil's nationalism has in fact started as early as in the 1960s, as noted in Section 6.2.1.

President Da Silva's announcement has resembled Minister Serra's decision in 2001 when he also threatened to issue a compulsory licence during his campaign to become a president, as noted in Section 6.4.1. To the general public, widening the access to medicines will always be a remarkable effort which surely will receive considerable support. Indeed, Mr Da Silva was re-elected as a President in the second term of his political career. The extent to which the compulsory licence for Efavirenz added value to his campaign is unclear but the fact remains that in this example, apart from the moral dimension, compulsory licensing has the political side, that is to rally public support in presidential elections.<sup>1005</sup> It is, arguably, not a coincidence that compulsory licensing twice occurred in the midst of Brazil's presidential primaries. As will be demonstrated in the next chapter on Thailand, this legal measure was used as a populist tool to pacify Thai people after a coup in 2006.

The compulsory licence for Efavirenz was granted for 5 years (until May 2012) and then was extended for another 5 years, until May 2017.<sup>1006</sup> The grant was non-exclusive and for non-commercial public use to patients who were covered by Sarney's Law No.9.319/96.<sup>1007</sup> The royalties paid to Merck were 1.5%, and the company must transfer all technical documents necessary for the production process.<sup>1008</sup> The exploitation of a patented medicine is carried out by the government or by duly contracted third parties.<sup>1009</sup> In cases where the public need cannot be met by the product placed on the market or by local manufacture, importation is allowed.<sup>1010</sup>

The author is of the view that in light of international law, Brazil's compulsory licensing of Efavirenz was entirely legitimate. Firstly, it is indisputable that the government made an

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<sup>1004</sup> Bruno Salama and Daniel Benoliel, 'Pharmaceutical Patent Bargains: The Brazilian Experience' (2010) 18 Cardozo J. of Int'l and Comp. Law 633, 662.

<sup>1005</sup> *Ibid.*

<sup>1006</sup> Decree No. 6.108 of 4 May 2007, art 1, para 1.

<sup>1007</sup> Decree No. 6.108 of 4 May 2007, art 1, para 1.

<sup>1008</sup> Decree No. 6.108 of 4 May 2007, art 2 – 3.

<sup>1009</sup> Decree No. 6.108 of 4 May 2007, art 4.

<sup>1010</sup> Decree No. 6.108 of 4 May 2007, art 5.

individual assessment of the medicine. Secondly, the issue fell into the category of public interest, and Brazil has established itself as a model in the fight against the AIDS epidemic, as noted at the beginning of this chapter. In addition, the country has established a legal framework for the treatment of the disease, i.e. Sarney's Law. Thirdly, although TRIPS waived the prior negotiation with the patent holder in case of public non-commercial use, the government of Brazil did consult with Merck over the years. Finally, other requirements under Article 31 of TRIPS, such as terms, conditions and termination, were also followed by Brazil. If the company had wished to challenge the decision, the only possible ground would have been the remuneration.

The government's decision to issue the compulsory licence profoundly disappointed Merck, which declared that it was an 'expropriation of IP'.<sup>1011</sup> Brazil defended the grant for the reason that they had to pay a royalty of 1.5%, whereas they would have paid nothing in case of breaking the patent.<sup>1012</sup> Merck stated that Brazil, as the world's 12th largest economy (at that time), had a greater capacity to pay for HIV medicines than countries that were poorer or harder hit by the disease.<sup>1013</sup> This argument, although it sounds convincing in economic terms, has no legitimate foundation. As was clearly shown in Chapter 4, the economic strength of a country is not a criterion to assess the legitimacy of a compulsory licence. Nevertheless, this factor has been frequently used to preclude middle-income countries like Brazil (and Thailand, as will be seen in Chapter 7) from exercising their legitimate rights. In contrast, it is very surprising to note that when Germany also granted a compulsory licence on the public interest ground,<sup>1014</sup> no single argument against the country's prosperity was raised. It seems that such a strong bias has been shaped against developing countries only.

Even though Merck was required to provide sufficient data for Brazil to produce Efavirenz, the company in fact only provided a small amount of information, which created major difficulties

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<sup>1011</sup> Merck and Co., Inc, 'Statement on Brazilian Government's Decision to Issue Compulsory License for Stocrin' (Corporate News, 4 May 2007) <<http://www.businesswire.com/news/home/20070504005566/en/Merck-Statement-Brazilian-Governments-Decision-Issue-Compulsory>> accessed 11 October 2017

<sup>1012</sup> The speech was given by the new Director of the Department of STDs, AIDS and Viral Hepatitis - Fábio Mesquita at the Workshop on Compulsory Licensing of Antiretroviral 14 August 2015, Rio de Janeiro.

<sup>1013</sup> Merck and Co., Inc, 'Statement on Brazilian Government's Decision to Issue Compulsory License for Stocrin' (Corporate News, 4 May 2007) <<http://www.businesswire.com/news/home/20070504005566/en/Merck-Statement-Brazilian-Governments-Decision-Issue-Compulsory>> accessed 11 October 2017.

<sup>1014</sup> BGH, Urteil vom 17.07.2017 - AZ: X ZB 2/17. This case will be touched upon in Section 9.1.

for the production.<sup>1015</sup> Brazil therefore had to import the medicine from an Indian supplier, at one third of the price offered by Merck, until local production was ready.<sup>1016</sup> In 2009, the first batch of Efavirenz to be produced domestically by Brazil entered the market at a unitary price of \$0.60 - half of the price charged by Merck.<sup>1017</sup> The irony is that Brazil's locally manufactured medicine was still more expensive than the Indian-sourced import. It is a very good example to show that exploiting a patent locally does not bring the customers the most affordable price, as argued in Section 4.2.3.

That led to two questions. Firstly, if the financial burden was the main justification for the compulsory licence, why did Brazil agree to purchase the domestically produced medicine at a more expensive price than that which was readily available from the Indian supplier? Secondly, if a shortfall in the health budget was not a major reason, what was it? There is only one answer. This thesis submits that compulsory licensing, to some extent, at least in the case of Brazil, has gone beyond the bounds of a health measure. It is true that the compulsory licence for Efavirenz was resulted from the financial shortage of HIV/AIDS treatment, but it is equally true that this licence was not granted to merely serve the healthcare purpose. In the example of Brazil, the compulsory licence further enhances the local industry, creating conditions in which Brazil's pharmaceutical sector can catch up with modern technologies. It should be remembered that Brazil could not utilise the 10-year transition and the country lost momentum in stimulating scientific development. Meanwhile, by compulsory licensing, a developing country like Brazil can gain maximum access to IP of developed nations.<sup>1018</sup>

In fact, since 2001 when Brazil first started the compulsory licence threats, its public laboratories have prepared for the reverse-engineering of Efavirenz.<sup>1019</sup> It was in that year that Farmanguinhos started the R&D process on the medicine. However, it was not until December 2006, the Managing Director of Farmanguinhos informed the government that the laboratory was ready to produce Efavirenz.<sup>1020</sup> The compulsory licence for Efavirenz, granted in May

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<sup>1015</sup> Carlos M. Correa, 'The Use of Compulsory Licences in Latin America' in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015) 31.

<sup>1016</sup> Elize Massard da Fonseca, 'Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil' (PhD thesis, University of Edinburgh 2011) 231.

<sup>1017</sup> *Ibid.*

<sup>1018</sup> Muhammad Zaheer Abbas, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments' (2013) 3 International Journal of Social Science and Humanity 254, 254.

<sup>1019</sup> Maurice Cassier and Marilena Correa, 'Scaling Up and Reverse Engineering: Acquisition of Industrial Knowledge by Copying Drugs in Brazil' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (EE 2008) 142 – 145.

<sup>1020</sup> *Ibid.*

2007, was the outcome of a long period of R&D focused on that medicine. This thesis therefore submits that Brazil's one and only compulsory licence did not stem entirely from fiscal restraints: it was also a test of the country's domestic industrial capacity. Such a view is also shared by two scholars who claimed that Brazil has used compulsory licensing as an additional tool to safeguard some expertise in pharmaceuticals.<sup>1021</sup> Brazil, in fact, is not the sole example. As will be analysed in the case study of Thailand (Chapter 7), its government also prioritised the locally made medicine rather than international generics, despite that the national product did not meet WHO standards.

When it comes to trade retaliation from the US, the reaction was mixed. While the USTR removed Brazil from its 'priority watch list' because of the country's improved IP protection,<sup>1022</sup> the removal of Brazil from the GSP was said to be in retaliation for the compulsory licence.<sup>1023</sup> However, in general, the US's reaction was observed to be milder than it had been at the time of the Kaletra deal. It should be noted here that Brazil's compulsory licensing took place in the wake of a similar decision made by Thailand regarding the same medicine. This thesis submits that an unintended coalition was formed, thereby increasing the pressure on the US government. In addition, the US might well have remembered the way Brazil had counter-challenged the US's Patent Code in reprisal for the latter's complaint against Article 68 of Brazil's Patents Act. Given the impact of the AIDS epidemic, the US could have anticipated damage to itself if it opposed Brazil, a country that was regarded as a model in the fight against HIV/AIDS and was applauded by many, including the UN.

## 6.5 An evaluation of Brazil's compulsory licensing strategy

This section will evaluate three facets of Brazilian compulsory licensing: the reasons for its use, the factors making such use successful, and the country's further development.

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<sup>1021</sup> Bruno Salama and Daniel Benoliel, 'Pharmaceutical Patent Bargains: The Brazilian Experience' (2010) 18 Cardozo J. of Int'l and Comp. Law 633, 661.

<sup>1022</sup> USTR, 'Special 301 Report' (Reports and Publications, 2007) 30 <<https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/archives/2007/2007-special-301-report>> accessed 7 March 2018.

<sup>1023</sup> Ben Shankland, 'U.S. Retaliates After Thai, Brazilian Decisions on Pharmaceutical IP' (World Markets Research Centre: Global Insight, 4 July 2007).

### **6.5.1 Reasons**

It can be seen from the preceding analysis that Brazil has adopted an aggressive approach to compulsory licensing in the field of patented medicines. This thesis offers compelling reasons for such behaviour.

Firstly, as analysed in Section 6.2.1, Brazil lost its opportunity to build and maintain a generic industry due to the early enactment of the patent law of 1996. The country's hasty attempt to implement TRIPS in a single piece of patent legislation jeopardised its legal and moral obligations to provide universal treatment for its citizens. Consequently, the Brazilian government was placed in a quandary regarding its duty to combat the AIDS epidemic. Furthermore, Brazil failed to utilise any of the flexibilities contained in TRIPS, flexibilities that would have helped it to carve out national policies.<sup>1024</sup> The country was left with one option: compulsory licensing

Secondly, the increasing costs of HIV/AIDS treatment increased the fiscal pressure on Brazil. HIV/AIDS is no longer a death sentence but requires life-long treatment. The longer the patients live, the more money Brazil needs, because the patients need to switch to new treatments to avoid developing a resistance to the older drugs. In addition to the growing number of people in need of treatment, the cost has outgrown the budget, as newly invented ARVs with patent protection enter the market. The increasing financial burden led to a constant use of or the threat of the use of compulsory licensing.

### **6.5.2 Factors**

Regarding the question of what makes Brazil's threats credible to patent owners, this thesis offers two primary factors.

Firstly, the country possesses a pharmaceutical manufacturing capacity that can produce the medicines, albeit to a limited degree. Ironically, although the local laboratories are weak in terms of technology, their existence was deemed sufficient to improve the government's

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<sup>1024</sup> In fact, how domestic implementation of TRIPS affected a country's treatment of compulsory licensing will be revisited in Chapter 8 where the implementation process of India, Brazil, and Thailand are juxtaposed in an interconnected manner.

bargaining strength in price negotiations. Accordingly, the pharmaceutical companies had to reduce prices in order to avert the compulsory licensing.

This thesis also enquires whether Brazil's scientific limitations are a myth and why its threats are so often fruitful. The answer is found not in any 'bullying' tactics on the part of the Brazilian government but in the pragmatic approach of the 'bosses', the patent holding companies.<sup>1025</sup> They made pure business decisions which keep their patents intact and maintain their foothold in a rich market like Brazil. After several years or more of marketing those medicines in the country, there is no doubt that these companies generated sufficient profits to offset the discounts. Brazil has served as a fine example of how the access to medicine campaign does not adversely affect the IP system even though it reduced the medicine prices, as highlighted in Section 1.2.4.

Secondly, this thesis argues that politics was another key factor. A prominent feature of the Brazilian experience was the personal contribution of the Minister of Health, Jose Serra who put forward the idea of using compulsory licences as a negotiating tool for obtaining cheaper medicine prices.<sup>1026</sup> In addition, the 2007 compulsory licensing was strongly marked with the political willingness of President Da Silva.

A supplementary element in the success of Brazil was the simultaneous occurrence of healthcare campaigns in the country, which created a climate in which the fight for the right to healthcare for HIV/AIDS patients had the potential to be heard. This, in turn, was fertile ground for the use of compulsory licensing to be widely employed and supported. It should be noted that Brazil is one of very few countries which has a tradition of challenging the right to health before the courts. The first lawsuits claiming individual entitlement to the latest medicines was filed in 1996, with the ruling in favour of the patients.<sup>1027</sup> Since then, Brazil's civil society organizations have, on numerous occasions, commenced legal proceedings concerning

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<sup>1025</sup> Shaira Bhanji, 'Bullying the Boss? Compulsory Licensing for Antiretroviral Drugs in Brazil and Thailand' (Global Health Review, 21 October 2011) <<http://www.hcs.harvard.edu/hghr/online/bullying-the-boss-compulsory-licensing-for-antiretroviral-drugs-in-brazil-and-thailand/>> accessed 10 December 2015.

<sup>1026</sup> Brazil's local production of ARVs started in early 1990s but was only scaled up in 1998 during Serra's tenure. He was also the one who was behind the regulatory changes and stimulated the local generic industry. He furthermore implemented a variety of policies to widen access to medicines in the country, and this endeavour made him the most influential and committed of all servants of public health See Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2009) 105.

<sup>1027</sup> Gabriela Costa Chaves *et al.*, 'Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society' (2008) 5 International Journal on Human Rights 163, 165.

pharmaceutical patent grants.<sup>1028</sup> The case against Kaletra in 2005 is one example of such an action.

### 6.5.3 Further development

The compulsory licence on Efavirenz was the first, and so far, the only one compulsory licence against a pharmaceutical patent in Brazil. It is far from clear whether Brazil will issue any compulsory licences in the near future. Fabio Mesquita, the Brazilian director of the Department of STDs, AIDS and Viral Hepatitis, in a speech in 2015, provides several reasons why Brazil no longer favours compulsory licences.<sup>1029</sup> Firstly, the government has found other measures, such as price negotiations and partnership strategies, which are more workable and beneficial than non-voluntary licensing. For example, in 2008 Brazil established the ‘Productive Development Policy’ which aims to promote local production in public and private laboratories through voluntary licensing.<sup>1030</sup>

Secondly, when medicines become more sophisticated, as is the case with those that treat hepatitis C, there is no available alternative to the brand-name drugs. Thirdly, the country has been undergoing political crisis and fiscal adjustment, as noted in section 6.2.1. The political climate is therefore not conducive to discussions about compulsory licensing. In addition, current debates have strongly focused on patent reform, and therefore compulsory licensing is no longer a priority.

Lastly and most importantly, Brazil has developed a strategic plan to select the candidate medicines that are subject to a compulsory licence. In addition to cost-savings, the country will also consider the scientific aspect of those drugs. To Brazil, apart from enhancing the access to medicines, compulsory licensing is employed to boost technology transfer. The government has therefore expressed an intention to grant mandatory licences for the drugs that have a long-term market, and not one that, for example, has 50 subsequent/alternative drugs in the pipeline.<sup>1031</sup> From the industrial perspective, it is critical to know what types of medicines are

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<sup>1028</sup> *Ibid.*, 179 – 183.

<sup>1029</sup> The speech was given by the new Director of the Department of STDs, AIDS and Viral Hepatitis - Fábio Mesquita at the Workshop on Compulsory Licensing of Antiretroviral 14 August 2015, Rio de Janeiro.

<sup>1030</sup> Laís Silveira Costa *et al.*, ‘Production Development Partnership in Healthcare: Public procurement within the Brazilian development agenda’ (2016) 40 *Saúde Debate* 270.

<sup>1031</sup> The speech was given by the new Director of the Department of STDs, AIDS and Viral Hepatitis - Fábio Mesquita at the Workshop on Compulsory Licensing of Antiretroviral 14 August 2015, Rio de Janeiro.

A drug pipeline refers to a set of drug candidates which are under the R&D process, as described in Section 3.4.2.

in the R&D process and at which stage they are. For example, if the government knows that a candidate medicine will soon be substituted by another which is at the marketing review stage, it might consider not licensing that medicine. Because by the time the technology transfer of that particular drug is completed in Brazil, the medication would already be obsolete, and the investment would be wasted.

## 6.6 Conclusions

This chapter has critically examined and evaluated Brazil's compulsory licensing policy. The first question posed is, does Brazil comply with international law? In general, the country has incorporated the conditions of Article 31 of TRIPS into its national law. However, the current law does not require the applicant, in most situations, to negotiate with the patent holder for a voluntary licence first, which contravenes TRIPS. Moreover, the backlog of the INPI could erode the efficiency and the effectiveness of the compulsory licence grant. In relation to government use, Article 71 of Brazil's Patents Act contains several requirements other than those stipulated in TRIPS. Those additional requirements should be erased to streamline the process.

It is noticeable that the working requirement is a key clause of the country's patent policy. Compulsory licensing under Brazil's patent law, arguably, should be viewed as a genuine tool for the encouragement of technology transfer in the country. This view, in effect, is in line with Brazil's historical perspective on national exploitation. Although the country has not issued any compulsory licence for a non-use patent, pharmaceutical companies should bear in mind this feature so as to ensure the availability, affordability and sufficiency of medicinal products on the Brazilian market.

Moreover, it is clearly shown that Brazil's policy-makers met difficulties in developing an articulate legal framework in relation to government use licensing. It seemed that the legislators failed to envisage how patent law could affect national health policies and they also failed to blend these two aspects harmoniously in Brazilian legislation. As a consequence, the law-makers had to create various twists and turns to cater for national needs through the two Decrees addressing the compulsory licence.

Moving to the country's practice, the author maintains that Brazil has been a unique example of using the compulsory licences as a bargaining chip to obtain price cuts rather than actually

issuing them. By applying this legal safeguard as a ‘stick’, the government attained their national goal: easing health expenses without breaking international rules while maintaining the trade relationship with the US. Such a bargaining position was partly supported by its local manufacture base. In some cases, the credibility of Brazil’s threats largely relied on the availability of international suppliers of generics while its national labs are incapable of making the medicines. Brazil’s bargaining power was additionally attributable to its significant international clout, which it can reprise where necessary.<sup>1032</sup> One of the principal conclusions of this thesis is that these features characterise Brazil as an exceptional case which does not represent a typical example in the community of developing countries.

Brazil has been an inspiration for the success of combating HIV/AIDS. Its victory, however, has not been straightforward because the government could not threaten to use compulsory licences whenever its fiscal health was challenged. In this context, the author argues that compulsory licensing does not appear as a healthy long-term policy. In fact, it should not be thought of as the only way to promote access to medicines or to address a country’s public health concerns. Compulsory licensing should be coupled with other measures. Brazil is on the way to patent reform, in which it seems to be following in India’s footsteps by increasing the threshold of patentability criteria.<sup>1033</sup> Brazil has started applying pre-grant patent oppositions to deny patent requests on some medicines. Use of the pre-screening mechanism would be less controversial than compulsory licensing, since it tends to be a technical rather than an ethical issue in the context of the right to health. This approach is more appropriate for developing countries. This conclusion accords with the recommendations made in 2002 by the UK Commission on IPRs.<sup>1034</sup>

It could be concluded that Brazil’s successful model regarding compulsory licences lies in a single element – the use of threats - and not in its pharmaceutical manufacturing capacity, which is deemed to be a vital requirement for the issue of such a licence. Compulsory licensing has proven to be unworkable where the medicines have become more technologically complex

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<sup>1032</sup> Brazil has had six opportunities to retaliate against the US but has never used them. Claudia Jurberg, ‘Brazil Issues Retaliation List of US Products; IP-Protected Items In Next Round’ (IP Watch, 17 November 2009) <<https://www.ip-watch.org/2009/11/17/brazil-issues-retaliation-list-of-us-products-ip-protected-items-in-next-round/>> accessed 17 October 2017.

<sup>1033</sup> The Brazilian Chamber of Deputies – Center for Strategic Studies and Debates, *Brazil’s Patent Reform: Innovation towards national competitiveness* (2013) 13 – 14.

<sup>1034</sup> UK Commission on IPRs, ‘Integrating Intellectual Property Rights and Development Policy’ (2002) 122 <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018.

to a degree that neither local production nor international supply is available. In any case, the author shares Urias's conclusion that developing countries should pursue capacity-building strategies in order to reinforce their bargaining position in price negotiations with pharmaceutical companies.<sup>1035</sup>

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<sup>1035</sup> Eduardo Muniz Pereira Urias, 'Improving access to HIV/AIDS treatment in Brazil. When are compulsory licenses effective in price negotiations?' (PhD thesis, University of Maastricht 2015) 181 – 194.

## CHAPTER 7: THAILAND

Subsequent to Chapters 5 and 6, which critically evaluated the compulsory licence regime of India and Brazil, Chapter 7 will concentrate on such a regime of Thailand – the third and final country case study in this thesis. Like the two previous chapters, this chapter aims to answer the third research question: given the little freedom provided by TRIPS, how have developing countries achieved their specific goals through the use of compulsory licensing? On the one hand, the Thai policy, similar to Brazil's, was characterised as government use in order to implement national health policies. On the other hand, unlike Brazil, where compulsory licensing was mainly applied as threats to achieve price discounts, Thailand actually granted non-voluntary licences.

Thailand's example is critical for the purposes of research because it is a 'collection' of firsts. It is the *first* nation to embrace mandatory licensing for medicines treating chronic diseases (heart diseases and cancers). Prior to the Thai practice, compulsory licences were limited to medicines which treat communicable illnesses, or epidemics such as HIV/AIDS, as examined in the preceding chapter on Brazil.<sup>1036</sup> From late 2006 until early 2008, Thailand mandatorily license the patents of seven drugs covering a wide range of diseases: two relating to HIV/AIDS, one relating to cardiovascular conditions and four relating to cancers.<sup>1037</sup> Eventually, as one patent holder - Novartis agreed to provide Glivec free to Thai patients with certain requirements, the compulsory licence for this medicine was revoked.<sup>1038</sup> Such a broad use has provoked a debate on whether this legal measure, as an exception to patent rights, has shifted from acute illnesses to everyday diseases. An answer to it is essential in current global healthcare where noncommunicable diseases have been listed as the top causes of death.<sup>1039</sup>

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<sup>1036</sup> Other countries also issued compulsory licences to combat HIV/AIDS and pandemic flu. They are Malaysia, Indonesia, Ghana, Zambia, South Africa, Taiwan. See Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis' (2012) 9 PLoS Medicine 1, 4.

<sup>1037</sup> The notifications of Thailand's compulsory licences are reprinted in the documents below:

- The Ministry of Public Health, 'Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand' (February 2007), hereinafter referred to as 'White Paper 2007'.
- The Ministry of Public Health, 'The 10 Burning Questions on the Government Use of Patents on the four anti-cancer drugs in Thailand' (February 2008), hereinafter referred to as 'White Paper 2008'

<sup>1038</sup> *Supra* note 1037, White Paper 2008.

<sup>1039</sup> WHO, 'The top 10 causes of death' (January 2017) <<http://www.who.int/mediacentre/factsheets/fs310/en/>> accessed 24 October 2017.

Adding another layer of complexity to this case-study of Thailand is the *extraordinary* involvement of politics since the government that granted the licences was formed after a coup d'état against the Prime Minister - Thaksin Shinawatra on 19 September 2006.<sup>1040</sup> The junta's decisions to seize private property in the name of sustaining public interest thus came under fire from all sides: the Western press, pharmaceutical companies, the countries sponsoring these companies, and even from academia, as will be analysed in depth in Section 7.4.3. Facing this wave of anger, the Thai government, for the *first* time, felt obliged to justify its policy in two White Papers.<sup>1041</sup> In addition, Thailand is also the *first* country to assess the economic impacts of government use licences after they were put into practice.<sup>1042</sup>

The bold moves of Thailand provoked a retaliation by a patent holding company, Abbott. The company withdrew seven new medicines from the Thai market in reprisal for the country's use of compulsory licences. It was believed to be the *first* tit-for-tat action of a right owner since the history of TRIPS compulsory licensing. Such withdrawal raises the following question: whether the balance of interest could be achieved if enhancing the medicine accessibility to a class of patients leads to others being deprived of similar access?

## 7.1 An introduction to Thailand

Thailand is the only nation in Southeast Asia never to have been colonised, whereas all its neighbours were occupied by Western powers. Such a feature, which distinguished Thai patent law from others, will be explored further in the next section. Since 1932, Thailand has formally possessed a constitutional monarchy with parliamentary government. Nevertheless, from 1947 until 1973 the country was primarily ruled by military governments, with some democratic interludes.<sup>1043</sup> From 2001 to 2006, Thailand was deeply divided between supporters and opponents of Thaksin Shinawatra, who served as the prime minister until he was exiled by the military in 2006. Coincidentally, 2006 is also the year when Thai compulsory licences commenced. Since 2014, the country has been in another political crisis caused by another

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<sup>1040</sup> Bate R, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013.

<sup>1041</sup> *Supra* note 1037.

<sup>1042</sup> Inthira Yamabha *et al.*, 'Assessing the implications of Thailand's Government Use Licenses, issued in 2006–2008' (Health Intervention and Technology Assessment Program, 2009) <<http://www.hitap.net/en/research/17635>> accessed 21 March 2018.

<sup>1043</sup> 'Thailand country profile' (BBC, May 2017) <<http://www.bbc.co.uk/news/world-asia-15581957>> accessed 18 October 2017.

coup against Prime Minister Yingluck Shinawatra, Thaksin's sister. Thai people have been under the control of the military thereafter.

However, Thailand's volatile situation has not prevented its economy from growing steadily. In 2011, it was reclassified as an upper-middle income economy.<sup>1044</sup> In 2016, its GNI (per capita) was \$5,640 and GDP was \$407,026 billion,<sup>1045</sup> making Thailand the second largest economy in Southeast Asia, after Indonesia. Thailand is a founding member of ASEAN, which was established in 1967 and is the world's third largest trading bloc (after the EU and the NAFTA). As referred to in Section 3.2.3, the ASEAN group played a key role in breaking the deadlock over the IP discussion during the Uruguay Round. The decision by ASEAN to include IPRs in the negotiation agenda partly broke up the coalition of developing countries, thus allowing the multilateral talk to progress further. In general, although Thailand is not viewed as a global rising power like India and Brazil, it is, arguably, a significant market.

## 7.2 Thailand's patent law and pharmaceutical manufacturing capacity

### 7.2.1 A brief history of Thai patent law

The fact that Thailand avoided colonisation gave its patent system a distinctive character. That is, while patent laws in many developing countries were enacted by the ruling powers, and exploited solely by foreign firms, as we have seen in previous chapters on India (Chapter 5) and Brazil (Chapter 6), the Thai regime developed voluntarily, without external pressure. The first Thai patent law was adopted in 1979 and was known as Patent Act B.E.2522. Prior to this Act, Thailand had had nothing similar. Compared to the first copyright legislation and the first trademark law, enacted in 1892 and 1914 respectively,<sup>1046</sup> the patent law is a recent phenomenon in the region. The rationale behind such implementation stems from the country's own ambitions, which was to enhance industrial and economic development, and to facilitate technology transfer.<sup>1047</sup> The country wanted to strengthen its global trade and keep pace with existing developments in the field of IPRs.

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<sup>1044</sup> WB, 'The World Bank in Thailand' (September 2017)

<<http://www.worldbank.org/en/country/thailand/overview>> accessed 7 March 2018.

<sup>1045</sup> WB, 'Thailand' (Databank) <<https://data.worldbank.org/country/thailand>> accessed 19 February 2018.

<sup>1046</sup> Julia Sorg, 'Thailand' in Paul Goldstein and Joseph Straus (eds), *Intellectual Property in Asia: Law, Economics, History and Politics* (Springer 2009) 304.

<sup>1047</sup> *Ibid.*

Accordingly, Thailand's patent law was not really influenced by any specific country but followed WIPO's model patent law for developing nations.<sup>1048</sup> As regards medicines, like other Third World economies prior to TRIPS, they were poorly protected under Thai patents. For example, pharmaceutical products were excluded from patentability, only pharmaceutical processes were given 15 years of protection from the filing date.<sup>1049</sup> In addition, a non-working patent was subject to compulsory licensing or revocation.<sup>1050</sup> Along with such low patent protection, other IPR flexibilities turned Thailand into the world capital of counterfeit products during the 1980s. Indeed, Thailand was considered as 'a country with one of the worst piracy records in the world',<sup>1051</sup> and the worst country in the Asia - Pacific region as regards IPRs.<sup>1052</sup> As a commentator stated, 'In the late 1960s, Hong Kong took over the role Japan held in the late 1950s as 'copycat of the world'. Then in the late 1970s, it was Taiwan's turn, and right now, Thailand is about to burst into the fake export scene.'<sup>1053</sup>

Since the mid-1980s, the US has embarked on various courses of action to battle Thailand's practice of piracy. Regarding copyright, in 1987, the International IP Alliance, the Motion Picture Export Association of America, and the Recording Industry Association of America filed a petition against Thailand.<sup>1054</sup> In 1989, asserting that the country's government failed to provide adequate and effective copyright protection, the US placed Thailand on the 'Priority Watch List' under Special 301 and dropped it from the GSP program.<sup>1055</sup> The withdrawal of

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<sup>1048</sup> R Ian McEwin and Sakda Thanitkul, 'Thailand: Medicines, Competition Law and Compulsory licensing' in R Ian McEwin (ed), *Intellectual Property, Competition Law and Economics in Asia* (Hart Publishing 2011) 281.

<sup>1049</sup> Lisa Forman, 'From TRIPS-Plus to Rights-plus? Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights through the Thai Experience' (2012) 2 Asian Journal of WTO and International Health Law and Policy 347, 359.

<sup>1050</sup> Stefan Kirchanski, 'Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand' (1994) 16 Loyola of Los Angeles International and Comparative Law Review 569, 573 – 574.

<sup>1051</sup> Samira Guennif, 'Access to essential drugs in Thailand: Intellectual property rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen and others (eds) *Intellectual property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries* (EE 2011) 290.

<sup>1052</sup> Thomas N. O'Neill III, 'Intellectual Property Protection in Thailand: Asia's young tiger and America's growing concern' (1990) 11 Journal of International Law 603, 605.

<sup>1053</sup> This statement made by Tony Gurka, a managing director of Commercial and Trademark Services, a Hong Kong-based group, was cited in Thomas N. O'Neill III, 'Intellectual Property Protection in Thailand: Asia's young tiger and America's growing concern' (1990) 11 Journal of International Law 603, 605

<sup>1054</sup> Samira Guennif, 'Access to essential drugs in Thailand: Intellectual property rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen et al. (eds) *Intellectual property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries* (EE 2011) 290.

<sup>1055</sup> *Ibid.*

the GSP caused economic damage to Thailand of up to \$165 million.<sup>1056</sup> Given that the US was its biggest export market, such a punishment severely affected the Thai economy.

In the field of pharmaceuticals, the US accused Thailand's inadequate patent system of causing them trade losses. Pfizer complained that, in 1984, while it had earned \$2.2 million on its genuine medicines, counterfeit products in Thailand made \$4.2 million, double the revenue of the original.<sup>1057</sup> Similarly, GSK claimed that they lost \$7.6 million in 1986 because of fake products.<sup>1058</sup> In 1991, a second petition against Thailand was filed by the PhRMA.<sup>1059</sup> As a result, the USTR initiated an investigation and moved Thailand from the Priority Watch List to the Priority Foreign Country list - the worst category of Special 301.<sup>1060</sup>

During the first phase of the TRIPS negotiations, Thailand also resisted the inclusion of IP in the agenda of the Uruguay Round. As noted in Section 3.2.3.1, Thailand and Brazil were the only two developing countries which raised such objections in writing. The Thai delegation asserted that IP norm-setting, which was based on the national self-interest of developed countries, did not fit the intentions and spirit of the Ministerial Declaration of the Uruguay Round.<sup>1061</sup> Moreover, Thailand supported an appropriate enforcement mechanism within the GATT context, and suggested a ban on unilateral actions from contracting parties.<sup>1062</sup> Such a suggestion was clearly aimed at the US at that time.

In general, at both the bilateral and multilateral levels, Thailand's opposition to IPRs potentially resulted in US trade coercion. Politically and economically, the suppression of Thailand was just a matter of time. Indeed, in order to avoid economic loss, the Thai government had no choice but to amend its Patent Act in 1992, four years before the completion of TRIPS.<sup>1063</sup> The

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<sup>1056</sup> *Ibid.*

<sup>1057</sup> Thomas N. O'Neill III, 'Intellectual Property Protection in Thailand: Asia's young tiger and America's growing concern' (1990) 11 Journal of International Law 603, 608.

<sup>1058</sup> *Ibid.*

<sup>1059</sup> Stefan Kirchanski, 'Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand' (1994) 16 Loyola of Los Angeles International and Comparative Law Review 569, 589.

<sup>1060</sup> *Ibid.*, 591.

<sup>1061</sup> GATT, Statement by Thailand (12-14 September 1988) MTN.GNG/NG11/W/27.

<sup>1062</sup> *Ibid.*

<sup>1063</sup> Patent Act B.E. 2522 (1979), as amended by Patent Act (No. 2) B.E 2535 (1992).

new law had not yet been translated into English, but due to American impatience, so the US Embassy in Bangkok quickly produced an unofficial, preliminary translation.<sup>1064</sup>

The amended Act recognised patent protection for pharmaceutical products and processes; extending the term of protection from 15 to 20 years; requiring prior negotiation between the potential licensee and the patent holder; and demanding the patentee be given notice and an opportunity to be heard before proceeding with a compulsory licence.<sup>1065</sup> Parallel importation was not allowed in the amendments because the US threatened to limit Thai textile imports to the US market.<sup>1066</sup> US trade power yielded fruitful outcomes in this case where the US had been an important trading partner to Thailand. Not only did Thailand lose the 10-year transition to implement TRIPS but it also enacted the full patent regime of medicines earlier than TRIPS required. Thailand is a very good example of how the US, through economic pressure, succeeds in altering IP policies of a small developing country to meet American standards.

In addition to the revision in 1992, Thailand, with the help of the US and the EU, created in 1996 the IP and International Trade Court, the first specialised court in ASEAN.<sup>1067</sup> Although Thailand follows a civil law tradition, the Court gives a significant amount of discretion and authority to the judges to create their own rules.<sup>1068</sup> The court was considered to represent a significant effort on the part of Thailand to reconcile its IP practice with that of developed nations.

In spite of the amended Act, the US was not wholly content. It criticised the creation of a Pharmaceutical Price Review Board, which was to control the pricing and availability of patented pharmaceuticals.<sup>1069</sup> Moreover, it was unhappy with the lack of pipeline protection and the broad compulsory licensing provisions.<sup>1070</sup> Under the 1992 Act, a compulsory licence

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<sup>1064</sup> Stefan Kirchanski, ‘Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand’ (1994) 16 Loyola of Los Angeles International and Comparative Law Review 569, 593.

<sup>1065</sup> *Ibid.*, 593 – 594.

<sup>1066</sup> Samira Guennif and Claude Mfuka, ‘Impact of Intellectual Property Rights on Aids Public Health Policy in Thailand’ in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 142.

<sup>1067</sup> Andrea Morgan, ‘Trips to Thailand: The Act for the Establishment of and Procedure for Intellectual Property and International Trade Court’ (2000) 23 Fordham International Law Journal 795, 825.

<sup>1068</sup> *Ibid.*, 829 - 830.

<sup>1069</sup> Preeti Sinha, ‘Special 301: An Effective Tool against Thailand’s Intellectual Property Violations’ (1993) 1 Pacific Rim law and Policy Journal 281, 293.

<sup>1070</sup> Julie S. Park, ‘Pharmaceutical Patents in the Global Arena: Thailand’s Struggle Between Progress and Protectionism’ (1993) 13 Boston College Third World Law Journal 121, 124.

was granted where a patent was not locally exploited within three years of the grant; or where there was no sale of patented products; or where the sale had been at an unreasonably high price, or where such sales did not meet the public demand.<sup>1071</sup> In particular, the US was extremely unhappy with the working requirement under the amended patent law.<sup>1072</sup> Moreover, the competent Thai authority retained control over patent rights. Even when no one applied for a licence, the patent office could, by itself, investigate the situation of patent abuse, and then call for such applications.<sup>1073</sup>

Therefore, in 1993, again under US pressure, Thailand introduced the Safety Monitoring Programme which was equivalent to pipeline protection. The programme granted exclusive marketing rights up to 5 years for medicines patented elsewhere between 1986 and 1991, but not protected under the 1992 Patent Act.<sup>1074</sup> The US's economic 'big stick' yielded success by forcing Thailand to suppress compulsory licensing in return for low customs duties on Thai gems and wood products.<sup>1075</sup>

After Thailand became a WTO member in 1995, the Thai Patent Act was amended again (in 1999), to be more compatible with TRIPS.<sup>1076</sup> Under the most recent law, provisions of compulsory licensing were modified to be consistent with TRIPS Article 31. Moreover, the Pharmaceutical Price Review Board was abolished. While pipeline protection remained, parallel importation was introduced because of the flexibility given by TRIPS.<sup>1077</sup>

In summary, this thesis submits that while the initial adoption of Thailand's patent system originated from self-interest, subsequent changes to the country's patent laws were mainly made in the face of external pressure. As a result, given the underdevelopment of Thai

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<sup>1071</sup> *Ibid.*, 130 – 131.

<sup>1072</sup> *Ibid.*

<sup>1073</sup> *Ibid.*

<sup>1074</sup> Samira Guennif, 'Access to essential drugs in Thailand: Intellectual property rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen and others (eds) *Intellectual property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries* (EE 2011) 291 – 292.

<sup>1075</sup> Samira Guennif and Claude Mfuka 'Impact of Intellectual Property Rights on Aids Public Health Policy in Thailand' in Jean-Paul Moatti and others (eds) *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 142.

<sup>1076</sup> Patent Act B.E. 2522 (1979), as amended by Patent Act (No. 2) B.E 2535 (1992) and by Patent Act (No. 3) B.E. 2542 (1999) 'the Thai Patent Act 1999'.

<sup>1077</sup> The Thai Patent Act 1999, section 36.7.

pharmaceutical capacity which will be discussed next, the country's premature and excessive implementation of TRIPS has probably jeopardised its national health policies.

## 7.2.2 Thailand's pharmaceutical market

The Thai pharmaceutical market was valued at over \$5 billion in 2016, making it the second largest market in Southeast Asia.<sup>1078</sup> It consists mainly of two types: private companies and state-owned enterprises. The first group, amounting to 90% of the industry, contains local companies which primarily package and formulate drugs, and multinational corporations which distribute imported medicines.<sup>1079</sup> While Thai- privately owned companies hold 75% of the market share, foreign firms nonetheless generate almost 50% of the sales revenue.<sup>1080</sup>

The second group comprises the Defence Pharmaceutical Factory, under the Ministry of Defence, and the GPO, under the Ministry of Health.<sup>1081</sup> The latter holds a monopoly power concerning government-run activities and has played a central role in the country's healthcare services. It manufactures more than 300 pharmaceutical products (which are mostly generics), and public hospitals must, by law, purchase most of their medicines from the GPO.<sup>1082</sup> Such a monopoly has given the GPO an enormous advantage, barring other generics-producing competitors from entering the Thai market. However, its dominant position might face the challenge of competition as, in August 2017, the government enacted a new law allowing public hospitals to buy more of their pharmaceutical needs from foreign manufacturers.<sup>1083</sup>

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<sup>1078</sup> Samira Guennif, 'Access to essential drugs in Thailand: Intellectual property rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen and others (eds) *Intellectual property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries* (EE 2011) 295. See also Pacific Bridge Medical, 'Thailand Drug Market Update 2017' (15 June 2017) <<https://www.pacificbridgemedical.com/publication/thailand-drug-market-update-2017/>> accessed 19 October 2017.

<sup>1079</sup> J. Kuanpooth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (EE 2010) 148.

<sup>1080</sup> Pacific Bridge Medical, '2013 Thailand Pharmaceutical Market Update' (21 June 2013) <<http://www.pacificbridgemedical.com/publication/2013-thailand-pharmaceutical-market-update/>> accessed 19 October 2017.

<sup>1081</sup> Jakkrit Kuanpooth, 'Intellectual Property Rights and Pharmaceuticals: a Thai Perspective on Prices and Technological Capability' (2007) 2 *Intellectual Property Quarterly* 186, 194.

<sup>1082</sup> Phamax, 'Healthcare Market Access: Thailand' (January 2015) 53

<<http://www.phamax.ch/Uploads/02082016040501AM.pdf>> accessed 23 July 2017.

<sup>1083</sup> Pacific Bridge Medical, 'Thailand Drug Market Update 2017' (15 June 2017) <<http://www.pacificbridgemedical.com/publication/thailand-drug-market-update-2017/>> accessed 19 October 2017.

Thailand is viewed as having middle level of medicine manufacturing capability.<sup>1084</sup> It means that Thailand can produce pharmaceutical intermediates from raw materials available in the country, and local firms mainly concentrate on the final stage of the manufacturing process - formulating and packing. The GPO can manufacture most of the first line AVRs, which it currently exports to other developing countries in Southeast Asia and Africa.<sup>1085</sup> However, there has been a concern about the quality of GPO-made medicines. The first ARV compound, called GPO-vir, successfully produced in 2002, was below the standard stipulated in the WHO's pre-qualification programme.<sup>1086</sup> The medicine quality was also one of the contentious issues of Thai licensing which will be investigated in Section 7.5.2.

In short, though Thailand has the ability to produce the medicines locally, it relies heavily on imported drugs to meet national demand, thus causing a significant trade deficit.<sup>1087</sup> The introduction of patents on pharmaceuticals in 1992 was said to bring fairly minimal benefit to its industry.<sup>1088</sup> Technology transfer has been minimal, no research units have been established, and little has been invested in R&D.<sup>1089</sup> To sum up, it is safe to conclude that Thailand's pharmaceutical industry is a net IP importer and a royalty exporter.

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<sup>1084</sup> Jakkrit Kuanpoth, 'Intellectual Property Rights and Pharmaceuticals: a Thai Perspective on Prices and Technological Capability' (2007) 2 Intellectual Property Quarterly 186, 191.

<sup>1085</sup> J. Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (EE 2010) 148. Further discussion about the medicine manufacturing process can be found at Warren Kaplan and Richard Laing, 'Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines. An Overview of Key Concepts, Issues and Opportunities for Future Research' (WB 2005) 27.

<sup>1086</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233, 246.

<sup>1087</sup> Phamax, 'Healthcare Market Access: Thailand' (January 2015) 56

<<http://www.phamax.ch/Uploads/02082016040501AM.pdf>> accessed 23 July 2017.

<sup>1088</sup> Samira Guennif, 'Access to essential drugs in Thailand: Intellectual property rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen and others (eds), *Intellectual property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries* (EE 2011) 294 – 300.

<sup>1089</sup> WHO, 'The TRIPS Agreement and Pharmaceuticals. Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals' (Jakarta, 2 - 4 May 2000) 24 <<http://apps.who.int/medicinedocs/en/d/Jh1459e/5.3.html>> accessed 13 February 2018; J. Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (EE 2010) 147 – 150; Samira Guennif, 'Access to essential drugs in Thailand: Intellectual property rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen and others (eds) *Intellectual property, Pharmaceuticals and Public Health. Access to Drugs in Developing Countries* (EE 2011) 294 – 300.

## 7.3 Thailand's compulsory licensing provisions

As mentioned in Section 7.2.1, before the amendments in 1999, the Thai Patent Act put in place an excessively broad compulsory licensing regime. In fact, no grant of a compulsory licence was recorded until 2006. Under the current law, a compulsory licence may be ordered in one of the following situations:

- Market-initiated demand (Section 46)
- Dependent patents (Section 47)
- Government use in case of public interest (Section 51) and a state of war or emergency (Section 52).

Given their relevance to this research, Sections 46, 51, and 52 of the 1999 Thai Patent Act will be analysed. It is noted that Thailand has not adopted Article 31bis of TRIPS which facilitates the export of generics from countries with manufacturing capacities to those having little or no pharmaceutical production. However, in June 2017, a draft amendment to the Thai Patent Act suggested that this ground should be incorporated.<sup>1090</sup> If this measure were to be adopted, Thailand would act as an exporter and importer within this new category of compulsory licensing.

### 7.3.1 Section 46: market-initiated licensing

Under Section 46 of the Act, any person can apply for a compulsory licence where a patented product is not being produced, or where a patented process is not being applied in the country, or where that patented product is not sold, or is sold at excessive prices, or in insufficient quantities, without any legitimate reasons.<sup>1091</sup> In line with international law, a compulsory licence can only be applied for once three years have expired since the original grant, or four years after the application date.<sup>1092</sup> According to Kuanpoth, Thailand does not consider importation to be equivalent to ‘working a patent’, meaning that the right owner must manufacture the patented article within the country.<sup>1093</sup> According to him, the Thai law which places the burden of proof of exploitation on the applicant rather than the patentee contradicts

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<sup>1090</sup> ‘Draft Amendment to the Thai Patent Act’ (Baker McKenzie 5 June 2017) <<http://www.bakermckenzie.com/en/insight/publications/2017/06/draft-amendment-thai-patent/>> accessed 22 October 2017.

<sup>1091</sup> The Thai Patent Act 1999, sec 46.

<sup>1092</sup> The Thai Patent Act 1999, sec 46.

<sup>1093</sup> Jakkrit Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (EE 2010) 185.

Article 5A(4) of the Paris Convention, whereby the right owner has to justify his non-exploitation.<sup>1094</sup> Such a reversal undermines the effectiveness of the compulsory licensing system, as the potential licensee cannot know whether the patentee has a legitimate reason for not manufacturing the invention.<sup>1095</sup>

Anyone seeking a compulsory licence must file the application with the Director-General of the patent office and set forth the proposed remuneration, terms, conditions, scope and duration of the licence.<sup>1096</sup> Also, the applicant must prove that the patented article, which will be produced under the prospective licence, must be mainly supplied to the domestic market, and that he has a plan for such exploitation.<sup>1097</sup> This thesis submits that this requirement, although not mentioned in the TRIPS Agreement, is intended to protect the owner's legitimate interests under the Thai Patent Act. It is to prevent a situation where the applicant has little or no intention of working the invention, but only wants to interfere with the right owner. By such a requirement, the prospective licensee needs to demonstrate his genuine purpose of exploring the patented article. The applicant is also required to establish that he made reasonable attempts to negotiate for a voluntary licence but was unable to reach an agreement with the patentee within a reasonable period of time.<sup>1098</sup> These requirements were adopted in conformity with Article 31(b) of TRIPS.

Upon receiving the application, the Director must send a copy to the patentee, and then inform both parties when the decision will be made.<sup>1099</sup> The right owner and the potential licensee can submit evidence to support their own arguments. On the basis of such submission, the Director will decide whether to grant a compulsory licence.<sup>1100</sup> If the Director decides to favour the applicant, both parties are given priorities to negotiate the terms, conditions and royalties. Only when no agreement can be reached will the Director determine said issues.<sup>1101</sup>

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<sup>1094</sup> *Ibid.*, 185.

<sup>1095</sup> *Ibid.*, 186.

<sup>1096</sup> The Thai Patent Act 1999, sec 47; Ministerial Regulation No.26 (B.E.2542), clause 11, par 2.3.

<sup>1097</sup> Ministerial Regulation No.26 (B.E.2542), clause 11, par 2.5 and 2.6.

<sup>1098</sup> The Thai Patent Act 1999, sec 46; Ministerial Regulation No.26 (B.E.2542), clause 11, paragraph 2.2.

<sup>1099</sup> The Thai Patent Act 1999, sec 49, par 2.

<sup>1100</sup> The Thai Patent Act 1999, sec 49, par 3.

<sup>1101</sup> The Thai Patent Act 1999, sec 50.

Any decision of the Director can be appealed to a Board of Patents within 60 days.<sup>1102</sup> The decision of the Board, if not challenged before the IP Court within 60 days, is final.<sup>1103</sup>

This thesis submits that, in general, Section 46 of the Thai Patent Act is consistent with TRIPS, ensuring that all minimum standards are met. On the letter of the law, the substantive and procedural provisions are simple, straightforward, and on the face of it, easy-to-apply. There are not many controversial issues apart from the provision of local working. As the law still embraces lack of local use as a ground for issuing a compulsory licence, the possibility of circumventing patent monopoly in the pharmaceutical field is still open. However, it is interesting to note that while Brazil's working clause was fiercely objected to by the US (Section 6.3.3), the same situation did not occur in Thailand's case. So far, no compulsory licences have been granted under Section 46. Consequently, it is hard to judge the effectiveness of the Thai system. Given the limited capacity of the country pharmaceutical industry, the likelihood of obtaining a compulsory licence by a private company remains low.

### **7.3.2 Sections 51 and 52: government use licensing**

The possible grounds for a government use licence are stipulated in Sections 51 and 52. The former covers a broad range of public interest, including the need to meet a severe shortage of drugs, and the latter is aimed solely at a state of war or emergency. The law did not elaborate further on the nature of such situations.

The competent authorities which are responsible for the compulsory licence grants are ruled differently under Sections 51 and 52. Section 51 dealing with public interest allows any ministry, bureau or department of the government, either by themselves or through a third party, to issue such a licence. Section 52, meanwhile, gives the responsibility to the Prime Minister solely. In both cases, the grace period and the prior negotiation can be dispensed with. The patentee will immediately be given a written notice and will be entitled to remuneration.<sup>1104</sup>

However, there are marked differences between Sections 51 and 52. Firstly, Section 51 (public interest), referring to Sections 48 and 50, allows the right owner to negotiate with the government for the royalty.<sup>1105</sup> Where no consensus is reached, the Director-General of the

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<sup>1102</sup> The Thai Patent Act 1999, sec 72.

<sup>1103</sup> The Thai Patent Act 1999, sec 74.

<sup>1104</sup> The Thai Patent Act 1999, sec 51, par 1 and sec 52, par 1.

<sup>1105</sup> The Thai Patent Act 1999, sec 51.

patent office will decide.<sup>1106</sup> However, the law is ambiguous in relation to the time and the way how the negotiation will be conducted. Section 52 (state of war or emergency), meanwhile, provides no scope for discussions between the patentee and the government, probably because of the urgency of the situation. The Prime Minister will unilaterally impose a remuneration even if the owner disagrees.<sup>1107</sup>

Secondly, Section 51 allows for the terms, conditions and remuneration, but *not* the ground of the grant, be appealed to the Board of Patents within 60 days.<sup>1108</sup> The decision of the Board can in turn be reviewed by the Court within the same period.<sup>1109</sup> It is stressed that the owner has no right to challenge the decision regarding the use, but solely the conditions thereof. By contrast, Section 52 allows *both* the validity and the remuneration of the grant to be reviewed by the *courts* only.<sup>1110</sup> In any case, the appeal lodged by the patent holder does not have a suspensive effect on the issuance of the compulsory licence.

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<sup>1106</sup> The Thai Patent Act 1999, sec 51, par 2.

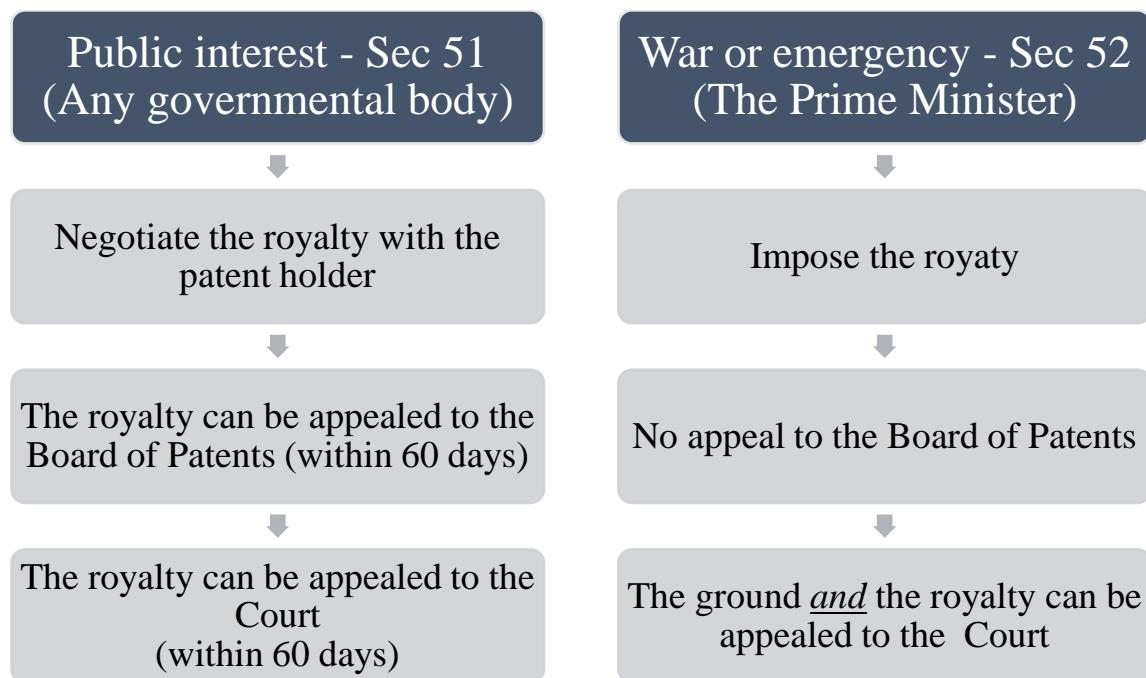
<sup>1107</sup> The Thai Patent Act 1999, sec 52, par 1.

<sup>1108</sup> The Thai Patent Act 1999, sec 51, par 2 refers to sec 50, which regulates the terms, conditions and the remuneration of a compulsory licence; sec 72.

<sup>1109</sup> The Thai Patent Act 1999, sec 74.

<sup>1110</sup> The Thai Patent Act 1999, sec 52, para 2

**Figure 5 Government use compulsory licensing under the Thai patent law**



This thesis submits that Thai law-makers have in their minds a fine distinction between two sub-categories of government use licensing: public interest, and other national emergencies. The author argues that such a distinction fits into the political situation in Thailand where military coups occur rather frequently. Under the scenarios regulated by Section 52, the steps that can cause the delay in the Prime Minister's actions such as negotiation for a royalty with the patent holder, or appeal to the Board of Patents, are eliminated to hasten the process. By comparison with TRIPS Article 31, Thailand has formulated policies to meet its own unique political situation despite the constraints of international law. In terms of Section 51, the procedure is relatively simple because Thailand incorporated the fundamental requirement of TRIPS without going beyond. Such simplicity minimises bureaucratic process and allows the use to be implemented promptly. Section 51 was brought into force in two phases: 2006 - 2007 and 2008.

## 7.4 The practice of Thai government use licensing

Because Thai compulsory licensing was initiated by the government, it is necessary to sketch out a general picture of the country's public health services. The Thai government is mainly responsible for healthcare expenditure. It contributes 76% of the total costs, while the

contribution of the private sector amounts to 24%.<sup>1111</sup> In 2001, a universal coverage scheme was launched to provide healthcare for 75% of the Thai population.<sup>1112</sup> In 2002, Thailand adopted the National Health Security Act, under which 99% of Thais were covered by one of the various national insurance schemes.<sup>1113</sup> The beneficiaries of these measures are entitled to full access to all medicines on an essential drug list that included almost 900 items.<sup>1114</sup> In essence, Thailand's government serves a central role in planning, promoting, and protecting the well-being of the entire society.

Although the country's compulsory licensing started in 2006, the first attempt was made much earlier. In 1999, the GPO requested a compulsory licence to manufacture Didanosine, an HIV drug.<sup>1115</sup> The request was rejected because it was lodged before the WTO Ministerial Meeting in Seattle and the Thai government wanted to avoid any potential trade dispute with the US.<sup>1116</sup> To circumvent patent infringement of Didanosine, the GPO had to develop a new formulation (in powder form) of the medicine.<sup>1117</sup> However, the new drug caused digestive difficulties and produced side effects.<sup>1118</sup> Clearly, there had been a substantial market demands for HIV generic drugs in Thailand.

In order to analyse Thai government use licensing, the author will group these licences into two time periods linked to the White Papers: 2006 – 2007 and 2008.

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<sup>1111</sup> Phamax, 'Healthcare Market Access: Thailand' (January 2015) 48

<<http://www.phamax.ch/Uploads/02082016040501AM.pdf>> accessed 23 July 2017.

<sup>1112</sup> *Ibid.*, 46.

<sup>1113</sup> National Health Security Act B.E. 2545 (A.D. 2002), adopted on 11 November B.E. 2545.

<sup>1114</sup> Issue No.1: What is the rationale behind the Government Use of Patents on the drugs? Is this movement in compliance with the national and international legal framework? (White Paper 2007, *supra* note 1037).

<sup>1115</sup> Nathan Ford *et al.*, 'The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand' (2004) 363 *The Lancet* 560, 560.

<sup>1116</sup> *Ibid.*

<sup>1117</sup> Preeti Sinha, 'Special 301: An Effective Tool against Thailand's Intellectual Property Violations' (1993) 1 Pacific Rim law and Policy Journal 281, 294; Samira Guennif and Claude Mfuka, 'Impact of Intellectual Property Rights on Aids Public Health Policy in Thailand' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 145.

<sup>1118</sup> Suwit Wibulpolprasert *et al.*, 'Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership' (2011) 7 *Globalization and Health* 1, 3.

#### **7.4.1 The first period: late 2006 till early 2007**

The first period of Thai use covered two types of diseases: HIV/AIDS and cardiovascular diseases.

Viewing HIV/AIDS as an epidemic, in 2003 Thailand started to provide free ARVs for HIV/AIDS patients.<sup>1119</sup> The infection rate in the country has always been well controlled, at around 1.1%.<sup>1120</sup> However, the healthcare budget expanded from around 4% in the 1980s to almost 10% in 2007, and the ARV fund increased more than tenfold in the six years following 2001.<sup>1121</sup>

Financial difficulties were aggravated by the growing number of patients, which rose from 20,000 in 2003 to approximately 120,000 in 2007.<sup>1122</sup> Thai HIV patients, like HIV patients elsewhere, became resistant to the old drugs and needed newer treatments, which were under patent, and therefore much more expensive. The budget deficit, together with high prices, hindered the government of Thailand from accomplishing its national goals. Therefore, in April 2005, the Thai government established an Ad Hoc Working Group to negotiate the prices of certain essential patented drugs.<sup>1123</sup> However, this group failed to achieve price discounts.<sup>1124</sup>

Left with no other choice, the country decided to exercise government use power. In fact, in 2005, the WB had recommended Thailand to consider this option, in order to allow local production of patented second-line ARVs.<sup>1125</sup> On 29 November 2006, citing public health as a reason, the Thai Minister of Health publicly announced the government use of Efavirenz for non-commercial purposes.<sup>1126</sup> This medicine, which is a first line treatment, is one of the safest and most highly effective ARV drugs, with very low side-effects. However, the Thai people had difficulties in accessing this medicine because Efavirenz was under patent protection,

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<sup>1119</sup> Beatrice Stirner, ‘Learning from Practice: Compulsory Licensing Cases and Access to Medicines’ (2012) 1 Pharmaceutical Patent Analyst 555, 562.

<sup>1120</sup> UNAIDS. ‘Thailand’ (2016) <<http://www.unaids.org/en/regionscountries/countries/thailand>> accessed 29 October 2017.

<sup>1121</sup> Issue No.1: What is the rationale behind the Government Use of Patents on the drugs? Is this movement in compliance with the national and international legal framework? (White Paper 2007, *supra* note 1037).

<sup>1122</sup> Beatrice Stirner, ‘Learning from Practice: Compulsory Licensing Cases and Access to Medicines’ (2012) 1 Pharmaceutical Patent Analyst 555, 562.

<sup>1123</sup> Public Health Ministerial Order, No. 360/B.E. 2548 (A.D. 2005) (White Paper 2007, *supra* note 1037).

<sup>1124</sup> Brief Report of the Output form the Ad Hoc Working Group for Price Negotiation of the Patented Essential Drugs (White Paper 2007, *supra* note 1037).

<sup>1125</sup> Charles T. Collins-Chase, ‘Comment: The Case Against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics’ (2008) 29 University of Pennsylvania Journal of International Law, 763, 786 – 787.

<sup>1126</sup> Compulsory licensing for Efavirenz of 29 November 2006 (White Paper 2007, *supra* note 1037).

which contributed to the unaffordable price and hampered the market entry of generics. The government of Thailand asserted that the current price of 1,400 Bath per month, charged by the patent owner, was double that of the generic manufactured in India, i.e. 650 Bath.<sup>1127</sup>

Compulsory licensing for Efavirenz was subject to the following conditions: the licence would last until the end of 2011, and only 200,000 patients covered by government-funded insurance would be entitled to the treatment. Thailand assigned the GPO as the only party to import or locally produce the medicine. A royalty fee of 0.5% would be paid to the patent holding company - Merck.

Not long after such a grant, the GPO imported the generic of Efavirenz from an Indian company while waiting for the local production, which was set to start later that year.<sup>1128</sup> At the same time, Merck carried out informal negotiations with the Thai Ministry in the hope of overturning the decision. In February 2007, the company agreed to reduce the price of Efavirenz to \$0.72 per tablet for Thai patients (around 780 Bath per bottle) and by 14.5% for other countries that were hardest hit by AIDS.<sup>1129</sup> However, as Thailand had placed a large order from India which would last for several months, the government had to compare the prices and conditions before making a final decision.<sup>1130</sup>

Two months after the first announcement, on 25 January 2007, Thailand announced to mandatorily license the patents of Lopinavir and Ritonavir (Kaletra®), owned by Abbott, and declared them to be under the government use.<sup>1131</sup> This medication is a second line treatment and is often used for patients who have become resistant to the basic formulation of HIV drugs, such as Efavirenz. The price charged by Abbott was around 72,000 Bath (appx. \$2,200) per year per patient, which was a significant burden for the national health budget.<sup>1132</sup> Right after the announcement, Abbott further lowered the price of Kaletra to \$1,000, arguing that such a

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<sup>1127</sup> Compulsory licensing for Efavirenz of 29 November 2006 (White Paper 2007, *supra* note 1037).

<sup>1128</sup> Jenny Wakely, 'The Impact of External Factors on the Effectiveness of Compulsory Licensing as a Means of Increasing Access to Medicines in Developing Countries' (2011) 33 EIPR 756, 762.

<sup>1129</sup> Letter from the Managing Director of Merck Sharp and Dohme (6 February 2007) to the Director General of the Disease Control Department and Announcement by Merck Sharp and Dohme (14 February 2007) (White Paper 2007, *supra* note 1037).

<sup>1130</sup> Issue No.3, Why has the Ministry of Public Health turned down requests from drug companies to discuss and negotiate, even after issuing the Government Use of patent? Is there any better way than compulsory licensing to improve access to medicines? (White Paper 2007, *supra* note 1037).

<sup>1131</sup> Compulsory licensing for Kaletra of 24 January 2007 (White Paper 2007, *supra* note 1037).

<sup>1132</sup> Issue No. 5: The Government Use of Patents will save the government some funds but what are the benefits to the people? (White Paper 2007, *supra* note 1037).

price is lower than any generic price available and is approximately 55% cheaper than the current average price in developing and LDCs.<sup>1133</sup>

However, the Thai government wanted the price to be less than \$400, hence it insisted on compulsory licensing.<sup>1134</sup> According to the grant, the compulsory licence for Kaletra would be valid until 31 January 2012, the medicine was confined to 250,000 individuals under the national health schemes, and Abbot would receive a royalty rate of 0.5%.<sup>1135</sup>

Even though these licences were controversial, they were not the ones that made headlines. On 26 January 2007, after the decision made on Kaletra, Thailand also exercised government power over Clopidogrel (Plavix®), a blood thinner used to treat heart diseases.<sup>1136</sup> This was a further blow to the global pharmaceutical industry, because it was the first time that a compulsory licence had been granted to cover a chronic disease. According to the grant, heart diseases are ranked among the top three causes of death in Thailand annually. Clopidogrel was included in the essential list, but could not be distributed to all patients because the medicine is expensive under patent protection and the government lacked sufficient finances.<sup>1137</sup> Accordingly, only 20% of patients who came within the scope of the universal coverage scheme had access to it.<sup>1138</sup> The government expected that, by use of the compulsory licence, the price would fall dramatically from 73 Baht per day to 7 Baht,<sup>1139</sup> and accessibility would increase 6 to 12 times.<sup>1140</sup>

Unlike previous compulsory licences, which were of limited duration, that on Plavix could be exercised until the patent expired or until there was no longer an essential need. Furthermore,

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<sup>1133</sup> Stephanie Skees, ‘Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?’ (2007) 19 Pace International Law Review 233, 242.

<sup>1134</sup> Yiming Shao, ‘A Practical Way to Improve Access to Essential Medicines Against Major Infectious Diseases’ in Yichen Lu and others (eds) *HIV/AIDS Treatment in Resource Poor Countries. Public Health Challenges* (Springer 2012) 63.

<sup>1135</sup> Compulsory licensing for Kaletra of 24 January 2007 (White Paper 2007, *supra* note 1037).

<sup>1136</sup> Compulsory licensing for Plavix of 25 January 2007 (White Paper 2007, *supra* note 1037).

<sup>1137</sup> Issue No.1: What is the rationale behind the Government Use of Patents on the drugs? Is this movement in compliance with the national and international legal framework? (White Paper 2007, *supra* note 1037).

<sup>1138</sup> Compulsory licensing for Plavix of 25 January 2007 (White Paper 2007, *supra* note 1037).

<sup>1139</sup> Compulsory licensing for Plavix of 25 January 2007 (White Paper 2007, *supra* note 1037).

<sup>1139</sup> Issue No.5: The government use of patents will save the government some funds but what are the benefits to the people? (White Paper 2007, *supra* note 1037).

<sup>1140</sup> Compulsory licensing for Plavix of 25 January 2007 (White Paper 2007, *supra* note 1037).

anyone protected by the national health system would have access to the medicine. The Thai government paid a royalty fee of 0.5% to the right owner.<sup>1141</sup>

The Thai licences incurred the wrath of the pharmaceutical industry, to the extent that the government felt the need to justify its actions. In February 2007, the Ministry of Public Health and the National Health Security Office issued a White Paper entitled ‘Facts and Evidence on the Ten Burning Issues Relating to the Government Use of Patents in Thailand’ to answer all the concerns that had been raised and list all the criteria for the selection of the drugs. This document went a step beyond merely dispelling doubts. It aimed to ‘inform and educate Thai and Global Society as a whole on the issue of pharmaceutical patent and the public health’.<sup>1142</sup> Remarkably, the Paper also disclosed Thailand’s intention to issue additional licences for up to 15% of all patented drugs.<sup>1143</sup>

It should be emphasised here that while these measures were taken, Thailand was facing a political crisis. Until 2006, Thailand was represented by the Prime Minister, Thaksin Shinawatra, who was responsible for the initiation of Thai-US FTA negotiations in June 2004.<sup>1144</sup> It is worth noting that, through this FTA, the US sought to restrict the compulsory licensing mechanism. On 19 September 2006, taking advantage of the absence of Thaksin at the United Nations General Assembly, the Thai military seized power, appointing a new cabinet and a new National Assembly. The FTA was therefore put on hold.

#### **7.4.2 The second period: early 2008**

The intention to issue more compulsory licences in Thailand was no longer merely stated on paper. In June 2007, the government established two exploratory committees to consider compulsory licensing of cancer medications. However, twelve rounds of negotiations, from October to December 2007, yielded no significant results.

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<sup>1141</sup> Compulsory licensing for Plavix of 25 January 2007 (White Paper 2007, *supra* note 1037).

<sup>1142</sup> ‘Preface’ (White Paper 2007, *supra* note 1037).

<sup>1143</sup> Issue no.4: What are the mechanisms and criteria used to determine which drugs to issue Government use of Patent and also the royalty fees? Will there be additional Government use for more drugs in the near future? Would these movements eventually lead to the failure of the IP systems? (White Paper 2007, *supra* note 1037).

<sup>1144</sup> Gaëlle Krikorian, ‘The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand’ in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property Contestation Over the Ownership, Use, and Control of Knowledge and Information* (EE 2009) 32.

At the same time, a general election was held in Thailand in December 2007, the first legislative election since the coup in 2006. A new government was established, and on 4 January 2008, less than a month before leaving office, the Thai Minister of Health announced the government use of four anti-cancer medicines.<sup>1145</sup>

It was argued that cancer was the main cause of mortality in Thailand for over a decade, and consequently was no less serious than HIV/AIDS.<sup>1146</sup> Nevertheless, since newly patented anti-cancer medicines are neither on the essential list nor covered by any of national health insurance schemes owing to their costliness, patients have to pay out of their own pocket. These drugs could not be accessed by the poor, or even by many members of the middle class. As a result, they either exhausted all their money or stopped taking the medicine, thus imposing a serious public health burden on the government.

According to these grants, the government had tried to negotiate with the right holders for price cuts but there had been no satisfactory outcome. Consequently, the Thai cabinet had to exercise the authorisation allowed under Section 51 of the Patent Act. These licences were to be effective until the patent expired or until no essential need existed, and they would be given to those patients who were eligible under the public-funded health scheme. The royalties ranged from 3% to 5%.

However, unlike previous licences which had been implemented without delay, the Thai government left its decisions open by undertaking further negotiations with the patent owners. This brought about an acceptable result: Novartis agreed to supply the medicine free to hundreds of Thai patients meeting certain requirements. The government therefore revoked the decision on Glivec.<sup>1147</sup> For other medicines, no agreement could be reached, and so Thailand continued its policy.

On 7 February 2008, on the first day of taking office, the new Thai Minister of Health announced that he would re-evaluate his predecessor's decisions and their impacts on the

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<sup>1145</sup> Compulsory licensing for these medicines can be found in White Paper 2008, *supra* note 1037.

<sup>1146</sup> Question 1: What is the rationale for the implementation of the Government Use of Patents on the four anti-cancer drugs? (White Paper 2008, *supra* note 1037).

<sup>1147</sup> Letter from Novartis Asia Pacific Pharmaceuticals Pte Ltd to Minister of Public Health of 23 January 2008 and compulsory licensing for Imatinib of 25 January 2008 (White Paper 2008, *supra* note 1037).

relationship with the US.<sup>1148</sup> The Minister cited Thailand's listing on the USTR Priority Watch List as a main reason for the review.<sup>1149</sup> Ultimately, he did not revoke any compulsory licences and a second White Paper was published, defending the licences issued in the second period. Like the first Paper, this one, entitled 'The 10 Burning Questions on the Government Use of Patents on the four anti-cancer drugs in Thailand', provided supporting evidence for Thai government use.<sup>1150</sup>

### 7.4.3 Reactions to Thai compulsory licences

Thailand's government use licences, like other compulsory licensing activities, created a dichotomy between supporters and objectors. While the country met with international praise and the congratulations of public health activists for advancing the access to medicines, the patent advocates fiercely criticised the Thai policy for expropriating private property.

On the one hand, UNAIDS, a UN agency that coordinated global actions on the HIV/AIDS pandemic, described Thai actions as 'strong and steadfast efforts' on behalf of people living with HIV.<sup>1151</sup> MSF, who welcomed the Thai licences, wrote a letter to the US trade representative - Ambassador Schwab, asking the US and the USTR not to interfere with the Thai decisions.<sup>1152</sup> MSF went even further, stating that Thailand's compulsory licences 'will create a larger global market for generic drugs, stimulate competition and lower prices everywhere for the newer products'.<sup>1153</sup> The Third World Network (an NGO) asserted that these licences were consistent with TRIPS and encouraged the country to make further use of TRIPS flexibilities.<sup>1154</sup> The Consumer Project on Technology (currently known as KEI) showed strong support for Thailand and requested the US not to put pressure on the country.<sup>1155</sup>

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<sup>1148</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 170.

<sup>1149</sup> 'Compilation of submissions – Asia-Pacific Regional Dialogue' (Global Commission on HIV and the Law, Bangkok, 16 -17 February 2011) 16 <<https://hivlawcommission.org/report-resources/submissions/>> accessed 7 March 2018.

<sup>1150</sup> White Paper 2008, *supra* note 1037.

<sup>1151</sup> Letter of UNAIDS to the Thai Minister of Health of 26 December 2006 (White Paper 2007, *supra* note 1037).

<sup>1152</sup> Letter of Medicines Sans Frontieres to US Ambassador Susan Schwab of 29 December 2006 (White Paper 2007, *supra* note 1037).

<sup>1153</sup> Letter of Medicines Sans Frontieres to US Ambassador Susan Schwab of 29 December 2006 (White Paper 2007, *supra* note 1037).

<sup>1154</sup> Letter of Third World Network to the Thai Minister of Health of 23 February 2007 (White Paper 2007, *supra* note 1037).

<sup>1155</sup> Letter of Consumer Project on Technology to the Thai Minister of Health of 11 December 2006 (White Paper 2007, *supra* note 1037).

They ran a series of blogs and articles to justify the legitimacy of the Thai licences.<sup>1156</sup> The Clinton Foundation expressed the same support, on the grounds that the licences ‘ensure more affordable access to high quality ARV drugs’.<sup>1157</sup> Obviously, to the general public, promoting medicines accessibility, particularly in less-developed countries, is always a welcome move, even when it is done at the expense of the pharmaceutical industry.

On the other hand, the Thai series of compulsory licences provoked a storm of controversy from the press, OECD countries, patent holding companies and the academia. In the media, the BBC portrayed Thailand as the ‘violator of IPRs’.<sup>1158</sup> The most vocal of the newspapers hostile to the Thai government’s actions was the Wall Street Journal. It ran a series of editorials characterising the compulsory licences as ‘theft’,<sup>1159</sup> a ‘seizure of foreign drug patents’, a ‘frontal attack on property rights’, and described those who supported Thailand as ‘anti-patent hooligans’.<sup>1160</sup> Other journals, such as the Guardian, the Financial Times, to a lesser extent, hinted that Thailand was violating international law.<sup>1161</sup>

Counteractions came from Western governments too. In spring 2007, the US Senate urged the USTR to respond strongly to Thailand, as they worried that such a practice might initiate new policies to expropriate patents without any significant public health grounds.<sup>1162</sup> In April 2007, the US condemned Thailand’s compulsory licences, stating that they represented ‘a serious concern’ and placed the country on its Special 301 ‘Priority Watch List’.<sup>1163</sup> In July 2007, the USTR removed some Thai products from the GSP programme.<sup>1164</sup>

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<sup>1156</sup> ‘Thailand’s Compulsory Licensing Controversy’ (KEI 20 June 2007) <<https://www.keionline.org/25989>> accessed 24 March 2018.

<sup>1157</sup> Letter of Clinton Foundation to the Thai Minister of Public Health of 16 February 2007 (White Paper 2007, *supra* note 1037).

<sup>1158</sup> Jonathan Head, ‘Thailand takes on drugs giants’ (BBC, 26 April 2007) <<http://news.bbc.co.uk/1/hi/world/asia-pacific/6587379.stm>> accessed 18 June 2017.

<sup>1159</sup> Editorial, ‘Theft in Thailand’ *The Wall Street Journal* (10 February 2007).

<sup>1160</sup> Editorial, ‘Bangkok’s Drug War Goes Global’ *The Wall Street Journal* (7 March 2007).

<sup>1161</sup> David Batty and agencies, ‘Clinton backs violation of Aids drug patents’ *The Guardian* (9 May 2007) <<https://www.theguardian.com/world/2007/may/09/aids.davidbatty>> accessed 7 March 2018; Amy Kazmin and Andrew Jack, ‘Thai government to break drug patents’ *Financial Times* (25 January 2007) <<https://www.ft.com/content/6889bbbc-ac98-11db-9318-0000779e2340?mhq5j=e2>> accessed 7 March 2018.

<sup>1162</sup> These letters can be found on the website of the CPT under the section ‘Government Documents’ <<http://www.cptech.org/ip/health/c/thailand/>> accessed 7 March 2018.

<sup>1163</sup> USTR, ‘Special 301 Report’ (Reports and Publications, 2007) 27 <<https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/archives/2007/2007-special-301-report>> accessed 7 March 2018.

<sup>1164</sup> Suwit Wibulpolprasert *et al.*, ‘Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership’ 7 (2011) *Globalization and Health* 1, 5.

At the same time, the US Ambassador, Ralph Boyce, wrote a letter directly to Thailand's Prime Minister, criticising Thai decisions.<sup>1165</sup> In this letter, the Ambassador agreed that WTO members could make appropriate use of flexibilities to address urgent situations, but 'these decisions should not be made lightly and only as a last resort'.<sup>1166</sup> In addition, he also requested the Ministry of Public Health to involve the pharmaceutical companies in the decision-making process in an open and transparent manner.<sup>1167</sup>

Although Thai government use licensing was issued by the Ministry of Health, the Ministry of Commerce was unavoidably engaged in the affair. In July 2007, the EU Trade Commissioner, Peter Mandelson, in a letter to Thailand's Minister of Commerce, complained about the Thai approach.<sup>1168</sup> Although he recognised the right to grant compulsory licensing, this legal measure, in his view, should be used at a last resort where all means had been explored but had failed to enhance the access to medicines.<sup>1169</sup> He therefore requested the Minister of Commerce to review the policy, in liaison with the Ministers of Foreign Affairs and Public Health, and to enter negotiations with patent holders.<sup>1170</sup> It is a very classic example of how trade pressure can potentially modify the IP policies of a developing country. The close interconnection between trade and IP is getting clearer particularly in the modern economy where world countries are becoming not only economically interdependent, but they also want to ensure cooperation in different areas including IPRs.

At the same time, Switzerland, the head office location of Novartis and Roche, two pharmaceutical companies that were the target of Thai compulsory licences, was believed to issue a public 'Aide Memoire' to express a concern over Thai actions.<sup>1171</sup> The document stated that if compulsory licensing was 'used not only in emergencies and other exceptional cases, but systematically for all kinds of pharmaceuticals', the patent system and R&D would be

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<sup>1165</sup> Gaëlle Krikorian, 'The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand' in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property Contestation Over the Ownership, Use, and Control of Knowledge and Information* (EE 2009) 33-34

<sup>1166</sup> 'Compilation of submissions – Asia-Pacific Regional Dialogue' (Global Commission on HIV and the Law, Bangkok, 16 -17 February 2011) 16 <<https://hivlawcommission.org/report-resources/submissions/>> accessed 7 March 2018.

<sup>1167</sup> *Ibid.*

<sup>1168</sup> The letter of Peter Mandelson to Thailand's Minister of Commerce of 10 July 2007 <<https://www.keionline.org/wp-content/uploads/mandelson07102007.pdf>> accessed 7 March 2018.

<sup>1169</sup> *Ibid.*

<sup>1170</sup> *Ibid.*

<sup>1171</sup> Cynthia M. Ho, 'Patent Breaking or Balancing? Separating Strands of Fact from Fiction Under Trips' (2009) 34 N.C. J. of Int'l. L. & Com. Reg. 371, 451.

detrimentally affected.<sup>1172</sup> Switzerland recommended negotiations as a cooperative and constructive solution.<sup>1173</sup>

At the industry level, the patent owners did not sit idle. Sanofi-Aventis, the patent owner of Plavix, threatened legal action against Cadila, an Indian company that was about to supply the generic version to Thailand.<sup>1174</sup> Owing to prospective litigation, Cadila postponed the delivery to the GPO until June 2008, even though the compulsory licence for Plavix had been issued in January 2007.<sup>1175</sup>

Meanwhile, Novartis, another patent owner, warned the Thai government that its decision might have an adverse effect on 900 leukaemia patients who were receiving treatment through the company's philanthropic programme.<sup>1176</sup> This warning seemed more substantial as it gained supports from assistance centres and physicians working in this programme in Thailand.<sup>1177</sup>

Abbott, the patent owner of Kaletra, adopted by far the most antagonistic approach. It took the radical step of withdrawing all seven new patent registrations of medicines from the Thai market, including the newest version of Kaletra (Aluvia), the HIV/AIDS drug, which was carefully formulated so as to work effectively in a tropical climate like that of Thailand.<sup>1178</sup> This was the first retaliatory reaction of a pharmaceutical company in response to a government's grant of a compulsory licence. Moreover, Abbot also sued Act Up-Paris, a group of people living with HIV/AIDS, for attempting to overload the company's website by

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<sup>1172</sup> 'Compulsory licences in Thailand on pharmaceuticals under patent protection' (Aide Memoire, 25 February 2007) <[https://www.ladb.ch/fileadmin/files/documents/Gesundheit/CL\\_in\\_Thailand\\_on\\_pharmaceuticals\\_under\\_patent\\_protection.pdf](https://www.ladb.ch/fileadmin/files/documents/Gesundheit/CL_in_Thailand_on_pharmaceuticals_under_patent_protection.pdf)> accessed 4 February 2015.

<sup>1173</sup> *Ibid.*

<sup>1174</sup> Rupali Mukherjee, 'Pharma firms under US pressure to stop generic sale' (The Times of India, 13 February 2008) <<https://timesofindia.indiatimes.com/business/india-business/Pharma-firms-under-US-pressure-to-stop-generic-sale/articleshow/2777692.cms>> accessed 7 March 2018.

<sup>1175</sup> 'Compilation of submissions – Asia-Pacific Regional Dialogue' (Global Commission on HIV and the Law, Bangkok, 16 -17 February 2011) 16 <<https://hivlawcommission.org/report-resources/submissions/>> accessed 7 March 2018.

<sup>1176</sup> Gaëlle Krikorian, 'The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand' in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property Contestation Over the Ownership, Use, and Control of Knowledge and Information* (EE 2009) 34.

<sup>1177</sup> *Ibid.*

<sup>1178</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233, 242.

multiplying simultaneous connections.<sup>1179</sup> This was the first time that a pharmaceutical company had sued an NGO, and such an action not only expressed the hostile attitude of Abbott but also demonstrated that the battle of compulsory licensing had gone far beyond the conventional boundaries of legal issues.

Abbott's move of withdrawing new medicines generated a public outcry, and sparked protests in Thailand, as well as consumer boycotts of Abbott products globally.<sup>1180</sup> Some NGOs participated in Abbott's annual shareholders' meeting to confront the company's actions.<sup>1181</sup> MSF described Abbott's decision as an 'immoral act'.<sup>1182</sup> In addition, other NGOs filed a complaint to the Thai Trade Competition Commission, containing the accusation that Abbott's withdrawal of new medicine registrations violated the Trade Competition Act.<sup>1183</sup> However, the company was held not to be in breach of the Act.<sup>1184</sup> Eventually, Abbott allowed Aluvia to be sold in Thailand, but only if no compulsory licence were imposed on Aluvia.<sup>1185</sup> However, Abbott continued to withhold six other new drugs from entry into the Thai market.<sup>1186</sup>

In addition, USA for Innovation, an NGO group, condemned the post-coup government for turning Thailand into a dictatorship like Burma, by illegally issuing compulsory licences.<sup>1187</sup> However, other health-related NGOs revealed that this group was the partner of a public relations company, the most important clients of which were Abbott and the ousted prime

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<sup>1179</sup> Gaëlle Krikorian, 'The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand' in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property Contestation Over the Ownership, Use, and Control of Knowledge and Information* (EE 2009) 46.

<sup>1180</sup> Thomas Fuller, 'Thailand takes on drug industry, and may be winning' *The New York Times* (Bangkok, 11 April 2007)

<[http://www.nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html?pagewanted=all&_r=0)> accessed 17 April 2015.

<sup>1181</sup> Jiraporn Limpananont and Kannikar Kijtiwatchakul, 'TRIPS Flexibilities in Thailand: Between Law and Politics' in Gaëlle Krikorian and Amy Kapczynski (eds), *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010) 447.

<sup>1182</sup> Darren Schuettler, 'Angered U.S. firm excludes Thailand from new drugs' (Reuters 14 March 2007) <<https://www.reuters.com/article/us-thailand-drugs-abbott/angered-u-s-firm-excludes-thailand-from-new-drugs-idUSBK27714620070314>> accessed 27 March 2018.

<sup>1183</sup> R Ian McEwin and Sakda Thanitkul, 'Thailand: Medicines, Competition Law and Compulsory licensing' in R Ian McEwin (edn) *Intellectual Property, Competition Law and Economics in Asia* (Hart Publishing 2011) 296.

<sup>1184</sup> *Ibid.*

<sup>1185</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233, 242.

<sup>1186</sup> *Ibid.*

<sup>1187</sup> Gaëlle Krikorian, 'The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand' in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property Contestation Over the Ownership, Use, and Control of Knowledge and Information* (EE 2009) 45; Jiraporn Limpananont and Kannikar Kijtiwatchakul, 'TRIPS Flexibilities in Thailand: Between Law and Politics' in Gaëlle Krikorian and Amy Kapczynski (eds), *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010) 444.

minister - Thaksin.<sup>1188</sup> Whatever the truth of the accusation may be, both sides pushed the limits to the extreme.

Thailand's compulsory licensing also sparked criticism from academia. Bate condemned Thailand's lack of dialogue with the pharmaceutical companies and described the compulsory licences as 'attacks' on the industry and the worldwide patent system.<sup>1189</sup> Most interestingly, in 2011, Kuanpoth, a well-known Thai IP expert, gave a warning against compulsory licensing, and suggested that developing countries should consider this option carefully before adopting it.<sup>1190</sup> However, in another work in 2014, he surprisingly contradicted himself by praising these licences and strongly recommending other developing countries to follow suit.<sup>1191</sup> Lybecker and Fowler were of the opinion that, in the case of Thailand, compulsory licensing had been intended to serve the industrial policy (the GPO), rather than the public health policy.<sup>1192</sup> Adelman expressly described the Thai actions as 'theft'.<sup>1193</sup>

## 7.5 An evaluation of Thailand's policy from a legal perspective

Thailand's government use licences were subject to strong criticism for many reasons. This section will provide an evaluation of Thai policy, taking each criticism in turn.

### 7.5.1 The justification for the Thai government's policies

As stated in the grants, Thai compulsory licences were aimed at addressing the health care purpose in the country. However, in the eyes of the patent advocates, this justification was open to serious doubts. The argument that government use licensing was a solution to a lack of finance, failed to convince the critics. Many believed that the country, having a middle-income

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<sup>1188</sup> Jiraporn Limpananont and Kannikar Kijtiwatchakul 'TRIPS Flexibilities in Thailand: Between Law and Politics' in Gaëlle Krikorian and Amy Kapczynski (eds) *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010) 444

<sup>1189</sup> Roger Bate, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013.

<sup>1190</sup> Jakkrit Kuanpoth, 'Proceed with caution on Compulsory Licensing' (Tilleke and Gibbins, 28 February 2011) <<http://www.tilleke.com/resources/proceed-caution-compulsory-licensing>> accessed 7 March 2018.

<sup>1191</sup> Jakkrit Kuanpoth, 'Compulsory Licences: Law and Practice in Thailand' in Reto M. Hilty and Kung-Chung Liu (eds), '*Compulsory licensing: Practical Experiences and Ways Forward*' (Springer 2015) 75.

<sup>1192</sup> Kristina M. Lybecker and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 *Journal of Law, Medicine and Ethics* 222, 229.

<sup>1193</sup> Hugh C Hansen (ed), *Intellectual Property Law and Policy. Volume 10* (Hart Publishing 2008) 961.

status, with a GDP ranked 33<sup>rd</sup> among 183 nations in 2006, could have afforded the medicines without resorting to compulsory licensing.<sup>1194</sup>

However, this thesis argues that among the dozen clauses of TRIPS Article 31, it is nowhere stated that middle income countries are excluded from granting a compulsory licence. Therefore, citing Thailand's wealth as a reason for rejecting its right to use the compulsory licence is not a valid argument. In fact, it is well documented that even developed nations have used this legal solution in the competition law context, as previously noted in Chapter 4. Therefore, this thesis argues that Thailand is entitled to grant compulsory licences.

The opponents further pointed out that, while the money spent on public healthcare was reduced by \$12 million per annum,<sup>1195</sup> the junta increased the military budget by almost 50% from 2006.<sup>1196</sup> The author views that this counter argument was not entirely baseless, if we recall the political climate at the time those licences were being implemented. In fact, because of regular occurrence of military coups, Thailand has frequently increased the defence budget at the expense of other priorities.<sup>1197</sup> In addition, Thailand was also criticised for its modest expense on healthcare. The Thai government only spent 3.3% of its GPD on health policies, whereas other middle-income countries allocated a bigger fund to health, for example, Brazil and China spent 7.6% and 5.6% of their GPD, respectively.<sup>1198</sup>

Moreover, the fact that Thailand levied a 10% tariff on almost all imported medicines (excluding vaccines and therapies for HIV, malaria and thalassemia) and 7% VAT on all

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<sup>1194</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233, 244; Ronald A. Cass, 'Compulsory licensing of Intellectual Property: The Exception that Ate the Rule?' (2007) Washington Legal Foundation, Working Paper Series No. 150 <[http://www.wlf.org/publishing/publication\\_detail.asp?id=1902](http://www.wlf.org/publishing/publication_detail.asp?id=1902)> accessed 7 March 2018; Roger Bate, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013; Feldman Jamie, 'Compulsory Licenses: The Dangers Behind the Current Practice' (2009) 8 Journal of International Business and Law 137, 151.

<sup>1195</sup> Kristina M. Lybecker and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 Journal of Law, Medicine and Ethics 222, 233.

<sup>1196</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233, 244 - 245

<sup>1197</sup> Edward Kelly, 'Thailand: Compulsory licences. Finding a middle ground' (2011) 40 Managing IP 1, 66 - 67; Prashanth Parameswaran, 'The Truth About Thailand's 2017 Defense Budget 'Hike'' *The Diplomat* (10 September 2016) <<https://thediplomat.com/2016/09/the-truth-about-thailands-2017-defense-budget-hike/>> accessed 16 January 2018.

<sup>1198</sup> Roger Bate, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013.

medicines was said to cause high prices.<sup>1199</sup> Pipes voiced the criticism that Thailand simply did not want to pay more for patented medicines, and described the country's actions in breaching patents as that of a '21<sup>st</sup> Century Robin Hood'.<sup>1200</sup> For these reasons, some authors arrived at the same conclusion, which is that Thailand's compulsory licences have very little to do with public health emergencies and much more to do with economic and political priorities.<sup>1201</sup> Indeed, it could be deduced from the political exigencies in Thailand that increasing defence spending led to cuts in other areas, for example public health.

### 7.5.2 Public non-commercial use

Some have contended that Thailand's government use licences did not qualify as public non-commercial.<sup>1202</sup> The source of this distrust was the GPO, the only organisation taking part in manufacturing or importing the generics under the compulsory licences. Some claimed that the GPO is a profit-making enterprise, which therefore seems not to qualify as 'non-commercial'.<sup>1203</sup> The GPO claimed to have made a profit of 642 million Baht in 2003, rising

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<sup>1199</sup> Kristina M. Lybecker and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 Journal of Law, Medicine and Ethics 222, 233.

<sup>1200</sup> Sally Pipes, 'Thailand's misuse of "compulsory licensing" allowed corrupt officials to steal millions' (Pacific Research, 31 March 2008)

<[http://www.pacificresearch.org/home/article-detail/?tx\\_ttnews%5Btt\\_news%5D=4771&ndcHash=33013dc7aea5329ce004274edf969d5a](http://www.pacificresearch.org/home/article-detail/?tx_ttnews%5Btt_news%5D=4771&ndcHash=33013dc7aea5329ce004274edf969d5a)> accessed 20 April 2015.

<sup>1201</sup> Roger Bate, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013; Kristina M. Lybecker and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 Journal of Law, Medicine and Ethics 222, 229; Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233; Sally Pipes, 'Thailand's misuse of "compulsory licensing" allowed corrupt officials to steal millions' (Pacific Research, 31 March 2008)

<[http://www.pacificresearch.org/home/article-detail/?tx\\_ttnews%5Btt\\_news%5D=4771&ndcHash=33013dc7aea5329ce004274edf969d5a](http://www.pacificresearch.org/home/article-detail/?tx_ttnews%5Btt_news%5D=4771&ndcHash=33013dc7aea5329ce004274edf969d5a)> accessed 20 April 2015.

<sup>1202</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233; Roger Bate, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013; Kristina M. Lybecker and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 Journal of Law, Medicine and Ethics 222; Edward Kelly, 'Thailand: Compulsory licences. Finding a middle ground' (2011) 40 Managing IP 1, 67.

<sup>1203</sup> Jeremiah Norris, 'The Unravelling of Compulsory Licenses – Evidence from Thailand and India', (International Policy Network, May 2007); Edward Kelly, 'Thailand: Compulsory licences. Finding a middle ground' (2011) 40 Managing IP 1, 67

to 1 billion Baht in 2005.<sup>1204</sup> It was said to have increased its revenue to 10 billion Baht by 2010.<sup>1205</sup>

Moreover, some authors have questioned the quality of the medicines manufactured by the GPO. They cited a study in 2005, which stated that drugs produced by this enterprise were inferior to the actual patented products, because they were not approved by the WHO.<sup>1206</sup> Unapproved drugs could be ineffective or could lead to drug resistance. After four years of pre-testing, the WHO still refused to list this drug in its pre-qualification programme.<sup>1207</sup> Since 2002, the WHO has recommended that this medicine should not be sold outside of Thailand, because the country had failed to prove its bio-equivalence.<sup>1208</sup>

At the same time, those supporting Thai compulsory licensing rebutted the accusation, claiming that the 2005 study did not provide references, and that the drug resistance rate is not related to the quality of the medicine at all.<sup>1209</sup> They argued that, as long as these medicines received marketing approval from the Thai FDA, their standards of safety and efficacy were met.<sup>1210</sup>

Nevertheless, this thesis maintains that it is difficult to accept that drug resistance has nothing to do with the quality of a medicine. As the WHO explains, side-effects can reduce the durability of current first-line treatments in some patients, in which case they would have to be switched to more expensive second-line or even third-line regimes.<sup>1211</sup> With higher levels of drug resistance, more resources would be needed to treat the same number of patients, or, what is more likely, fewer patients could be treated with the same resources.<sup>1212</sup> From a healthcare perspective, drug resistance will lead to higher treatment costs, thus undermining the justification for the Thai programme. In October 2006, the Global Fund to Fight HIV/AIDS

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<sup>1204</sup> Kristina M. Lybecker and Elisabeth Fowler, ‘Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules’ (2009) 37 *Journal of Law, Medicine and Ethics* 222, 232.

<sup>1205</sup> *Ibid.*

<sup>1206</sup> Daniel Ten Kate, ‘Safe at Any Cost?’ *Asia Sentinel* (Hong Kong, 24 January 2007); Jeremiah Norris, ‘The Unravelling of Compulsory licenses – Evidence from Thailand and India’ (International Policy Network, May 2007).

<sup>1207</sup> Jeremiah Norris, ‘The Unravelling of Compulsory licenses – Evidence from Thailand and India’ (International Policy Network, May 2007).

<sup>1208</sup> Jeremiah Norris, ‘The Unravelling of Compulsory licenses – Evidence from Thailand and India’ (International Policy Network, May 2007).

<sup>1209</sup> Jiraporn Limpananont and Kannikar Kijtiwatchakul, ‘TRIPS Flexibilities in Thailand: Between Law and Politics’ in Gaëlle Krikorian and Amy Kapczynski (eds) *Access to Knowledge in the Age of Intellectual Property* (Zone Books 2010) 444.

<sup>1210</sup> *Ibid.*

<sup>1211</sup> WHO, ‘Development of the Global Action Plan on HIV drug resistance, 2017-2021’ <<http://www.who.int/hiv/drugresistance/hivdr-action-plan-2017-2021/en/>> accessed 12 June 2017.

<sup>1212</sup> *Ibid.*

withdrew its funding of \$133 million which had previously been granted for the GPO in 2003 to upgrade its manufacturing plant so as to meet international standards.<sup>1213</sup> The reason given was the GPO's failure to meet WHO standards.

The historical corruption within the GPO was also a factor that cast doubt on whether Thai compulsory licensing was granted for the public purpose. In 2002, the GPO was found to have stolen approximately \$13 million from the government over the previous four years.<sup>1214</sup> It was criticised for selling about 60% of its medical products to government agencies at above market prices.<sup>1215</sup> In some cases, products were marked up by 1000%.<sup>1216</sup> Consequently, the real motives of the Thai government, which claimed to be promoting public health, were brought into question.

As confirmed in Section 4.2.4.2, neither TRIPS nor Doha define the term 'public non-commercial use'. For this reason, national laws have complete freedom to determine how this term should be understood. However, as this thesis argued in the same Section, even though a compulsory licence is issued to a private entity, it can still be considered as for the public, provided that the chief aim is to bring benefit thereto. Thai non-voluntary licences were of this kind. They were issued by the government to render a benefit to the nation. Moreover, such licences only applied to those covered by public health insurance, as stated in the grants. Those who could afford out-of-pocket payment were excluded.

Although many attacked the profit-making nature of the GPO, this thesis submits that it is important to draw a clear distinction between the character of the entity which undertakes the compulsory licences and the nature of those licences *per se*. As long as the aim of a mandatory licence is to serve the society, it is regarded as not-for-profit, even though the entity exploiting the licence is a commercial entity. That was the case of the GPO. The author's view is also supported by Deroo, who rejected the idea that the involvement of the GPO gave those licences

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<sup>1213</sup> Daniel Ten Kate, 'Safe at Any Cost?' *Asia Sentinel* (Hong Kong, 24 January 2007); Jeremiah Norris, 'The Unravelling of Compulsory licenses – Evidence from Thailand and India' (International Policy Network, May 2007).

<sup>1214</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233, 246.

<sup>1215</sup> *Ibid.*

<sup>1216</sup> Roger Bate, 'Thailand and the Drug Patent Wars' (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013.

a commercial purpose.<sup>1217</sup> He argued that when healthcare is a government-run and government-funded enterprise, the licences ‘fall squarely within the meaning of public non-commercial use’.<sup>1218</sup>

However, this thesis argues that such a grey area could have been dispelled if other entities, both local and international, took part in the Thai government use policy, thereby enabling competition amongst them as well as ensuring the quality of the medicine. The fact that only the GPO, having controversial business practices and holding a monopoly position in the Thai market, was requested to participate in the process invited criticism. In other words, the author views that there was a lack of transparency during the implementation of the Thai compulsory licensing.

### 7.5.3 The legitimacy of the Thai post-coup government

Another factor which gave rise to great controversy over Thailand’s government use is the presence of the military junta. The post-coup government was condemned for paying no regard to IP rights and was accused of using populist rhetoric and policies to curry favour with the Thai people.<sup>1219</sup> Also owing to the coup d’état, the Thai Minister of Health had *carte blanche* in the decision-making process, and did not seek advice from other ministries, such as the Ministry of Commerce or Ministry of Foreign Affairs.<sup>1220</sup> This situation contrasts with that of Brazil, where there were consultations between ministries, as described in the previous chapter. Skees accused the interim government of being irresponsible in their granting of several compulsory licences, as they were not accountable to anyone, and that they would leave the next elected regime to clear up the mess.<sup>1221</sup>

The author believed that such criticism is not wholly unfounded as there was a shift in the country’s policy right after a democratic government was elected at the end of 2007. As previously mentioned in Section 7.4.2, after the election, the newly appointed Minister of Health

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<sup>1217</sup> Pier DeRoo, “Public Non – commercial Use” compulsory licensing for pharmaceutical drugs in government health care programs’ (2011) 32 Michigan Journal of International Law 347.

<sup>1218</sup> *Ibid.*, 365.

<sup>1219</sup> James Hookway and Nicholas Zamiska, ‘Thai Showdown Spotlights Threat to Drug Patents’ *The Wall Street Journal* (Bangkok, 24 April 2007) <<http://www.wsj.com/articles/SB117735181629579246>> accessed 21 April 2015.

<sup>1220</sup> Gaëlle Krikorian, ‘The Politics of Patents: Conditions of Implementation of Public Health Policy in Thailand’ in Sebastian Haunss and Kenneth C. Shadlen (eds), *Politics of Intellectual Property Contestation Over the Ownership, Use, and Control of Knowledge and Information* (EE 2009) 44.

<sup>1221</sup> Stephanie Skees, ‘Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand’s AIDS Epidemic?’ (2007) 19 Pace International Law Review 233, 240.

was about to reconsider the licences (even though he did not revoke any). He was also alleged to have removed the Chairman of the GPO - a key supporter of the compulsory licensing – from his current position.<sup>1222</sup>

On the one hand, it can be argued that the military government was not recognised by law. On the other hand, this thesis submits that the uniqueness of Thai politics – the high frequency of coups compared with other countries - might invite a rethinking of the issue. Thailand has a long history of military regimes and military interventions in politics. With 19 military coups and attempted coups between 1932 and 2014, the coup d'état has been a distinctive part of Thai political culture.<sup>1223</sup> Political uncertainty, obviously, called into question the whole purpose of Thai licensing but the fact remains that it is also a national specificity of the country.

#### **7.5.4 Scope of Thai licences**

Thai government use licensing was considered wider than that allowed by TRIPS. The compulsory licence for Plavix was seen as a breach of patent, since it is commonly believed that compulsory licensing is confined to epidemics such as HIV/AIDS and other infectious diseases.<sup>1224</sup> Accordingly, heart diseases were therefore regarded to be exempt from such use. The licence issued in relation to Plavix was seen as inappropriate, as it signified a new era, in which compulsory licenses would be authorized to treat illnesses which are not infectious diseases.<sup>1225</sup>

Bate argued that because less than 1% (about 300,000) of the Thai population suffers from heart diseases, it was not feasible to claim that there was a public health emergency in Thailand.<sup>1226</sup> This view is also shared by Skees, who described this compulsory licence as constituting ‘a contempt for patents rather than a genuine effort to relieve a public health

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<sup>1222</sup> ‘Thai govt purge indicates CL shift’ (thepharmaletter, 10 March 2008)

<<https://www.thepharmaletter.com/article/update-thai-govt-purge-indicates-cl-shift>> accessed 25 March 2018.

<sup>1223</sup> Nicholas Farrelly, ‘Thailand’s Elite Coup Culture’ (Australian Institute of International Affairs, 24 March 2014) <<http://www.internationalaffairs.org.au/australianoutlook/thailands-elite-coup-culture/>> accessed 26 March 2018.

<sup>1224</sup> Roger Bate, ‘Thailand and the Drug Patent Wars’ (American Enterprise Institute, 04 April 2007) <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013.

<sup>1225</sup> Feldman Jamie, ‘Compulsory Licenses: The Dangers Behind the Current Practice (2009) 8 Journal of International Business and Law 137, 151.

<sup>1226</sup> Roger Bate, ‘Thailand and the Drug Patent Wars’ (American Enterprise Institute, 04 April 2007) 2 <<http://www.aei.org/article/health/thailand-and-the-drug-patent-wars/>> accessed 01 May 2013

crisis'.<sup>1227</sup> McGill characterized the Thai action as an example of failure in the widespread use of compulsory licensing.<sup>1228</sup>

This thesis argues that this view is improper, both from the health care and legal perspectives. First of all, limiting a compulsory licence to a number of specific diseases goes against the current understanding of global burden of diseases, which are shifting from common communicable diseases to chronic diseases. According to the WHO, ischaemic heart disease was the world's most common cause of death in 2015.<sup>1229</sup> The same tendency is also observed in upper middle-income countries,<sup>1230</sup> including Thailand, despite the popular belief that infectious diseases are the main cause of fatality there. A similar shift has also taken place in low income countries, albeit to a lesser extent.<sup>1231</sup>

Granted that there has been a demographic change in the burden of diseases in developing nations, pharmaceutical companies should now acknowledge this fact to act timely and accordingly. The variation in each country's epidemiological profile requires individual analysis of each. As mentioned in Chapter 1, developing countries are far from being homogeneous, and this thesis believes that such an understanding should also be applied in the health context. For example, HIV/AIDS is a health emergency in Sub-Saharan countries, but is no longer so in nations such as Brazil (Chapter 6) or Thailand (Chapter 7), as we have seen. As asserted by Ho, while communicable and non-communicable diseases may be considered differently by the owners of drug patents, and even the general public, from the public health perspective both can be considered as national epidemics if a large population is affected.<sup>1232</sup>

Secondly, from the legal perspective, the arguments for a limited scope of diseases subject to a compulsory licence are flawed. It should be reiterated that all Thai compulsory licences were issued in accordance with Section 51, under the rubric of 'public non-commercial use', and not

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<sup>1227</sup> Stephanie Skees, 'Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' (2007) 19 Pace International Law Review 233, 243.

<sup>1228</sup> Aileen M. McGill, 'Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis under The Doha Declaration' (2010) 10 Wake Forest Intellectual Property Law Journal 69, 89.

<sup>1229</sup> WHO, 'The top 10 causes of death' (January 2017) <<http://www.who.int/mediacentre/factsheets/fs310/en/>> accessed 24 October 2017.

<sup>1230</sup> WHO, 'The top 10 causes of death' (January 2017) <<http://www.who.int/mediacentre/factsheets/fs310/en/index1.html>> accessed 24 October 2017.

<sup>1231</sup> *Ibid.*

<sup>1232</sup> Cynthia M. Ho, 'Patent Breaking or Balancing? Separating Strands of Fact from Fiction Under Trips' (2009) 34 N.C. J. of Int'l. L. & Com. Reg. 371, 430.

national emergency. Therefore, the argument that heart disease does not constitute an emergency is invalid in this case. However, surprisingly, in the midst of Thai compulsory licensing, the term ‘public non-commercial use’ did not receive adequate attention and the situation of ‘national emergency’ was given greater emphasis. For example, a scholar claimed that Thailand’s government use licences were granted because of national urgency at that time.<sup>1233</sup>

One document which is commonly (but falsely) mentioned as a justification for the exclusion of chronic diseases from the use of such licences is the Doha Declaration. A few authors insisted that only HIV/AIDS, tuberculosis, malaria and other epidemics are sufficient grounds.<sup>1234</sup> For example, McGill argues that the Doha Declaration intends to tackle ‘epidemics’ and ‘circumstances of extreme urgency’ but not under any circumstances.<sup>1235</sup> However, this thesis reasserts that the Doha Declaration does not intend to limit the diseases subject to a compulsory licence. Paragraph 5 of the Declaration explicitly states as follows:

‘(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.’

It is clear from the language of Paragraph 5 that ‘HIV/AIDS, tuberculosis, malaria’ are mentioned as mere examples of public health crises. This list is not exhaustive and therefore, the claim that chronic diseases cannot justify the use of compulsory licences is an untenable distortion of the Doha Declaration.<sup>1236</sup> Nor does TRIPS restrict the type of disease that could be a reason for compulsory licensing, as was emphasized in Section 4.2.2.

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<sup>1233</sup> Edward Kelly, ‘Thailand: Compulsory licences. Finding a middle ground’ (2011) 40 *Managing IP* 1, 67.

<sup>1234</sup> Ronald A. Cass, ‘Compulsory licensing of Intellectual Property: The Exception that Ate the Rule?’ (2007) Washington Legal Foundation, Working Paper Series No. 150, 17–19

<[http://www.wlf.org/publishing/publication\\_detail.asp?id=1902](http://www.wlf.org/publishing/publication_detail.asp?id=1902)> accessed 7 March 2018; Aileen M. McGill, ‘Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis under The Doha Declaration’ (2010) 10 *Wake Forest Intellectual Property Law Journal* 69, 84.

<sup>1235</sup> Aileen M. McGill, ‘Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis under The Doha Declaration’ (2010) 10 *Wake Forest Intellectual Property Law Journal* 69, 84.

<sup>1236</sup> Brent Savoie, ‘Thailand’s Test: Compulsory Licensing in an Era of Epidemiologic Transition’ (2007) 1 *Virginia Journal of International Law* 212; Kevin Outterson, ‘Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?’ 2008 (34) *American Journal of Law and Medicine* 317; Cynthia M. Ho, ‘Patent

However, patent advocates have persisted in the view that compulsory licensing should be used restrictively as an exception to patent rights, where all alternatives have been explored but have failed to produce satisfactory outcomes. Such a perspective is clearly illustrated in the communications of the US Ambassador - Ralph Boyce, the EU Trade Commissioner, Peter Mandelson, and the Swiss government (Aide Memoire) to Thailand.<sup>1237</sup> They all agreed that under WTO rules, members have the right to grant compulsory licences. These licences, however, must remain an exception and should be deployed as a last resort.

In light of the above analysis, the author asserts that by law, Thai compulsory licensing of Plavix was entirely consistent with TRIPS. Nevertheless, this thesis submits that despite such legality, the government should take into account all associated effects, for example, the retaliation by the right owners and trade sanctions of the US and consider whether a victory in the patent battle might be overshadowed by such effects.

### 7.5.5 Prior negotiation

Lack of prior negotiation is another common but false charge made against Thailand. The patent owners were angered because they were not informed about compulsory licensing and because the government did not attempt to negotiate a reasonable price. Steinbrook criticised the Thai government's unilateral action for rejecting dialogues with the right owners, which could have resulted in a discount on drug prices or a voluntary licence.<sup>1238</sup> Kieldgaard - A representative of PhRMA was of the opinion that there were many alternative ways to increase access to medicines, but that Thailand did not consider any, apart from compulsory licensing.<sup>1239</sup> He contended that the negotiating process with Thailand was a mere formality because either the patent owners did not have any voice or the government was not in a genuine dialogue with them.<sup>1240</sup> Merck, the patent owner of Efavirenz, also stated that they came to

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Breaking or Balancing? Separating Strands of Fact from Fiction Under Trips' (2009) 34 N.C. J. of Int'l. L. & Com. Reg. 371; Jerome H. Reichman, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options (2009) 37 Journal of Law, Medicine and Ethics 247.

<sup>1237</sup> See Section 7.4.3 of this thesis.

<sup>1238</sup> Robert Steinbrook, 'Thailand and the Compulsory Licensing Efavirenz' (2008) 6 New England Journal of Medicines 544, 546. Steinbrook favoured Brazil's approach, where the country merely threatened to issue compulsory licences, but had not actually done so by that time: Brazil instead negotiated price discounts and voluntary licences. He also pointed out that Merck had agreed to provide a voluntary licence in South Africa. In his view, they were the options which Thailand could have considered as alternatives rather than compulsory licensing.

<sup>1239</sup> Hugh C Hansen (ed), *Intellectual Property Law and Policy. Volume 10* (Hart Publishing 2008) 955.

<sup>1240</sup> *Ibid.*, 954, 958.

know about the decision only two days in advance, whereas the normal consultation period is 90 days.<sup>1241</sup>

Critics linked prior negotiation to Article 31(b), by which this legal condition is required to take place within a reasonable period of time. However, this provision should be read with caution so as not to distort its meaning. The Article states: ‘This requirement [prior negotiation] may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use’.<sup>1242</sup>

It should be emphasised that all the Thai compulsory licences were issued under the ‘public non-commercial use’ criterion, a circumstance in which prior negotiation may be waived and compulsory licensing activated immediately. Therefore, this thesis submits that it was in direct contravention of Article 31 for the patentees and other concerned parties to ask for prior negotiation.

Although consultation is not mandatory, Thailand’s government claimed that it had been in discussion with the pharmaceutical companies since 2004.<sup>1243</sup> With regard to the cancer drugs, it argued that although the Minister of Health could have exercised his authorisation immediately, consultations with the right owners still took place before final actions were taken.<sup>1244</sup>

As Ho observed, both sides differed markedly in what amounted to ‘prior negotiation’.<sup>1245</sup> The government of Thailand considered the negotiation as having begun years before. The pharmaceutical companies, however, took the view that prior negotiation should take place shortly before the licensing, and that the government should notify the intention of undertaking the compulsory licence if no price cuts were achieved.<sup>1246</sup> In this regard, this thesis submits

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<sup>1241</sup> Amy Kazmin and Andrew Jack, ‘Thai government to break drug patents’ *Financial Times* (25 January 2007) <<https://www.ft.com/content/6889bbbc-ac98-11db-9318-0000779e2340?mhq5j=e2>> accessed 7 March 2018.

<sup>1242</sup> TRIPS, art 31(b).

<sup>1243</sup> See Section 7.4.1 of this thesis.

<sup>1244</sup> Question No. 2: Has there been any negotiation with the patent-owners before deciding to implement the Government use of Patents on the four anti-cancer drugs? (White Paper 2008, *supra* note 1037).

<sup>1245</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 187 – 188.

<sup>1246</sup> *Ibid.*

that Brazil has established a much better model for price bargaining negotiations (Chapter 6). Differences in this regards between two countries will be elaborated in the next chapter.

### **7.5.6 Adequate remuneration**

The royalty of 0.5% that Thailand offered to pay to the pharmaceutical companies was considered by the latter to be too low. Aldelman called it an embarrassment and claimed that the Thai government should not make this kind of offer.<sup>1247</sup> Even though James Love, a health activist who fully supported Thailand's licensing, confessed that such an amount was inadequate, yet the patent owners made no counter offers.<sup>1248</sup> This prompts the question: if the royalties were deemed insufficient, why did the pharmaceutical companies not negotiate or appeal to the Board, whereas they were entitled to do so, as mentioned in Section 7.3.2.2? This thesis submits that the patent holders, in all probability, tried to avoid establishing a royalty standard that was likely to be used by others in future. If the pharmaceutical companies compromised on a remuneration which was fixed by the government, they would be effectively facilitating such licences. To the patent advocates, the optimal solution is to nip the compulsory licence in the bud, rather than to negotiate terms and conditions. In their view, compulsory licensing is definitely non-negotiable; it is completely a dead-end and cancellation is the only solution. Accordingly, pharmaceutical companies did not even try to propose an alternative and instead focused on eliminating compulsory licenses.<sup>1249</sup>

In fact, the author views that there was no bargaining process in the context of Thailand because the government and the patent holders held completely different expectations about the final result. While the former shaped the negotiation around the central idea of how to use compulsory licensing to obtain price cuts, the latter had in their minds the absolute rejection. In other words, both parties did not work towards a common end.

It could be seen that the topic of remuneration seems to be conspicuously missing from the scholarly literature about compulsory licences. The author observes that when such a licence is granted, it is solely the ground of the grant that is in the spotlight, and neither the remuneration nor the terms and conditions thereof are hardly worth discussing. This is mainly

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<sup>1247</sup> Hugh C Hansen (ed), *Intellectual Property Law and Policy. Volume 10* (Hart Publishing 2008) 958.

<sup>1248</sup> *Ibid.*

<sup>1249</sup> Cynthia M. Ho, 'Patent Breaking or Balancing? Separating Strands of Fact from Fiction under Trips' (2009) 34 N.C. J. of Int'l. L. & Com. Reg. 371, 440.

because the existing global framework has given inadequate attention to royalty payments.<sup>1250</sup> For example, the Paris Convention does not even mandate the requirement of remuneration. The concept of an ‘adequate amount’ is not either defined under TRIPS.<sup>1251</sup> International guidelines on this matter did not attract public attention.<sup>1252</sup> How much a granting country should pay to the patentees in order to achieve ‘adequacy’ is a somewhat tricky question. The patent owners have avoided negotiating the royalty rate while the law fails to outline a comprehensive process or a set of detailed conditions, and instead leaves the matter to the discretion of national governments. As a result of those gaps, differing views on the meaning of an ‘adequate’ amount is therefore inevitable.

## **7.6 An evaluation of Thailand’s policy from the economic perspective**

In 2009, Thailand conducted a project which assessed the economic impacts of its compulsory licensing policies.<sup>1253</sup> The work was carried out when the licences were still in effect: compulsory licensing for Efavirenz and Kaletra expired in 2011 and 2012 respectively. For the remaining medicines, the compulsory licences were operative until the patent expired or until there was no longer an essential need. This work had therefore had certain limitations. For example, there were no imports of generic cancer drugs at that time, so the number of patients accessing these drugs was merely a projection. Also, because the time when the study was being conducted was too close to the time of implementation of Thai government’s policy, the assessment of the overall impacts might have been inaccurate.

Despite these shortcomings, this thesis argues that Thailand is the only country that has attempted to ensure transparency after the policy was operated. It could be seen as an effort to make up for the country’s non-transparency during the implementation of Thailand’s

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<sup>1250</sup> See Section 4.2.4.8 of this thesis.

<sup>1251</sup> TRIPS, art 31(h).

<sup>1252</sup> Cynthia M. Ho, ‘Patent Breaking or Balancing? Separating Strands of Fact from Fiction under Trips’ (2009) 34 N.C. J. of Int'l. L. & Com. Reg. 371, 440.

<sup>1253</sup> Inthira Yamabha *et al.*, ‘Assessing the implications of Thailand’s Government Use Licenses, issued in 2006–2008’ (Health Intervention and Technology Assessment Program, 2009)

<<http://www.hitap.net/en/research/17635>> accessed 21 March 2018. This study was funded by the Health Insurance System Research Office and the Bureau of Policy and Strategy, Ministry of Public Health, Thailand. The authors recommended not to cite or quote anything from this work without their permission because it was not endorsed by the funding agencies. As of this writing, the final report cannot be found. However, the same group of authors published their research in academic journals. This thesis will therefore refer to these publications in this Section.

government use licensing, as referred in Section 7.5.2. From the vantage point of the present, the evaluation of Thailand's policy allows us to look at the full picture from a different angle and take away some key lessons.

Following the 2009 study, similar research was carried out in 2011 – 2012, when some of the compulsory licences expired, allowing a more comprehensive picture to be painted.<sup>1254</sup> Within the 5-year period, such a policy of Thailand was claimed to have saved the country \$370 million.<sup>1255</sup> However, there were wide discrepancies amongst the medicines with regard to their economic impact.

**Table 3 Cost savings by drugs through Thai government use policy<sup>1256</sup>**

Drugs included in the patent policy	Cost savings through government use licences policy (million US dollars)
Erlotinib	6.33 – 7.57
Clopidogrel	22.00 – 22.31
Docetaxel	46.10 – 52.67
Lopinavir and ritonavir (Kaletra)	78.96 – 80.25
Letrozole	88.57 – 101.79
Efavirnez	116.45 – 118.84
<b>Total</b>	<b>358.41 – 383.42</b>

It is observed that Efavirnez received the lowest discount but was used by the greatest number of patients. It thus had the greatest economic effect.<sup>1257</sup> The cost saving of Efavirnez was between \$116.45 and \$118.84 million. By contrast, Erlotinib - one cancer drug and Clopidogrel – the heart disease medicine had minimal impact due to the small number of recipients.<sup>1258</sup>

<sup>1254</sup> Adun Mohara *et al.*, ‘Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand’ (2012) 15 Value in Health S95; Inthira Yamabha *et al.*, ‘Government Use Licenses in Thailand: An Assessment of the Health and Economic Impacts’ (2011) 7 Globalization and Health 1; Suwit Wibulpolprasert *et al.*, ‘Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership’ (2011) 7 Globalization and Health 1.

<sup>1255</sup> Adun Mohara *et al.*, ‘Impact of the Introduction of government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand’ (2012) 15 Value in Health S95, S95.

<sup>1256</sup>This table was extracted from Inthira Yamabha *et al.*, ‘Government Use Licenses in Thailand: An Assessment of the Health and Economic Impacts’ (2011) 7 Globalization and Health 1

<sup>1257</sup> Adun Mohara *et al.*, ‘Impact of the Introduction of government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand’ (2012) 15 Value in Health S95, S98.

<sup>1258</sup> *Ibid.*

Clopidogrel saved the government around \$22 million, while the saving on Erlotinib was the smallest: between \$6.33 million and \$7.57 million. If the government of Thailand could project the significant differences in economic savings of those medicines, it might have considered other alternatives for those with marginal impacts. This thesis therefore argues that drug selection played a key role in optimizing the benefit of compulsory licences.

A study also revealed that the arrival of the generics in Thailand encountered substantial delay.<sup>1259</sup> It took a year and 20 months for the generic equivalent of Kaletra and Clopidogrel, respectively, to be delivered in the country.<sup>1260</sup> The reason for such delay was that some patent holding companies threatened to take legal action against the generic companies, which were about to supply the low-cost medicines to Thais, as noted in Section 7.4.3. Efavirenz had the shortest delay as the generic from India was imported only one month after the grant.<sup>1261</sup> This thesis therefore submits that the successful grant of a compulsory licence might remain a merely moral victory if practical challenges cannot be defeated.

After 2007, Thailand discontinued its government use licences, probably because of the country's trade policy. One of the discussion topics under the FTA between the EU and Thailand concerns IPRs. The EU's policy is also to limit compulsory licences, as will be seen in Chapter 9.

## 7.7 Conclusions

On the one hand, Thailand provided a very fine example of how law and politics were strongly and inevitably intertwined in government use licensing. The political tone was, in fact, overwhelming in this case. The distinctive presence of politics has shaped Thailand into a very exceptional case compared with other country case studies in this thesis, namely India and Brazil. Thailand's compulsory licensing granted by a post-coup government was seen as a compensation for the financial shortage resulting from its political turmoil rather than an appropriate means to address the national public health. The backlash caused by the Thai government has less to do with the legal issues than with the rationale behind its decisions.

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<sup>1259</sup> Inthira Yamabha *et al.*, 'Government Use Licenses in Thailand: An Assessment of the Health and Economic Impacts' (2011) 7 Globalization and Health 1, 3.

<sup>1260</sup> *Ibid.*

<sup>1261</sup> *Ibid.*

Overall, it might be hard to say that the Thai policy violated TRIPS but its ulterior motive has remained questionable.

On the other hand, the author maintains that Thailand has also served as a classic example of how the use of mandatory licences can create great abundance of different stories wherein truth and fallacy are blended together. In the Thai example, the details are not generally known, and it is not easy to extract a factual account of the events from what was told by each side. This is also a dramatic demonstration of how patents and compulsory licences, when coming to the access to medicines, have caused a heated confrontation on many fronts: the politics, the economics, and the media.

It is true that by the publication of the two White Papers in 2007 and 2008, Thailand made great efforts to explain the validity of its decisions, the selection criteria of the candidate medicines, the decision-making processes, etc. Consequently, Thailand's actions were hailed in Geneva 'as a model of gentleness and transparency' and also of generosity and courage since the country was not obliged to act as it did.<sup>1262</sup> However, it is equally true that such attempts were made *after* the grant of compulsory licensing in order to allay mounting concerns of the right owners. The author can only speculate that the government of Thailand failed to anticipate the negative reaction which would be sparked by its decisions. Otherwise, the two White Papers could have been published before the licences were announced.

The example of Thailand also demonstrates that compulsory licensing, if poorly handled, can prompt retaliation from the patent owners. Therefore, in order to mitigate and circumvent said situations, prior negotiation with these companies is always advisable, even when such a consultation is not required by TRIPS. Such a gesture will convey to the government the willingness to consult and will legitimize its further use. Moreover, prior negotiation should be accompanied by explicit reference to the possibility that a compulsory licence could be imposed where the talks fail to reach a consensus or are the cause of substantial delays.

Remarkably, the expansion of Thai compulsory licences to chronic disease medications, albeit provoking controversy, has signified the possibility of similar mandatory licensing in the near

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<sup>1262</sup> Suwit Wibulpolprasert *et al.*, 'Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership' 7 (2011) Globalization and Health 1; KEI, 'Q&A Session on Thai White Paper' (8 March 2007) <<http://www.keionline.org/content/view/31/1>> accessed 3 February 2015.

future. The growing burden of chronic diseases is having an even greater economic impact on developing countries than HIV/AIDS. Pharmaceutical companies and developed nations should anticipate those needs and give the poor greater access to medicines before a compulsory licence is sought. Whereas the truth regarding the decision to grant compulsory licences remains unclear in the Thai case, the underlying public health pressures driving similar decisions in other countries may lead them to take an unambiguous stance.

A final observation is that, patent advocates expound a very restrictive view on compulsory licensing that financial constraints can be removed by other means, for example, by eliminating all taxes or allocating more funds, not by ‘taking away’ their private rights. Patent holding companies have put up strong resistance whenever the legal mechanism of compulsory licensing is employed, thus closing the doors to any further discussion. That leads to a question, *can* a country issue a compulsory licence if its people cannot afford the patented medicines? On the surface, this question seems too easy to answer. Under global law, yes, it can. If one looks a little deeper, however, the practice is revealed as more complex, dubious and cumbersome than in legal theory. As we have seen in Chapters 5 and 6, despite being up-and-coming powers in the global economy and international relation, India and Brazil have faced formidable obstacles to exercising their legitimate rights. This chapter on Thailand has further emphasised that such impediments, for example the retaliation from patent holding companies and economic coercion of countries sponsoring those companies, are magnified when the market is much smaller, and the country is less significant.

# **CHAPTER 8: A COMPARATIVE ANALYSIS OF INDIA, BRAZIL AND THAILAND**

As can be seen from Chapters 5, 6, and 7, India, Brazil and Thailand, all have shown differences in their general application of compulsory licensing for patented medicines. For example, if the Indian compulsory licence (2012) was entirely driven by market demand, Brazil's and Thailand's compulsory licences, 2007 and 2006 – 2008, respectively, were the outcome of public needs. Although India and Brazil are being viewed as up-and-coming economic powers, they adopted differing approach in employing the compulsory licence. At the same time, although Brazil and Thailand appear to be dissimilar in the international relation, they demonstrate similar behaviour in the implementation of public health policies. Both resorted to using direct government action to safeguard the national interest. Indian authorities, on the other hand, have performed a minor role in using compulsory licensing to promote public health.

Chapter 8 therefore aims to answer research question No.4, which includes two sub-sections. (1) What are similarities and differences between the three case-study countries? (2) Most importantly, why is there such a variety? This chapter will shed considerable light on the commonality and variation of their law in theory and law in action. On the one hand, the frameworks of India, Brazil and Thailand have sat firmly under the chapeau of international law, on the other hand, their national variations can be mainly accounted for two factors: their implementation process of TRIPS and pharmaceutical capacity.

As stated in Chapters 1 and 2, previous comparative research on compulsory licensing of developing countries is relatively simple. For this reason, this chapter is a key component of the author's doctoral research as its underlines distinctions in the compulsory licensing policies in these three country case studies and deeply analyses the drivers behind their various regimes. The findings of this chapter will benefit not only countries currently in the process of patent reform but also those considering whether or not they want to grant such a licence. For the first group, they can draw some key lessons from the experience of the countries being critically evaluated. For the second group, the analysis in this chapter enables them to identify the factors which contribute towards a successful grant.

## 8.1 General observations of three countries on the international stage

Over the last two decades, the world has witnessed a paradigm shift, not only in global economic governance but also in global power relations, with India and Brazil viewed as important players, despite the fact that they are developing countries. Both are members of the G-20 and are considered rising economic powers within the ‘BRIC’ group, which is projected to rival many countries in the OECD by 2050. Moreover, India and Brazil are also the only two emerging countries aspiring to permanent status in the reformed Security Council of the UN.<sup>1263</sup>

There are, however, subtle differences between them. Brazil has earned a reputation for its expertise in political diplomacy on the international affairs.<sup>1264</sup> As seen in Section 6.1, the country has demonstrated its worldwide influence over trade, energy and climate change as well as promoting its image as a leader in the South-South cooperation. Brazil’s diplomatic tactics yielded a successful outcome in the dispute with the US regarding the working provision under Brazil’s 1996 Patents Act (Section 6.3.2). As also demonstrated in Chapter 6, Brazil has held itself out as an active player in international trade liberalisation and it is, indeed, one of the world’s leading agricultural exporters.

Meanwhile, India is observed to weakly integrate in the global and regional economy.<sup>1265</sup> It has displayed a tendency to resist opening the market to OECD countries.<sup>1266</sup> While India has a relatively weak agriculture sector, it has huge advantages in cutting-edge technologies and other high-tech industries that have developed to advanced international levels. The pharmaceutical sector is such an example, as thoroughly analysed in Chapter 5. This thesis

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<sup>1263</sup> Alejandro Neut and Javier Santiso, ‘India and Brazil: The Elephant and the Toucan’ (2007) OECD Emerging Markets Network Working Paper, 3 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1398645](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1398645)> accessed 7 March 2018.

<sup>1264</sup> Stephanie Hanson, ‘Brazil on the International Stage’ (The Council on Foreign Relations, 2 July 2012) <<https://www.cfr.org/backgrounder/brazil-international-stage#>> accessed 9 November 2017; Carlos Pio, ‘Brazil’s Influence on the World Economy Is Nominal, at Best’ *The New York Times* (19 June 2013) <<https://www.nytimes.com/roomfordebate/2012/05/11/have-the-bric-nations-lost-their-momentum/brazils-influence-on-the-world-economy-is-nominal-at-best>> accessed 9 November 2017; David R. Mares and Harold A. Trinkunas, *Aspirational Power: Brazil on the Long Road to Global Influence* (Brookings Institution Press 2016).

<sup>1265</sup> Robert Kappel, ‘On the Economics of Regional Powers: Comparing China, India, Brazil, and South Africa’ (2010) GIGA Working Papers No. 145, 19 <<https://www.giga-hamburg.de/de/publication/on-the-economics-of-regional-powers-comparing-china-india-brazil-and-south-africa>> accessed 26 March 2018.

<sup>1266</sup> Kristen Hopewell, ‘Different paths to power: The rise of Brazil, India and China at the World Trade Organization’ (2015) 22 *Review of International Political Economy* 311, 321.

therefore submits that an ever increasing progress in innovative sectors will probably drive India towards a stringent IP regime as a means of encouraging and protecting innovation. Follow this tendency, Indian IP policies will be geared towards the West.

In contrast to India and Brazil which are being watched as emerging superpowers, Thailand, dubbed a ‘tiger economy’, has increased its economic strength through its association with ASEAN, the biggest trading bloc in Asia. For example, Thailand’s GPD is only ranked 25<sup>th</sup> in the world, but collectively, ASEAN’s GDP was almost \$2.6 trillion in 2016, making the group the world’s 6<sup>th</sup> largest economy.<sup>1267</sup> Although the position of Thailand in world trade is modest compared with India or Brazil, it is one of the FDI hubs of Asia<sup>1268</sup> and ranked 19<sup>th</sup> in the Global FDI Confidence Index.<sup>1269</sup> Arguably, therefore, in order to maintain such an attractive investment target, Thailand might feel the need to strengthen its IP regime.

It is interesting to note that on a macro-level, India and Brazil manifest great similarity, for example their GDP is ranked in the world’s top 10 largest. However, being examined more closely, the economic prosperity of these two BRIC countries has developed on divergent paths. Measured by GNI per capital (income per person), Brazil and Thailand are both classified as upper-middle income economies while India falls into the lower-middle income group.

Regardless of differences, India, Brazil and Thailand are considered as being prosperous, which excludes them from the differential pricing for LDCs, such as countries in the Sub-Saharan region. Countries such as India, Brazil and Thailand are supposed to be able to provide medicines for their own people without having to resort to compulsory licences. It explains why the patent owners have always relied on economic development to oppose these countries authorising the compulsory licence, Therefore, their grants of such licences were viewed by the pharmaceutical industry as improper.

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<sup>1267</sup> This calculation and statistic are provided by the author. WB, ‘Gross Domestic Product 2016’ (World Development Indicators, 15 December 2017) <<http://databank.worldbank.org/data/download/GDP.pdf>> accessed 5 March 2018.

<sup>1268</sup> UNCTAD, ‘World Investment Report 2017. Investment and Digital Economy’ (UNCTAD 2017) <[http://unctad.org/en/PublicationsLibrary/wir2017\\_en.pdf](http://unctad.org/en/PublicationsLibrary/wir2017_en.pdf)> accessed 18 October 2017.

<sup>1269</sup> Paul A. Laudicina and Erik R. Peterson, ‘The 2017 A.T. Kearney Foreign Direct Investment Confidence Index®. Glass Half Full’ (ATKEARNEY) <<https://www.atkearney.com/foreign-direct-investment-confidence-index/article/?a/glass-half-full-2017-foreign-direct-investment-confidence-index-article>> accessed 29 October 2017.

## **8.2 Domestic variations within the compulsory licensing frameworks**

### **8.2.1 Market-initiated compulsory licensing**

#### **8.2.1.1 Possible grounds**

Firstly, as observed by Mueller, India has the broadest and most comprehensive grounds for compulsory licensing of all the world's patent systems.<sup>1270</sup> While such an observation may need to be reassessed, it is true that compared with other country case-studies in this thesis, India adopted a wider range of situations upon which a compulsory licence can be issued. While Brazil (Section 6.3) and Thailand (Section 7.3) established conventional grounds for market-driven licences (unavailability, unaffordability, and lack of local working), India has greatly expanded those grounds to a dozen circumstances in which the Indian public requirement is not met (Section 5.3). Moreover, India implemented the compulsory licensing mechanism under TRIPS Article 31bis, whereas Brazil and Thailand have not adopted the new regime yet. These two countries are considering reforming their patent systems to introduce some radical changes.

Secondly, all three country case studies adopted different approaches to the local working provision. As explained in Section 4.2.3, it is highly debatable whether importation can be considered as local exploitation. So far, relevant international patent law has not tackled this thorny issue thoroughly; there has been no precedent established while academic scholars have expressed a wide range of views (Section 4.2.3). Local working has thus stood still as an unaddressed legal matter. The provisions of both Thailand and Brazil require the patent holder to manufacture the invention within their territories (Sections 6.3.1 and 7.3.1). Brazil, in particular, takes a more aggressive stance. It should be remembered that Article 68 of its 1996 Patents Act, which imposed a local working requirement, caused the US-Brazil dispute before the WTO in 2001 (Section 6.3.2). Under Brazil's law, the duty to exploit a patented invention is strictly applied to not only the right owner but also to the licensee. It is mandatory for the latter to use the invention, in the absence of legitimate prohibitive reasons, within one year

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<sup>1270</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 580.

from the date of grant.<sup>1271</sup> Otherwise, the compulsory licence can be revoked at the patent holder's request.<sup>1272</sup>

India, however, has been more complex in this regard. Section 84.1(c) of its 1970 Patents Act permits a compulsory licence when a patented invention is not worked in the region, without specifying what amounts to a local working patent. Prior to *Natco*, a number of authors linked it to local manufacturing.<sup>1273</sup> The Controller of Patents in the case, even held the same view. The IP Appellate Board and High Court, nonetheless, slightly disagreed. They accepted importation as equal to local working in certain situations and emphasised that local manufacturing is not always necessary (Section 5.4.1). Such facilitation, however, is not to be taken for granted, and each case needs to be assessed individually.

Voices of dissent between the two leaders of the developing world – India and Brazil - in fact, began to rise as earlier as the Uruguay Round (Section 4.2.1). For Brazil, compulsory licensing was of the utmost importance during the TRIPS negotiations. Since the early 20<sup>th</sup> century, the country has taken the lead in encouraging revision of the Paris Convention to secure the government's greater discretion to intervene in case of a non-working patent. Compulsory licensing in Brazil has been an effective means of enabling governmental interference in the pharmaceutical market.

Meanwhile, the flexible interpretation of Indian authorities is in line with the country's perspective since the discussion of TRIPS. Given its market significance, while drafting Article 31, India was confident that no patent holder would fail to notice the prosperity of the region (Section 4.2.1). For this reason, a strict application of the 'local working' rule was seen as unnecessary.

Paradoxically, this thesis submits that while both Brazil and Thailand are very keen on compelling the patent holder to work his invention domestically, they have never granted any

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<sup>1271</sup> Brazil's Patents Act 1996, art 74(1).

<sup>1272</sup> Brazil's Patents Act 1996, art 74(2).

<sup>1273</sup> Santanu Mukherjee, 'The Journey of Indian Patent Law towards TRIPS Compliance' (2004) 35 IIC 125, 136; Shamnad Basheer and Mrinalini Kochupillal, 'The Compulsory Licence regime in India: Past, Present and Future' (A Report for the JPO, 2005) 9 <<https://ssrn.com/abstract=1685129>> accessed 19 March 2018; Srividhya Ragavan, 'Of the Inequals of the Uruguay Round' (2005) 10 Intellectual Property L. Rev 273, 290; Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 596; BN Pandey and Prabhat Kumar Saha, 'Compulsory Licence for Diabetes Drug. Legality of Lee Pharma's Application' (2016) 51 Economic & Political Weekly 17, 19.

licence on such a basis. India takes a very different stance. Although it does not adopt a conservative viewpoint towards local working, Natco's licence was issued under Section 84 where lack of local working is one of the three grounds.

Such differences of approach among the three countries can be attributed to the difference in their pharmaceutical capacity, which will be examined in Section 8.5. However, it is necessary to offer a brief explanation here. Because India possesses an enormous manufacturing ability, it would be more problematic for the patent owners to defend their non-exploitation in the country, citing economic and technical obstacles as legitimate reasons. On the contrary, as Thailand and Brazil have limited capacity, it is more understandable why foreign companies cannot perform their duty to work there. Such a finding leads to a conclusion that the presence of the 'local working' requirement in national framework, in fact, is more a 'scarecrow' than an imminent danger. The key element of the successful grant of a compulsory licence, as the author has several times argued, largely lies in a country's industrial development.

### **8.2.1.2 The procedure**

One of the few shared features of the three countries under scrutiny is their choice of the administrative grant. A request for a compulsory licence must be filed with the Controller of Patents in India, the Director-General in Thailand, and the INPI in Brazil. Compared with the court procedure, the administrative route is less cumbersome and hence faster.

India, Brazil and Thailand otherwise exhibit a great deal of variation. Firstly, while the patent law of both India and Thailand contains the requirement of prior negotiation for a voluntary licence in order to comply with TRIPS, Brazil's law has no such requirement. In fact, India even rejected an application because the applicant did not display plausible efforts to engage in prior negotiation (Section 5.4.1.4 – *BDR*). Although both India and Thailand recognise the importance of the consultation between two parties, the rejection of BDR's application further demonstrated the strict approach of the Indian patent office. That is, prior negotiation is not a mere requirement but needs to be carefully followed.

Secondly, although both India and Thailand are compliant with TRIPS, India displayed particular skill in drafting legislation; that is the law-makers introduced a six-month cap on consultations between two parties (Section 5.3.2). Such creation arose from Ayyangar's work where he identified substantial delay in prior negotiation with the right holder as one of the

disadvantages of Indian patent law (Section 5.2.2). The stipulated time limitation prevents the right owner from bypassing the reasonable voluntary licence while ensuring his enjoyment of the reasonable terms and conditions of such a licence. Therefore, the author recommends Thailand to impose a similar provision to maximise the effectiveness of the compulsory licensing system.

Thirdly, both India<sup>1274</sup> and Brazil<sup>1275</sup> require the patent holder to prove the exploitation of his patent. Thailand, on the other hand, places the burden of proof on the applicant.<sup>1276</sup> Although it may be a matter of law-drafting technique, such a requirement could pose a practicable challenge to the applicant when a compulsory licence request is filed.

Last but not least, it can be observed that Brazil (Section 6.3.1) and Thailand (Section 7.3.1) adopt a much simpler granting process, which comprises three main stages: filing the application, decision-making, and appealing. By comparison, Indian rules prove to be more rigid and bureaucratic, as was seen in Section 5.3.1. Brazil and Thailand give the right owner little room to manoeuvre, whereas Indian patent law provides the patentee with unlimited opportunities to oppose. *Natco* has served as a clear illustration of the ways in which a patent holder can exploit all possible loopholes in the Indian system to prevent the compulsory licence (Table 1, Chapter 5). The legal process therefore seems to be more user-friendly and less time consuming in Brazil and Thailand than that in India. The following figures feature the juxtaposition of two legal proceedings with Brazil and Thailand on the one hand, and India on the other hand.

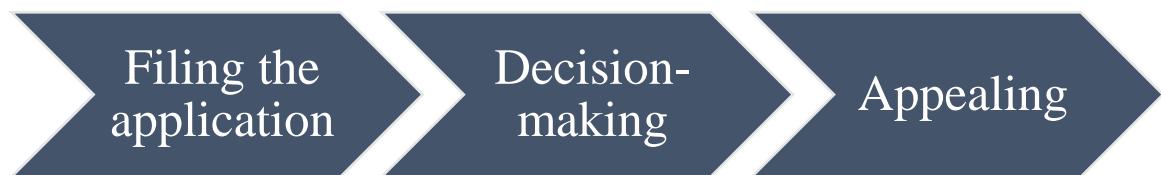
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<sup>1274</sup> Both the Indian Patents Act 1970, sec 146.2 and the Indian Patent Rules 2003, sec 131.1, require the patent holder to submit Form 27 concerning the working status of his patent.

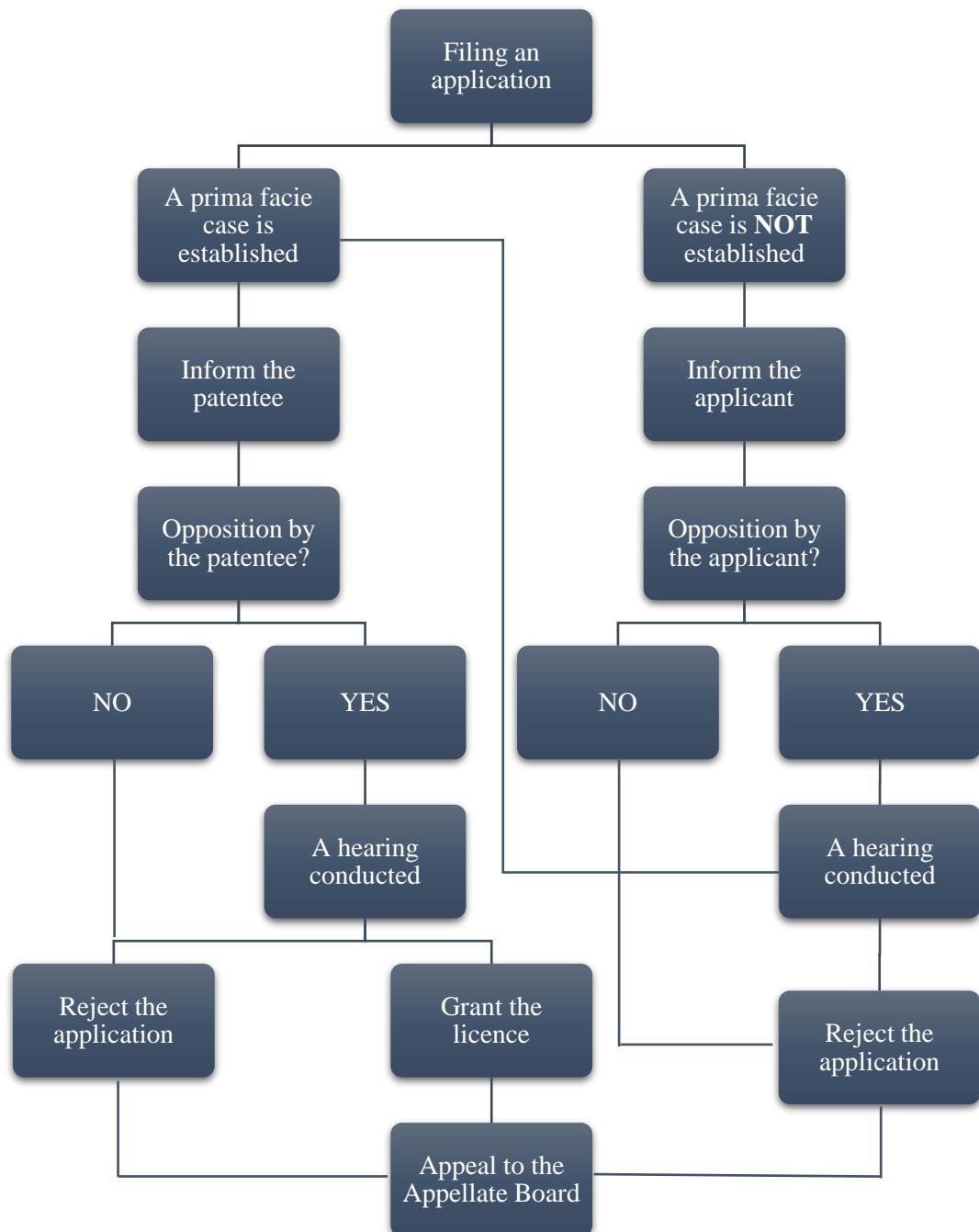
<sup>1275</sup> Brazil's Patents Act 1996, art 73.3.

<sup>1276</sup> Ministerial Regulations No.26 (be. 2524), Clause 14(1).

**Figure 6 Compulsory licensing grant under Brazil's 1996 Patents Act and Thailand's 1999 Patent Act**



**Figure 7 Compulsory licensing grant under India's 1970 Patents Act**



## **8.2.2 Government use licensing**

### **8.2.2.1 Possible grounds**

Overall, the potential grounds provided by the three countries' patent laws are not different from each other, since all three adopted the minimum requirements set out by TRIPS.<sup>1277</sup> For example, they all permit the government to override patent monopoly in certain situations, including national emergency or public non-commercial use. Moreover, there is no lapse period, meaning that a compulsory licence can be issued at any time after the date of the patent grant. Since government use licensing occurs in situations that necessitate quick intervention, public authorities are not obliged to negotiate with the patent holders, only to inform them as soon as practicably possible.

### **8.2.2.2 The procedure**

However, the three country case studies display some differences in the procedure of the grant. Firstly, while India and Brazil mandate a formal declaration of the circumstance leading to the compulsory licence, Thailand does not. In India and Brazil, the notifications are published in the Official Gazette and compulsory licensing will then be implemented, meaning that there is a time gap between the notification and the actual issue. Such a 'pause' gives the right owner a period of time to overturn the government's decision. In fact, in 2005, Abbott succeeded in preventing the Brazilian government from granting the compulsory licence for Kaletra at the last minute (Section 6.4.3). Therefore, it should be borne in mind that a declaration does not always turn into a compulsory licence. Meanwhile, in the example of Thailand, compulsory licensing was set out directly in the announcement, leaving the patent holders no time to act. The author therefore asserts that India and Brazil have set good examples in increasing procedural transparency, thereby alleviating sharp reactions from the patent owners.

Secondly, the Indian Patents Act has the broadest range of eligible applicants. Upon notification, *anyone* interested can apply for the compulsory licence. This provision is well-suited to India where there is multitude of domestic companies having the capacity to reverse-engineer the medicine. The result of such an explicit provision is that, it encourages more generic manufacturers to participate in the process, thus leading to competitive pricing. It should be recalled that, immediately after the Indian Minister of Health revealed his intention

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<sup>1277</sup> See Sections 5.3.2, 0, and 7.3.2 of this thesis.

to mandatorily license a patented drug, two private companies approached, announcing their readiness for generic production (Section 5.5).

As for Thailand and Brazil, although their laws are silent on this matter, the practice has shown that only state-owned organisations are involved in the process. They are FarManguinhos in Brazil and the GPO in Thailand. FarManguinhos, which is the largest public laboratory linked to the Ministry of Health, plays an important role in supplying the medicines to the public sector. Likewise, the GPO, a state enterprise under the Thai Ministry of Health, is the main provider to government-run services. The dominant position of such state-owned entities bars other generic companies from entering the market, that might lead to unfair competition practice and thus prejudice the efficiency of the compulsory licensing system. Such a significant divergence between India on the one hand, and Brazil and Thailand on the other, reflect the wide disparity in the industrial development and market structure of the three countries, as will be mentioned in Section 8.5.

Thirdly, there are differences regarding the roles played by the competent authorities. Under Indian law, the Controller settles the terms and conditions of the grant, which are based on the prospective licensee's application (Section 5.3.2.2). In the case of Brazil and Thailand, however, it is the Minister of Health who is vested with that power (Sections 6.3.2.2 and 7.3.2.2). In fact, the only administrative task of the Brazilian patent office (INPI) is to record the compulsory licences, together with amendments and termination.<sup>1278</sup>

Lastly, *any* decision of the Indian authorities, including the grounds for issuing the compulsory licence, is appealable (Section 5.3.2), whereas Brazil (Section 6.3.3) and Thailand (Section 7.3.2) permit only the remuneration, and *not* the grounds, to be subject to higher review.

Following from the above critical analysis, two salient points can be gleaned. Firstly, Brazil and Thailand have established a government use policy in which power is intense and concentrated in the Ministry of Health, whereas in India, the authorisation of such use is spread among different public authorities (the Ministry of Health and the Controller of Patents). In addition, India, owing to its reputation as the world's largest democracy, needs to achieve an

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<sup>1278</sup> Decree No. 3.201/1999 of 6 October 1999, art 13.

internal consensus among the main ministries before making a final decision.<sup>1279</sup> Those concerned are the Ministries of Commerce and Industry, Finance, Agriculture, Rural Development and Communications, the Foreign Ministry and the Ministry of Information Technology.<sup>1280</sup> Such multiplicity complicates the government use licensing where a fast track process is much needed.

Secondly, the Minister of Health of Brazil and Thailand hold power *de jure* and *de facto*, so that there is no room for the patent holder to manipulate the decision-making process. By contrast, India tends towards a more market-driven environment, even where the situation entails government intervention. Indian law awards the decisive role to the Controller of Patents, while the Minister of Health bears no significant responsibility. Such a situation, coupled with the pharmaceutical capacity (Section 8.4) permits the author to conclude that, while Brazil and Thailand consider compulsory licensing as a tool to mainly serve the public health, India uses it to promote the thriving pharmaceutical industry.

### **8.3 Comparison of the practice of the three country case studies**

#### **8.3.1 Brazil and Thailand - Compulsory licensing to serve public health**

As stated at the start of this chapter, Brazil and Thailand have a lot of similarities in the front of public health. As investigated in Chapters 6 and 7, their government use licences were mainly linked to the responsibility of the State to ensure medicine access for their citizens. Another key principle (and perhaps, the most important) observation is that, Brazil and Thailand succeed in their strategy because both established manufacturing capacities albeit with certain limitations. This feature will be returned to in Section 8.5.

The right to health is enshrined in Brazil's Constitution and later Sarney's Law was adopted to offer free medicines to HIV/AIDS patients (Section 6.2.2). In a similar vein, the Thai government is tied by the National Security Act to provide free treatment to all Thais (Section 7.3). In other words, the government's duty to guarantee access to public healthcare in Brazil

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<sup>1279</sup> Omar Serrano and Mira Burri, 'Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India' (2016) World Trade Institute Working Paper no. 1, 9 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2748447](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2748447)> accessed 7 March 2018.

<sup>1280</sup> *Ibid.*

and Thailand is not a mere moral responsibility but also a legal obligation. As a result, they are the only two developing countries that achieved the universal access to ARVs.<sup>1281</sup>

Furthermore, as established in Chapters 6 and 7, both Brazil and Thailand have developed and maintained a government-funded health insurance system through their state-run pharmaceutical organisations. The government of Brazil provides treatment for 75% of its citizens through the SUS, making it the largest public health system in the world (Section 6.2.2). Similarly, almost the entire population of Thailand (99%) is protected under the Universal Coverage Scheme (Section 7.2.2).

The benefit of having guaranteed health insurance is twofold. For the citizens, the scheme secures essential treatment. For the pharmaceutical companies, the author views that such a system turns the government into the largest and most consistent purchaser of medicines, which signifies a fruitful trade relationship. Certainly, public health insurance combined with huge populations make Brazil and Thailand extremely lucrative from a commercial perspective. Such a public health policy in turn amplifies the government's bargaining strength in price negotiations with the patent holders. It is evidenced in Chapters 6 and 7 that the pharmaceutical companies offered discounts to Brazil and Thailand<sup>1282</sup> in order to evade the non-voluntary licence. Any price loss can be compensated by the huge volume purchased by the governments.

Due to the involvement of public authorities as referred above, the political aspect was predominant in the practice of Thailand and Brazil. The Minister in charge acted directly in the procedure and played a decisive role in issuing compulsory licences. Notably, the political crisis in Thailand gave the Minister of Health full discretion to act as he saw fit. Moreover, a quick implementation of government use licensing entails the presence of strongly individualistic politicians who were present in the practice of these two countries. Brazil's President and Minister of Health, as well as the Thai Minister of Health who were key

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<sup>1281</sup> Daniel Benoliel and Bruno Salama, 'Towards an Intellectual Property Bargaining Theory: The Post-WTO Era' (2010) 32 U.Pa.J. Int'l L. 265, 323.

<sup>1282</sup> In the case of Thailand, Novartis agreed to provide free medicines to eligible patients and Thailand revoked the compulsory licence. See the start of Chapter 7.

supporters of compulsory licensing, all had experience either in the medical field and/or previous experience of fighting against health injustices.<sup>1283</sup>

The author further observes that, while there was no collective usage by the two countries, a correlation between them nevertheless existed. Brazil's compulsory licence for Efavirenz in 2007 (Section 6.4.4) was inspired by the decision of Thailand in 2006 (Section 7.4.1). Brazil used Thai pricing as a benchmark to bargain with Merck. This could be an important lesson for other developing countries, that is they should form a coalition or adopt a collective bargain approach which could lead to better prices rather than acting individually.<sup>1284</sup>

However, to a certain extent, the implementations of Brazil's and Thailand's government use displayed varied degrees. While the former's practice was strategic, justifiable and transparent, that of the latter was controversial, sceptical and equivocal. Brazil's only compulsory licensing, that of Efavirenz, was a last resort, and took place when the country had exhausted all alternatives, whereas Thailand mandatorily licensed seven patented medicines in an extremely short time.

Moreover, Brazil's patent law, which requires a formal notification before the grant is enacted, conveyed a clear message to the right owners that a compulsory licence is on the verge of being granted. Accordingly, pharmaceutical companies could not make an excuse for being uninformed. Thai law, however, does not contain a similar provision, and the patent holders claimed that they were not informed about the government's decisions (Section 7.7). Although a prior negotiation can be waived in a government use licence, such a gesture, as recommended earlier, is always advisable to increase process transparency.

Another notable feature is that Thailand's licences were issued amidst an unfavourable political climate. The national health budget decreased, while the military fund increased, and the real motives of the government use were therefore questionable. In addition, the government of Thailand designated the GPO to produce the medicine locally, regardless of the fact that some GPO products did not meet WHO standards (Section 7.5.2). By contrast, Brazil refused to issue

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<sup>1283</sup> Stephanie T. Rosenberg, 'Asserting the primacy of Health over Patent rights: A comparative study of the processes that led to the use of compulsory licensing in Thailand and Brazil' (2014) 14 *Developing World Bioethics* 83, 89.

<sup>1284</sup> Robert C. Bird and Daniel R. Cahoy, 'The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargain Approach' (2008) 45 *American Business Law Journal* 283; Peter K. Yu, 'Access to Medicines, BRICS Alliances, and Collective Action' (2008) 34 *American Journal of Law and Medicines* 345.

a compulsory licence on Kaletra in 2005, despite the demands of health activists, partly because there was no generic version approved by the WHO at that time (6.4.3). Consequently, Thai licences were subject to strong criticism and retaliation from the patent holders (Section 7.4.3), whereas this did not occur in Brazil.

### **8.3.2 India - Compulsory licensing to promote the pharmaceutical industry**

Compared with Thailand and Brazil, India does not operate a national health insurance or a universal healthcare system, and this has allowed the private sector to become the main healthcare supplier in the country. Today, the private sector provides nearly 80% of outpatient and 60% of inpatient care.<sup>1285</sup> Only around 10% of the Indian population is covered by any form of social or voluntary health insurance.<sup>1286</sup>

In fact, India, as a (lower) middle-income country, has traditionally been a low spender on health care, and government expenditure amounts to only 1.4% of GDP.<sup>1287</sup> This amount is extremely low in comparison with the average figure of 2.4% in low-income countries.<sup>1288</sup> In contrast, the expenditure of Brazil and Thailand is 3.8% and 3.2% respectively, higher than the average for a middle-income economy (3%).<sup>1289</sup> In short, the role of the Indian government in the public health sector is negligible compared with its counterparts in Brazil and Thailand.

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<sup>1285</sup> K. Srinath Reddy, ‘India’s Aspirations for Universal Health Coverage’ (2015) 373 *The New England Journal of Medicine* 1.

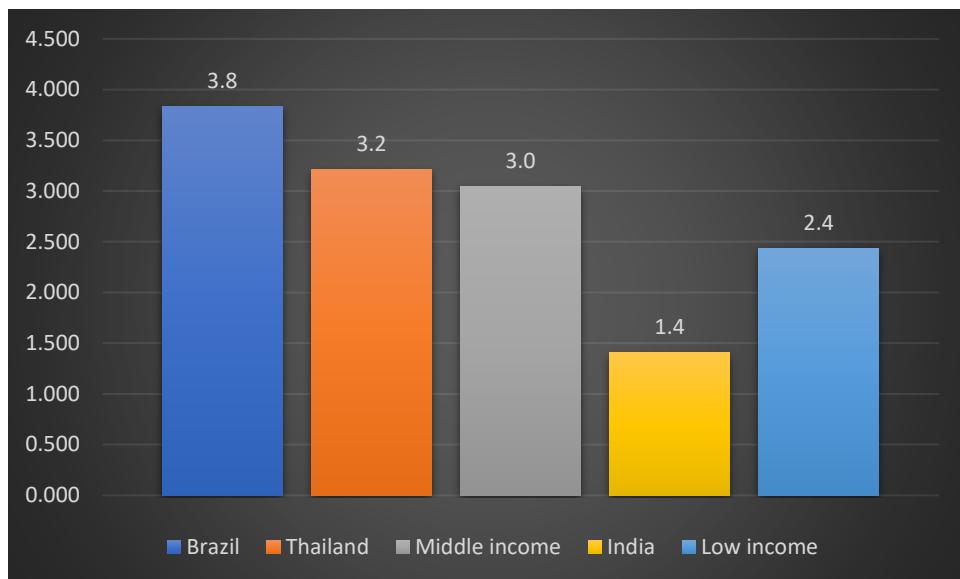
<sup>1286</sup> Yarlini Balarajan *et al.*, ‘Health care and equity in India’ (2011) 377 *Lancet* 505, 509.

<sup>1287</sup> WB, ‘Health expenditure, public (% of GDP)’ (World Development Indicators, 2014) <<https://data.worldbank.org/indicator/SH.XPD.PUBL.ZS>> accessed 22 February 2018.

<sup>1288</sup> *Ibid.*

<sup>1289</sup> *Ibid.*

**Figure 8 Public health expenditures (% of GDP) of India, Brazil and Thailand compared with the average spend of middle income and low-income countries**



As was seen in Chapter 5, India issued its first compulsory licensing very late compared with its distant neighbours - Brazil and Thailand. The first Indian compulsory licence was granted in 2012, seven years after India adopted full TRIPS patenting. Meanwhile, Thailand commenced the government use licensing in 2006 and Brazil started the strategic threats as early as 2001. The tardiness of India was mainly for the reason that, Indian companies could imitate patented medicines until 2005, meaning that affordable generics were not at stake in the country. As a result, compulsory licences were not in the interest of national companies. Since 2012, Indian generic manufacturers have commenced acting on their own initiative to start the legal procedure, whereas the government was totally inactive.

Unlike the compulsory licences of Brazil and Thailand, which chiefly served the public health policies, the Indian licence granted to Natco had a profit-making purpose. The royalty that Natco had to pay to the right owner – Bayer - was therefore much higher than that paid to the relevant patent holders by Thailand and Brazil. Natco paid 7% (Section 5.4.1) whereas Brazil only paid 1.5% to Abbott (Section 6.4.4). Thailand paid 0.5% in the first period of its government use licensing (Section 7.4.1) and in the second one, the amount varied from 1.5% to 3% (Section 7.4.2). Interestingly, the remuneration in Natco's licence is even higher than

the rate which Bayer has to pay to a respective patent owner (4%) in another compulsory licence order taking place in Germany in 2017.<sup>1290</sup>

There are two reasons for such differences in the royalty rates between Brazil, Thailand and India. Firstly, while the compulsory licences in Brazil and Thailand were restricted to the patients covered by national health insurance, the patient pool in *Natco* was of an indeterminate number. Not only can the company provide the medicine within India but can also supply to areas beyond its borders (after the expiry of the patent in 2020). Secondly, Brazil's and Thailand's licences were of definite duration, while *Natco*'s licence would last for the whole term of the patent, meaning that the right owner's monopoly was lost right after the market entry of the generic. Consequently, *Natco* can potentially generate a huge profit, and therefore has to pay more to the right owner.

In contrast to private companies, India's public authorities seem to be more cautious. So far, the Indian government has not issued any compulsory licence for public health purposes (Section 5.5). The DIPP hesitated to grant such a licence upon the request of the Indian Minister of Health, as it did not consider that the disease treated by the target medicine qualified as a national emergency. The DIPP seems to share the same view as the advocates of patents, namely that compulsory licences should be used exceptionally, for example, in cases of urgency.

This thesis submits that a dearth of governmental participation has led Indian mandatory licensing to be seen as a pure legal issue. The litigation was indeed very intense, as we saw in Section 5.4.1. Also, when the responsibility was shifted from public authorities to a private party, the condemnation of the use also moved accordingly. When Thailand issued the compulsory licence for Clopidogrel, it was severely criticised by many who viewed heart disease - a chronic disease – as being unqualified for such use. Notwithstanding, in *Natco*, Nexavar, the orphan drug treating cancer, escaped from similar criticism. While a chronic disease might not be an appropriate reason for proclaiming a national emergency under government use, in case of market-initiated compulsory licensing, it was not a moot point.

It is also observed that the private nature of the Indian licence kept the NGOs from actively engaging in the issue. They would have been more enthusiastic if the affair had involved the

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<sup>1290</sup> *Supra* note 502.

government. As will be illustrated in the next chapter, the NGOs have always been vocal in the medicines access debates. In the case of Brazil and Thailand, these organisations played as supportive actors, acting side-by-side with the governments to defend against the US and to counteract the strategies of the patent holders. We have already seen how the NGOs supported Brazil in the dispute with the US and how prominent they were in creating pressure against Abbott so that the company had to relaunch the medicines in the Thai market after the withdrawal from Thailand.

## 8.4 Different paths to TRIPS implementation

Prior to comparing TRIPS implementation in the three country case studies, it is relevant to outline here their pre-TRIPS patent policies. Such a brief summary will paint a more comprehensive picture of each nation because at the end, implementation process has to harmonise with the general IP context.

Before the TRIPS Agreement was enacted, there was a degree of disrespect for the IP climate in all three countries.<sup>1291</sup> None of them patented pharmaceutical products. While Thailand and India had a certain protection for pharmaceutical processes, Brazil proved to be an extreme anti-patent country, since it revoked such protection in 1969.

Although they all developed an unfavourable stance towards medicine patents, the circumstances that led to their discrimination against patents are different in each case. Since Thailand's first patent law followed the WIPO model, exclusion of pharmaceutical products from patenting simply resulted from the international practice which had been established at that time. In a similar vein, Brazil had been a member of the WIPO patent treaties since the 19<sup>th</sup> century. It was the founding member of the Paris Convention in 1883 and joined the PCT in 1971. Brazilian patent law was hence under the influence of international agreements.

India, however, took a different path. Since the very first Patents Act, India was under the strong influence of English patent law. The 1970 Patents Act, which was the turning point of the country's patent system, also followed its former colonial master's model with substantial modifications. This may explain why, whereas Brazil (before 1969) and Thailand provided 15 years of patent term of protection for pharmaceutical processes, India drew a line between

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<sup>1291</sup> See Sections 5.2.2 (India), 6.2.1 (Brazil) and 7.2.1 (Thailand) of this thesis.

medicines and other products, by providing 7 years for the former and 15 years for others. The complete overhaul of the Indian patent regime post-independence was, therefore, more specific and tailored to the country's needs, thanks to the intensive review of the Ayyangar Committee in 1957 (Section 5.2.2). In contrast to Brazil and Thailand which were under the influence of international patent law, India did not join any patent treaty until the formation of TRIPS in 1995. It also refused to be a member of the Paris Convention and the PCT until 1998.

Although it was said that Indian and Brazilian patent laws brought scarcely any benefits to either of their economies, they became equipped at an early stage with experience in the IP arena. As we saw in Chapters 3 and 4, the developing world, under the leadership of Brazil and India, opposed the developed countries regarding patenting medicines during the Uruguay Round. India, in particular, has long been recognised as having great expertise in global IP policy.<sup>1292</sup> Thailand, which did not lend a substantial voice apart from its only written submission in 1988 did not make significant use of TRIPS flexibilities.<sup>1293</sup>

National variations regarding compulsory licensing of India, Brazil and Thailand in fact have close links with their implementation process of TRIPS. Brazil and Thailand adopted the full patent protection of medicines before the transitional period ended in 2005. Brazil started patenting drugs in 1996, the deadline which was given to WTO developed countries while Brazil was (and still now) considered as a developing member state.<sup>1294</sup> Thailand had introduced such a regime much earlier, in 1992. Both of them failed to capitalise on the 10-year transition period, which was intended as a 'warming-up exercise' to boost the scientific capacity before incorporating TRIPS. By contrast, India started its patent reform as late as in 1999 in a piecemeal manner and completed the entire process in 2005 after significant pressure from the US and Western-based companies (Section 5.2.3). In other words, amongst the three

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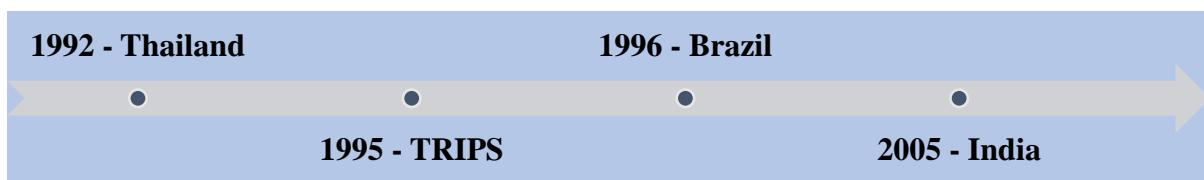
<sup>1292</sup> Omar Serrano and Mira Burri, 'Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India' (2016) World Trade Institute Working Paper no. 1, 9 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2748447](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2748447)> accessed 7 March 2018.

<sup>1293</sup> This view is also shared by El Said who observes that 'those developing countries, particularly India and Brazil, which actively participated in the TRIPS negotiations during the Uruguay Round have been the most successful ones in implementing and incorporating the flexibilities of TRIPS within their national legislation. The opposite can be said of those developing and least developed countries which were less active during the negotiations on intellectual property and TRIPS throughout the Uruguay Round'. Mohammed El Said, *Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region*' (WHO and ICTSD 2010) 58.

<sup>1294</sup> See Figure 1 Different deadlines to implement TRIPS.

countries India was the only one which successfully delayed the whole ratification of TRIPS for 10 years after this Agreement came into effect.

**Figure 9 The implementation of pharmaceutical patent regimes in India, Brazil and Thailand**



Accordingly, early adherence to TRIPS has exerted far-reaching effects on national policies of Thailand and Brazil.<sup>1295</sup> Not only did they lose such a critical opportunity to build a capable pharmaceutical industry but also have put their public health at a distinct disadvantage. In addition, such a swift enactment led those countries to exercise excessive patent protection for medicines which has been disproportionate to their industrial development. Both voluntarily implemented pipeline patents which were not required by TRIPS, and Brazil even disallowed parallel importation in the first instance which compromised its policy decisions to a much further extent.

On the other hand, India implemented neither of these measures. To mitigate the adverse impacts of stringent standards contained in TRIPS, India adopted strict patentable criteria to rule out incremental drug patents. Section 3(d) is such an example (Section 5.2.3). It is therefore argued that India has significantly reduced negative effects of TRIPS on a developing country, whereas both Brazil and Thailand were at a greater disadvantage. In particular, Brazil had to make a number of legislative changes to compensate for its previous mistakes: its government

<sup>1295</sup> Nathan Ford *et al.*, ‘Sustaining Access to Antiretroviral Therapy in Developing Countries: Lessons from Brazil and Thailand’ (2007) 21 AIDS 21; Daniel Benoliel and Bruno Salama, ‘Towards an Intellectual Property Bargaining Theory: The Post-WTO Era’ (2010) 32 U.Pa.J. Int’l L. 265; Sarath K. Ganji, ‘TRIPS Implementation and Strategic Health Policy in India and Brazil’ (2011) Josef Korbel Journal of Advanced International Studies 29; Stephanie T. Rosenberg, ‘Asserting the Primacy of Health over Patent Rights: A Comparative Study of the Processes that Led to the Use of Compulsory Licensing in Thailand and Brazil’ (2014) 14 Developing World Bioethics 83; Omar Serrano and Mira Burri, ‘Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India’ (2016) World Trade Institute Working Paper no. 1, 9 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2748447](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2748447)> accessed 7 March 2018; Piergiuseppe Pusceddu, ‘Access to medicines and TRIPS compliance in India and Brazil’ (2016) 36 EIPR 190.

passed Sarney's Law (1996), the law of Generics (1999), a compulsory licensing decree in 1999, and the amendment thereof in 2003 (Chapter 6).

Such differences of the three countries in implementing TRIPS patenting can be explained firstly by the trade relationship of each country with the US. At that time, the US was the largest trading partner of both Brazil and Thailand. Exports to the US accounted for 25% and 15% of the total value of Brazil's<sup>1296</sup> and Thailand's exports,<sup>1297</sup> respectively. Secondly, IPRs were not the main concern of these two countries when TRIPS was being written, as discussed in Chapters 3, 6 and 7. To them, IP was more of a bargaining chip for trade-offs in other main sectors in which they had interests.

To the Thai negotiators, agriculture and service trade were far more significant than IP, as they were the backbone of the country's economy.<sup>1298</sup> For Thailand (and other ASEAN countries), the success of outward-looking industrialization programmes would depend critically on whether foreign markets remained open.<sup>1299</sup> Ultimately, Thailand is considered to have made a net gain from the Uruguay trade round.<sup>1300</sup> Such an achievement was won at the expense of its premature implementation of drug patents. A non-IP factor which had an impact on Thai rushed enactment is that, since 1954, Thailand has been an American treaty ally and an important partner of the US strategic presence in the Asia – Pacific region.<sup>1301</sup> Economically and politically, Thailand has established an independent and close relationship with the US by which policy changes were 'injected' into Thai law without any hostility.

Similarly, Brazil concentrated very much on goods negotiations, in order to open up its farm produce market to OECD countries.<sup>1302</sup> For long, Brazil has built an international reputation as

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<sup>1296</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 105.

<sup>1297</sup> Samira Guennif, 'Access to essential drugs in Thailand: Intellectual Property Rights and other institutional matters affecting public health in a developing country' in Kenneth C. Shadlen and others (eds), *Intellectual Property, Pharmaceuticals and Public health. Access to Drugs in developing Countries* (EE 2011) 286.

<sup>1298</sup> Mohamed Ariff, 'The Role of ASEAN in the Uruguay Round: Opportunities and Constraint' (International Center for Economic Growth 1993) 41.

<sup>1299</sup> *Ibid.*

<sup>1300</sup> Peter G. Warr, 'The Uruguay Round and the Developing Countries: Thailand and Philippines' (1997) 35 *The Developing Economies* 142.

<sup>1301</sup> Emma Chanlett-Avery *et al.* 'Thailand: Background and U.S. Relations' (The US Congressional Research Service, 2015).

<sup>1302</sup> Juan A. Marchetti and Petros C. Mavroidis, 'The Genesis of the GATS (General Agreement on Trade in Services)' (2011) 22 *The European Journal of International Law* 689, 714 – 716.

the greatest promoter of trade liberalisation in terms of agricultural products.<sup>1303</sup> In the Doha Round - the most recent round of trade negotiations amongst the WTO membership, Brazil confirmed its primary interest is to expand markets for agricultural exports.<sup>1304</sup> As a result, Brazil is also considered as a unique success story of a developing country engaging with the world trading system.<sup>1305</sup>

In sharp contrast to both Thailand and Brazil, India had no trade interests with the US, since it had followed a self-reliance policy in the decades following independence.<sup>1306</sup> Unlike Brazil, India had a weak agricultural sector, consisting primarily of peasant farmers, and highly vulnerable to trade liberalization.<sup>1307</sup> For this reason, the ‘carrot’ of the US market did not appear too appealing. In addition, it should be reiterated that India has a flourishing generic sector due to the absence of drug patents since 1970, so private industry also pressed the government not to accept TRIPS requirements. Therefore, even when it was unavoidable to follow TRIPS, India resisted external pressures for as long as it was able, and introduced legislative changes as slowly as possible (Section 5.2.3).

It is true that foreign pressure was an influence on these countries’ compliance with international patent law, but it is equally true that economic and political shifts carried weight in their decisions. Change in the economic policy of India (Section 5.2.3) and democratisation occurring in Brazil (Section 6.2.1) at that time were pushing the two towards a more open market. The new governments that took office in Brazil and India in the early 1990s believed that, embracing IPRs would be a welcome means of attracting foreign investment and a first step towards integration into the global trade. Furthermore, geopolitical factors, such as the reunification of Germany, which took place when TRIPS was underway, gave these countries further motivation to enter the world economy in merchandise services and intangibles (Section 3.2.3).

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<sup>1303</sup> Roge’rio De Souza Farias, ‘Sowing the Seeds of Leadership: Brazil and the Agricultural Trade Negotiations of the Uruguay Round’ (2010) 44 *Journal of World Trade Law* 661.

<sup>1304</sup> Kristen Hopewell, ‘Different paths to power: The rise of Brazil, India and China at the World Trade Organization’ (2015) 22 *Review of International Political Economy* 311, 320.

<sup>1305</sup> Meredith A. Taylor Black, *King Cotton in International Trade: The Political Economy of Dispute* (Brill 2016) 86 – 87.

<sup>1306</sup> Jayashree Watal, ‘Patents: An Indian perspective’ in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 296.

<sup>1307</sup> Kristen Hopewell, ‘Different paths to power: The rise of Brazil, India and China at the World Trade Organization’ (2015) 22 *Review of International Political Economy* 311, 321.

Given the above analysis, it can be argued that the path of each country to pharmaceutical patentability involved a nexus of interests. It would be an oversimplification to attribute the adaptation of their patent laws to the extrinsic trade sanction of the US. Each country's intrinsic economic motivation was also a contributory factor. However, the fact remains that while early enforcement of TRIPS in Thailand and Brazil potentially hampered their national policies, India's gradual compliance with TRIPS obligations cushioned the adverse effects of the high level of patent protection.

This thesis submits that more recently, Brazil has become more vocal in the development agenda of the international patent regime, whereas India has remained inactive. For example, in 2004 Brazil, together with Argentina, submitted a first proposal for the establishment of a development agenda for WIPO (document WO/GA/31/11), which was subsequently supported by 12 other developing countries (not including India).<sup>1308</sup> The proposal was considered an extraordinary breakthrough, which took into account the public interest of developing countries. It was a step of particular importance, considering the history and mission of WIPO, which has been to underline the absolute benefits of IPRs, as will be seen in the next chapter. India did not co-sponsor the Agenda until 2006, which implied that the country (at least initially) supported stronger patent protection.<sup>1309</sup>

India's current position should not come as a surprise when considering the general context of its economic initiatives (Section 5.1). That is, India has been attempting to position itself as a global hub of manufacturing, and strong IP protection is necessary for that purpose. Also, as the country presents a uniquely situated laboratory for advanced developing country patent systems,<sup>1310</sup> this thesis submits that India has slowly drifted apart from the remaining of the developing world. Also, in the specific context of pharmaceuticals, its manufacturing capacity as will be examined next, has and will set the country apart from other developing nations.

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<sup>1308</sup> WIPO, Proposal by Argentina and Brazil the Establishment of a Development Agenda for WIPO (27 August 2004) WO/GA/31/11.

<sup>1309</sup> Omar Serrano and Mira Burri, 'Making Use of TRIPS Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India' (2016) World Trade Institute Working Paper no. 1, 9 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2748447](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2748447)> accessed 7 March 2018.

<sup>1310</sup> Janice M. Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 38 University of Pittsburgh Law Review 491, 503.

## 8.5 Pharmaceutical manufacturing capacity

India, Brazil and Thailand are among the very few countries of the developing world that possess capable pharmaceutical industries.<sup>1311</sup> Nevertheless, a wide disparity exists between the three. If Brazil's, and to a lesser extent, Thailand's scientific development is limited to formulation and packaging, India's pharmaceutical capability has progressed to a very large degree that India can master the whole manufacturing process (Section 5.2.4). It now has the world's third-largest Active Pharmaceutical Ingredients (API) manufacturing industry, producing more than 400 different APIs, and accounting for approximately 6.5% of the world's API production.<sup>1312</sup> Impressively, India is one of only two countries in the world where generic manufacturers, not transnational corporations, control a larger share of the domestic market.<sup>1313</sup>

As repeatedly stressed in this thesis, the role of Indian generics is significant not only to the people of India but also to those of other developing countries. It should be recalled that the agreement of the Brazilian government over Kaletra was concluded partly because the Indian price was higher than that offered by the patent holder (Section 6.4.3). In the case of Thailand, all the medicines subject to compulsory licensing were imported from India. When a patent owner – Sanofi - threatened litigation against an Indian company who was about to supply the generic to Thai patients, the company suspended the delivery for one year to avoid the lawsuit (Section 7.4.3).

Recently, under Gilead's voluntary licensing scheme, the company signed agreements with 11 Indian companies to manufacture generic versions of hepatitis C medicines to distribute across 101 developing countries.<sup>1314</sup> It is a clear indication that Indian generic manufacturers have become strategic partners with research-based pharmaceutical companies in the West. Those said examples prove the enormous potential of India's pharmaceutical industry and more importantly, imply that such partnership will avert the possibility for seeking compulsory licences of Indian companies.

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<sup>1311</sup> A more detailed description of the medicine manufacturing process can be found in Warren Kaplan and Richard Laing, 'Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines. An Overview of Key Concepts, Issues and Opportunities for Future Research' (WB 2005) 4.

<sup>1312</sup> William Greene, 'The Emergence of India's Pharmaceutical Industry and Implications for the US Generic Drug Market' (US ITC, May 2007) 5.

<sup>1313</sup> The other country is Japan. William J. Bennet, 'Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India' (2014) 13 Washington University Global Studies Law Review 535, 538.

<sup>1314</sup> Gilead, 'Chronic Hepatitis C Treatment Expansion. Generic Manufacturing for Developing Countries' (Factsheet, October 2015) <<http://www.gilead.com/news/fact-sheets>> 21 February 2018.

Another distinct feature in the case of India is that, its pharmaceutical sector is perceived as part of its industrial programme, rather than its health policy.<sup>1315</sup> Pharmaceutical policies have traditionally been formulated by the Ministry of Chemicals and Fertilizers, with only limited input being provided by the Ministry of Health.<sup>1316</sup> This is in sharp contrast to Brazil and Thailand, where the pharmaceutical plan is mainly written by the Ministry of Health. Moreover, the Indian government has adopted a wide range of measures to incentivise pharmaceutical R&D, such as major tax benefits and grants for researchers.<sup>1317</sup>

The policies implemented by the Indian government have led to a paradigm shift in the sector. At the beginning of the 1990s, India was known as a powerhouse in reverse engineering. Nowadays, certain companies have started investing in the pre-clinical development of small molecules.<sup>1318</sup> The extent to which these R&D activities will grow remains to be seen, but there is no doubt that India is gradually moving away from the role of follower to that of innovator. At the crossroads, the ulterior motive of India in bolstering IP protection has become clearer.

By contrast, Brazil's pharmaceutical market is not self-reliant (Section 6.2.3). There are industrial limitations to the first two phases of R&D and production of pharmaceuticals which require large amounts of investment and have a high degree of uncertainty. Developments occur mainly in academic/university environments, with no significant presence of private companies.<sup>1319</sup> Some multinational companies also operate in the synthesis process and the production of drugs, but in insufficient volumes to meet national needs and with dependence on active ingredients and intermediates.

The Brazilian pharmaceutical market is relatively weak in comparison with that of India, but sufficient to support the government in bargaining with the patent holders. As seen in Chapter 6, Brazil's industrial limitation failed to maintain the credibility of its compulsory licensing threats. In Brazil's sole instance of government use (*Efavirenz* in 2007), the government had

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<sup>1315</sup> Ramesh Govindaraj and Gnanaraj Chellara, 'The Indian Pharmaceutical Sector Issues and Options for Health Sector Reform' (WB Discussion Paper No. 437, 2002) 5.

<sup>1316</sup> *Ibid.*

<sup>1317</sup> Reji K Joseph, "The R&D Scenario in Indian Pharmaceutical Industry", (2011) Discussion paper No. 176, 7

<sup>1318</sup> Tanjore Balganesh *et al.*, 'Drug Discovery Research in India: Current State and Future Prospects' (2014) 5 ACS Medicinal Chemistry Letters 724.

<sup>1319</sup> Julia Paranhos and Lia Hasenclever, 'The Relevance of Industry-University Relationship for the Brazilian Pharmaceutical System of Innovation' in A. Pyka and M. da Graca Derengowski Fonseca (eds), *Catching Up, Spillovers and Innovation Networks in a Schumpeterian Perspective* (Springer 2011) 257 – 268.

to import the medicine from India for two years before its public laboratory had the capacity to manufacture (Section 6.4.).

Likewise, Thailand's pharmaceutical industry relies heavily on imports, and 90% of its domestic companies are involved in packaging or formulating drugs. The Thai pharmaceutical industry has no research-based companies at all. Although Thailand can manage to export some medicines to the countries in the ASEAN region or Africa, it has a negative balance of trade. Each year, Thailand imports, on average, more than \$1 billion's worth of pharmaceutical products and exports \$268 million's worth pharmaceutical products.<sup>1320</sup> The Thai market is therefore a net importer and distributor of drugs.

What, then, are the drivers that create such differences between India, Brazil and Thailand? As carefully assessed in Chapter 5, India's thriving indigenous industry was the outcome of a long absence of patents on medicines. Why did a similar absence from the patent laws of Thailand and Brazil fail to yield a similar outcome?

The author offers a possible explanation. As regards Thailand, its people (like those of many other Southeast Asian countries) have a long history of using traditional and herbal medicines, which are considered among the most valuable elements of their ancestral heritage. In spite of the popularity of Western medicine, Thai traditional medicine is strongly promoted by the government and is hence used alongside modern therapies.<sup>1321</sup> In 1999, Thailand's government adopted the 'Protection and Promotion of Thai Traditional Medicine Knowledge Act B.E. 2542' to protect that form of medical heritage. In addition, the use of Thai traditional medicines is part of the national health care system.<sup>1322</sup> This continuing use of traditional methods of treatment, arguably, is one of the reasons why modern pharmaceutical technology is not well developed in Thailand, despite the long absence of patent protection.

Meanwhile, the underlying cause of Brazil's limited industrial development is largely due to the exclusion of patentability, which was initially applied to medicine products in 1945 and then extended to processes in 1969. Since Brazil did not protect drugs under any form of patent,

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<sup>1320</sup> Phamax, 'Healthcare Market Access: Thailand' (2015) 65

<<http://www.phamax.ch/Uploads/02082016040501AM.pdf>> accessed 23 July 2017.

<sup>1321</sup> WHO, 'Traditional Medicine in Kingdom of Thailand'

<[http://www.searo.who.int/entity/medicines/topics/traditional\\_medicines\\_in\\_sear/en/](http://www.searo.who.int/entity/medicines/topics/traditional_medicines_in_sear/en/)> accessed 7 March 2018.

<sup>1322</sup> *Ibid.*

it failed to create a guaranteed return on the R&D investments of the industry. The practice of ‘free-riding’, coupled with other control policies in Brazil, resulted in a lack of stimulation for technological development and a disincentive to take risks in highly capital intensive R&D sectors like pharmaceuticals.<sup>1323</sup> Therefore, this thesis argues that Brazil is a good example of a country in which an extreme lack of patent protection has had a regressive effect on its industrial capacity.

## 8.6 Conclusions

In this chapter, domestic implementation of TRIPS and pharmaceutical capacity have been identified as the two key drivers behind the various use amongst three country case studies.

In the wake of TRIPS, Indian law-makers started the legislative changes in a steady fashion, optimising all the flexibilities given so as to accustom its industry to such changes. Accordingly, apart from the compulsory licence, India reserves other options to oppose drug patents or to intervene when the rights owners misbehave. Moreover, its compulsory licensing regime, in many aspects, has proven to be not only TRIPS-compliant but also creative. Compared with Thailand and Brazil, India has carved out a more pragmatic and coherent policy to best serve its industry.

The last few years have seen a reshaping and reposition of India in the realm of healthcare and pharmaceuticals. As a result, the country has achieved a high-ranking position in the global market. The fact that India is now heading towards an innovation-driven economy and that domestic companies have commenced collaboration with Western corporations, might eliminate its possibility for using the compulsory licence. Ironically, India’s capacity to innovate has become its Achilles heel, making it more cautious in overriding patent rights. The country is therefore portrayed as a model of medium bargaining power.<sup>1324</sup>

At the same time, rapid amendments to patent laws and excessive compliance with TRIPS in Brazil and Thailand hindered these countries from achieving national goals, forcing them to use compulsory licences earlier and more frequently than India. Apart from the legal tool of

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<sup>1323</sup> Viviane Yumy Mitsuuchi Kunisawa, ‘The Brazilian patent system: challenges for the future’ in Ryo Shimanami (ed), *The future of the Patent System* (EE 2012) 281.

<sup>1324</sup> Daniel Benoliel and Bruno Salama, ‘Towards an Intellectual Property Bargaining Theory: The Post-WTO Era’ (2010) 32 U.Pa.J. Int’l L. 265, 329 – 332.

compulsory licensing, both countries have almost no other potent weapon to safeguard the public interest.

Brazil has long considered patents as an obstacle to the industrial progress of a developing country but early adherence to TRIPS suddenly reversed its policy. As a result, Brazil had to take many regulatory twists and turns to regain the opportunities lost. India is well-known as a land of contrasts, but in the field of compulsory licensing, it is Brazil that has displayed the greatest number of contradictions in its policies. For this reason, some scholars have called the country's approach 'schizophrenia' in the form of 'incoherence of actions'.<sup>1325</sup>

Compared with India, Brazil is much weaker in the field of pharmaceutical innovation. Paradoxically, such a weakness has turned the country into a model of high bargaining power.<sup>1326</sup> Brazil has, arguably, expressed the most aggressive attitude towards compulsory licensing which can be seen through its threatening tactics as well as the confrontation with the US over international litigation. Judging by Brazil's perspective on the compulsory licence, it has appeared as a 'black sheep'. Despite the high possibility to issue such licensing, Brazil's actual ability remains to be seen as duplicating patented medicines involves more and more advanced scientific know-how, which the country currently does not possess.

Turning to Thailand, its Patent Act is still in its infancy. Compared with India or Brazil, Thailand has the least global influence in terms of economics and politics. As a consequence, it was the country which yielded to the US's demand of patenting medicines the earliest. However, as a matter of prudence, Thailand chose the path of least resistance. That is, it only incorporated the minimum requirements contained in TRIPS without going much beyond. Such incorporation, on the one hand, ensures the fundamental compliance with international legal norms and avoids being challenged by developed countries, but, on the other hand, fails to leverage the regulatory space provided by TRIPS.

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<sup>1325</sup> Mônica Steffen Guise Rosina and Adelina de Oliveira Novaes, 'Brazil and the Case of Patents and Access to Medicines: A Medical Condition?' in César Rodríguez Garavito and Rochelle Cooper Dreyfuss (eds), *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America* (OUP 2014) 92.

<sup>1326</sup> Daniel Benoliel and Bruno Salama, 'Towards an Intellectual Property Bargaining Theory: The Post-WTO Era' (2010) 32 U.Pa.J. Int'l L. 265, 313.

Within the context of TRIPS Article 31, Thailand issued the greatest number of compulsory licences. Accordingly, like Brazil, it was also classified as having a high bargaining power,<sup>1327</sup> but in truth, the country should be regarded as a ‘shooting star’ rather than an established model. It is important to note that Thai licences which were issued by an unlawful regime is unlikely to be repeated by a legitimate and *de jure* government.

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<sup>1327</sup> *Ibid.*, 319.

# **CHAPTER 9: MULTILATERAL ORGANISATIONS AND COMPULSORY LICENSING**

As seen so far, the debate over compulsory patent licensing and access to medicines has expanded its conventional boundary beyond countries' governments and transnational companies. The four previous chapters have accomplished the primary objective of this thesis as set out in Chapter 1, that is to critically evaluate the compulsory licensing regimes of three carefully selected developing countries. The aim of this chapter is to complete the secondary objective, that is to critically assess multilateral organisations which have also participated in the current debate. Chapter 9 will answer the last research question, namely, what are the philosophical approaches of multilateral organisations in discussing the access to medicines?

Compulsory licensing, as described by Ho, is an accurate reflection of competing patent views.<sup>1328</sup> As demonstrated so far, at one extreme are the pharmaceutical industry and the US, and at the opposite extreme are developing countries. However, apart from these actors, there are others: the EU, WIPO, WHO, and NGOs which, in one way or another, all take part in the ongoing deliberations. The objective of this chapter is to establish and analyse the stance of the four aforementioned actors and determine to what extent their roles influence the world's compulsory licensing regimes and policies.

Until now, the role of the US in formulating the TRIPS Agreement has been clearly highlighted (Chapter 3). Its strong influence on altering other countries' IP policies is also carefully assessed (Chapters 5, 6, and 7). That prompts a question: is the US the only actor in this play? The answer to this question is obviously 'no' because there was a contribution of the EU too. However, in contrast to its US ally which has always been a focal point in medicine IP-related debates, the presence of the EU in the debate is not so evident. Therefore, a general assessment of the role of the EU is needed to provide an analytical balance.

Equally, a treatment of WIPO is important as it represents for the patentee community – an essential actor in the ongoing discussion. Prior to the signing of TRIPS, WIPO has, arguably,

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<sup>1328</sup> Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 158.

the greatest control over IPRs. It administers the Paris Convention – the first international agreement regulating IP and the PCT – the treaty which streamlines patent applications.<sup>1329</sup> Nevertheless, the signing of TRIPS has diluted the influence of WIPO in world IP activities. This chapter will critically evaluate the role of WIPO in current developments in the patenting landscape.

By the time of writing TRIPS, the WHO was not invited to the negotiating process. More recently, this organisation has, however, slowly entered into current discussions about patent and health. In contrast to WIPO carrying with itself the tasks of promoting IPRs, the WHO plays a central role in governing and coordinating global health. As a result, it exerts an indirect influence on the use of compulsory licensing. For example, in 2015 the WHO introduced some new, expensive medicines to its Model Lists of Essential Medicines.<sup>1330</sup> Interestingly, in 2016, Colombia sought support from the WHO to issue a compulsory licence for a cancer drug, which is covered by that list.<sup>1331</sup> As also demonstrated in Chapter 6, countries' governments have expanded the discussion about trade and health to this organisation. For these reasons, the increasing involvement of the WHO is getting deeper.

As briefly mentioned in Section 8.3.1, the participation of NGOs in the use of compulsory licences has been intense in the cases of Brazil and Thailand. As also touched upon in Section 4.3.1, the NGOs played a part in the adoption of the Doha Declaration. It is not an exaggeration to state that the NGOs have lent considerable support to developing countries in any dispute concerning access to medicines. Without their assistance, those countries would not have achieved such victories or, could only have done so with considerable difficulty.

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<sup>1329</sup> There are other patent-related treaties administered by WIPO. They are the Budapest Treaty and the Strasbourg Agreement Concerning the International Patent Classification. See WIPO, 'Patent-related Treaties administered by WIPO' <<http://www.wipo.int/patent-law/en/treaties.html>> accessed 5 April 2018.

<sup>1330</sup> Ellen FM 't Hoen *et al.*, 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016' (2018) 96 Bulletin WHO 185, 189.

<sup>1331</sup> *Ibid.*

## 9.1 Compulsory licensing in the EU

The EU is not a single state but consists of 28 member states in which medicine manufacturing capability varies from one country to another. There are countries that have an advanced pharmaceutical industry, such as Germany, Switzerland,<sup>1332</sup> France, and the UK, and also those which lack the sophisticated capacity, such as Eastern Europe states. Such a variety of membership adds the complication to the issue. In this section, the author will examine the compulsory licence practice at two levels: individual country and, the EU. It should be noted that this part does not cover all EU members but will draw a sketch map instead by providing some insights into Germany, Ireland, the Netherlands, Switzerland and Sweden.

First and foremost, it is observed that compulsory licensing within the EU is aimed at responding to the anti-competitive behaviour of IP holders rather than addressing healthcare concerns or the public interest. IPRs in the EU are sometimes characterized as hindering the free movement of goods and raising prices.<sup>1333</sup> Because displaying a dominant position has a lower threshold in the EU, non-voluntary licences are issued more often in the region.<sup>1334</sup> Recent compulsory licences in Europe, which were issued either by the Court of Justice of the EU (CJEU)<sup>1335</sup> or by European countries,<sup>1336</sup> are on the grounds of competition law, not patent law.

At the level of individual countries, although compulsory licences found to involve Article 31 of TRIPS are very rare in the EU, this thesis submits that the awareness of this legal mechanism has started to develop in the region. The defining moment occurred in 11<sup>th</sup> July 2017 when German courts granted a compulsory licence on the ground of public interest under Section 24 German Patent Act, which addressed TRIPS Article 31.<sup>1337</sup> This ruling is a milestone in the

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<sup>1332</sup> The reason why Switzerland is present in this section has been stated in Chapter 1, *supra* note 77.

<sup>1333</sup> Rita Coco, ‘Antitrust Liability for Refusal to License Intellectual Property: A Comparative Analysis and the International Setting’ (2008) 12 Marquette Intellectual Property Law Review 1, 7.

<sup>1334</sup> Jerome H. Reichman and Catherine Hasenzahl, ‘Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA’ (UNCTAD-ICTSD, June 2003) 21.

<sup>1335</sup> Case T-201/04 *Microsoft Corp. v Commission*, ECR [2007] II-03601; Case C-418/01 *IMS Health GmbH and Co. OHG v NDC Health GmbH and Co. KG* [2004] ECR I-05039; Joined cases C-241/91 P and C-242/91 P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities*, ECR [1995] I-00743.

<sup>1336</sup> James Packard Love, ‘Recent European Union Compulsory Licenses’ (KEI Research Note 2014) <<https://www.keionline.org/cl/europe-compulsory-licensing>> accessed 16 March 2018. In this research note, the author presented a number of cases concerning compulsory licences in the EU. However, no cases were found to involve Article 31 of TRIPS.

<sup>1337</sup> BGH, Urteil vom 17.07.2017 - AZ: X ZB 2/17. On 31<sup>st</sup> August 2016, the German Federal Patent Court granted a compulsory licence to Merck to distribute the ARV drug, Isentress, which contains Raltegravir - a patented

country's patent law history as compulsory patent licensing is a highly unusual phenomenon in the Federal of Germany. The previous attempt occurred more than 20 years ago, in 1996 when a request was initially accepted by the Federal Patent Court but then was overturned by the Federal Court of Justice, the highest civil court in Germany.<sup>1338</sup>

In fact, before the German ruling, in April 2017, the Irish medical organisation also called upon the government to issue a compulsory licence for sofosbuvir treating hepatitis C for public non-commercial use as per Article 70 of the Patents Act.<sup>1339</sup> Similarly, in November 2017, the Council for Public Health and Society of the Netherlands has recommended compulsory licensing as a means to lower medicine prices.<sup>1340</sup> The author argues that although this recommendation is unlikely to be implemented, particularly when Amsterdam replaced London to become a new home of the European Medicines Agency (EMA) in the wake of Brexit, it sets an alarming trend for pharmaceutical companies. In a very recent development, in May 2018, Swiss health NGO Public Eye has launched a campaign calling on Swiss Federal Council to use compulsory licensing to make medicine more affordable for Swiss people.<sup>1341</sup> Given the fact that Switzerland is a hub of transnational pharmaceutical companies, such a bold move will encourage other countries, both developed and developing, to follow suit.

As the practice in Germany, Ireland, the Netherlands and Switzerland has suggested, there has been a real and rising demand for affordable medicines in Western European countries. Pharmaceutical companies might, therefore, want to reconsider their market strategy or voluntarily license their patents to a third party before a compulsory licence is proposed. It also

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active ingredient owned by Shionogi. The patent holding company appealed the case to the Federal Court of Justice. However, on 11<sup>th</sup> July 2017, the Court of Justice upheld the original ruling. On 21<sup>st</sup> November 2017, the Federal Patent Court set the licence fee at 4% of sales which Merck has to pay to Shionogi. See further at 'Festsetzung der Lizenzgebühr für Zwangslizenz für HIV-/AIDS-Medikament' (22 November 2017, Press release, Bundespatentgericht)

<[https://www.bundespatentgericht.de/cms/index.php?option=com\\_content&view=article&id=153%3A2017-11-22-14-40-14&catid=9%3Apressmitteilungen&Itemid=79&lang=de](https://www.bundespatentgericht.de/cms/index.php?option=com_content&view=article&id=153%3A2017-11-22-14-40-14&catid=9%3Apressmitteilungen&Itemid=79&lang=de)> accessed 16 May 2018. As of this writing, the written opinion by the Federal Patent Court is not yet available.

<sup>1338</sup> Philipp Maume, 'Compulsory Licensing in Germany' in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015) 98 - 99.

<sup>1339</sup> General Motions 2017, Session 2 (Irish Medical Organisation, 21 April 2017)

<<https://www.imo.ie/news-media/agm/agm-2017/motions/general-motions-2017/>> accessed 2 May 2018.

<sup>1340</sup> The Netherlands's Council for Public Health and Society, 'Development of new medicines. Better, faster, cheaper' (The Hague, 2017) 30 – 31 <<https://www.raadrvs.nl/en/item/development-of-new-medicines.-better-faster-cheaper>> accessed 1 April 2018.

<sup>1341</sup> Public Eye, 'Public Eye calls on Swiss Federal Council to use compulsory licensing against exorbitant drug prices' (22 May 2018)

<[https://www.publiceye.ch/en/media/press-release/public\\_eye\\_calls\\_on\\_swiss\\_federal\\_council\\_to\\_use\\_compulsory\\_licensing\\_against\\_exorbitant\\_drug\\_prices/](https://www.publiceye.ch/en/media/press-release/public_eye_calls_on_swiss_federal_council_to_use_compulsory_licensing_against_exorbitant_drug_prices/)> accessed 9 June 2018.

should be stressed that compulsory licensing in Germany, Ireland and the Netherlands was granted and has been recommended on the ground of public interest. As assessed in the three country case studies in this thesis, access to medicines is, undoubtedly, a key factor in determining public interest.

In 2015, a member of the European Parliament raised a possibility of the use of compulsory licensing for hepatitis C patients, and of whether or not the EU or the EMA can join together to negotiate with pharmaceutical companies.<sup>1342</sup> Although the EU conveyed a clear message that issuing a compulsory licence, is not within the power of the EU, but is left to the discretion of member states,<sup>1343</sup> there is no doubt that compulsory licensing is now expanding its potential application to Europe.

Sweden appears to be the only EU member to have made a substantial contribution to TRIPS compulsory licensing, by means of a thorough study, published in 2008.<sup>1344</sup> Although this work primarily examined the special compulsory licensing scheme under Article 31bis, which falls outside the scope of this thesis, it provides some valuable insights from an EU member. It stated the fact that medicine prices are influenced by various factors, including procurement policies, taxes, regulatory costs and distribution costs, many of which fall outside the coverage of patent law.<sup>1345</sup> Consequently, compulsory licences may be useful tools in certain cases, but they are also associated with risks and limitations, and that they cannot improve other deficiencies in health care systems, such as lack of trained personnel.<sup>1346</sup> The most important advantage of this legal tool, according to the Swedish study, lies in its power as a threat in the negotiations with the patent holders and in influencing them to agree to lower their prices, rather than its actual use.<sup>1347</sup> Such strength has been illustrated in the example of Brazil (Chapter 7).

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<sup>1342</sup> ‘Hepatitis C and the TRIPS Agreement’ (Parliamentary questions, 24 March 2015) <<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2015-004613+0+DOC+XML+V0//EN>> accessed 8 March 2018.

<sup>1343</sup> ‘Answer given by Ms Bieńkowska on behalf of the Commission’ (Parliamentary questions, 23 June 2015) <<http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2015-004613&language=EN>> accessed 8 March 2018.

<sup>1344</sup> Sweden’s National Board of Trade, ‘The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?’ (2008) 7 <<https://www.kommers.se/In-English/Publications/2010-and-older/The-WTO-decision-on-compulsory-licensing/>> accessed 14 March 2018.

<sup>1345</sup> *Ibid.*, 20.

<sup>1346</sup> *Ibid.*, 7.

<sup>1347</sup> *Ibid.*, 37.

At the EU level, the ideology of the EU with regard to compulsory licensing has been complex and sophisticated. During the negotiations of the Uruguay Round, the EU was viewed a ‘quiet free-rider’ on the US’s efforts.<sup>1348</sup> As deeply explored in the previous chapters, the US constantly used trade power to modify IP policies of developing countries and then economically coerced them into negotiating TRIPS. Once these countries entered the negotiating table, the EU simply signed bilateral agreements on IP with them.<sup>1349</sup> During the drafting of TRIPS, compared to the US, which displayed an almost total ban on compulsory licensing, the EU was more flexible in its approach. Its early proposal set out four possible justifications for a grant of a compulsory licence: lack of local working, dependent patents, official licences, or public interest.<sup>1350</sup>

This thesis further submits that, like the US, the EU has also imposed pressure on non-EU countries to change their IP regimes, albeit in a subtle manner. For example, while US Special 301 has been globally infamous (Sections 3.3.2 and 8.3), it is less known that, in 1988, with respect to copyright analogy, the Commission issued a Green Paper that allowed it to take a wide range of actions, including trade retaliations against ‘illicit commercial practices’.<sup>1351</sup> Nevertheless, these measures are rarely used because of the difficulties in building a consensus amongst EU members.<sup>1352</sup> Also, while the US’s unilateral economic coercion has been subject to criticism, the EU’s similar measures did not receive equal attention. For example, the EU’s move against Indonesia and Thailand for record piracy as well as its suspension of Korea’s GSP privileges for failing to provide IP protection for European companies<sup>1353</sup> did not feature prominently in literature.

In order to implement Paragraph 6 of the Doha Declaration, the EU, together with the US, proposed to confine compulsory licensing to LDCs, while developing countries with higher

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<sup>1348</sup> Peter Drahos, ‘Negotiating Intellectual Property Rights: Between Coercion and Dialogue Global’ in Peter Drahos and Ruth Mayne (eds), *Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan and Oxfarm 2002) 178.

<sup>1349</sup> *Ibid.*

<sup>1350</sup> UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 463.

<sup>1351</sup> Commission, ‘Green Paper on Copyright and the Challenge of Technology – Copyright Issues Requiring Immediate Action’ (Communication) COM (88) 172 final. See further discussion of EU attempts on monitoring IP standards of non-EU countries at Maximiliano Santa Cruz S., *Intellectual Property Provisions in European Union Trade Agreements. Implications for Developing Countries* (ICTSD 2007).

<sup>1352</sup> Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 50.

<sup>1353</sup> Peter Drahos, ‘Negotiating Intellectual Property Rights: Between Coercion and Dialogue Global’ in Peter Drahos and Ruth Mayne (eds), *Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan and Oxfarm 2002) 178.

incomes could only use this provision for exportation in case of ‘national emergency or extreme urgency’.<sup>1354</sup> Moreover, ten EU countries, (the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia), agreed that they would use compulsory licensing as importers only in situations of national emergency or other circumstances of extreme urgency.<sup>1355</sup> Upon their accession to the EU, they would opt out of using the system as importers.<sup>1356</sup> It is hard to imagine that the EU played no role in the attainment of such agreements.

One of the very rare contributions of the EU to the debate on compulsory licences and public health within the TRIPS context is the working document entitled ‘Compulsory licensing and Data Protection. Legal issues related to compulsory licensing under the TRIPS Agreement’.<sup>1357</sup> In this document, the EU for the first time reflected on this topic, in particular the provision of a ‘local working patent’. As already established in Chapter 4, the concept of a ‘local working’ patent is a very controversial one which has been interpreted differently by academic scholars. Opposing the strict approach of developing countries, the EU is more flexible when viewing that local working can be understood as either industrial use (local manufacture) or commercial use (importation) as long as the market demand is reasonably met.<sup>1358</sup>

The author maintains that a narrow interpretation of ‘local working’ associated with local manufacture apparently goes against the ideology of free movement of goods and services, two of the four fundamental freedoms of the EU internal market. In fact, as far back as the early 1990s, the CJEU ruled out similar provisions under UK and Italian patent law.<sup>1359</sup> Interestingly, in almost all European countries nowadays, there is no requirement for the patentee to show working of or use of his patented invention.<sup>1360</sup>

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<sup>1354</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4<sup>th</sup> edn, Sweet and Maxwell 2012) 56.

<sup>1355</sup> WTO, ‘Obligations and exceptions’ (Fact Sheet: TRIPS and Pharmaceutical Patents, September 2006) <[https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm)> accessed 6 March 2018.

<sup>1356</sup> WTO, ‘Obligations and exceptions’ (Fact Sheet: TRIPS and Pharmaceutical Patents, September 2006) <[https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm)> accessed 6 March 2018.

<sup>1357</sup> Commission, ‘Legal Issues Related to Compulsory Licensing under the TRIPS Agreement’ (Issues and Policies, 21 February 2001) <[http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc\\_122031.pdf](http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf)> accessed 16 May 2018.

<sup>1358</sup> *Ibid.*, 4.

<sup>1359</sup> Case C-30/90 *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland*, ECR [1992] I-00829; Case C-235/89 *Commission of the European Communities v Italian Republic*, ECR [1992] I-00777.

<sup>1360</sup> David Perkins, ‘Compulsory Licensing in Europe’ (ICC and AIPLA Joint Conference: The Future of TRIPS: Impact of the Doha Public Health Declaration, Paris 13 September 2002). In addition, in 2007, the Association of Patent Law Firms (APLF) reiterated that except for Spain, other European countries do not have the working

In general, the EU has displayed a protective behaviour towards the pharmaceuticals industry since it is the third largest research-intensive sector of the region.<sup>1361</sup> It is also one of the three sectors where EU companies outperform or show comparable performance to their global counterparts.<sup>1362</sup> In addition, Novartis and Roche (Switzerland) are the only two European pharmaceutical companies ranked in the world's top 10 R&D investing companies.<sup>1363</sup> Almost all R&D costs in Europe are financed from the industry's own resources. As the EC observed in 1994, 90% of R&D is industry-financed.<sup>1364</sup> In a report in 2009, the EC concluded that the sector is R&D-driven and that continued innovation is only possible when the protection of IPRs (primarily patents) is adequately ensured.<sup>1365</sup>

Furthermore, the pharmaceutical (& biotechnology) industry generates the greatest profitability (17.9%) of all industrial sectors,<sup>1366</sup> and has been one of the gems of European industry with regard to economic growth.<sup>1367</sup> At the member state level, for example, the UK's pharmaceutical sector is praised as 'a jewel in the crown'<sup>1368</sup> of the economy which adds more economic value than any other sector.<sup>1369</sup>

These are the reasons to believe that the EU, albeit in a less antagonistic manner, attempted to limit compulsory licensing in the developing world. It should be recalled that in the practice of Thailand, the EU Trade Commissioner, Mr. Peter Mandelson, wrote a letter to the Thai Minister of Health expressing deep concern about the action: 'Neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licence wherever medicines exceed a certain price.'(Section 7.4.3)<sup>1370</sup> At the same time, the EU Parliament passed a resolution 'endorsing full implementation of the flexibilities in the TRIPS

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requirement in their patent laws. See APLF, 'Compulsory licence provisions across Europe' (26 September 2007) <[https://www.aplf.org/compulsory\\_licence\\_provisions\\_across\\_europe/index.html](https://www.aplf.org/compulsory_licence_provisions_across_europe/index.html)> accessed 21 May 2018.

<sup>1361</sup> Commission, 'The 2017 EU industrial R&D investment Scoreboard' (EU 2017) 55.

<sup>1362</sup> *Ibid.*, 12.

<sup>1363</sup> Commission, 'The 2016 EU industrial R&D investment Scoreboard' (EU 2016) 42.

<sup>1364</sup> Commission, 'The Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community' (Communication) COM (93) 718 final 5.

<sup>1365</sup> Commission, 'Pharma Sector Inquiry' (Staff Working Document) Final Report, 8 July 2009, 19.

<sup>1366</sup> Commission, 'The 2016 EU industrial R&D investment Scoreboard' (EU 2016) 58.

<sup>1367</sup> Commission, 'Pharmaceutical Industry: A Strategic Sector for the European Economy' (Staff Working Document) SWD (2014) 216 Final/2, 2.

<sup>1368</sup> Health Committee, *The influence of the pharmaceuticals industry* (HC 2004 – 2005, 42 – I) 3.

<sup>1369</sup> Association of British Pharmaceutical Industry (ABPI), 'Delivering value to the UK: the contribution of the pharmaceuticals industry to patients, the NHS and the economy' (January 2016) 6 <<http://www.abpi.org.uk/about-us/resources/publications-library/delivering-value-to-the-uk-the-contribution-of-the-pharmaceutical-industry-to-patients-the-nhs-and-the-economy/>> accessed 16 March 2018.

<sup>1370</sup> The letter of Mr Peter Mandelson to Thailand's Minister of Commerce of 10 July 2007 can be found on <<https://www.keionline.org/wp-content/uploads/mandelson07102007.pdf>> accessed 7 March 2018.

Agreement as recognised in the Doha Declaration'.<sup>1371</sup> This signifies division between the executive (EU Commission) and the legislative (EU Parliament) branches of the EU in attitude to compulsory licensing.<sup>1372</sup>

In 2013<sup>1373</sup> (and again in 2015),<sup>1374</sup> the EC voiced specific concerns about the compulsory licensing practices in Thailand and India, which were deemed detrimental to EU pharmaceutical companies. In May 2015, the Swiss government dissuaded Colombia from issuing a compulsory licence on a cancer medicine owned by Novartis, a Swiss company.<sup>1375</sup> In 2017, a statement made to the TRIPS Council by Mr. Marc Vanheukelen – the EU ambassador to the WTO - reaffirmed that medicines are created, not by public authorities, but by the pharmaceutical industry, and that the industry needs a guaranteed return in order to continue incentivising innovation.<sup>1376</sup> He has reiterated the view that there are many and various causes of lack of access to medicines, which renders it misleading to attribute the problem merely to, or even principally to, IPR related aspects.<sup>1377</sup> IPRs, which are important for pharmaceutical R&D activities, play a minor role in the problem, but have a disproportionate presence in the debate on trade and health.<sup>1378</sup>

The EU has established rigorous patent standards, which are applied not only to the products circulated within the region but also to those entering and released within it. In 2003, the EU adopted a regulation which allowed customs officials to seize goods that breach IP rights when they enter or leave the EU's customs area.<sup>1379</sup> This regulation sparked an outcry in January 2009, when Dutch authorities seized a shipment of Indian generic drugs as it passed through

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<sup>1371</sup> Parliament, 'Resolution on TRIPS Agreement and Access to Medicines' P6\_TA (2007) 0353.

<sup>1372</sup> Jonathan Burton-Macleod, 'Tipping point: Thai compulsory licences redefine essential medicines debate' in Thomas Pogge and others (eds), *Incentives for Global Public Health Patent Law and Access to Essential Medicines* (CUP 2010) 423 – 424.

<sup>1373</sup> Commission, 'Report on the protection and enforcement of intellectual property rights in third countries' (Staff Working Document) SWD(2013) 30 final, 9 – 10, 18.

<sup>1374</sup> Commission, 'Report on the protection and enforcement of intellectual property rights in third countries' (Staff Working Document) SWD(2015) 32 final, 10 – 12, 23.

<sup>1375</sup> KEI, 'Switzerland pressures Colombia to deny compulsory license on imatinib' (17 August 2015) <<http://www.keionline.org/node/2312>> accessed 29 September 2016.

<sup>1376</sup> Marc Vanheukelen, 'EU statement - TRIPs Council' (30 January 2017)

<[https://eeas.europa.eu/delegations/world-trade-organization-wto/19507/eu-statement-ambassador-marc-vanheukelen-trips-council-30-january-2017\\_en](https://eeas.europa.eu/delegations/world-trade-organization-wto/19507/eu-statement-ambassador-marc-vanheukelen-trips-council-30-january-2017_en)> accessed 24 March 2017.

<sup>1377</sup> *Ibid.*

<sup>1378</sup> *Ibid.*

<sup>1379</sup> Council Regulation (EC) 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2003] OJ L196/7.

Rotterdam on its way to Brazil.<sup>1380</sup> After a month, the Dutch authorities released the consignment to the exporter, who sent it back to India.<sup>1381</sup> The medicines never reached Brazilian patients.

As a result, in May 2010, India<sup>1382</sup> and Brazil<sup>1383</sup> individually filed a case against the EU before the WTO for the violation of TRIPS provisions. To ease the conflict with India while the FTA between the EU and the country was ongoing, the EU quickly reached an agreement with the Indian government in late 2010: the EU would amend the Regulation in exchange for latter's suspension of the claim.<sup>1384</sup> The regulation was repealed and replaced with new legislation in 2013.<sup>1385</sup>

On the other hand, no progress had been made in the Brazilian case, due to an absence of economic pressure.<sup>1386</sup> So far, there has been no further record. However, as we have seen in previous chapters, disputes over compulsory licensing or health-related IP issues are generally settled by political, rather than legal means, and this thesis suggests that the EU might enter into a quiet political agreement with Brazil.

Compared to the US, which expresses an unconcealed opposition to compulsory licensing in the pharmaceutical industry, European countries have been more tactful. When South Africa introduced the Medicines and Related Substances Control Amendment Act in 1997 allowing a broad use of compulsory licensing, the US challenged the Act.<sup>1387</sup> Meanwhile, European leaders, such as the Presidents of France, Switzerland and Germany, tackled the issue

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<sup>1380</sup> Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 287.

<sup>1381</sup> 'Dutch Seizure of Generic Drugs Sparks Controversy' (2009) 13 Bridges Weekly Trade News Digest 5.

<sup>1382</sup> WTO, *European Union and a Member State: Seizure of Generic Drugs in Transit. Request for Consultation by India* (19 May 2010) WT/DS408/1.

<sup>1383</sup> WTO, *European Union and a Member State: Seizure of Generic Drugs in Transit. Request for Consultation by Brazil* (19 May 2010) WT/DS409/1.

<sup>1384</sup> Justin Erickson, 'Call for Reform: Analyzing Trips Through European Seizure of Generic Medication' (2012) 21 Minnesota Journal of International Law 383, 392 – 393.

<sup>1385</sup> Regulation EU 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 [2013] OJ L181/15.

<sup>1386</sup> Justin Erickson, 'Call for Reform: Analyzing Trips Through European Seizure of Generic Medication' (2012) 21 Minnesota Journal of International Law 383, 393.

<sup>1387</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 86. See further discussion at Section 4.3.1 of this thesis.

discreetly, in private talks with South Africa's government.<sup>1388</sup> Unlike the US, which habitually faced public-relations nightmares, European countries scarcely provoked any public outcry.

In summary, advanced European countries take a hard line on the protection of IPRs and the EU itself has made determined efforts to safeguard the pharmaceutical industry - a key asset of the regional economy. They are willing to assist poorer countries in advancing the access to medicines through a number of programmes.<sup>1389</sup> Together with its member states, the EU is the greatest contributor to the Global Fund on controlling AIDS, tuberculosis and malaria in developing countries, and its contribution amounts to 50% of the Fund.<sup>1390</sup> It also works in partnership with other organisations to provide quality products to developing countries.<sup>1391</sup> The EU's support has focused on R&D with regard to neglected diseases.<sup>1392</sup> It has also assisted a special WHO tropical disease programme in Africa, established the African Network for Drugs and Diagnostics Innovation, and promoted the transfer of technology.<sup>1393</sup> In other words, the EU respond to health concerns in the developing world through other channels, such as financial donations and technical assistance, and not by lowering the level of protection of IP.

## 9.2 WIPO

WIPO is the successor of BIRPI<sup>1394</sup> – an organisation founded in 1893 to administer the Paris and Berne Conventions.<sup>1395</sup> Consequently, in the first place, WIPO members consisted primarily of developed European countries. After WW2, the economies of former colonies started to expand, leading to an increase in its membership. In 1970, BIRPI was transformed into WIPO which became a specialised agency of the UN in 1974.<sup>1396</sup> As Okediji commented, WIPO's decision to join the UN system was not about enhancing its responsibility to the global

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<sup>1388</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 7.

<sup>1389</sup> Commission, 'Pharmaceutical Industry: A Strategic Sector for the European Economy' (Staff Working Document) SWD (2014) 216 Final/2, 21 – 22.

<sup>1390</sup> Commission, 'Access to Medicines. EU global health actions for low- and middle-income countries' (Key actions, April 2016) <[http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/access-to-medicines/index\\_en.htm](http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/access-to-medicines/index_en.htm)> accessed 21 March 2018.

<sup>1391</sup> Commission, 'Pharmaceutical Industry: A Strategic Sector for the European Economy' (Staff Working Document) SWD (2014) 216 Final/2, 21 – 22.

<sup>1392</sup> Commission, 'Access to Medicines. EU global health actions for low- and middle-income countries' (Key actions, April 2016) <[http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/access-to-medicines/index\\_en.htm](http://ec.europa.eu/trade/policy/accessing-markets/intellectual-property/access-to-medicines/index_en.htm)> accessed 21 March 2018

<sup>1393</sup> *Ibid.*

<sup>1394</sup> BIRPI is the French term of the United International Bureaux for the Protection of Intellectual Property (Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle)

<sup>1395</sup> WIPO, 'WIPO - A brief history' <<http://www.wipo.int/about-wipo/en/history.html>> accessed 16 March 2017.

<sup>1396</sup> *Ibid.*

community but consolidating its authority over IP against other UN agencies, such as UNCTAD, UNDP, UNIDO, and UNESCO.<sup>1397</sup>

Since the establishment of WIPO in the late 19<sup>th</sup> century, its mission has been to encourage creativity, to promote the protection of IP and to provide administrative management of the IP systems throughout the world. In other words, WIPO is an organisation that has the chief aim of strengthening IPRs on the global scale. As a result, WIPO was ‘conspicuously’ absent from contemporary debates about international health governance.<sup>1398</sup> During the negotiation of the Doha Declaration, WIPO played no visible role.<sup>1399</sup> This thesis submits that WIPO’s sole mandate of supporting and harmonising IP has placed it at this critical juncture where competing visions of the IP system have started to challenge core values and key tasks of the organisation. However, the involvement of WIPO in the access to medicines debate is no longer avoidable as patents are an important component of both public interest and private rights.

For almost a century, from the birth of the BIRPI in 1893 until the establishment of the WTO in 1995, WIPO was the main forum accountable for patenting activities worldwide. However, the signing of TRIPS shifted the IP regime from WIPO to the WTO, largely due to the virtual non-existence of a WIPO enforcement mechanism, as indicated in Section 3.2.3. On the one hand, TRIPS took away the exclusive control of WIPO over IP norm-setting, forcing WIPO to share the power with TRIPS. On the other hand, thanks to TRIPS, WIPO membership has been increased as the signatories to the TRIPS Agreement are also members of the Paris Convention.<sup>1400</sup> The interrelation between TRIPS and Paris has been clarified in Section 3.3.

Moreover, the signing of TRIPS has lent WIPO an important role. It is now in charge of providing developing countries with legal advice and technical assistance to implement the provisions of TRIPS.<sup>1401</sup> According to Deere, WIPO is the most generous donor providing

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<sup>1397</sup> Ruth Okediji, ‘WIPO-WTO Relations and the Future of Global Intellectual Property Norms’ (2009) 39 *Netherlands Yearbook of International Law* 1, 9 – 10.

<sup>1398</sup> Ruth L. Okediji, ‘The Role of WIPO in Access to Medicines’ in César Rodríguez Garavito and Rochelle Cooper Dreyfuss (eds), *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America* (OUP 2014) 310.

<sup>1399</sup> Frederick M. Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’ (2002) 5 *Journal of International Economic Law* 469, 476.

<sup>1400</sup> TRIPS, art 1.3. After TRIPS came into effect, signatories to the Convention has gone from 100 to 177. See WIPO, ‘Contracting Parties: Paris Convention’ <[http://www.wipo.int/treaties/en>ShowResults.jsp? treaty\\_id=2](http://www.wipo.int/treaties/en>ShowResults.jsp? treaty_id=2)> accessed 2 April 2018.

<sup>1401</sup> Susan K. Sell, ‘The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions’ (2004) 77 *Temp. L. Rev.* 363, 385; Pablo Zapatero Miguel, ‘World

training on IP issues to the developing world.<sup>1402</sup> Between 1996 and 2007, WIPO spent more than \$400 million on technical support to the developing world.<sup>1403</sup>

However, as criticised by many commentators, WIPO's assistance has primarily taken the form of a high level of protection for IP when recommending legislation to those countries without taking into account all the flexibilities available in TRIPS.<sup>1404</sup> For instance, when WIPO helped Cambodia to draft a new patent law, it did not inform the country about either the Doha Declaration or the possibility of delaying patent grants on pharmaceuticals until 2016.<sup>1405</sup> Furthermore, parallel importation was not recommended, even though this measure was left to the discretion of TRIPS members, as per Article 6 of the TRIPS Agreement.<sup>1406</sup>

Another clear example can be found in WIPO's assistance in revising the Bangui Agreement of the African Intellectual Property Organization (OAIP).<sup>1407</sup> It imposed early TRIPS implementation, regardless of the fact that most of the countries in the OAIP were in the least-developed category. The revision also limited the use of compulsory licences to a greater extent than TRIPS required, and explicitly disallowed parallel import.<sup>1408</sup> WIPO's role in giving

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Policy Battles on Pharmaceutical Patent Protection: Micro-History of a Forum Shift and Its Legal Implications' (2013) 5 Cuadernos Derecho Transnacional 217, 219.

<sup>1402</sup> Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 180.

<sup>1403</sup> *Ibid.*

<sup>1404</sup> UK Commission on IPRs, 'Integrating Intellectual Property Rights and Development Policy' (2002) 162 <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018; 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to get it right' (International Conference Centre of Geneva, 28 March 2002) 2 <<http://www.eldis.org/document/A12075>> accessed 8 March 2018; Ellen F.M.'t Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 57; Susan K. Sell, 'The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions' (2004) 77 Temp. L. Rev. 363; Jenny Wakely, 'The Impact of External Factors on the Effectiveness of Compulsory Licensing as a Means of Increasing Access to Medicines in Developing Countries' (2011) 33 EIPR 756, 764; Ruth L. Okediji, 'The Role of WIPO in Access to Medicines' in César Rodríguez Garavito and Rochelle Cooper Dreyfuss (eds), *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America* (OUP 2014) 311 - 312; Germán Velásquez, 'Intellectual Property, Public Health and Access to Medicines in International Organisation' (2017) South Centre Research Paper 78, 10 <<https://www.southcentre.int/research-paper-78-july-2017/#more-9989>> accessed 2 April 2018.

<sup>1405</sup> Jenny Wakely, 'The Impact of External Factors on the Effectiveness of Compulsory Licensing as a Means of Increasing Access to Medicines in Developing Countries' (2011) 33 EIPR 756, 764.

<sup>1406</sup> 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to get it right' (International Conference Centre of Geneva, 28 March 2002) 3 <<http://www.eldis.org/document/A12075>> accessed 8 March 2018.

<sup>1407</sup> Ellen F.M.'t Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 57.

<sup>1408</sup> UK Commission on IPRs, 'Integrating Intellectual Property Rights and Development Policy' (2002) 162 <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018.

technical assistance has thus been regarded as an underachievement, since it focused on changing these countries' laws, rather than on how they might benefit from the TRIPS Agreement.<sup>1409</sup>

The author believes that WIPO has built its image around the central ideal of maintaining and supporting a robust patent system worldwide, and the organisation therefore, paid scarcely any attention to its disadvantages, which were experienced particularly in developing countries. As the UK Commission on IPRs commented, WIPO's primary mission is to assist those who made intensive use of IP, and not consumers; and from WIPO's point of view, IPRs were unequivocally beneficial.<sup>1410</sup> Such a view was regarded as inappropriate. The UK Commission argued that patent rights are accompanied by both costs and benefits, and that WIPO recognised only the latter.<sup>1411</sup> The NGO community also criticised WIPO objectives because they were inconsistent with various stages of development in non-industrialised countries.<sup>1412</sup>

In a more systematic manner, Okediji put down a number reasons why WIPO's IP philosophy was improper. Firstly, WIPO disguised normative challenges about the role of IP in the development of technical assistance programmes.<sup>1413</sup> Secondly, WIPO purposely enhanced IP protection in 'former colonies' without taking into account their economic development and

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<sup>1409</sup> UK Commission on IPRs, 'Integrating Intellectual Property Rights and Development Policy' (2002) 162 <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018; 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to get it right' (International Conference Centre of Geneva, 28 March 2002) <<http://www.eldis.org/document/A12075>> accessed 8 March 2018; Ellen F.M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 57; Susan K. Sell, 'The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions' (2004) 77 Temp. L. Rev. 363; Jenny Wakely, 'The Impact of External Factors on the Effectiveness of Compulsory Licensing as a Means of Increasing Access to Medicines in Developing Countries' (2011) 33 EIPR 756, 764; Ruth L. Okediji, 'The Role of WIPO in Access to Medicines' in César Rodríguez Garavito and Rochelle Cooper Dreyfuss (eds), *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America* (OUP 2014) 311 - 312; Germán Velásquez, 'Intellectual Property, Public Health and Access to Medicines in International Organisation' (2017) South Centre Research Paper 78, 10 <<https://www.southcentre.int/research-paper-78-july-2017/#more-9989>> accessed 2 April 2018.

<sup>1410</sup> UK Commission on IPRs, 'Integrating Intellectual Property Rights and Development Policy' (2002) 157 <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018.

<sup>1411</sup> *Ibid.*, 158 – 159.

<sup>1412</sup> 'Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance – How to get it right' (International Conference Centre of Geneva, 28 March 2002) 2 <<http://www.eldis.org/document/A12075>> accessed 8 March 2018; Ellen F.M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 43, 57.

<sup>1413</sup> Ruth Okediji, 'WIPO-WTO Relations and the Future of Global Intellectual Property Norms' (2009) 39 Netherlands Yearbook of International Law 1, 9.

local conditions.<sup>1414</sup> Lastly, the WIPO has subordinated other values, such as human rights, to the IP system.<sup>1415</sup> As a result, the WIPO was called upon to change its culture and to tailor IP law to national needs.<sup>1416</sup>

A possible but also the most important reason, perhaps, which could explain WIPO's strong interest in robust IP protection is that WIPO's finance heavily depends on patent applicants. WIPO administers the international patent system under the PCT, through which a patent applicant needs to file only one international application to gain protection in a very large number of countries. Notably, two-thirds of WIPO's income comes from fees paid by patentees,<sup>1417</sup> which creates a culture within WIPO that, 'the more patents, the better'.<sup>1418</sup> For this reason, it is not an exaggeration to say that the patentee community is the lifeblood of the existence and operation of WIPO.

WIPO, both institutionally and financially, has been closely connected to a robust international patent system, and this thesis submits that patents (and other IPRs) are the reasons for the formation and survival of the organisation. Although WIPO has begun gradually to include development objectives in its agenda and activities, it is far from clear that it will redirect its resources to achieve a new and more balanced approach. In 2004, it adopted a development agenda, wherein the needs of all nations, regardless of their capacities, had to be considered.<sup>1419</sup> However, the fact that this agenda was proposed by developing countries, i.e. Argentina and Brazil, was an indication of WIPO's lack of initiative in responding to rising demands.

In relation to patenting activities, WIPO established the SCP in 1998 to start the process of harmonising substantive patent law rights.<sup>1420</sup> As mentioned in Section 1.2, TRIPS is a

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<sup>1414</sup> *Ibid.*

<sup>1415</sup> *Ibid.*

<sup>1416</sup> UK Commission on IPRs, 'Integrating Intellectual Property Rights and Development Policy' (2002) 161 <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018; Ellen F.M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 57; James Boyle, 'A Manifesto on WIPO and the Future of Intellectual Property' (2004) 3 Duke Law and Technology Review 1, 2.

<sup>1417</sup> WIPO, *Program and Budget for the 2018/19 biennium* (15 August 2017) WO/PBC/27/8 8 <[http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=246143](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=246143)> accessed 8 March 2018.

<sup>1418</sup> Germán Velásquez, 'Intellectual Property, Public Health and Access to Medicines in International Organisation' (2017) South Centre Research Paper 78, 10 <<https://www.southcentre.int/research-paper-78-july-2017/#more-9989>> accessed 2 April 2018.

<sup>1419</sup> WIPO, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO* (27 August 2004) WO/GA/31/11.

<sup>1420</sup> WIPO, 'Draft Substantive Patent Law Treaty' <[http://www.wipo.int/patent-law/en/draft\\_splt.htm](http://www.wipo.int/patent-law/en/draft_splt.htm)> accessed 6 February 2018.

minimum harmonisation agreement which provides flexibilities to its signatories so that they can shape their domestic policies. In order to reduce discrepancies in countries' national law due to such freedom, the US, Japan and the EPO submitted to the SCP a joint proposal that defined 'prior art', 'grace period', 'novelty' and 'inventive step'.<sup>1421</sup> These concepts had been left totally undefined in the IP international arena and India is a successful example of using such lack of precision to reject incremental medicine patents, as noted in Section 5.2.3.

It is obvious that developed countries have attempted to achieve in WIPO what could not be achieved at the WTO. Abbott has voiced the concern that, since WIPO does not operate on the same consensus principles as the WTO, there was indeed a risk that rules would be adopted without the active support of many members from developing countries.<sup>1422</sup> These rules could be used as benchmarks by OECD patent offices, and then could be effectively transferred to the patent systems of developing countries.<sup>1423</sup> This fear, however, was allayed: the Substantive Patent Law Treaty failed to gain consensus amongst the parties, and has consequently been on hold since 2006.<sup>1424</sup>

In relation to compulsory licensing, WIPO, since 2011, has conducted surveys and studies regarding the ways in which members regulate relevant provisions in their domestic laws.<sup>1425</sup> The works, however, have shied away from evaluating the effectiveness of compulsory licensing. They are 'reference books' rather than 'guidebooks', as they do not explain either

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<sup>1421</sup> WIPO, *Proposal from the United States of America, Japan, and the European Patent Office regarding the Substantive Patent Law Treaty* (22 April 2004) SCP/10/9.

<sup>1422</sup> Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 Journal of International Economic Law 469, 476.

<sup>1423</sup> *Ibid.*

<sup>1424</sup> WIPO, 'Draft Substantive Patent Law Treaty' <[http://www.wipo.int/patent-law/en/draft\\_splt.htm](http://www.wipo.int/patent-law/en/draft_splt.htm)> accessed 6 February 2018.

<sup>1425</sup> Examples of WIPO's surveys are:

- Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses of Intellectual Property Rights (4 October 2011) CDIP/4/4REV./STUDY/INF/5.
- Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part I) (3 November 2014) SCP/21/4 REV.
- Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part II) (7 November 2014) SCP/21/5 REV.
- Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels (18 August 2010) CDIP/5/4REV.
- Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part II (18 April 2012) CDIP/7/3 ADD.
- Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part III (16 February 2015) CDIP/13/10 REV.
- Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part IV (20 October 2015) CDIP/15/6 CORR.

how this legal tool could advance the accessibility of medicines in needy member states or encourage their use therein.

Recently, in order not to be left behind in current developments, WIPO has included TRIPS flexibilities in its activities. For example, in 2010, WIPO built a database which allows searches for implementation of flexibilities in certain countries' IP law.<sup>1426</sup> It could be seen as an attempt by WIPO to respond to the criticisms of its narrow agenda. However, it was not enough. Velásquez specifically condemned WIPO training programs as intentionally ignoring TRIPS flexibilities.<sup>1427</sup> He further criticised that WIPO, through various means, swayed decision makers to strengthen the use of IP.<sup>1428</sup> To him, WIPO is more a part of the problem than the solution in terms of public health.<sup>1429</sup>

Nevertheless, it should not be forgotten that WIPO was, in the first place, established to administer, not to criticise, IPRs. It is an organisation whose sole objective is to foster the growth of innovation and invention on a global scale. This thesis, therefore, argues that it would be unlikely that WIPO would act against its stated mission.

As WIPO is a pro-patent organisation, it would not explicitly advocate any measure which might damage the core value of patents. For instance, in a work prepared by the SCP, the role of compulsory licensing of pharmaceuticals in less developed countries was said to be overstated.<sup>1430</sup> WIPO's scepticism regarding this legal tool was well-illustrated in its response to the 2012 Indian ruling. The General Director of the WIPO, despite admitting that compulsory licensing was a recognised legal measure, refused to comment on whether it was an effective one.<sup>1431</sup> Implicit in his silence was the assertion that WIPO does not side with compulsory licensing or at least, avoids any statement which might be understood to support

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<sup>1426</sup> WIPO, 'Database on Flexibilities in the Intellectual Property System' <<http://www.wipo.int/ip-development/en/agenda/flexibilities/database.html>> accessed 30 October 2017.

<sup>1427</sup> Germán Velásquez, 'Intellectual Property, Public Health and Access to Medicines in International Organisation' (2017) South Centre Research Paper 78, 10 <<https://www.southcentre.int/research-paper-78-july-2017/#more-9989>> accessed 2 April 2018.

<sup>1428</sup> *Ibid.*

<sup>1429</sup> *Ibid.* Further discussion of how WIPO training programmes focus on building high IP regimes can be found at Carolyn Deere, *The Implementation Game. The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 181 – 182.

<sup>1430</sup> Coenraad Visser, 'Patent Exceptions and Limitations in the Health Context' (WIPO 2 September 2010) SCP/15/3 Annex V, 4.

<sup>1431</sup> 'Compulsory licensing a recognised instrument, says WIPO Chief Francis Gurry' *The Economic Times* (New Delhi 15 January 2015) <<http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/compulsory-licensing-a-recognised-instrument-says-wipo-chief-francis-gurry/articleshow/45892034.cms>> accessed 6 March 2017.

such use. WIPO, as generally mandated in its founding charter and demonstrated in its historical institutional development, has maintained a strong role in bolstering IP protection. Arguably, such a mandate has shaped WIPO's underlying resistance to the debates about patent and access to medicines.

### 9.3 The WHO

Despite the fact that imposing universal patent protection on pharmaceuticals would have a huge impact on public health governance, the WHO was completely absent from the discussions on TRIPS. As highlighted in Section 3.4.1, medicines have an incomparable value, and any regulatory changes in the sector therefore require not only legal understanding but also technical knowledge, both of which the WHO possesses. However, at the time TRIPS was under negotiation, the link between trade and health was not as fully recognised as it is today.<sup>1432</sup>

Moreover, the idea of expansive patentability largely came from industries and professional organizations that had vested interests, as critically analysed in Section 3.2.2. The WHO obviously was not a player in that game. Nevertheless, as the implications of TRIPS on human rights has become better understood, the organisation has gradually shifted its position. The WHO is no longer absent from health-related discussions and is making its presence felt. This thesis nonetheless submits that there is an inconsistency in its approach towards compulsory licensing and access to medicines, as will be examined soon.

There is no doubt that IP matters have stood as an extremely vexing problem in the 21<sup>st</sup> century. In the global knowledge economy, IP policy, on one side, is a central pillar of advanced countries which insist on a rigorous protection. On the other side, it has been a barrier to the access to existing inventions in poorer nations where lower protection is much preferred.<sup>1433</sup> As an intergovernmental organisation, the WHO has been and will be caught in the crossfire.<sup>1434</sup>

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<sup>1432</sup> Thomas Cottier, 'Working together towards TRIPS' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 91.

<sup>1433</sup> Suerie Moon, 'WHO's role in the global health system: what can be learned from global R&D debates?' (2014) 128 Public Health 167, 170.

<sup>1434</sup> *Ibid.*

It was not until 1996 that the medicine deliberations caught the attention of the WHO thanks to the efforts made by health activists and developing countries including Brazil,<sup>1435</sup> South Africa and Zimbabwe.<sup>1436</sup> At the WHA in that year, they pushed this matter forward. As a result, the linkage between trade and medicines was addressed in Resolution WHA49.14 where the WHA requested the General Director to report on the impact of the WTO and to make commendations for collaboration between the WTO and the WHO.<sup>1437</sup>

As an initial response to such a request, in 1997, two WHO employees - Germán Velásquez and Pascale Boulet - published a document titled *Globalization and Access to Drugs, Perspectives on the WHO/TRIPS Agreement*,<sup>1438</sup> commonly known in the WHO as the ‘red book’ on the TRIPS Agreement.<sup>1439</sup> While the resolution WHA49.14 did not mention a single word about TRIPS, this study identified TRIPS patents as a hindrance to such access.<sup>1440</sup> Accordingly, these two authors considered compulsory licensing as the easiest and most effective way to remedy the monopoly and to increase the supply of medicinal products.<sup>1441</sup> The US and the EU tried unsuccessfully to suppress this publication.<sup>1442</sup>

Following the ‘red book’, in January 1998, the Zimbabwean Minister of Health - a member of the WHO’s Executive Board - invited two NGOs (HAI and CPT), to draft a new resolution for consideration at the WHA in May that year.<sup>1443</sup> This resolution, entitled EB101.R24, explicitly addressed the adverse consequences of TRIPS on the health situation in developing countries.<sup>1444</sup> It further urged member states to place public interests above the commercial interests of the pharmaceutical industry. It was not surprising that, despite being recommended

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<sup>1435</sup> It is another evidence of Brazil’s early and active engagement in the forefront of healthcare, as demonstrated in Chapter 8. In contrast, India was absent from that joint effort.

<sup>1436</sup> Susan K. Sell, ‘The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions’ (2004) 77 Temp. L. Rev. 363, 389.

<sup>1437</sup> WHO (Resolution of the Executive Board) ‘Revised Drug Strategy’ (25 May 1996) WHA49.14.

<sup>1438</sup> Germán Velásquez and Pascale Boulet, ‘Globalization and Access to Drugs, Perspectives on the WHO/TRIPS Agreement’ (2<sup>nd</sup> edn, 1999) WHO/DAP/98.

<sup>1439</sup> Germán Velásquez, ‘Intellectual Property, Public Health and Access to Medicines in International Organisation’ (2017) South Centre Research Paper 78, 3 <<https://www.southcentre.int/research-paper-78-july-2017/#more-9989>> accessed 2 April 2018.

<sup>1440</sup> Germán Velásquez and Pascale Boulet, ‘Globalization and Access to Drugs, Perspectives on the WHO/TRIPS Agreement’ (2<sup>nd</sup> edn, 1999) WHO/DAP/98 42

<sup>1441</sup> *Ibid.*, 36.

<sup>1442</sup> Ellen F.M.‘t Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’ in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries. Issues and Challenges* (ARNS 2003) 48.

<sup>1443</sup> Duncan Matthews, *Intellectual Property, Human Rights and Development. The role of NGOs and Social Movements* (EE 2011) 29.

<sup>1444</sup> WHO (Resolution of the Executive Board) ‘Revised Drug Strategy’ (27 January 1998) EB101.R24.

by the Executive Board, this Resolution was opposed by the US and European delegations.<sup>1445</sup> No consensus was reached on the wording of the resolution, and the WHA had to send it back to the Board for further consideration.<sup>1446</sup>

In January 1999, after being modified, Resolution EB101.R24 was replaced by EB103.R1 where the offensive terms attacking TRIPS were substituted with more neutral ones.<sup>1447</sup> As stressed by Beall, getting on the agenda of the WHA is never an easy task.<sup>1448</sup> Although the resolution shied away from clearly analysing the impacts of TRIPS on public health, such an adoption was still very significant to the health advocates and developing countries. Resolution EB101.R24 is the first mandate of the WHO under which conflict of trade and medicine access was explicitly recognised. Owing to this resolution, discussions over patents were no longer limited to IP specialists, but expanded to reach other fora, and received attention from a wider range of people. Furthermore, it is a clear signal that the WHO could no longer watch the medicine debate from the side-lines. In fact, between 1996 and 2012, the WHO adopted 17 resolutions referring to IP and public health.<sup>1449</sup> Nevertheless, the back and forth movement of Resolution EB101.R24 presented a fact that WHO found itself in a quandary, as it has been pulled from all sides.

Therefore, there is a contrast between WHO studies that are conducted by independent authors and those that are officially published by the WHO itself. Unlike the first type of works which highly recommends compulsory licensing in developing countries, the second one expresses scepticism about the effect of compulsory licensing whilst supporting drug patents. The ‘red book’ written by Velásquez and Boulet is a clear example of the first kind. Another example is a report in 2006 by an independent international commission on IPRs, Innovation and Public Health.<sup>1450</sup> This work urged developing countries to incorporate the legal mechanism of

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<sup>1445</sup> The WHO Executive Board approved the resolution only because of the absence of the US that year. Susan K. Sell, ‘TRIPS and the Access to Medicines Campaign’ (2002) 20 Wisconsin International Law Journal 481, 504.

<sup>1446</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 81.

<sup>1447</sup> WHO (Resolution of the Executive Board) ‘Revised Drug Strategy’ (26 January 1999) EB103.R1.

<sup>1448</sup> Reed Beall, ‘What Is the International Landscape of Essential Medicine Patent Protection and How Can Developing Countries’ Medicine Access Be Accelerated Within It?’ (PhD thesis, University of Ottawa 2017) 197.

<sup>1449</sup> Germán Velásquez, ‘Intellectual Property, Public Health and Access to Medicines in International Organisation’ (2017) South Centre Research Paper 78, 6 <<https://www.southcentre.int/research-paper-78-july-2017/#more-9989>> accessed 2 April 2018.

<sup>1450</sup> Commission on IPRs, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights* (WHO 2006). This work put a following disclaimer: ‘This publication contains the collective views of an

mandatory licensing into their legislation as a means of alleviating health problems.<sup>1451</sup> In addition, it asserted that the granting of compulsory licences would *not* lead to a decline in R&D.<sup>1452</sup>

In contrast, a good example of the second category is a joint publication between the WHO and the WTO secretariat in 2002.<sup>1453</sup> On the one hand, this joint publication recognises that compulsory licensing is one way to make the price of medicines more affordable.<sup>1454</sup> But, on the other hand, it casts doubt on the extent to which patent protection adversely affects medicine prices.<sup>1455</sup> It makes reference to other research, which claims that patent protection in developing countries, i.e. Thailand and India, does not raise prices.<sup>1456</sup> This work further claims that although the vast majority of the WHO Model Lists of Essential Medicines are not under patent protection anywhere, people still lacked access to them.<sup>1457</sup> It therefore dismisses the statement that patents are the major cause of healthcare problems, and asserts that there were many other factors responsible for the situation.<sup>1458</sup>

This joint study undermines the arguments for the use of compulsory licences, particularly for those on vaccines, as these products are manufactured through know-how, which is not protected under patent law. Compulsory licensing is thus not a viable solution.<sup>1459</sup> The study recommends other measures beyond TRIPS, for example differential pricing and donations of drugs by pharmaceutical companies, in association with financial aid from the international community.<sup>1460</sup>

A similar scepticism can be found in another collaborative report written by the WHO, the WTO, and WIPO in 2013 under the title '*Promoting Access to medical Technologies and Innovation: Intersections between public health, intellectual property and trade*'.<sup>1461</sup> Even

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independent international commission and does not necessarily represent the decisions or the stated policy of the World Health Organization.'

<sup>1451</sup> *Ibid.*, 55.

<sup>1452</sup> *Ibid.*, 120.

<sup>1453</sup> WTO and WHO, *WTO Agreements and Public Health – A joint study by the WHO and the WTO Secretariat* (WTO/WHO 2002).

<sup>1454</sup> *Ibid.*, 88.

<sup>1455</sup> *Ibid.*, 94 – 96.

<sup>1456</sup> *Ibid.*, 95.

<sup>1457</sup> *Ibid.*, 96.

<sup>1458</sup> *Ibid.*, 96.

<sup>1459</sup> *Ibid.*, 97.

<sup>1460</sup> *Ibid.*, 102.

<sup>1461</sup> WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections public health, intellectual property and trade* (WHO/WIPO/WTO 2013) 174.

though it is recognised as a cooperation and coordination between the ‘Big 3’ in response to evolving global health, it has been subject to criticism. Abbott is of the view that this study does not break new ground and merely keeps pace with the times.<sup>1462</sup> With more force, Velásquez claims that the trilateral publication is ‘weak, unambitious and does not reflect the work that the WHO has carried out under its mandate’.<sup>1463</sup>

In fact, the 2013 collaborative study merely states what had been recognised under the international norms and practices. For example, it emphasised the freedom of member countries to grant compulsory licences, stating that the notion of compulsory licensing being restricted to emergencies or other urgent situations was a misinterpretation.<sup>1464</sup> However, it particularly cautions that overuse of non-voluntary licences could lead to a decline in R&D, and claims that compulsory licensing does not require the transfer of ‘know-how’, which is essential for pharmaceutical manufacturing capacity.<sup>1465</sup>

Likewise, in a recent WHO study published in 2016, a sceptical tone was also adopted. Although the work affirmed that compulsory licensing strengthens the government’s negotiating position vis-à-vis the patent holders, it argued that local production under such a licence is not cost-effective and gave similar reasons to those cited in previous publications.<sup>1466</sup>

The hesitant, or even inconsistent, approach of the WHO towards compulsory licensing is not only expressed in its publications but is also best illustrated in practice. When Thailand issued government use licensing during 2006-2008, Margaret Chan, then the General Director of the organisation, warned that this legal method should be pursued cautiously. She said: ‘I’d like to underline that we have to find a right balance for compulsory licensing. We can't be naive about this. There is no perfect solution for accessing drugs in both quality and quantity.’<sup>1467</sup> Unsurprisingly, her comments caused outrage among international health NGOs. More than

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<sup>1462</sup> Frederick M. Abbott, ‘Review: The Trilateral Study on Health, Intellectual Property, and Trade: The Virtue in Paving a Cleared Roadway’ (2013) 16 *Journal of International Economic Law* 493, 497, 502.

<sup>1463</sup> Germán Velásquez, ‘Intellectual Property, Public Health and Access to Medicines in International Organisation’ (2017) South Centre Research Paper 78, 6 <<https://www.southcentre.int/research-paper-78-july-2017/#more-9989>> accessed 2 April 2018.

<sup>1464</sup> WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections public health, intellectual property and trade* (WHO/WIPO/WTO 2013) 174.

<sup>1465</sup> *Ibid.*, 87.

<sup>1466</sup> WHO, *The role of intellectual property in local production in developing countries. Opportunities and challenges* (WHO 2016) 14.

<sup>1467</sup> Martine Khor, ‘WHO DG regrets her reported remarks on Thai compulsory licenses’ (Third World Network, 13 February 2007, quoting Chan’s statement during her visit to the Thai National Health Security Office on 1 February 2007) <<http://www.twn.my/title2/health.info/twninfohealth076.htm>> accessed 10 March 2017.

400 groups and individuals expressed disappointment at her statement and asked her to reconsider it.<sup>1468</sup> Under public pressure, Margaret Chan eventually withdrew her words and blamed the media for misinterpreting the speech. In a subsequent letter to the Thai Minister of Health, she assured him that Thai compulsory licensing ‘is entirely the prerogative of the government, and fully in line with the TRIPS agreement’.<sup>1469</sup>

Generally observed, the WHO has gradually entered into the debate over patents and access to medicines after being on the fringe of TRIPS negotiations, but its views are contradictory. Abbott has pointed out that the organisation depends financially on the OECD country members, which gives pharmaceutical companies a substantial voice in its policies.<sup>1470</sup> The largest annual contributions to the WHO come from the US, Japan, Germany, France, and the UK.<sup>1471</sup> These top five members, which host big multinational pharmaceutical companies, amount to 50% of the total contributions to the WHO. As a consequence, a fact is established that the WHO does not wish to clash with those member states although it recognised that the current IP system does not work properly in relation to health.<sup>1472</sup>

## 9.4 The NGOs

NGOs have been defined by the World Bank as private organizations that pursue activities to relieve suffering, promote the interests of the poor, protect the environment, provide basic social services, or undertake community development’.<sup>1473</sup> By this definition, the term NGO is very broad and consists of many different types of non-profit organisations that are independent of governments.<sup>1474</sup> However, in the context of this thesis, the term NGO mainly refers to international NGOs, the functions of which are health-related and which have been prominent in defending poorer countries in an IP context. In 1999, MSF in collaboration with other NGOs such as Oxfam, TAC, ACT UP, and CPT (currently known as KEI) launched the Access to Medicines campaign to increase the affordability and availability of medicines in developing

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<sup>1468</sup> Martine Khor, ‘WHO DG regrets her reported remarks on Thai compulsory licenses’ (Third World Network, 13 February 2007) <<http://www.twn.my/title2/health.info/twninfohealth076.htm>> accessed 10 March 2017.

<sup>1469</sup> *Ibid.*

<sup>1470</sup> Frederick M. Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’ (2002) 5 *Journal of International Economic Law* 4679, 475.

<sup>1471</sup> WHO, ‘Assessed contributions payable summary for 2018-2019’ (WHO) <<http://www.who.int/about/finances-accountability/funding/assessed-contributions/en/>> accessed 8 March 2013.

<sup>1472</sup> Adriana Nilsson, ‘Making Norms to Tackle Global Challenges: The Role of Intergovernmental Organisations’ (2017) 46 *Public Policy* 171, 177.

<sup>1473</sup> Carmen Malena, *Working with NGOs. A Practical Guide to Operational Collaboration between The World Bank and Non-Governmental Organizations* (WB 1995) 13 – 14.

<sup>1474</sup> *Ibid.*, 13 – 14.

countries.<sup>1475</sup> This section mainly deals with these organisations. However, other NGOs will be mentioned where necessary.

When the TRIPS Agreement was being drafted, no NGO took any part in the process, with the exception of Greenpeace.<sup>1476</sup> However, as soon as the TRIPS entered its implementation phase, the NGOs were swift in initiating a course of action. In 1996, the impact of TRIPS on access to medicines was brought sharply into focus in an event organised by Health Action International (HAI), a Netherlands-based NGO having its headquarters in Amsterdam.<sup>1477</sup> This seminar, which included participants from other NGOs, brought together a large group of health experts, IP experts, academics, and activists to discuss healthcare matters.<sup>1478</sup> At this meeting, James Love from KEI recommended compulsory licensing as a tool for advancing access to medicines.<sup>1479</sup>

It was also the first NGO meeting on healthcare and TRIPS, and it paved the way for later activities of the NGO community, as well as motivating other NGOs to join the network. As a result of this event, it became generally accepted that the TRIPS Agreement had negative implications for public health, particularly in the developing world.<sup>1480</sup> This thesis argues that compared with the WIPO, which did not include developmental objectives in its agenda until 2004 (Section 9.2), and the WHO, which officially recognised TRIPS effects on international health only in 1999 (Section 9.3), NGOs were many years ahead on this front.

The NGOs' actions are not only prompt but also harsh and strong which were testified in the example of South Africa. As briefly noted in Section 4.3.1, in 1997, the country amended its Medicines Act to permit a broad use of compulsory licensing as a response to the growing

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<sup>1475</sup> Thomas Owen, *Patents, Pills, and the Press* (Peter Lang 2015) 14.

<sup>1476</sup> Thomas Cottier, 'Working together towards TRIPS' in Jayashree Watal and Antony Taubman (eds), *the Making of the TRIPS Agreement. Personal Insights from the Uruguay Round Negotiations* (WTO 2015) 91.

<sup>1477</sup> Duncan Matthews, 'NGO Coalitions and the Global Access to Medicines Campaign: The Impact of Intellectual Property Rights on Developing Countries' in Jude Howell (ed), *Global Matters for Non-Governmental Public Action* (Palgrave Macmillan 2012) 70.

<sup>1478</sup> Viviana Munoz Tellez, 'The Global Campaign on Access to Medicines: Re-shaping intellectual property rules at the World Trade Organisation' (IP-NGOs Research Project of Queen Mary University, 2005 – 2006); Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 78.

<sup>1479</sup> Susan K. Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 Wisconsin International Law Journal 481, 499 – 500.

<sup>1480</sup> Viviana Munoz Tellez, 'The Global Campaign on Access to Medicines: Re-shaping intellectual property rules at the World Trade Organisation' (IP-NGOs Research Project of Queen Mary University, 2005 – 2006); Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 78.

HIV/AIDS epidemic in the country.<sup>1481</sup> At the request of the US pharmaceutical industry, the US government, led by Vice President Al Gore, pressed South Africa to repeal the law.<sup>1482</sup> The US halted the preferential tariff treatment for South Africa's exports until it terminated the new law.<sup>1483</sup> Moreover, it also placed South Africa on the Special 301 Watch List.<sup>1484</sup>

When coming to know about Al Gore's role and the fact that he was running for his presidential campaign, ACT UP and James Love from KEI decided to intervene.<sup>1485</sup> Taking it as a window of opportunity, ACT UP protested vigorously against Al Gore in June 1999 during his public speech on his presidential campaign tour, accusing him of putting the profit of the pharmaceutical industry over the lives of millions in South Africa.<sup>1486</sup> It was one of many examples of ACT UP's actions against Al Gore throughout the presidential primaries in that summer.<sup>1487</sup> This strategy proved so effective that Gore felt obliged to meet with Love and other health activists. As a result of the meeting, Gore reversed his stance, from supporting the US pharmaceutical industry to favouring compulsory licensing and parallel import in South Africa.<sup>1488</sup> In September 1999, the US removed South Africa from the Special 301 watch list, and in April 2001 the pharmaceutical companies withdrew from the litigation and the case was settled.<sup>1489</sup> It can be inferred from this case that the activities of the NGOs are not necessarily limited to the formulation of health policies, but extend to effective political action.

While the lawsuit against South Africa's government was taking place, HAI and KEI supported other developing countries to score a decisive victory at the WHO with the endorsement of Resolution EB101.R24 in 1998, as noted in Section 9.3. This resolution was considered as the

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<sup>1481</sup> Alexandra G. Watson, 'International Intellectual Property Rights: Do TRIPS Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?' (2009) 32 Boston College International and Comparative Law Review 143, 152.

<sup>1482</sup> Thomas Owen, *Patents, Pills, and the Press* (Peter Lang 2015) 35.

<sup>1483</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 83.

<sup>1484</sup> M. Monirul Azam, 'The Experiences of TRIPS-Compliant Patent Law Reform in Brazil, India, and South Africa and Lessons for Bangladesh' (2014) 7 Akron Intellectual Property Journal 61, 86.

<sup>1485</sup> Susan K. Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 Wisconsin International Law Journal 481, 502 – 503.

<sup>1486</sup> Thomas Owen, *Patents, Pills, and the Press* (Peter Lang 2015) 38.

<sup>1487</sup> A more detailed discussion on the confrontation between ACT UP and Al Gore can be found in Thomas Owen, *Patents, Pills, and the Press* (Peter Lang 2015) 35 – 39.

<sup>1488</sup> Susan K. Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 Wisconsin International Law Journal 481, 502 – 504.

<sup>1489</sup> Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 7.

first international success which was achieved by a coalition between NGOs and developing countries in relation to medicine access.<sup>1490</sup>

Such a coalition led to a second victory, that is the adoption of the Doha Declaration. As noted in Section 4.3.1, the language of the Declaration was inspired by a proposal from the African Group. However, as observed by Drahos, the Group would have never achieved that without tremendous support from the NGOs.<sup>1491</sup> They cleverly sharpened the debate over drug patents as a confrontation between the right to protect public health and the extension of patent monopoly power. Such a strategy easily won the heart of the public against US multinationals which framed the contest as one between the protection of private property rights and piracy by developing countries.<sup>1492</sup> The adoption of the Doha Declaration proved that NGOs' wide range of support is capable of advancing developing countries' interests and influencing global policy. However, it is important to emphasise that the Declaration was the outcome of many factors and events, including 9/11, the Anthrax attacks in the United States, and public disquiet about the HIV/AIDS pandemic, as discussed previously in Section 4.3.1. It would be overly simplistic to give all the credit for this success to the NGOs.

This thesis nonetheless submits that, the coalition between NGOs and developing countries exposed limitations when it came to how to implement Paragraph 6 of the Doha Declaration dealing with access to medicines in countries with insufficient or no pharmaceutical manufacturing capacities. As frequently mentioned in this thesis, Article 31(f) erects an export barrier against those countries. When Article 31bis was proposed, the NGOs nevertheless criticised this solution, since it was too complicated and troublesome – ‘a gift bound in red tape’.<sup>1493</sup> They advised developing countries to reject the deal.<sup>1494</sup> They in fact wanted all the

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<sup>1490</sup> Duncan Matthews, ‘NGO Coalitions and the Global Access to Medicines Campaign: The Impact of Intellectual Property Rights on Developing Countries’ in Jude Howell (ed), *Global Matters for Non-Governmental Public Action* (Palgrave Macmillan 2012) 72.

<sup>1491</sup> Peter Drahos, ‘Four lessons for developing countries from the trade negotiations over access to medicines’ (2007) 28 Liverpool Law Review 11, 18 – 19.

<sup>1492</sup> *Ibid.*, 18.

<sup>1493</sup> ‘Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines: A “Gift” Bound in Red Tape’ (CP Tech, 10 September 2003) <<http://www.cptech.org/ip/wto/p6/ngos09102003.html>> accessed 2 April 2017; MSF, ‘Neither Expedited, Nor a Solution: The WTO August 30th Decision is Unworkable’ (30 August 2006) <<https://www.msfaccess.org/content/neither-expedited-nor-solution-wto-august-30th-decision-unworkable>> accessed 2 April 2017.

<sup>1494</sup> Duncan Matthews, ‘NGO Coalitions and the Global Access to Medicines Campaign: The Impact of Intellectual Property Rights on Developing Countries’ in Jude Howell (ed), *Global Matters for Non-Governmental Public Action* (Palgrave Macmillan 2012) 84

barriers within TRIPS to be taken down.<sup>1495</sup> In 2002, they sent a joint letter to the TRIPS Council, advocating the use of TRIPS Article 30 as an alternative.<sup>1496</sup> However, their proposal was not acted upon by developing countries. As a result of such separation, Article 31bis was ratified and came into effect on 23 January 2017.

Although the coalition between the NGOs and developing countries did not bear fruit in the implementation of Paragraph 6, the fact remains that this coalition has been a vital counterbalance to the pharmaceutical companies and the nations which house them, insofar as trade and access to medicines are concerned. However, the NGOs' attitude towards patents and the pharmaceutical industry is somewhat extreme since they have long viewed patent as one of their core concerns.<sup>1497</sup> This thesis argues that the NGOs demand not only cheap medicines; they also need a permanent, constant, cheap supply, which can only be achieved by compulsory licensing, or by a more extreme form, i.e., the abolition of patents on essential medicines.<sup>1498</sup>

The strong opposition from the NGOs to patented medicines can be found in many examples. In May 2000, when some pharmaceutical companies announced significant discounts for AIDS drugs to certain African countries, MSF instantly and harshly criticised such an intention.<sup>1499</sup> It took the view that the offer was merely a cynical attempt to prevent these countries from overriding these companies' patents, and that the price cut was not a long-term solution, but a 'bandage' for the HIV/AIDS epidemic in the region.<sup>1500</sup> Similarly, Pfizer's donation of drugs worth \$50 million was portrayed as a successful attempt to divert attention from the question of patents and voluntary licensing.<sup>1501</sup> In 2015, MSF criticised Gilead's voluntary licensing scheme because it mainly covers the LDCs and bars the medicines under the scheme from

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<sup>1495</sup> Baogang He and Hannah Murphy, 'Global Social Justice at the WTO? The Role of NGOs in Constructing Global Social Contracts' (2007) 83 International Affairs 707, 720 – 721.

<sup>1496</sup> Peter Drahos, 'Four lessons for developing countries from the trade negotiations over access to medicines' (2007) 28 Liverpool Law Review 11, 21; Duncan Matthews, 'TRIPS flexibilities and access to medicines in developing countries: the problem with technical assistance and free trade agreements' (2005) 27 EIPR 420, 422. In their opinions, Article 30 was the most direct, the simplest administratively, and the least contentious approach, in that an activity falling within the provision exception is not an infringement of the patent and did not need permission from the patent holder—or even for notice to be given to the patent holder, or compensation to the patent holder arranged, as per the Article 31 compulsory licensing provisions.

<sup>1497</sup> Thomas Owen, *Patents, Pills, and the Press* (Peter Lang 2015) 14 – 15.

<sup>1498</sup> James Love, 'The role of prizes in stimulating R&D' (KEI, Comment to WHO IGWG, 30 September 2007) <[http://www.who.int/phi/public\\_hearings/second/contributions\\_section2/en/](http://www.who.int/phi/public_hearings/second/contributions_section2/en/)> accessed 8 March 2018.

<sup>1499</sup> Susan K. Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 Wisconsin International Law Journal 481, 508.

<sup>1500</sup> Charan Devereaux *et al.*, *Case Studies in US Trade Negotiation. Volume 1: Making the Rules* (Institute for International Economics 2006) 92 – 93.

<sup>1501</sup> *Ibid.*, 92 – 93.

flowing into high and middle-income countries.<sup>1502</sup> MSF therefore urged Indian companies to reject the voluntary licensing project of which they were a part.

This thesis submits that, even though the NGOs cannot participate in intergovernmental negotiations, they exert a significant influence through their networks and subtle lobbying. Not only did the NGOs partner with certain developing countries in health-related patent disputes, they also acted as their ‘proxy representatives’<sup>1503</sup> in the international area. The adoption of Resolution EB103.R1 at the WHO and of the Doha Declaration were examples of a successful coalition between these two actors.

However, as Matthews argues, such a coalition, which works effectively in the case of medicines which are fundamental to human rights, and are of concern to both developed and developing countries, might not be successfully replicated in other sectors, such as agriculture, genetic resources and traditional knowledge.<sup>1504</sup> He also emphasized that the relationship between NGOs and developing countries is a constantly evolving one which changes in accordance with the issues and institutions that are involved.<sup>1505</sup> It was clear from the case of Paragraph 6 that both parties drifted apart. Moreover, unlike the NGOs, developing countries have trade relations with developed nations which might prevent them from adopting an extreme attitude so as to maintain the commercial relationship.

## 9.5 Conclusions

This chapter has joined together a number of actors who play significant roles in influencing and advancing the global policies concerning access to medicines but arguably, they have not received as much attention in the academic literature as they should have. Putting the matter in its simplest terms, the EU, WIPO, and, to a lesser extent, the WHO, stand on one side to back private industry, while the NGOs stand on the other in support of the developing countries. In general, while the EU and NGOs set clear policies and adopt a plan of action, the WHO and

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<sup>1502</sup> MSF, ‘Indian generic companies should reject Gilead’s controversial hepatitis C ‘Anti-Diversion’ programme’ (19 March 2015) <<http://www.msf.org/en/article/indian-generic-companies-should-reject-gilead%20%99s-controversial-hepatitis-c-%E2%80%98anti-diversion%E2%80%99>> accessed 20 November 2017.

<sup>1503</sup> UK Commission on IPRs, ‘Integrating Intellectual Property Rights and Development Policy’ (2002) 166 <[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)> accessed 14 March 2018.

<sup>1504</sup> Duncan Matthews, ‘NGO Coalitions and the Global Access to Medicines Campaign: The Impact of Intellectual Property Rights on Developing Countries’ in Jude Howell (ed), *Global Matters for Non-Governmental Public Action* (Palgrave Macmillan 2012) 85, 87.

<sup>1505</sup> *Ibid.*, 89.

WIPO have become battlefields for patent advocates and health activists. When patents and health clash, these two intergovernmental organisations inevitably become involved.

This chapter has demonstrated that the EU has been a tactful player on the IP front as it has mostly used its diplomacy to settle any controversies. The EU, which quietly opposed compulsory licensing in the developing world, has long been taking measures to protect its innovative and profitable sector, while avoiding criticism. Unlike the US, which prefers an aggressive approach, the EU employs quiet diplomacy to try and minimise compulsory licences in developing countries. The reason for the EU's subtlety is largely due to the variety of its membership where industry capacity widely differs from one member state to another. Very recently, a tendency towards using compulsory licences has been revealed in the EU and it is getting stronger. Even though compulsory licensing has not yet proliferated in the EU, a growing awareness of more affordable medicines might drive EU member states towards an uncompromising stance to protect their public interest.

Sharing the same perspective with the EU and the pharmaceutical industry is the WIPO - an explicit patent supporter. The forum shifting from WIPO to TRIPS has given WIPO a new role: helping developing countries to exercise TRIPS obligations. As critically analysed in Chapter 8, domestic enactment of TRIPS is one of the key drivers of a country's attitude towards compulsory licensing. Taking this critical condition into consideration, WIPO, not the WTO, 'has been the most powerful [body] in influencing, establishing, and nurturing the domestic normative context in which TRIPS norms are implemented'.<sup>1506</sup> However, as the objective of this organisation is linked to the promotion of IPRs worldwide, its technical assistance for developing countries in complying with TRIPS is tailored to that role. That is, instead of helping those countries to maximise TRIPS flexibilities, WIPO has guided them to fulfil legal international obligations in a way to increase IP protection. Following the initiative of developing states, WIPO has slowly expanded its agenda to encompass development objectives that take into account the realities of Third World economies. However, its involvement in this issue remains to be seen.

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<sup>1506</sup> Ruth L. Okediji, 'The Role of WIPO in Access to Medicines' in César Rodríguez Garavito and Rochelle Cooper Dreyfuss (eds), *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America* (OUP 2014) 311.

Turning to the WHO, even though it is no longer on the sidelines of the debate over health and patents, as it once was, its present view remains undecided. Perhaps, until the creation of TRIPS, WHO activities mainly focus on governing global health in a more technical sense. It has little to do with trade policies. However, the 1995 TRIPS Agreement, which globalised patent laws, has brought about a profound change to the global pharmaceutical R&D system. TRIPS impacts are more far-reaching in developing countries where drug patents were enacted for the very first time. As a consequence, TRIPS has brought trade and health terms into a polemical issue, the one which the WHO was not well prepared to deal with.

Given its centrality as the most influential organisation in terms of health governance, the WHO should have been more active and engaged in current discussions. In fact, the WHO has been relatively passive. As it is not a self-financed organisation but, instead, mainly relies on financial contributions from wealthy member states, the WHO has a reason to avoid a confrontation with such member states. As a result of its ‘sandwich’ position, the WHO has decided to stay as neutral as it possibly can. Due to the organisation’s structure, size, and finance, its neutrality in the current debate is, possibly, the best available option, even though it is not the ideal one. For this reason, although the WHO is not a declared ally of the group that supports patents, it has expressed subtle opposition to compulsory licensing.

NGOs, meanwhile, have displayed the most hostile attitude towards pharmaceutical patents. Some of them, for example, MSF or KEI, have sometimes considered patents as the enemy of public health and human rights. In order to strike the balance which was shifted to the pharmaceutical industry and developed countries due to the high patent standards of TRIPS, the NGOs have partnered with developing countries to soften the impact of TRIPS thereon. As demonstrated in this chapter, these organisations have acted as ‘proxy representatives’ for developing nations in international fora. In many cases, the role of the NGOs has gone beyond health advocacy and has extended to lobbying and offering expertise knowledge.

Although NGOs are not invited as official participants in the WTO decision-making process, their participation in the run-up to the Doha Declaration challenged such conventional practice. Compared with WIPO or the WHO which are significantly under the influence of OECD countries, the NGOs considered in this thesis are financially and politically independent. In addition, they are big in number and diverse in structure which allows them to create an intensive network and tackle developed countries and pharmaceutical companies in a more

effective manner. Their involvement in the debates about access to medicines has mitigated the effect of TRIPS and made this trade agreement fairer for the developing world.

# CHAPTER 10: CONCLUSIONS

## 10.1 Introduction

This thesis has mapped and critically evaluated various uses of the compulsory licence within the TRIPS context in India, Brazil and Thailand. Compulsory licensing, one of the many TRIPS flexibilities, has become a favourite legal tool used by certain WTO developing countries to address their health-related concerns which have been said to be caused by patents. Patent monopoly, albeit capable of hampering the access to medicines in poor countries, is essential to ensure R&D of new medical products. It is therefore ‘a necessary evil’ to incentivise innovation in the pharmaceutical industry.<sup>1507</sup> Where patent rights are being used in an inappropriate manner which potentially does harm to the public, compulsory licensing is ‘another necessary evil’<sup>1508</sup> to correct the right owner’s misbehaviour. The interface between IP, mainly patents, and trade policies has made this topic an extremely intricate one for the past two decades. As a consequence, developed and developing countries have been involved in an emotional and political tug-of-war over access to medicines.

The effects of compulsory licensing of patents in relation to public health in the developing world is a classical topic which has been studied intensively, as highlighted in the first two chapters. Legal comparison on this topic is, nevertheless, scarce. This thesis has therefore contributed a specifically comparative analysis, in which India, Brazil, and Thailand are used as case studies to highlight the convergences and divergences in the implementation of compulsory licensing. This work has sought to provide a comprehensive understanding of the regulatory policy process and the underlying legal and political conditions in each country. The research objective was achieved by using the comparative method on two different tiers: the first tier is to compare national legislation and international law; while the second one compares the legal frameworks of the three country case studies.

This thesis argues that research of this comparative, qualitative kind is essential to an understanding of the extent to which international IPRs give rise to the ongoing debate. It is also important to evaluate the role of different elements within each case study’s compulsory licensing policy, and to assess the degree to which these countries have complied with

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<sup>1507</sup> Muhammad Zaheer Abbas, ‘Pros and Cons of Compulsory Licensing: An Analysis of Arguments’ (2013) 3 International Journal of Social Science and Humanity 254, 256.

<sup>1508</sup> *Ibid.*

international law, to regulate compulsory licences, and to understand why there are national variations in their regulatory norms.

This work concludes that each country case study has developed its own distinctive regime. The fact that India's compulsory licences were initiated by private companies signifies that this legal tool has mainly served its thriving pharmaceutical industry. Meanwhile, Brazil and Thailand applied government use licences to respond to their national health needs. While Brazil efficiently employed these licences as strategic threats in return for price cuts offered by patent holding companies, the seven licences issued by the post-coup government of Thailand are considered extraordinary. Given each country's unique characteristics, it is clear that compulsory licensing should not be regarded as a 'one-size-fits-all' solution to combat all healthcare issues in less-developed nations. This legal measure is certainly not and should not be considered as the only solution to solve the lack of access to medicines in Third World countries.<sup>1509</sup> Some of the other viable solutions are, for example, partnership with research-based pharmaceutical companies to build a local manufacturing capacity, investing more in R&D in the medicine sector, allowing the public drug procurement, etc...

## 10.2 Research questions and answers

### **Question No.1: How has patent law evolved within the international context?**

#### **Why and to what extent are patents essential to pharmaceuticals?**

The answer to this question is found in Chapter 3, where the development of international patent law was historically described and critically analysed. The author established that the link between IP and trade did not exist at the time of the Paris Convention, and was not really recognised until the Tokyo Round, by the US and the EU. However, their efforts began in earnest and then bore fruit later, at the Uruguay Round, where the TRIPS Agreement was adopted and came into force in 1995. TRIPS is undoubtedly the most important touchstone for patent (and other IPR) protection of the 20<sup>th</sup> century. TRIPS has brought about radical changes within nations and science and technology-based industries, such as pharmaceuticals.

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<sup>1509</sup> Robert C. Bird, 'Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effect' (2009) 37 Journal of Law, Medicine and Ethics 209, 210; Kristina Lybecker, 'Compulsory Licenses Won't Solve a Healthcare Crisis' (IP Watchdog, 1 April 2014) <<http://www.ipwatchdog.com/2014/04/01/compulsory-licenses-wont-solve-a-healthcare-crisis/id=48827/>> accessed 26 December 2017; Chang-fa Lo, 'Compulsory licensing. Threats, Use and Recent Trends' in Bryan Mercurio and Daria Kim (eds), *Contemporary Issues in Pharmaceutical Patent Law. Setting the Framework and Exploring Policy Options* (Routledge 2017) 159.

International agreements prior to TRIPS either simplified the procedure for patent filing (in countries where patents are available) (the PCT) or ensured an equal treatment between foreign and domestic applicants (the Paris Convention).

TRIPS changed all that by setting up an unprecedented platform for the patent system. It is the first international agreement that requires countries to grant patent protection to both pharmaceutical products and processes. Moreover, such protection must last for at least 20 years, a longer period than any country's patent law provided at that time. TRIPS is also significant in the sense that it creates an enforcement mechanism that can penalise member states that fail to comply with TRIPS. In effect, TRIPS is the most enforceable international IP agreement. Compared to previous treaties, this Agreement is a giant leap towards the internationalisation and the (minimum) harmonisation of the patent mechanism. International patent law has come a long way.

Chapter 3 also demonstrates that the TRIPS negotiations manifest the North-South division. The writing of this Agreement did not take place in a threat-free bargaining environment. Developing countries constantly faced economic aggression, mainly from the US, to accept the expansion of patentability to include medicines. In addition to such external pressure, other factors, such as geopolitics, and the varied shifting economic interests amongst developing countries, profoundly affected the entire gamut of the negotiation. As a result, TRIPS has been a bitter pill for developing countries to swallow in return for favourable trading conditions for other products.

The signing of the TRIPS Agreement sealed a significant victory for the pharmaceutical industry, insofar as it smoothed out inconsistencies in patent requirements that had existed under national laws prior to TRIPS. Unlike other products, in which patentability is diffused among various components, medicine patents are chiefly directed at a single molecule, which makes pharmaceuticals more vulnerable to being replicated. Given the risks associated with product development and commercialisation, as well as the competitive nature of the industry, the pharmaceuticals sector is highly dependent on patent exclusivity. Drug companies in particular advocate a strong patent mechanism, by which they can generate economic profitability to cover their massive financial outlay and to fund future R&D activities. In other

industries, the extent to which patents really incentivise innovation is difficult to measure, but critics readily concede that pharmaceutical drugs are an exception to this rule.<sup>1510</sup>

### **Question No.2: How has compulsory licensing developed within international patent law and to what extent has it affected pharmaceutical innovation?**

The development of compulsory licensing within the international patent landscape is assessed in Chapter 4. It was first governed by Article 5A of the Paris Convention through The Hague revision. Under the TRIPS Agreement, compulsory licensing was stipulated in Article 31, and this provision did not set limits on the grounds for granting such a licence. Against the backdrop of mandatory patents for medicines, Article 31 offered a means to ensure access to medicines when a public health crisis occurred.

However, whereas Article 5A gives member states substantial freedom to formulate their policies, Article 31 imposes restrictions on that freedom. It can be considered therefore that TRIPS revolutionised the compulsory licensing regime that previously existed. Article 31 mandates specific conditions that have to be followed by a signatory wishing to grant a licence. In addition to adding more requirements, TRIPS also expands the scope of application. While Article 5A principally addresses the case of a non-use patent, Article 31 extends its governance to all situations. Therefore, it is safe to argue that under TRIPS the effect of compulsory licensing has been minimised.

After the adoption of the Doha Declaration, compulsory licensing activities proliferated in developing countries. Compulsory licensing has emerged as the most effective legal measure by which developing countries' governments could strike a balance between private rights and public interests. This thesis argues that, to a certain extent, the rigorous patent regime covered under TRIPS has driven developing countries towards a more aggressive use of compulsory licences, particularly when those states failed to capitalise on other flexibilities. Compulsory licensing is therefore left as their sole option. In other words, it serves to counter the 'one-size-fits-all' patent policy set up by TRIPS.

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<sup>1510</sup> Shamnad Basheer, 'The Invention of an Investment Incentive for Pharmaceutical Innovation' (2012) 15 The Journal of World Intellectual Property 305, 311.

The power of compulsory licensing rests with the fact that it modifies the most essential element of a patent - the rights to exclude others from using, making, or selling an invention. Exclusivity is the greatest benefit that a right owner can derive from his patent, since it makes him the only exploiter in a particular market. A compulsory licence, however, enables the commercial participation by other companies, impeding the original exploiter's maximum return. Such economic loss is amplified in the case of pharmaceuticals, where the patent ownership is mostly concentrated on a single active ingredient, as was explained in Question No.1. On the other hand, the modification of a patent monopoly is essential for the government to retain the control where the public interest is endangered. In the interests of public health, compulsory licensing is widely hailed whenever it is believed that the overriding of patent rights brings more benefits to society than would be the case if exclusivity were upheld.

Empirical studies have failed to give a clear-cut answer to the issue about the extent to which compulsory licensing will affect pharmaceutical R&D. Despite the lack of conclusive findings, the pharmaceutical industry has displayed the strongest opposition to the compulsory licence. As widely known, countries that sponsor research-based pharmaceutical companies, for example the US and Germany do not frequently compel the patent owners to license their IPRs.<sup>1511</sup> Developing countries, which have favoured compulsory licensing, meanwhile, do not possess the capacity to innovate. In either situation, asymmetric information makes it very hard to gauge the impact of compulsory licensing in the industry. As a result, while the hypothesis that compulsory licensing deters pharmaceutical innovations remains unverified, the resistance of patent holding companies towards it will not change regardless.

**Question No.3: How have the three strategically selected countries of India, Brazil and Thailand, implemented a compulsory licence regime which caters for their own interests?**

This research question is not confined to one chapter but spans three separate ones. Chapters 5, 6, and 7 are devoted to the examination of the compulsory licensing regimes in India, Brazil, and Thailand, respectively. Compared to many countries in the developing world, these three

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<sup>1511</sup> It should be emphasised that the German compulsory licence granted to Merck in 2017 is considered extraordinary.

countries are considered to be relatively prosperous and possess a certain degree of pharmaceutical manufacturing capacity.

The effect of compulsory licensing does not only lie in its practical use but is also linked to the part which it plays in domestic patent laws. As clearly demonstrated in the three country case studies, having a coherent, pragmatic compulsory licensing framework is an early warning to the patent owner. Any improper use might lead to the grant of a compulsory licence by which, the patentee will lose his comparative advantage. The reality has proved that a mere threat to use the compulsory licence is sufficient to force pharmaceutical companies to lower the price of medicines.

It is very clear that compulsory licensing has brought significant advantages to society as a whole. When being granted, a mandatory licence breaks the patent monopoly, allowing more affordable medicines to be made. As seen in all three country case studies, as soon as a compulsory licence is issued, the price of relevant medicines dramatically drops. In some situations, such a licence created a domino effect. That is, not only the target medicine but other drugs are reduced by the patent owners for fear of similar actions. In this way, society as a whole gets tremendous benefit from such a grant.

### ***India***

The Indian compulsory licensing regime, which was critically evaluated in Chapter 5, serves chiefly to promote domestic industries, rather than to meet public health needs. Along with other provisions, the country's framework purposely supports its indigenous generic sector. Under the Indian 1970 Patents Act, a market-driven policy is given overwhelming priority even when the licence is driven by a public-based need.

Subsequent to the first-ever compulsory licence grant in 2012, the Indian Controller of Patents rejected two requests. The second application did not fulfil the obligation for genuine negotiation with the patent holder, and the third application failed to justify the need of a compulsory licence on one of the listed grounds. In addition to these refusals, the competent authority turned down a request by the Indian Ministry of Health. While these facts might lead to the conclusion that India does not favour prospective licensees, it does not mean that India

is greatly in favour of patent holders. A number of rejections of patent claims, issued by the Controller, invites reconsideration of any such assumption.<sup>1512</sup>

The findings in Chapter 5 demonstrate that India's regime is creatively compliant with international obligations, while giving the patent holders sufficient room to defend their legitimate rights. This thesis also found that in addition to compulsory licensing, India has utilised all possible freedoms given by TRIPS. It delayed full patentability for medicines until 2005, raising the threshold of patentable criteria to prevent the ever-greening practice of pharmaceutical companies, and allowing parallel importation. By these measures, India is able to alleviate the adverse impacts of TRIPS without resorting to compulsory licences.

On the one hand, the practice in India illustrates that the country has a robust generic industry, compared with other countries in the developing world. As a result, Indian national companies are more enthusiastic than public authorities in challenging drug patents of Western pharmaceutical companies. On the other hand, Chapter 5 reveals the Indian government's intention to gradually turn the nation into an innovation-driven economy. Interestingly, all these facts point in the same direction, i.e., that India tends towards ever increasing IP protection to synchronise with other economic initiatives. While at the same time, the likelihood of compulsory licences being issued remains low.

### ***Brazil***

As explored in Chapter 6, Brazil is an exceptionally good example of a country that successfully uses compulsory licences as a bargaining chip to obtain price cuts from patent holders. The country has only ever issued one compulsory licence for Efavirenz in 2007, after the failure to acquire a further price deduction. Such a strategy is, in fact, in line with the

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<sup>1512</sup> T.V. Padma, 'Indian court rejects Novartis patent' (Nature, 1 April 2013) <<https://www.nature.com/news/indian-court-rejects-novartis-patent-1.12717>> accessed 22 January 2018; Sumeet Chatterjee, 'India rejects Gilead's Hepatitis C drug patent request' (Reuters, 14 January 2015) <<https://www.reuters.com/article/us-gilead-india-patent/india-rejects-gileads-hepatitis-c-drug-patent-request-idUSKBN0KN1ZE20150114>> accessed 22 January 2018; 'India rejects patent on Pfizer's arthritis drug' (Reuters, 7 September 2015) <<https://www.reuters.com/article/us-pfizer-india-patent/india-rejects-patent-on-pfizers-arthritis-drug-idUSKCN0R70UF20150907>> accessed 22 January 2018; R. Prasad, 'India rejects patent claims on two HIV/AIDS drugs' (The Hindu, 17 September 2016) <<http://www.thehindu.com/sci-tech/health/India-rejects-patent-claims-on-two-HIV/AIDS-drugs/article16879640.ece>> accessed 22 January 2018.

country's reputation for balancing 'commercial diplomacy with political diplomacy in an unprecedented way'.<sup>1513</sup>

Brazil's bargaining tactics were workable and fruitful because of the country's local manufacturing capacity and its positive political attitudes. Brazil's state-owned laboratories, despite their scientific limitation, paradoxically, could reinforce the government's position in negotiations with patent owners. Furthermore, at the heart of the country's innovative approach towards compulsory licensing were its influential politicians, who played a critical role in shaping the regulatory framework and initiating the strategy. Coincidentally, these individuals threatened to issue or issued a compulsory licence during their presidential campaigns. Such a fact suggests that compulsory licensing and politics are strongly interlinked.

Since 2007, Brazilian governments have discontinued their policy, due to the technological sophistication of current medicines, for which, mandatory licences of patents are insufficient to guarantee production. Brazil, on the way to patent reform, is shifting away from compulsory licensing and embracing other measures. For example, it is following in India's footsteps by (potentially) raising the patent bar and including the health perspective in changes to national of patent law, so as to deny incremental innovations of pharmaceutical patents.<sup>1514</sup>

Brazil's compulsory licensing strategy was aimed at combatting HIV/AIDS, which, in the past, was a public health crisis in the country. For decades, Brazil's story was seen inspiring and heroic, and as a model for the developing world to follow. Brazil's aggressive use of compulsory licence threats is attributed to its loss of capacity to leverage the available flexibilities that TRIPS provides. Brazil's premature and excessive implementation of TRIPS in relation to drug patents has impaired the development of the national pharmaceutical industry and its overall health policies. The country was left with no choice but to employ the potent threat of compulsory licensing in order to compensate for that mistake. A number of changes to Brazil's patent law has demonstrated the complicated difficulties of a developing

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<sup>1513</sup> Kellie Meiman and David Rothkopf, 'The United States and Brazil. Two perspectives on dealing with partnership and rivalry' (Center for American Progress, 2009) 9  
<<https://www.americanprogress.org/issues/security/reports/2009/03/12/5834/the-united-states-and-brazil-two-perspectives-on-dealing-with-partnership-and-rivalry/>> accessed 8 February 2018.

<sup>1514</sup> In fact, not only Brazil but a number of countries such as Philippines, China, Australia, Argentina also adopted the Indian approach towards strict patentability. See further at Mohammed K. El Said, 'TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries' (2016) 31 American University International Law Review 373, 406 – 408.

country attempting to balance its access to existing innovations and the incentive for future inventions following multilateral trade deals.

### ***Thailand***

Chapter 7 examines seven Thai government use licences, all issued in an exceptional political climate. Such licences, which were justified on the public health grounds, were granted by the post-coup government in 2006. Consequently, political voices dominated discussions in Thailand, since it was viewed that an unlawful government was trying to curry favour with its people. The legitimacy of these licences was placed in significant doubt. Besides, the *de facto* government also set a precedent for compulsory licensing, by extending such use to medicines for the treatment of chronic diseases. Prior to this development, the use of compulsory licensing had been limited to infectious diseases.

Unsurprisingly, Thai use of compulsory licensing also provoked an unprecedented reaction from the patent holders. They either withdrew patent registrations from the Thai market, or lobbied other domestic organisations that were beneficiaries of their philanthropy or threatened to take legal action against companies that were about to supply the generics to the Thai government. These moves have demonstrated that compulsory licensing, if employed to an extreme extent, has the potential to exceed the normal boundaries of a legal battle and to turn into political tragedy.

So far, Thailand has been the only country that has assessed the economic effect of government use licences. The assessment indicates that some licences were not cost-effective, due to the small number of recipients, while others had short implementation periods because of legal obstacles posed by the patent holders.

While this thesis considers India and Brazil as best-in-class developing countries, Thailand is typically representative of countries with little manufacturing capacity and little influence and power in international relations. Thailand has not achieved an advanced stage of industrial development (as is the case with India) nor does it possess high-profile diplomatic power (as is the case with Brazil). It has been shown that Thailand surrendered to US pressure to implement full patentability at an early stage. However, such a surrender took place with an advantageous trade-off as Thailand is considered to be a net gainer from the Uruguay Round.

Therefore, this thesis argues that economic benefits from other trade areas might compensate for the country's loss in the area of patented medicines.

**Question No.4: What are the similarities and differences in the compulsory licensing regimes of India, Brazil and Thailand? Why is there such a variety?**

These questions were answered in Chapter 8. It should be noted that, although the countries under examination have developed their own compulsory licensing systems, as answered in Question No.3, their regimes have to follow international law, as noted in Question No.2. In general, all their compulsory licence grants, to some extent, produced significant effects on the whole society. In the short term, these licences eroded the monopoly of patent holding companies, driving down the price of medicine, thereby increasing the number of patients in treatment. Furthermore, in the examples of India and Brazil, mandatory licensing also resulted in price deductions of other medicines which were not subject to such licences in the first place.

The practice of India, Brazil and Thailand nevertheless shows that a country wishing to use compulsory licensing should consider adverse consequences that occur. Amongst the three examined countries the use of Thailand produced the most negative political effects. It should also be noted that potential consequences do not only arise from the external pressure but also from the internal conflicts within a country's government. Brazil provided such a very good example in the Kaletra deal where the conflict between the Ministry of Health and the Ministry of Trade partly led to the failure of the compulsory licence grant for that medicine.

The greatest difference between the three systems is that, while India's compulsory licensing tends to be market-driven, the licensing employed by Brazil and Thailand is driven by public need. As a result, while India's compulsory licence is of benefit to one pharmaceutical company, Brazil's and Thailand's licences tend towards the public interest. The key factors behind such divergence are presented in the following table:

**Table 4 Key factors affecting a national compulsory licensing regime**

Factors		Patent requirements			Advanced pharmaceutical manufacturing capacity	Public health insurance	Strong Governmental intervention	Compulsory licensing outcomes
Countries	Transitional period	Parallel importation	Strict patentable criteria	Pipeline protection				
<b>India</b>	YES	YES	YES	NO	YES	NO	NO	- Market-driven - Promote industry
<b>Brazil</b>	NO	YES (after many regulatory changes)	NO	YES	NO	YES	YES	- Government-use - Enhance access to medicines
<b>Thailand</b>	NO	YES	NO	YES	NO	YES	YES	

## **Question No.5: What are the philosophical approaches of multilateral organisations in the debate on access to medicines in developing countries?**

This research question which is answered in Chapter 9 has stemmed from the fact that the establishment of TRIPS was aggressively pushed by the private industries with the support of the EU and the US, whereas the WHO, WIPO and health-related NGOs were largely absent from the proceedings. The negotiations of TRIPS witnessed the influence of the business sector in driving and shaping international IP standards. As a result, TRIPS has reflected the strong economic interests of the right owners and those benefiting from weaker levels of protection for IPRs.<sup>1515</sup> It is undeniable that TRIPS was a major victory for developed countries and big pharmaceutical companies, who now have patents on their medicines in almost every corner of the world. When IPRs and health clash, it is time for the multilateral organisations to step in.

It was not easy to obtain a full comprehension of the EU's approach towards compulsory licensing. On the one hand, its overall policy is to protect creative sectors, including pharmaceuticals. On the other hand, the Union consists of 28 member states, all having different economic policies. There are countries which are the world's leaders in the pharmaceutical sector but also others which have a low technology like many developing nations. For this reason, the EU explicitly expressed the view that compulsory licensing is totally a matter for national law, from which it stands apart. The EU has nevertheless taken sufficient diplomatic steps and has employed a wide range of measures to protect its highly profitable industry. Compared with the US, its like-minded ally in increasing the level protection of IPRs on a global scale, the EU is more subtle and tactful when dealing with the compulsory licensing practice in developing countries. Its moves rarely spark a public outcry. Under close scrutiny, striking developments in Europe as regards proposals of overriding patent rights which have been increasingly put forward, coupled with a rising tide of nationalism in the region, might lead to a change in these countries' approach towards compulsory licensing.

As for WIPO, this organisation has adopted a pro-IP ideology. Since the majority of its income comes from patent fees, it is not surprising that WIPO promotes patenting activities globally. Undoubtedly, WIPO gains considerable benefits from patent filings, and the corollary being that it is not in favour of compulsory licensing. WIPO has long been criticised for focusing

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<sup>1515</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2001) 7- 9.

only on the benefits of the patent system, while overlooking the downside thereof. For the past decade, the organisation has slowly kept pace with ongoing deliberations. Its fundamental mission and function, however, have remained substantially unchanged.

As IP discussions now increasingly focus on access to medicines, the WHO cannot step aside from the present international debate. On the one hand, the WHO Model List of Essential Medicines are significant for developing countries as the latter rely on that list to adjust their public health policies, including their compulsory licensing regimes. On the other hand, the WHO's finances are largely dependent on the contributions by rich countries, such as the US, Japan and the countries of Western Europe, and it has tried to avoid conflicts with these member states. As a result of this dichotomy, dissenting voices are heard within the WHO with regard to compulsory licensing.

In contrast to the pro-IP approaches of the EU and WIPO, and the hesitancy of the WHO, the NGOs have actively lent their support to developing countries. The NGOs that joined the 'access to medicines' campaigns are large in number and diverse in structure. Thus, despite the fact that they have not acquired any official status in the WTO, they still exert influence on access to medicines disputes and push the debate to favour developing countries. Unlike the original TRIPS negotiations, which was significantly underscored by the role of the US and the EU, the Doha Declaration and the Paragraph 6 negotiations were marked by a higher profile for NGOs. However, the coalition between NGOs and developing countries was unsustainable, as the former, unlike the latter, do not have vested interests in trading with developed states.

### **10.3 Major findings of this research**

This thesis has a number of major findings.

Firstly, although the three countries under examination, i.e. India, Brazil and Thailand, all granted compulsory licensing for medicines, to judge from the political, practical, and economic perspectives, this legal tool's effectiveness varies from situation to situation. All three case studies show that these countries' use of compulsory licensing provoked sharp, political responses from countries sponsoring the pharmaceutical companies. For example, in Thailand, the retaliation by the patent holders undermined the effectiveness of the country's government use policy. In addition, the compulsory licence grants did not always generate the desired economic savings.

Secondly, this thesis submits that each country's application of compulsory licensing is closely linked to two factors: how it has implemented TRIPS and, its pharmaceutical manufacturing capacity. Where a state capitalises on TRIPS flexibilities and has a well-developed manufacturing capacity, it is unlikely to use compulsory licensing (e.g. India). In contrast, where TRIPS flexibilities are underutilised combined with a low industrial development, then the grant of compulsory licences is highly likely (e.g. Brazil and Thailand).

Thirdly, it is true that a compulsory licence can, in certain situations, respond to short-term healthcare issues, but it is equally true that granting a compulsory licence 'is not like flipping a switch that opens floodgates for affordable medicines'.<sup>1516</sup> The author shares the view that the poor's access to medicines is not just affected by patent protection but also by other factors such as poverty, poor health care infrastructure and shortage of human resources. In order to solve long-term health-related problems, WTO member states are recommended to utilise other TRIPS flexibilities in association with other economic, social and technological measures.

Finally, this thesis identifies the various stances of the EU, the WHO, WIPO, and the NGOs on the debate between compulsory licensing and medicine access. The EU has built an image as a quiet and tactful player but at the same time, the heterogeneous legal systems and economic policies of the 28 member states make it unlikely that the Union will speak with one voice on this matter. WIPO leans towards a stronger patent regime while displaying subtle opposition to compulsory licensing. If the WHO shows its hesitancy in the ongoing deliberations and attempts to maintain a neutral stance then, the NGOs can be vocal opponents of medicine patents and have a profound influence on setting global health policies that support developing countries.

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<sup>1516</sup> Robert C. Bird, 'Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effect' (2009) *Journal of Law, Medicine and Ethics* 209, 210

## **10.4 Key lessons to be drawn from the collective experience of the country case studies**

Key lessons from which other developing countries can learn from the experience of India, Brazil, and Thailand are as follows:

- LDCs that are given until 2033 to implement TRIPS provisions regarding medicine patents should take full advantage of this period to establish a pharmaceutical manufacturing capacity, build health infrastructure and adopt appropriate public health measures. It is inadvisable for their governments to have medicine patents while their pharmaceutical capability is still underdeveloped. In addition, as compulsory licensing is a component of patent law, it should be synchronised with other patent policies. In this way, policy makers should envisage the future application of such licences, even compulsory licensing is not being used now, to adopt a straightforward framework without undertaking many regulatory changes.
- Compulsory licensing is neither a silver bullet nor a uniform solution to long-term healthcare problems but can be used to address short-term issues. Prospective granting countries should consider other mechanisms, such as negotiations, partnerships and voluntary licences before resorting to the compulsory licence. It should be the last measure, when all alternatives fail to yield fruitful outcomes.
- It was noted that countries with an existing national health insurance scheme had considerable bargaining power in price negotiations with the patent holders. In many cases, pharmaceutical companies can offer price cuts as a reward for the large volumes purchased by governments to supply to their citizens.
- In every case of a compulsory licence, first and foremost, prior negotiation between the government/prospective licensee and the right owner is always recommended, even where it is not mandatory. Secondly, as this thesis has repeatedly argued, a compulsory licence will reduce the economic value of a patent, a country's government is advised to offer reasonable compensation to mitigate the loss. Thirdly, the scientific aspect of target medicines should be factored in, so that the technology necessary for the manufacture of such medicines is up-to-date and will not be obsolete by the time of

transfer. Lastly, the economic impact has to be considered to include the drugs that possibly generate significant cost savings.

## 10.5 Scope for further research

Despite the fact that this thesis only covers three country case studies, namely India, Brazil and Thailand, their compulsory licensing regimes had significant impact on the worldwide public. Accordingly, the findings on their policies can provide valuable insights to decision makers of other WTO members on the legislative environment and on how to best act within the scope of TRIPS.

On the other hand, future legal research on this topic can be further expanded in at least three different ways.

First of all, country selection can be extended to LDCs or even developed countries. As indicated in Chapter 2, current literature has paid more attention to middle income countries than any other countries. This thesis therefore suggests that future research could look into the legal frameworks of LDCs to understand their TRIPS implementation processes as well as evaluating whether their lack of access to medicines is really caused by patent standards contained in TRIPS. In addition, as pointed out in Chapter 9, the practice of compulsory licensing has started to develop in the EU which reveals a rising demand for affordable medicines in the region. This recent development shows that compulsory licensing is not exclusive to developing countries any more but gradually exceeds its conventional boundary. For this reason, legal evaluation of the compulsory licensing regimes in developed countries/EU member states will provide a more satisfactory answer to such an emerging need. It is argued that only by conducting an individual assessment within each country, can the full impact of compulsory licensing be provided, while allowing legislators to shape their own frameworks.

Secondly, as concluded in this thesis, WTO member states should not rely only on compulsory licensing but consider their choices to include other TRIPS flexibilities, for example Article 30. This provision provides an exception to patent rights so as to allow countries to do research and experiment on a patented invention without infringing it. Member states are advised to start using this flexibility to build and increase their pharmaceutical manufacturing capacity. Or another option is the new compulsory licensing regime, the paragraph 6 system. Future legal

research on these two regimes can be carried out to present countries with more options to enhance medicines accessibility.

Last but not least, as stated previously, empirical studies on compulsory licensing are scarce. The author therefore suggests that this type of research could potentially produce interesting findings. Future works might look into how compulsory licensing affects FDI and innovation so as to paint a more comprehensive picture. Furthermore, another avenue to explore is the extent to which compulsory licensing is economically effective compared with other alternatives, such as international procurement, voluntary licensing or negotiation.

## 10.6 Concluding remarks

1. Despite the fact that neither TRIPS nor the Doha Declaration restrict the right to grant compulsory licences, there is no doubt that developing countries have encountered great difficulties in exercising their legitimate rights. The difficulties lie not only in the inherently controversial nature of compulsory licensing, but also in the practical aspects, such as the retaliation of patent holding companies and economic coercion on the part of countries sponsoring these firms.
2. Patent holding companies would welcome negotiation, voluntary licences, donations or other constructive approaches as amicable solutions to the problem. Although they all agree that compulsory licensing is permissible under international law, they believe that this legal mechanism should be the last option, for use in situations where two parties are unsuccessful in their attempts to reach an agreement, or when an extremely urgent situation arises.
3. Each compulsory licensing regime is distinct and unique, and therefore, there is no ‘one-size-fits-all’ policy. However, a key point should be borne in mind, that being that compulsory licensing and politics are inevitably intertwined, to the extent that victory on the political front can distract public attention from the legal aspect.
4. After the grant of compulsory licences, generic medicines become more affordable compared with patented drugs. However, medicines for compulsory licensing must be strategically selected. In the practice of the three countries studied, the generics were not made at the cheapest price, compared with the substitutes available on the market, as important consideration for those who seek such licences. If the financial saving is insignificant, other solutions ought to be sought. The practice in India, Brazil and

Thailand has clearly demonstrated that the compulsory licensing process is unpleasant, lengthy, and entails long-running legal as well as political battles. It is important therefore that whatever positive effects flow from such a process outweigh any negative effects.

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