Master Thesis

International and European Law

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Compulsory license: analysis of the effectiveness in providing access to medicines

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LIST OF ABBREVIATION

AGCM - Autorità Garante della Concorrenza e del Mercato (Italian Competition Authority)

AIDS - Acquired Immune Deficiency Syndrome

ART - Antiretroviral therapy

ARV - Antiretroviral

BMS - Bristol-Myers Squib

CARM - Canadian Access to Medicines Regime

CESCR - Committee on Economic, Social and Cultural Rights

EU – European Union

FIS - Fabbrica Italiana Sintetici SpA

GSK - Glaxo Group's

GULs – Government use license

HIV – Human Immunodeficiency Virus

ICESCR - International Covenant on Economic, Social and Cultural Rights

LDC – Least developed countries

MOH – Ministry of Health

MOPH – Ministry of Public Health

MSD - Merck Sharp and Dohme

NAP - National Aids Program

NGO - Non-governmental organization

NLEM - National List of Essential Medicines

OECD - Organization for Economic Co-operation and Development

PAHO - Pan American Health Organization

QALYs - Quality-adjusted life year

R&D – Research and Development

SPC - Supplementary Protection Certificates

SUS – Sistema Único da Saúde Brasileiro (Brazilian Universal System Care)

TAR - Italian Regional Administrative Tribunal

TFEU – Treaty of the Functioning of the European Union

TRIPS-Agreement - Trade-Related Aspects of Intellectual Property Rights Agreement

UCS - Universal Coverage Scheme

UDHR - Universal Declaration of Human Rights

UHS - Universal Healthcare Coverage system

UN – United Nations

WHO – World Health Organization

WIPO - World Intellectual Property Organization

WTO – World Trade Organization

LIST OF LEGISLATION

Brazilian Decree 6.108

Brazilian Law nº 9.279 (15 May 1996)

Constitution of the Federative Republic of Brazil (1988)

Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration)

Indian Patent Act

International Covenant on Economic Social and Cultural Rights (ICESCR)

Taiwanese Patent Act

Trade-Related Aspects of Intellectual Property Rights' (TRIPS Agreement)

Treaty on the Functioning of the European Union (TFEU)

Universal Declaration of Human Rights (UDHR)

Vienna Convention on the Law of Treaties (VCLT)

ABSTRACT

This study analyzes the effectiveness of the compulsory license in providing access to medicine between 2005 and 2012 through six case studies (Taiwan, Italy, Rwanda, Brazil, Thailand and India). This study aims to consider whether the compulsory license affected the innovation cost for pharmaceutical companies. The cases were selected based on the different reasons the countries had for issuing the compulsory license, the countries' wealth and location, and the different categories of medicines. The discussion and comparison of the results demonstrate the necessity to enhance the compulsory license legislation and to adapt it to be better for less developed countries. These countries cannot process medicines by themselves or depend on the Doha Declaration and Waiver Mechanism, since both are complex, bureaucratic and expensive. This study demonstrates that the compulsory license is more effective in countries that offer universal health systems to its citizens. Compulsory license legislation on its own is not completely successful in providing indiscriminate access to medicine because it depends on the wealth of the country as well as its internal laws and health system.

1. INTRODUCTION

The World Trade Organization (WTO) and the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) first regulated the concession of patents for medicines in 1995 with the clear objective of standardizing the rules regarding intellectual property. The TRIPS Agreement provides clear articles about the protection of intellectual property and innovation. The TRIPS Agreement established, as a rule, the possibility of a monopoly for 20 years for the exploitation of new inventions for the inventors (private individual or legal entity). As a result, companies start to expend resources and time (Research & Development) in innovative areas and new medicines in order to be able to commercialize and make a profit off of those medicines in market.

However, new laws on intellectual property raised awareness regarding barrier to the population's right to health and consequently its access to essential medicines. These rights were established in the most important documents of international law, including the Universal Declaration of Human Rights and the International Covenant on Economics, Social and Cultural Rights, among others. The main reason for the barrier is that pharmaceutical companies, in their 20-year period of exploitation, would sell medicines at astronomical prices since there was no competition. Therefore, the compulsory license was created in 1995 as a means of loosening patent exclusivity.

The compulsory license, first established in article 31 of the TRIPS Agreement is an exception to the rule of monopoly and allows for the government and third parties to manufacture a patented product or process with or without the consent of the patent holder, depending on the regional/domestic laws of each Member State of the WTO. However, the compulsory license made it difficult to grant access to medicines to least developed countries (LDC) in the exact terms outlined in article 31; therefore, the TRIPS Agreement was amended in 2001 by the Doha Declaration and in 2005 by the Waiver Mechanism in order to provide more criteria that would allow LDC to make use of the compulsory licenses and finally obtain medicines.

Indeed, the 2001 modification altered the reality of the compulsory license and made it possible for LDC to request and issue compulsory licenses. It began to be a prevalent topic in the commercial world. At first, the compulsory license was used more for HIV medication, but since 2010, it has been possible to analyze some compulsory

licenses for oncology, heart disease, and even anti-inflammatory medicines. The table in Appendix 1 of this thesis provides an overview of the compulsory licenses issued since 1995 and the category of medicines attached to each license. However, the data in the table is not exhaustive. The cases were found through articles and desk research for this thesis.

Brazil was a huge case in the international scene because by 2007, the country was a growing economy and not an LDC with an extreme lack of medicine. However, the Brazilian president at the time did not consider the international scope and agreed to issuing a compulsory license for the medicine efavirenz for the treatment of HIV. The grant for the license was highly criticized in the media, but also brought consequences for the Brazilian health system, which shall be analyzed further in the study.

The limitation of the patents by the compulsory license is one could argue a threat to the main idea behind the TRIPS Agreement regarding patents: the encouragement of innovation and spending on research and development to create new medicines for the population.

This study seeks to answer the following question: ***has the mechanism of compulsory licensing in fact made some considerable improvements to the population's access to medicine***? I plan to analyze whether the countries that requested the licenses are actually using the mechanism in order to provide medicine to its citizens or whether they are using it as a threat or as a way to save money even when the population is not in need or there is not outcome of an particular disease. The main answers that the thesis plans to reach, besides discovering the effectiveness of the compulsory license in providing the population with access to medicines to, are as follows: **(i)** whether the possibility of granting a compulsory license has or has not affected innovation, the main pillar of the WTO regarding patenting; **(ii)** whether the compulsory license works better in low, medium or high income countries (Italy compared to Brazil, Thailand, India, Taiwan, and Rwanda); **(iii)** whether the populations of countries that have a better health coverage system benefit more from the compulsory license compared to those countries that do not have a structured health system (Brazil, Thailand, and Italy compared to India and Rwanda); **(iv)** the different types of requested compulsory licenses (government use license, emergency use, anti-trust), the different outcomes of the license, the skepticism

regarding it, and whether the law needs to clarify the reasoning behind the license; and **(v)** the effectiveness of lower prices for the medicines subject to the compulsory license.

First, this study provides a complete legal background on the right to health and access to essential medicines, using international documents and mandates by the United Nations (UN) and the World Health Organization (WHO) on the matter. It is possible to check how the "right to health" is still a topic yet to be discussed today, as it is a part of the 2015 Sustainable Development Goals. In addition, this study discusses the parallel framework of patenting provided by the WTO in conjunction with the TRIPS Agreement, the expectation that caused the development of the compulsory license and its limitations, as well as an analysis and an overview of the Doha Declaration and the Waiver Mechanism (international and regional).

Secondly, this study offers a critical point of view on compulsory licenses in order to oppose the first part. This section aims to discuss the main issues that may result from the practice. The idea of providing medicine at a low cost to the population can be exciting, but some criticism is also possible. One can analyze the possibility that the license affects research and developing costs and, consequently, innovation.

Thirdly, this study focuses on a complete and integrative analysis of some chosen case studies of compulsory licenses. The cases and countries were selected based on the availability of data and evidence; the different reasons for the issuance of the license (governmental use, non-public commercial use, waiver mechanisms, antitrust); different countries, from developed and LDC countries, medium income and developed countries, such as Brazil, Thailand, Rwanda-Canada, Italy, India, and Taiwan; and differential types of medicines (antiretroviral, cancer drugs, heart diseases).

To that end, the methodology for this thesis consists of a full analysis of books, articles, newspapers, international documents, pharmaceutical websites, and reports. For this thesis, a total of 62 articles from databases provided by Tilburg University, such as HeinOnline, Jstor, Hudoc, Collected courses of The Hague Academy of International Law - Recueil des Cours, Curia, Ju"ra, Oxford Public International law (OPIL), etc. Since this thesis is also related to medical approaches, it was also necessary to use some databases on the subject, such as Ovid, Medline, US National Library of Medicine National Institute of Health, and Elsevier. This study also used legal documents and declarations – not only the Universal Declaration of Human Rights (UDHR) and the International Covenant on

Economics, Social and Cultural Rights (ICESCR), but also documents from the WTO, WHO, and WIPO. Sources of literature, government releases, the WHO database, and legal and medical scientific papers were used to obtain the data prices of the medicines in the cases discussed.

Lastly, the study provides answers to the questions mentioned in this introduction, integrated with a range of studies and works of literature.

2. LEGAL FRAMEWORK: THE RIGHT TO HEALTH

2.1 Human Right to Health

First, health is defined as the state of complete physical, mental and social well-being and not merely an absence of a disease or infirmity.[1] Regardless of age, gender, socio-economic or ethnic background, health can be considered the most basic of the essential assets.[2]

Health is recognized as a human right at the national and international level, as it is discussed in the main documents regarding rights: the UDHR[3] from 1948, the ICESCR[4] from 1966[5], and the Committee on Economic, Social and Cultural Rights (CESCR) General Comment n. 14. Furthermore, the right to health is one of the main pillars of the United Nations. In the WHO's constitution – in the preamble – it states the following principle: 'enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being'.[6] It is interesting to note that the ICESCR gives both mental health and physical health equal consideration in its article 12.

In the CESCR General Comment 14 - The Right to the Highest Attainable Standard of Health - health is a 'fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity'.[7]

Comment n. 14 precisely states that the right to health is different to the right to be healthy, since the right to health contains both freedoms and entitlements. While the

[1] WHO 'Constitution' International Health Conference, New York, (19-22 June, 1946; signed on 22 July 1946) <http://www.who.int/governance/eb/who_constitution_en.pdf> accessed at 22 March 2018 (WHO Constitution).
[2] UN Office of the High Commissioner for Human Rights (OHCHR) and the WHO 'Fact Sheet No. 31, "*The Right to Health*''. Publisher' (June 2008) Reference, UN Doc 1014-5567 <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf> accessed at 10 June 2018.
[3] Article 25 (i) of the UDRH states: "(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."
[4] International Covenant Economic Social and Cultural Rights (adopted in 16 December 1966, entered into force in 3 January 1976) 2200A (XXI) (ICESCR). It entered into force in 1976 and by 1 December 2007 had been ratified, in 2018, by 157 States. The Covenant has a binding effect
[5] ICESCR (n 4) art. 12.
[6] WHO 'Constitution' (n 1) preamble.
[7] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)' (11 August 2000), UN Doc E/C.12/2000/4, 14 (1)

freedom is the right of an individual to control his or her own body (including sexual and reproductive freedom), the entitlements include the right to have a health system that may provide protection and equality to a society.[8]

Apart from the UDHR, the ICESCR, and the Comment 14, it is possible to list other international documents that consider the right to health important in their texts:

i. The 1965 International Convention on the Elimination of All Forms of Racial Discrimination: art. 5 (e) (iv);
ii. The 1979 Convention on the Elimination of All Forms of Discrimination against Women: arts. 11 (1) (f), 12 and 14 (2) (b);
iii. The 1989 Convention on the Rights of the Child: art. 24;
iv. The 1990 International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families: arts. 28, 43 (e) and 45 (c); and
v. The 2006 Convention on the Rights of Persons with Disabilities: art. 25.

The right to health is also part of regional documents, such as the African Charter on Human and Peoples' Rights (1981), the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, known as the Protocol of San Salvador (1988), and the European Social Charter (1961, revised in 1996).

Furthermore, the right to health is not only associated with access to healthcare and the building of hospitals, but also includes a range of factors that can help a human being have a healthy life. The Committee on the ICESCR understands that this 'range of factors' can include safe drinking water[9], safe food[10], adequate nutrition[11], etc.

It possible to say, in accordance with the factors listed above, that the right to health is linked with the right to water[12], for example. Illnesses can be associate with the lack of potable water. The WHO estimates that in 2002, diarrhea was caused by this

[8] ibid 8.
[9] UN Committee on Economic, Social and Cultural Rights (CESCR) 'General Comment No. 15: The Right to Water (Arts. 11 and 12 of the Covenant)' (20 January 2003) UN Doc E/C.12/2002/11.
[10] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No. 12: The Right to Adequate Food (Art. 11 of the Covenant)' (12 May 1999).
[11] ibid.
[12] The Human Right to Water and Sanitation (HRWS) was recognized as a human right by the United Nations (UN) General Assembly on 28 July 2010.

factor, contributing to the deaths of 1.5 million of people that year.[13] Since human rights are considered to be interdependent, indivisible and interrelated[14] according to the Vienna Declaration, it is clear that the right to health can overlap with other rights.

2.2 Access to essential medicines as part of the right

According to the WHO in its World Medicines Situations Report of 2011, at least one third of the world's population has no regular access to medicine.[15]

Once again, the CESCR General Comment n. 14 indicates the interrelated and essential elements that make up the right to health, which need to be applied by a particular state:

(i) Availability: for full compliance with the right to health, a State has to provide a functioning public health system and healthcare facilities, goods, and services, including essential drugs "*as defined by the WHO Action Programme on Essential Drugs.*" [16]

(ii) Accessibility: the health facilities have to be accessible to everyone with regard to four overlapping dimensions: non-discrimination; physical accessibility; economic accessibility/affordability, and information accessibility.[17]

(iii) Acceptability: the health facilities must be respectful of medical ethics and must be culturally appropriate –respectful to minorities, peoples, and communities.[18]

[13] Lorna Fewtrell and others 'Water, sanitation and hygiene: quantifying the health impact at national and local levels in countries with incomplete water supply and sanitation coverage' World Health Organization (Geneva, 2007) (WHO Environmental Burden of Disease Series No. 15).
[14] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (1969 Vienna Convention) art 5: 'All human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis. While the significance of national and regional particularities and various historical, cultural and religious backgrounds must be borne in mind, it is the duty of States, regardless of their political, economic and cultural systems, to promote and protect all human rights and fundamental freedoms.'
[15] Warren Kaplan and Colin Mathers, 'World Medicines Situations Report of 2011' by the WHO, (Geneva 2011) <http://apps.who.int/medicinedocs/documents/s20054en/s20054en.pdf?ua=1> accessed 24 March 2018.
[16] CESCR 'General Comment 14' (n 7) art 12(a).
[17] CESCR 'General Comment 14' (n 7) art 12(b).
[18] CESCR 'General Comment 14' (n 7) art 12(c).

(iv) Quality: the health facilities must also be scientifically and medically appropriate and of good quality.[19]

The General Comment n.14 specifies that the provision of medicines is an important part of providing the right to health, with a special focus on so-called essential medicines.

Essential medicines by definition are those medicines that "*satisfy the priority healthcare needs of the population*," and according to the WHO, those medicines are selected on the basis of their estimated current and future public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. The list of these medicines are published every two years, in the WHO's inventory, a model list of essential medicines.[20] The essential medicines are supposed to be available in health systems worldwide at all times in adequate amounts and in the appropriate dosage forms according to law. These medicines should also be available with assured quality and adequate information and at a price that the community can afford.[21] According to the WHO, the countries shall use the inventory list as a tool to prioritize medicines based on their domestic needs.

To summarize, the WHO also outlined the four essential building blocks in order to ensure access to medicines at a national level:

1. Rational selection and use of essential medicines based on national lists of essential medicines and treatment guidelines
2. Affordable prices for governments, healthcare providers, and individuals through the use of bulk procurement, generic policies, equitable pricing, and reduction of taxes
3. Sustainable financing of essential medicines as part of a national healthcare system through adequate funding levels and equitable prepayments systems

[19] CESCR 'General Comment 14' (n 7) art 12(d).
[20] WHO Expert Committee 'The select and use of essential medicines' (Geneva 2003) 8 <http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html#Js4875e.5.2> accessed 10 June 2018.
[21] ibid.

4. Solid health and supply systems to protect sufficient and a locally appropriate combination of public and private service suppliers.[22]

Comment 14 emphasizes a country's obligation to protect an individual's right to health and requires states to refrain from interfering directly or indirectly with this fundamental right. Although the ICESCR takes into consideration the limitations of accessible resources and provides for a gradual fulfillment of the right to health, state parties to the Covenant have an urgent obligation to take the necessary steps to achieve the obligations in article 12 of the Covenant.[23] This article guarantees that the right to health applies without any kind of discrimination. Therefore, states must create programs and actions to improve the health systems in their countries. International law provides guidance to states so that the implementation of their systems can be monitored.

2.3 The right to health and access to medicines in the UN 2030 Sustainable Development Goals (SDGs)

On June 23, 2018, the United Nations Human Rights Council adopted resolution n. A/HRC/35/L.18/Rev.1 on the right to health in the *UN 2030 Sustainable Development Goals (SDGs),*[24] including a call for access to all medicines and vaccines.

The resolution recognizes the lack of medicines in either developed countries and LDC and the fact that individuals still do not have access to affordable, safe efficacious and quality medicines, vaccines, and diagnostic and medical devices.[25]

In the document, the United Nations Human Right Council urges that the SDGs be fully implemented and outlined targets to be achieved, such as target 3.8, which describes the responsibility to achieve universal health coverage, with financial risk

[22] WHO, 'Equitable Access to Essential Medicines: A Framework for Collective Action' Policy Perspectives on Medicines Bulletin (2004) 2, <http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf> accessed 25 March 2018.
[23] ICESCR (n 4) art 2(1).
[24] On September 25th 2015, countries that are part of the UN Council adopted a set of goals to end poverty, protect the planet and ensure prosperity for all as part of a new sustainable development agenda. There are a total of 17 goals to be achieved over the following 15 years after 2015. The third goal is called "Good Health and Well-Being". The resolution issued by the UN Human Rights Council in to explain and five directive to the goal
[25] United Nations Human Rights Council (UNHRC), Res A/HRC/35/L.18/Rev.1 'The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the implementation of the 2030 Agenda for Sustainable Development' (21 June 20017).

protection, and access to quality and essential healthcare services all over the world that are safe, effective, and make essential medicines and vaccines affordable for all.

The council's resolution also 'calls upon the international community to continue to **assist developing countries in promoting the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, including through access to medicines**, in particular essential medicines, vaccines, diagnostics and medical devices that are affordable, safe, efficacious and of quality; financial and technical support and training of personnel, while recognizing that the **primary responsibility for promoting and protecting all human rights rests with States**; and recognizes the fundamental relevant importance of the transfer of environmentally sound technologies on favorable terms, including on concessional and preferential terms, as mutually agreed'.

The human right to health is and will continue to be a prevalent topic in the world, especially in the LDC, which have more difficulties in maintaining their populations' health for several reasons. Proof of this is that legal entities are still discussing the possibilities and achievements regarding the right to health.

3. LEGAL FRAMEWORK: PATENTS AND COMPULSORY LICENSES

3.1 History of the WTO and TRIPS Agreement

To fully understand the topic of the present paper, it is essential to discuss the background of patents and how they became counterpoint to the right of health in this specific area.

During the period between 1986 and 1994, 123 countries joined The Uruguay Round, the largest trade negotiation ever and probably the largest negotiation in history up to that time,[26] to discuss trades. The discussion covered a range of topics, from toothbrushes and pleasure boats to banking and telecommunications, to the genes of wild rice and HIV treatments. However, 49 of the 98 members to the Paris Convention[27] excluded pharmaceutical medicines from patent protections during the settlements. This was because according to public understanding at the time, naming some things, such as pharmaceuticals or food, intellectual property was considered an act against public interest.[28] Supakankunti and others state that in this scenario, the government could produce drugs at reduced prices, provide medicines to the population, and improve the public health of the country.[29]

Firstly, intellectual property right is outlined in article 27(2) of the UDHR and in article 15(1)(c) of the ICESCR as the right to protect moral and material interests that may result from any scientific, literary, or artistic production of which some individual claims to be the author.

The establishment of the WTO and the TRIPS Agreement in 1995, ratified by 159 countries in 2018, was an initial marker of today's globalization and harmonization of international property laws, creating global minimum standards for the creation and protection of intellectual property. These standards would facilitate the transfer of

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[26] WTO 'Understanding The WTO: Basics' <https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm> accessed 10 June 2018.

[27] The Paris Convention for the Protection of Industrial Property (1883) was one of the first multilateral IP Agreement and today is administered by the WTO and today counts 173 States, as well as the Patent Cooperation Treaty (PCT), the Strasbourg Agreement Concerning the International Patent Classification, the Patent Law Treaty and the Budapest Treaty. Later, they were all harmonized by the WTO into the TRIPS Agreement.

[28] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (1st Edi, Health Action International, 2016) 79.

[29] Siripen Supakankunti and others 'Impact of the World Trade Organization TRIPS Agreement on the pharmaceutical industry in Thailand' (2001) 79 Bulletin of the World Health Organization 461.

technology and serve to further increase incentives for investing in innovation.[30] The TRIPS Agreement describes the international legal definition of a patent as an exclusive monopoly (use and exploitation) over an invention, whether a product or a process,[31] for the minimum period of 20 years.[32] This makes the patenting of medicines (product) or a method of producing the chemical ingredients for medicines possible today, providing a new area for long-term pharmaceuticals companies to explore and grow under this scenario, which was impossible before 1995.

Patents can be used for new, useful, and non-obvious inventions.[33] Patents can be granted domestically, regionally or internationally, depending on the type of innovation and what is deemed most suitable.[34] The price also depends on the type of the invention. The application must meet the requirements indicated in article 27 of the TRIPS Agreement, mainly the requirements of specification and description, to prevent confusion in patent conflicts and ensure that the knowledge becomes publicly available in the correct manner.

Once a patent in granted, the holder can prevent others from using his/her/its invention, and the patent allows the holder to control the production, distribution, use by others, importation, and, of course, the price of the product.[35]

Patents were permitted to supposedly compensate the inventor for making this new knowledge available. Patents are used as a monopoly, reworded to grant compensation for the costs of an inventor's research and development, before the

[30] World Trade Organization, 1995

[31] The Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. (TRIPS-Agreement). Art 27 'Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'

[32] ibid art. 33. It is possible of the countries to rule its internal laws regarding patents, nevertheless it's have to be more beneficial than the TRIPS Agreement (which regulates only the minimum standards). 'The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date'.

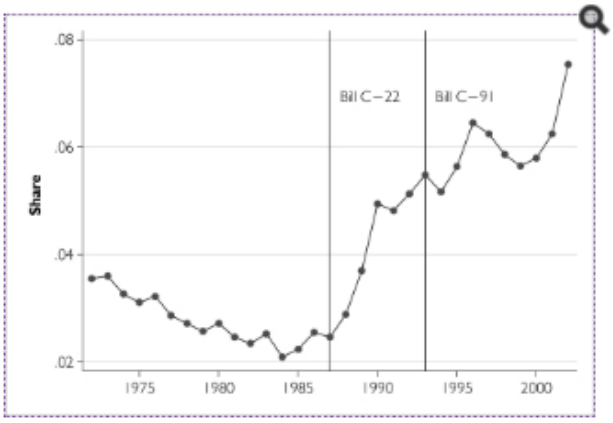
[33] ibid art. 27 'For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively'

[34] Paul B de Laat, 'Copyright or copyleft? An analysis of property regimes for software development' (2005) 34 10 Research Policy, 1511 <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.453.6425&rep=rep1&type=pdf> accessed 10 June 2018

[35] United Nations Development Programme (UNDP) 'Global Commission on HIV and the Law, Risks, Rights and Health' (New York, July 2012) <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf> accessed 10 June 2018.

knowledge can be used by society after the patent term. For example, since all analyses and processes for creating medicine become fully disclosed and available with the admissibility of patents, it is easy, after the patent term, to create generic and cheaper medicines.[36]

Furthermore, the main justification for granting patents is that they represent an incentive for research and development (R&D). Patents encourage innovation and technological progress.[37] Thus, given the possibility of gaining millions through the monopoly of medicines, pharmaceutical companies started developing, researching, and spending money on R&D. The chart below, for example, displays the difference in amounts spent by pharmaceutical companies in Canada before and after patented medicines were allowed at the beginning of 1990.



Pharmaceutical and medicine sector share of total industrial R&D expenditures, Canada, 1972–2002

Source: Paul Grootendorst and Livio Di Matteo, "The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada" (2007)

However, even if pharmaceutical companies and sometimes even governments claim that patents encourage R&D, it can be argued that the lack of transparency of R&D expenditure makes it impossible to determine the true cost of medicines compare to the amount expended by those pharmaceutical companies and governments, which is discussed in Part 4.[38]

However, it is possible to analyze shortfalls from R&D in developing countries where high-priority diseases are fixed. Once pharmaceutical companies uses patents to

[36] de Laat (n 34).
[37] Tom Nicholas, 'Are Patents Creative or Destructive' (2014) 79 2 Antitrust Law Journal 405
[38] 't Hoen, '*Private Patents and Public Health'* (n 28) 90.

prevent competition, they are also capable of maintaining monopoly pricing on their medicines, making the purchasing of the drugs almost impossible for patients who must pay for these life-saving medicines with their own money and do not have medical insurance.[39]

Nevertheless, the admissibility of patents and the creation of monopoly has led to a new awareness of the increase of prices and the limitation of access to medicines, especially for LDC. In addition, new essential medicines are priced out-of-reach of patients in high-income countries as well.[40]

3.2 The limitations of the TRIPS-Agreement and the compulsory license

Due to the new scenario created by the TRIPS Agreement, a new awareness and concerns were raised regarding the implications of patenting medications. There was a large chance of increasing the values of medicines in the market and consequently, dribbling the access to health and medication for the population, which would not have the chance to spend their money on low-priced generic medication. Monopoly limits generic competition and compromises the accessibility of medicines. Prices become unaffordable, especially for the poorest communities and those that need the medicine the most, since the majority of diseases are found in LDC.[41]

A UN expert consultant wrote the following on access to medicine:

> 'While intellectual property rights have the important function of providing incentives for innovation, they can, in some cases, obstruct access by pushing up the price of medicines. The right to health requires a company that holds a patent on a lifesaving medicine to make use of all the arrangements at its disposal to render the medicine accessible to all'.[42]

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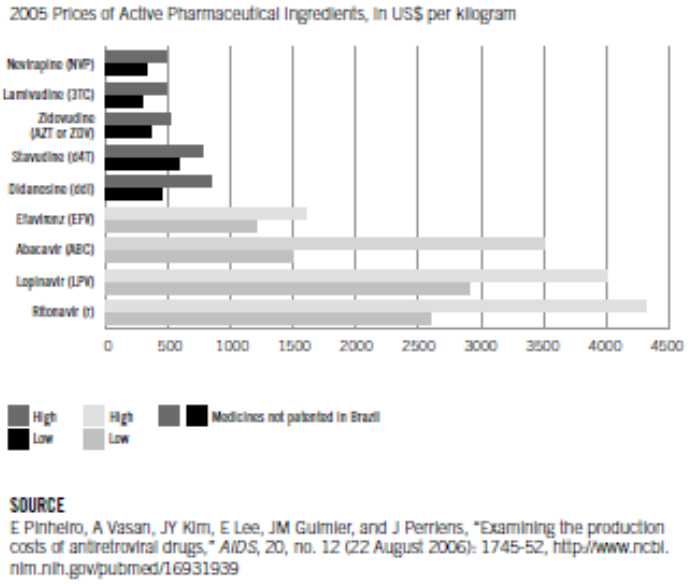
[39] Lisa Forman, 'A Transformative Power? The Role of the Human Right to Medicines in Accessing AIDS Medicines – International Human Rights Law, TRIPS, and the South African Experience' (SJD thesis, University of Toronto, 2007)

[40] The European Consumer Organization, ' BEUC Position on Access to Medicines' (Brussels, BEUC, 2015), <http://www.beuc.eu/publications/beuc-x-2015-104_access_to_medicines.pdf> accessed 11 June 2018

[41] Robert. C. Bird, 'Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines while Minimizing Investment Side Effects' (2009) 37 2 Journal of Law, Medicine & Ethics 209, 210.

[42] United Nations General Assembly, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health – Expert Consultation on

Successful HIV treatments provided by the governments in Brazil and Thailand in 1996 and 2003, respectively, were possible because pharmaceuticals were not patent-protected at the time, and companies could produce medications in a cheaper price. The production of HIV medication, antiretroviral (ARV), by the Brazilian government dropped from US$ 15,000 to US$ 66 per patient per year because of the lack of patent protection. The table below also demonstrates the prices of Brazilian ARV medicines (non-patent-protected in Brazil in 1996) in comparison with those that were actually patented. [43]



SOURCE
E Pinheiro, A Vasan, JY Kim, E Lee, JM Guimier, and J Perriens, "Examining the production costs of antiretroviral drugs," *AIDS*, 20, no. 12 (22 August 2006): 1745-52, http://www.ncbi.nlm.nih.gov/pubmed/16931939

Moreover, the TRIPS Agreement provides some flexibility in Article 31, which states that a third party or the government can use a patent without the authorization of the right holder in cases of public interest, such as cases of public health emergencies when it is necessary to lower the prices of medication. This is possible if the parties meet the requirements set by the exhaustive list in the article 31, which is formally called compulsory licenses.

Access to Medicines as a Fundamental Component of the Right to Health'(March 16, 2011), UN Doc. A/HRC 17/43..

[43] 't Hoen, '*Private Patents and Public Health'* (n 28) 42. Despite the TRIPS-Agreement application counts after January 1st, 2000, were allowed the delay implementation of products patents until 2005 for undeveloped countries, such as Taiwan.

The limitations and restrictions to granting a compulsory license that are set out in subsection (a)-(i) of article 31 are as follows:

a. To evaluate these on a case-by-case basis, according to individual merits
b. Prior negotiation with the right holder for reasonable commercial terms
c. Limited scope and reasonable, limited time
d. Non-exclusivity
e. Non-transferability
f. Domestic use
g. Termination upon expiry for a deserving circumstance
h. Adequate remuneration to the right holders
i. Possibility of judicial review

Article 31(f) explicitly states that the compulsory license must only be granted to supply the medicine of the domestic market.[44] While compulsory licenses provided a solution in critical circumstances, they did not provide solutions for cases in which countries did not have manufacturing capacities. Developed countries that have a generic medicine industry are not allowed under TRIPS to issue a compulsory license authorizing third parties to produce a patented pharmaceutical product to export to LDC.[45] As a result, while developed countries were satisfied with the intellectual property protection obtained through TRIPS, developing countries were at a disadvantage.

3.3 The Doha Declaration

As expected, the possibility of patenting medication generated a barrier for mainly undeveloped countries to access medication. In these countries, the government and population could not, after full compliance with the TRIPS Agreement, afford the amounts requested by the pharmaceutical companies. Those undeveloped countries are also the countries with lower health statuses and higher needs for medicine.

Nevertheless, with the medicine crises installed and the emergence of the HIV, malaria, and tuberculosis, some modifications to the TRIPS Agreement were requested during the fourth WTO ministerial conference. The focus of the conference was to

[44] TRIPS Agreement (n 31) art. 31(f) 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'.
[45] Richard Elliott and Marie-Hélène Bonin 'Patents, International Trade Law and Access to Essential Medicines' (2002) Canadian HIV-AIDS Legal Network 1

specifically debate the topic of access to pharmaceuticals in LDC. The Doha Declaration was adopted by the TRIPS Agreement 2001 and stipulates that even with the TRIPS Agreement, WTO Member States should not prevent others from taking necessary measures to protect public health during epidemics such as HIV, tuberculosis, or malaria[46]. It is important to note that the Doha Declaration covers "health problems" in general. The declaration uses the three examples of diseases to illustrate some of the problems in the year 2001.[47]

The Doha Declaration contains seven paragraphs. The first four set out the scope and the reasons for which the declaration is needed. The third paragraph discusses the link between the importance of developing new medicines and the recognition of how the declaration affects the prices of the medicines for less developed countries. Most importantly, the fourth paragraph in the Doha Declaration gives priority to public health and access to medication over the protection of patents:[48]

> 'We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.'

On the other hand, paragraphs five to seven are the substantive sections of the Doha Declaration. Paragraphs four and five are the key to how compulsory licenses can be used to overcome intellectual property barriers to facilitate access to medicines in LDC.[49]

> 'Paragraph 5[…]
>
> b) Each Member has the right to grant compulsory licenses and freedom to determine the grounds upon which such licenses are granted;
>
> c) Each Member has the right to determine what constitute a national emergency or the other circumstances of extreme urgency, it being understood that public health crises,

[46] World Trade Organization, 'Ministerial Declaration of 14 November 2001' WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) (Doha Declaration) art 1.
[47] 't Hoen, '*Private Patents and Public Health'* (n 28) 32.
[48] ibid 33.
[49] ibid.

including those relation to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency

[…].'

Lastly, article 6 recognizes that there are countries with insufficient or no manufacturing capacities in the pharmaceutical sector, and for that reason, those countries could face difficulties in making effective use of compulsory licensing based on the laws established under the TRIPS Agreement. Nevertheless, the Doha Declaration itself did not provide a solution, but instructed the Council of the TRIPS Agreement to find an expeditious solution before the end of 2002.

Acknowledging 'the seriousness of the concerns expressed by the least-developed countries (LDCs)' the Doha Declaration also allows these countries not to grant or enforce pharmaceutical product patents until at least 2016. Least-developed countries are also not required to provide patent protection to any invention at all until July 1, 2021, or until 'they cease to be a least developed country member', whichever date is earlier.[50]

3.4 Article 31bis

On December 6, 2005, after a long period of negotiation, the WTO General Council adopted the protocol to amend the TRIPS Agreement, as was required by the Doha Declaration (paragraph 6). The protocol provided additional flexibilities to states to grant special compulsory licenses for the export of medicines, which was first called the waiver mechanism by the Doha Declaration.

The new article 31bis partly waives Article 31(f) for undeveloped countries according to the WTO,[51] allowing them to issue compulsory licenses for public health reasons and import the drugs from other countries. The article also contains an open definition of "pharmaceutical products" and some formalities, which the importer and

[50] WTO, 'Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations With Respect to Pharmaceutical Products', Decision of the Council for TRIPS of 6 November 2015 (2015), Doc No. IP/C/73.

[51] For the WTO, the least-developed countries are those that the United Nations designated as, and are members of the WTO. Afghanistan, Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Democratic Republic of Congo, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Leo Peoples Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, Vanuatu, Yemen and Zambia. WTO "least developed countries" <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm> accessed at 28 March 2018

exporter countries should comply with in order to prevent fraud. The mechanism itself required some negotiations and notification of the holders.[52]

Article 31bis was only used once in the case of Rwanda-Canada in 2007 (to be discussed in Part III of this paper). For that reason, developing countries question the effectiveness of the mechanism, as is discussed in following sections of the present thesis.

3.5 The Regional Waiver

Item six of paragraph six from the Doha Declaration is related to the possibility of development for regional trade communities or LDC, which are part of regional trade agreements.[53] Article 31(f) of the TRIPS-Agreement '*shall be waived to the extent necessary to enable a pharmaceutical product produces or imported under a compulsory license in that Member to be exported to the markets of those other developing or LDC parties to the regional trade agreement that share the health problem in question.*'

In practice, this means that LDC can import or produce generic versions of any medicine patented on their territory.[54] Until the beginning of 2018, the countries had not yet used this mechanism.

This thesis has already covered the most important aspects of the legal framework necessary for one to completely understand this thesis. This thesis has gone from discussing the consolidation of the TRIPS Agreements and the main reasoning behind the granting of compulsory licenses to the goals behind its practice in the legal framework. The following section presents another point of view of critical aspects of the compulsory license.

3.2 Concluding remarks for the legal framework: right to health, patents and compulsory license

As analyzed in sections two and three of the study, although the right to health has been present in legal texts since at least 1948, it is still far from being concrete in the

[52] Neil George Cherian 'Using compulsory licenses to access pharmaceuticals' (Eu-HEM thesis, University of Oslo, 2016).
[53] Today qualification of trade groups is established in Article XXIV of the GAAT 1994 and the Decision of 28 of November 1979 on Differential and more Favorable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903). Today the trade unions to be considered are Southern African Development Community, East African Community, Common Market for Eastern and Southern Africa and the African Union.
[54] 't Hoen, '*Private Patents and Public Health'* (n 28) 47.

world today. There are still countries with systems that are incapable of providing health to their citizens (and other basic rights), especially LDC. The 2015 Sustainability Development Goals attempted to improve access to health and medicines in those countries with a great deal of effort and help from international bodies and organizations.

In 1995, with to the possibility of patenting medicines and the fear of making the access to medicines even more difficult, the WTO created also the compulsory license, which was later amended by the 2001 Doha Declaration. The law itself, in legal theory, is a mechanism to facilitate and make easier the access to medicines by loosening patents on the medicines from the patent holder.

As demonstrated in theory, access to medicine and the achievement of the right to health is possible because of the compulsory license's emergence in the legal context. In the next section, this study critically analyzes the compulsory license, demonstrating that it is not as beneficial as the law demonstrated. The following sections provide real case studies of compulsory licenses to see this mechanism in practice.

4. INNOVATION, R&D AND PRICES

4.1 Prices X Monopoly

In the last decade, there has been a growing trend of those favoring limiting intellectual property rights in order to promote public interests worldwide.[55] Issues regarding the prices of medicine are not limited to low-income countries.[56] Developing countries have two needs and points of view when discussing access to medicine. The first point of view is that accessible medicines already exist at prices that developed countries can afford (buy, distribute, healthcare system), and the second point of view is that new medicines should be developed to treat the diseases that are primarily affecting developing countries.[57]

As already mentioned in the first section, R&D intensely increased after patenting medicines was made possible, particularly in R&D-intensive industries such as pharmaceuticals.[58] After the 20-year permission of monopoly exploitation, the production of generic medicines would no longer be legal, making drug prices even higher and more unaffordable. However, the exact cost of R&D is 'deliberately shrouded in mystery', since the pharmaceutical industry strongly resists providing information.[59] Thus, without the exact price of manufacturing and creating a medicine, it is impossible to affirm with certainty whether the high and elevated prices of the medicine are fair or not.

With the existence of compulsory licenses, some economists agree that to avoid the possibility of granting compulsory license in their medicines, pharmaceutical companies would price their medicines at a lower level so people could afford buying them, instead of losing the monopoly.[60] These economists see this as a commercial incentive.[61] Large pharmaceutical companies argue that the by putting the price below expected rates to maintain the monopoly, the profit would decrease so much that it would be better to lose the monopoly in some parts of the world (western markets). Others could

[55] Frank Fine, 'European Community Compulsory Licensing Policy: Heresy Versus Common Sense' (2004) 24 Northwestern Journal of International Law & Business 619.
[56] Frederick M. Abbott, 'Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health' (2016) 6 3 UC Irvine Law Review 281.
[57] Patricia M. Danzon and Adrian Towse, 'Differential Pricing for Pharmaceuticals; Reconciling Access, R&D and Patents' (2003) 3 International Journal of Health Care Finance and Economics 183.
[58] ibid.
[59] Abbott (n 56) 290.
[60] Jerome H. Reichman, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 2 The Journal of Law, Medicine & Ethics 247.
[61] Danzon and Towse 'Differential Pricing' (n 57).

still maintain the high prices in the high-income countries as the profit would be better.[62] For that reason, it is possible to criticize multinational companies for using the patenting law and the TRIPS Agreement as a form of exploitation to pursue profits against human wellbeing and health.[63]

However, there are opportunities to keep products at different prices for poor or high-income countries based on price discrimination of the medicines and the products on per capita. Companies can still have a large volume of sales at low profits in LDC and can maintain their monopolies of the same medicine at high prices in highly developed countries, reducing the deadweight loss imagined in the paragraph above.[64]

Companies seem to decline the possibility of keeping the monopoly and changing the prices of medicines in certain countries because of 'reference pricing', the bodies that maintain price-control regimes in pharmaceuticals. This is especially true in rich countries that are part of the Organization for Economic Cooperation and Development.[65] This regulating entity may complicate the profits of pharmaceutical companies if they sell a medicine for one price in some locations, but for another in a different location, even though regulators understand that the companies are only trying to recoup the millions and billions dollars expended during R&D for the manufacturing of those drugs.[66] Danzon and Towse propose the creation of a system of "secret rebates" to promote greater price discrimination by limiting foreign regulations from discovering the prices of medicines in the LDC.[67]

In addition, on December 3, 2013, during the FT Global Pharmaceutical and Biotechnology Conference in London, Bayer's CEO Marijn Dekkers, when questioned regarding the compulsory licensed drug sorafenib in India, said the following:

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[62] John. E. Calfee and Roger Bate, 'Pharmarceutical and the worldwide HIV Epidemic: Can Stakeholders Moldel Wok' (2004) 23 2 Journal of Public Policy and Marketing 140.
[63] Amy F. Wollensack, 'Closing the Constant Garden: The Regulation and Responsibility of U.S. Pharmaceutical Companies Doing Research on Human Subjects in Developing Nations' (2007) 6 Washington University Global Studies Law 747.
[64] Reichman (n 70) 251.
[65] Danzon and Towse 'Differential Pricing' (n 57) 198
[66] Sean Flynn, Aiden Hollis, and Mike Palmedo, 'An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries' (2009) 37 2 Journal of Law, Medicine & Ethics 184.
[67] Patricia M. Danzon and Adrian Towse, 'Theory and Implementation of Differential Pricing for Pharmaceuticals' in Keith E. Maskus and Jerome H. Reichman (eds) *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005).

> 'Is this going to have a big effect on our business model? No, because we did not develop this product for the Indian market, let's be honest. We developed this product for Western patients who can afford this product, quite honestly. It is an expensive product, being an oncology product'.[68]

It is understandable that at least some pharmaceutical companies do not lower the price of medicines and lose the monopoly because the concession of compulsory license does not affect their business model. However, in the reality, the lowering of prices in general, would affect their profits and business models.

4.2 The effects of compulsory license on innovation

It is easy to see the important benefits of the compulsory license and removal of barriers to provide life-saving benefits and improve health in general. Since the creation of the compulsory license, it has received support from scholars, jurists, activists, and also NGOs on behalf of poor countries.[69]

Professor Robert Bird, despite understanding the concept of the compulsory license as a form of obtaining access to medicine for those who cannot afford it, is slightly skeptical about the use of the compulsory license itself and how it can 'negate the benefits from increases access' because of the governments lack of consideration.[70]

Professor Bird states that despite the fact that the existence of the compulsory license does not necessarily provoke the reduction of foreign investment, the compulsory license may cause patent-owing firms to look for more business-friendly legal environments because the licenses create costly litigation for both sides. He also mentioned that the licenses attract manufactures who only want to profit from the low-cost access. Another concern of Bird's is the possibility that governments could retaliate against countries that ask for the license with trade sanctions, which could debilitate the economy of the less developed country. This creates the problem of issuing the

[68] Marijn Dekkers, CEO of Bayer, Keynote on panel "Buffering the Pharma Brand: Restoring Reputation, Rebuilding Trust," Financial Times Global Pharmaceuticals and Biotechnology Conference: New Businesses, New Markets, London, 3 December 2013 available at: https://archives.cjr.org/the_audit/bloombergs_viral_misquote_1.php

[69] Luis Ferreira, "Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations" (2002) 71 3 Fordham Law Review 1133.

[70] Bird (n 41) 210.

compulsory license to the LDC, which may not issue a compulsory license because of the fear of the side effects.[71]

As already mentioned in Part I, there is continuous concern regarding the effects of innovation. Critics of the compulsory license say that compulsory licenses may indeed reduce incentives for innovation. Mansfield published a study implying that around 65% of medicines would not be launched by companies but "for the existence of legal patent protection,"[72] since companies invest significant amounts into the development of new medicines. Most drugs created do not enter the market because of regulatory problems or even because they are not profitable,[73] and there is a possibility that the compulsory license could block a small part of profitable drugs and the return on investments (and consequently the incentives to innovation).

However, a study by Chien and others[74] has a contrasting conclusion regarding the effects of the compulsory license on innovation. Chien analyzed a total of six cases of compulsory licenses between 1980 and 1990 (before the TRIPS Agreement) from different pharmaceutical companies (Baxter International, Roche Holding, Chiron Corporation), looking at the reason for issuing the license, the type of license, and the impact on HIV medicines. The study concluded that there was no significant decline in innovation for HIV medicines by the companies during the years studied, but Chien states that the licensing of orphan drugs was more likely to de-incentivize innovation in the pharmaceutical area.

Along the same lines, Moser, in 2013, proved that the loss of an intellectual property right actually promotes innovation, since the companies want to remain competitive.[75] In addition, the compulsory license can also encourage domestic research to be equivalent/complementary to foreign-owned inventions.[76] Moser made a surprising

[71] Bird (n 41) 210.
[72] Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) The Institute of Management Sciences 173.
[73] Daniel. R. Cahoy, 'Confronting Myths and Myopia on the Road from Doha' (2007) 42 1 Georgia Law Review 131.
[74] Colleen Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation' (2003) 18 Berkeley Technology Law Journal 853.
[75] Petra Moser, 'Patents and Innovation: Evidence from Economic History' (2013) 27 1 Journal of Economic Perspectives 23, 27.
[76] Suzanne Scotchmer, 'Investing in Knowledge' 31 in Suzanne Scotchmer (ed), *Innovation and Incentives* (MIT Press, 2006).

finding that compulsory licenses may even increase innovation in the licensing countries, domestically, as opposed to the evidence that would discourage innovation.[77]

An earlier study by Scherer & Weisburst in 1995 examined cases of compulsory licenses in the United States specifically to analyze the amount spent in R&D, and, similar to the other studies already mentioned, they did not find conclusive evidence that would suggest a decrease in the cost of R&D by pharmaceutical companies. The main point is that the companies kept the cost because of the competitive scenario.[78]

This confirms that the compulsory license did not indeed have a real effect on innovation and the cost of R&D. There is a report by the WHO that confirms this for the developing and LCD countries.[79]

As it is possible to analyze, Bird's concern in his article regarding innovation is not indeed a problem, but he also provides a way to solve the other three main issues in his criticism of the compulsory license (anti-climate environment, retaliation of the developing states, and what the author calls "shadow prices" – the deadweight loss because of the price).[80]

Bird concludes that despite the fact that the compulsory license can indeed favor less fortunate countries, developing countries have to consider the cause and effect of issuing compulsory licenses, especially the role of corruption and the illegal parallel trade of imported medicines.[81]

Another point of view on the compulsory licenses states that they are not supposed to promote long-term, sustainable access to essential medicines, as most countries use them, but rather, they are meant to be a short-term fix for market conditions that exclude patients from receiving the right treatment.[82]

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[77] Moser (n 75) 34.
[78] Frederic M. Scherer and Sandy Weisburst, 'Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy' (1995) 26 6 International Review of Industrial Property Right and Copyright law
[79] Commission on Intellectual Property Rights, Innovation and Public Health and WHO, 'CHPIH Report 'Public Health innovation and intellectual property right: report of the Commission on Intellectual Property Rights, Innovation and Public Health' (Switzerland, 1st Ed. 2006) 84
[80] Bird (n 41) 216.
[81] ibid 220.
[82] Shyama V. Ramani and Eduardo Urias, 'Access to critical medicines: When are compulsory licenses effective in price negotiations? ' (2015) 135 The Netherland Social Science & Medicine75

4.3 Concluding remarks of compulsory license and innovation

As was demonstrated in the literature review and discussion, it is possible to conclude that innovation has not been affected by the existence of the compulsory license, the legal framework created by TRIPS Agreements, and subsequent treaties mentioned during section three. The companies mentioned in section 3.1 continued to expend on R&D to create new medicines to sell to western countries that would indeed spend their money on the medicines, instead of lowing the prices to maintain the monopoly. Therefore, innovation and R&D has not changed for the last 15 years. The following sections are not related to innovation, but deal with the effects of compulsory licenses in real cases.

5. THE ANALYSIS OF COMPULSORY LICENSES IN PRACTICAL CASES

5.1 The Compulsory License in Reality

It is possible to note on the table in the Appendix I several cases that required the compulsory license since the creation of the TRIPS Agreement and the Doha Declaration and how the Doha Declaration influenced and encouraged the issuance of the compulsory license after 2001.

Although several of the licenses issued are for medicines related to the treatment of HIV, especially those focused on LDC, high- and medium-income countries have also issued compulsory licenses. After September 11, Canada and the United States asked for a compulsory license for Bayer for the medicine Ciprofoxacin, an anthrax antibiotic, fearing a mass anthrax attack. The United States wanted enough medicine to treat 10 million people.[83] According to the timelines below, other developed countries that have requested a compulsory license are include Italy, for example, and more recently Germany in 2016, which is studied in this paper.

Low- and medium-income countries, such as Zimbabwe, Malaysia, Mozambique, Zambia, Indonesia, and Eritrea, issued compulsory licenses between 2001 and 2005 that were all relate to ARV treatments.[84] In 2003/2004, Malaysia and Indonesia were the first countries to import HIV medicine from India, a country that did not have patents for their pharmaceuticals at the time.[85] The license was based on public non-commercial use under article 31(b) of the TRIPS Agreement. Similarly, Eretria and Ghana issued their compulsory licenses in 2005. These cases were followed by Thailand in 2006, Brazil in 2007, and the iconic case of Rwanda-Canada in 2007, the waiver solution in its only use.[86] These last three cases are discussed in this section.

After 2005, there is a different pattern in the compulsory licenses. In 2005, Italy and Taiwan issued their first compulsory licenses for Imipenem, an antibiotic, and

[83] Examples of health-related compulsory license are available at <https://www.cptech.org/ip/health/recent-examples.html> accessed at 10 June 2018.

[84] World Bank Country and Lending Groups 'Country Classification' <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups> 12 June 2018.

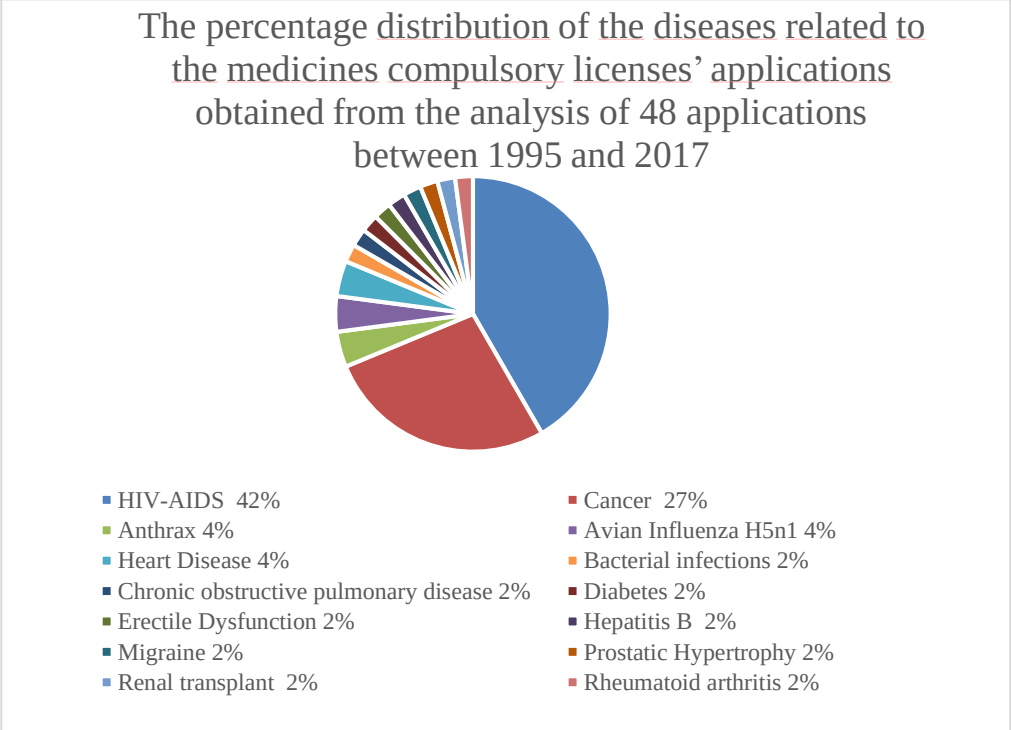
[85] Since India did not have yet patents in pharmaceutical, it cannot be considered part of the Waiver mechanism of the article 31bis

[86] Jamie Feldman, 'Compulsory Licenses: The Dangers Behind the Current Practice' (2009) 8 1 Journal of International Business and Law 137, 150.

Oseltamivir, an anti-virus influenza, respectively. In 2008, Thailand used Government Use License (GULs) in cancer and heart disease medication.[87]

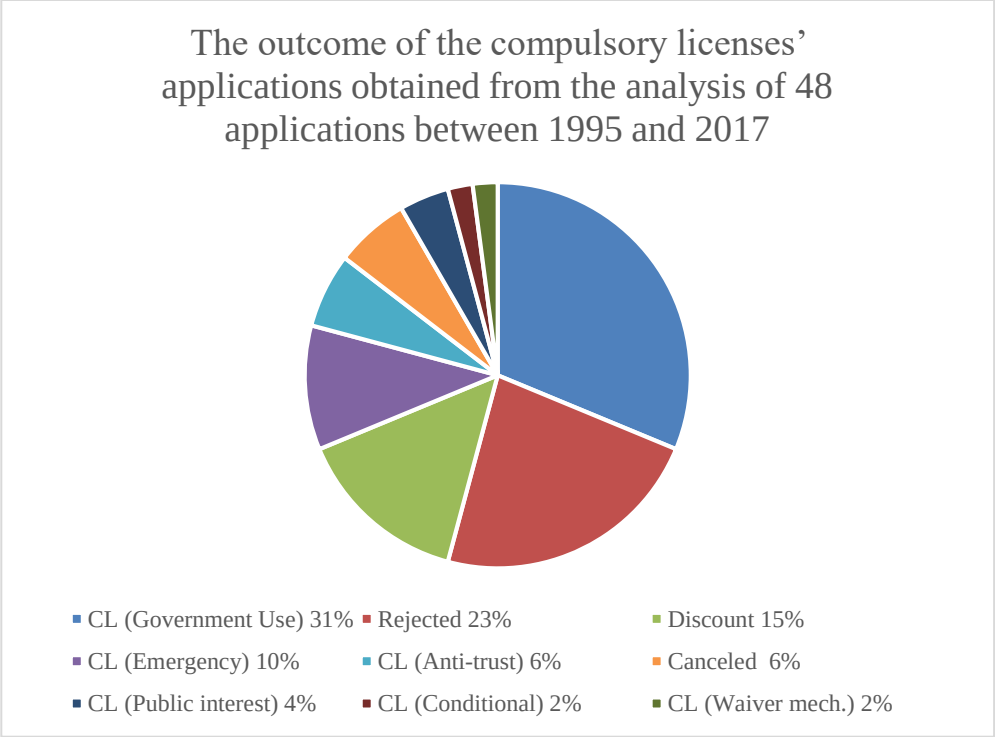
Moreover, between 2010 and 2018, the licenses issued for HIV medicines were more common than the licenses for other diseases, such as oncological and heart diseases. An increasing number of oncology medicines that turn to be subject of compulsory license after 2010 reflect the high prices being charged for those new cancer medications.[88] The following chart displaces the instances of licenses per disease area.

In the graphic below, it is possible to analyze the percentages of compulsory licenses that have been issued in the last 15 years, divided into types of medicines, a total of forty eight (48) compulsory licenses. We can see that 42% of the compulsory licenses are related to HIV medicines. The disease area with the second highest percentage of licenses, by a clear difference, is oncological drugs, with only 27% of medicines with compulsory licenses, followed by a tie at 4% between Avian Flu, Anthrax and Heart Diseases.



[87] Cherian (n 52) 18.
[88] Ibid 51.

Of the total 48 compulsory licenses found during the research, it was possible to generate a graphic of the outcome of the requests.



The table below provides a quick summary of the cases discussed in the present paper. The Appendix 1 contains a list of the main compulsory licenses issued since 1995 and the data for the creation of the graphics in more details.

Six case studies were chosen for a more detailed analysis of compulsory licenses. The case studies researched for the purpose of the present paper include Taiwan (2005), Thailand (2007-2008), Italy (2006), Brazil (2007), Rwanda-Canada (2007), and India (2012). These cases were selected based on the availability of data online, the variety between LDC and developed countries (low-, medium-, and high-income countries), and the mixture of ARV medicines and other types of medicines, such as the oncological medicine in India or Italy's sumatriptan. The cases also have a mix of different reasons for issuing the compulsory licenses, including public interest and governmental use (Brazil and Thailand), waiver mechanism (Rwanda-Canada), judicial license (India), or anti-trust license (Italy), and conditional compulsory license (Taiwan).

Year	Country	Drug	Indication	Results
2005	Taiwan	oseltamivir	Avian Influenza H5N1	Conditional CL
2006	Italy	sumatriptan	Migraine	CL (Anti-trust)
2006	Thailand	Efavirenz	HIV-AIDS	CL (Government Use)
2007	Italy	finasteride	Prostatic Hypertrophy	CL (Anti-trust)
2007	Thailand	lopinavir/ritonavir ; clopidogrel	HIV-AIDS / Heart Disease	CL (Government Use)
2007	Brazil	Efavirenz	HIV-AIDS	CL (Government Use)
2007	Rwanda	zidovudine; lamivudine; nevirapine	HIV-AIDS	CL (Waiver mech.)
2012	Índia	Sorafenib	Hepatic and Renal Carcinoma	CL (Government Use)

5.2 CASE STUDIES

5.2.1 Taiwan (2005) – The Conditional Compulsory License

In October 2005, Taiwan received the world's attention as the first country to issue a compulsory license in order to ensure that it would receive a stockpile of the medicine Tamiflu® (oseltamivir) from the Switzerland pharmaceutical company F. Hoffmann-La Roche Ltd. (Roche) for emergency use. Oseltamivir is an antiviral used for the treatment of Avian Influenza.[89] The reason for the request was that the WHO working group report had stated that there were insufficient global piles of the medicine.[90] The same report stated that in November 2005, 62 deaths were caused by the Avian Flu (H5N1), considered an influenza pandemic in Vietnam, Thailand, Cambodia, and Indonesia.

Oseltamivir is one of the two medicines recommended by the WHO as an antiviral for this exact disease, and it is preferred over the medicine zanamivir. However, because

[89] Kathrin Hille, 'Taiwan employs compulsory licensing for Tamiflu' *Financial Times* (NY 27 November 2005) <https://www.ft.com/content/cebeb882-5dcb-11da-be9c-0000779e2340> accessed 29 April 2018.
[90] WHO 'Avian Influenza: assessing the pandemic threat' (2005) <http://apps.who.int/iris/bitstream/handle/10665/68985/WHO_CDS_2005.29.pdf?sequence=1> accessed 10 June 2018

of the demand caused by the WHO report, Roche was not able to provide the quantity of product demanded.[91]

Legally, the Taiwanese Patent Act was promulgated on February 6, 2003, and its enforcement started by July 1, 2004. In 2003, Taiwan also implemented the TRIPS Agreement on the condition that the country be considered part of the high-income OECD countries, avoiding the transition period established for the low-income and LDC.[92] Curiously, the WTO is the only intergovernmental organization that recognizes Taiwan as a State.[93] The Taiwanese government prepared a full program to combat the possibility of the pandemic with the issuance of a compulsory license to prevent against the country run out of stock of the medicine.[94] The WHO report from 2004 also stated that stockpiling of the drug Oseltamivir was the only way to assure that the world would have a sufficient amount of medicine in case of the pandemic. The report also encouraged countries with enough resources to stockpile the drug.[95]

According to the Intellectual Property Office (2014), article 5 of the Taiwanese Patent Act set up the grounds on which compulsory licenses are applicable, and with the 2003 modifications, the act included the possibility to grant compulsory licenses during national emergencies:

> 'In response to national emergency or other circumstances of extreme urgency, the Specific Patent Agency shall, in accordance with an emergency order or upon notice from the central government authorities in charge of the business, grant compulsory licensing of a patent needed, and notify the patentee as soon as reasonably practicable.'

In May 2005, the ministry of health from Taiwan approached Roche with a request for a voluntary license to manufacture their own Oseltamivir domestically, since the pharmaceutical company was facing problems with the delivery of the product. However, Roche denied the license and argued that the National Health Research Institute of Taiwan would be unable to produce their medicine. Unsatisfied with the answer, in October 2005,

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[91] Ibid.
[92] Cherian (n 52) 42 quoting Charnovitz (2016).
[93] WTO, 'Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu (Chinese Taipei) and the WTO' <https://www.wto.org/english/thewto_e/countries_e/chinese_taipei_e.htm> accessed in 12 June 2018.
[94] Mei Chou and others 'Comprehensive Report of Prevention Strategy for Influenza Pandemic' (2008) 24 12 Epidemiology Bulletin 853
[95] WHO, 'The World health report : 2004 : Changing history. Geneva : World Health Organization' <http://www.who.int/iris/handle/10665/42891> accessed 10 June 2018.

the Ministry of Health applied for the compulsory license, and the National Health Research Institute of Taiwan fabricated the drug with competence.[96]

The Intellectual Property Office issued *ex-officio* the compulsory license for the domestic manufacturing of Oseltamivir on December 8, 2005, arguing that 68 confirmed deaths it constituted an emergency status according to the Doha Declaration, article 5(c). The license was valid from the date mentioned until December 31, 2007 only on domestic territory because of Roche's incapability to provide the medicines.[97] However, the license was considered conditional. Once Roche would meet the terms of the license by being able to provide the medicine, the license would terminate.[98] Roche did not appeal.[99]

Ultimately, the license was not used, as the public emergency was contained and Roche demonstrated its ability to deliver the drug (2.3 million Tamiflu® doses) by 2007 and covered 10% of the population of the country, according to the guidelines of the WHO.[100] Apart from this, in 2009, Taiwan purchased 2.68 million doses of the drug from Roche, and another 900,000 doses of Relenza, the other drug indicated by the WHO. Taiwan released a total if 250,000 doses into the public healthcare system for distribution following a Swine flu epidemic.[101]

In the second case analyzed, based on the data acquired, it seems that granting the compulsory license for emergency cases in Taiwan was indeed useful, although in the end, there was no need to use it. However, the possibility of the granting the compulsory license was already a relief to the Taiwanese population facing a pandemic of avian influenza.

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[96] Jason Dean, 'Taiwan Says It Copied Flu Drug Made by Roche'. *The Wall Street Journal* (25 October 2005) <http://www.wsj.com/articles/SB113013347204677356> accessed 10 June 2018.

[97] Avian Flu Watch 'Avian influenza situation' *Avian Flu Watch Blog* (29 July 2005) <http://avianfluwatch.blogspot.com/2005/07/?_sm_au_=iVV17rVsvWN2QRWF> accessed 12 June 2018

[98] Cherian (n 52), quoting 江亮頡, 2007.

[99] Cherian (n 52) 44.

[100] Centers for Disease Control, ROC (Taiwan) 'Central Epidemic Command Center announces purchasing progress of Tamiflu and pandemic influenza A (H1N1) vaccine' *Centers for Disease Control* (3 September 2009)
<http://www.cdc.gov.tw/Professional/info.aspx?treeid=2e36d6003c51a7d0&nowtreeid=EE0A2987CFBA3222&tid=6B4D15E07642A259> accessed 12 June 2018

[101] Centers for Disease Control, ROC (Taiwan) 'Central Epidemic Command Center announces release of first 250,000 doses of Tamiflu from national stockpile' (1 September 2018) <http://www.cdc.gov.tw/english/info.aspx?treeid=bc2d4e89b154059b&nowtreeid=ee0a2987cfba3222&tid=DE9803ED7BB1988E> accessed 12 June 2018

5.2.2 Italy (2005): Understanding Compulsory Licenses in the Context of Measures Against Anti-Competitive Practices

The compulsory license and patent laws are different in developed countries compared to the other cases already analyzed. This is firstly because developed countries benefit from having stricter intellectual property provisions, rigorous legal infrastructures, and a severe competition law that aims to promote the balance of welfare and the intellectual property rights.[102] Therefore, in Europe, the compulsory license is often issued to avoid and prevent monopolistic abuses.[103]

Competition law in the EU is designed to ensure that both private firms (pharmaceuticals in the case) and Member States are able to operate in a liberal economy without restricting competition that would inhibit the operations of a free market.[104]

The compulsory license is a mechanism in international and national laws of the Member States of the EU and in the Treaty on the Functioning of the European Union (TFEU).[105] It is outlined in article 34 - in conjunction with 35 - 36, 101, and 102, which dictate the scope and limitations of compulsory licensing in regard to both rights and remedies. Article 34 of the TFEU prohibits Member States from enacting laws or enforcing judgments that serve as a quantitative restriction on imports.[106] Article 36, on the other hand, provides an exception to article 34, as it allows Member States to limit import and exports on the grounds of public morality, public policy, or public security and others. However, it does not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.[107]

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[102] Reichman (n 70) 258.

[103] Atif I. Azher, 'Antitrust Regulators and the Biopharmaceutical Industry: Compulsory Licensing Schemes Ignoring Gene Therapy Patients' (2004) 25 University of Pennsylvania Journal of International Economic Law 383, 384.

[104] Jarrod Tudor, 'Compulsory Licensing In The European Union', 4 2 George Mason Journal of International Commercial Law 222, 224.

[105] European Union, 'Consolidated version of the Treaty on the Functioning of the European Union', (26 October 2012), OJ L. 326/47-326/390 (TFEU). Art. 2 and 3 make European Union law applicable to the entire territory comprised by the European Union Member-States where the Treaty confers power on the European Union.

[106] Ibid art.36 'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Member States." Article 24, on f the TFEU is also a provision to promote the free movement of goods. Art. 35 states: "Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.

[107] Ibid art. 36: 'The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such

On the other hand, articles 102 and 102 focus on the rules regarding competition. Article 101 prohibits agreements between commercial entities that interfere with the operation of a common market, allowing for the free flow of goods, services, capital, and labor.[108] Article 101 focuses mainly on the agreements between private parties and non-governments. However, Member-State governments are not allowed to enforce such agreements.[109]

Article 102 continues to prohibit successful market participants who enjoy a dominant position from abusing that dominant position, whether directly or indirectly, and also prohibits Member States from allowing the abuse of a dominant position to continue.[110] The application of Article 102 is conditional on the abuse of a dominant position in a relevant market that may notably disturb trade between Member States. To establish a violation of this article, both markets must be, at least independent from each

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prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.'

[108] ibid art. 101. '1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:

(a) directly or indirectly fix purchase or selling prices or any other trading conditions;

(b) limit or control production, markets, technical development, or investment;

(c) share markets or sources of supply;

(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.

3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:

- any agreement or category of agreements between undertakings,
- any decision or category of decisions by associations of undertakings,
- any concerted practice or category of concerted practices,

which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;

(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question'.

[109] Ibid.

[110] ibid Art. 102 'Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;

(b) limiting production, markets or technical development to the prejudice of consumers;

(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.'

other, justify the conclusion of an illegitimate expansion of market power.[111] Market leveraging refers to a dominant company's practice of illegitimately expanding a well-acquired position into another technically or commercially related, but economically self-contained market, to gain an unjustified competitive advantage in that market and constitute exclusionary abuse.[112] It is important to mention that all countries of the EU are part of the WTO.[113] The scholar Meyers has taken notice of the clash between the free movement of goods and open competition on the one hand and intellectual property rights on the other hand. [114]

On February 23, 2005, the Italian Competition Authority (*Autoritá Garante Della Concorrenza a Del Mercato* – AGCM) opened an investigation to analyze abuses of prices and refusals to license rights to theirs drugs by two large pharmaceutical companies, GlaxoSmithKline and MSD.[115] In June 21, 2005, the AGCM ordered a compulsory license for imipenem/cilastatin, an antibiotic from MDS, and on February 26, 2006, it ordered one for sumatriptan succinate to treat migraine headaches from GSK. On March 26, 2007, the AGCM ordered a compulsory license for the active ingredient finasteride, also from MSD, focusing on the treatment of benign prostate enlargement and male baldness.[116]

Merk's drug imipenem/cilastatin was the first case of a compulsory license since the AGCM was established in 1990, and it was adopted as an interim measure only. The AGCM did so without having any such power under national law, but simply by relying on EU law.[117] It was later confirmed to be legal by the Italian Regional Administrative Tribunal ('TAR') of Lazio.[118] In this case, in 2002, the large Italian pharmaceutical

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[111] Hanns Ullrich and others, *TRIPS plus 20: From Trade Rules to Market Principles* (1st Ed, Springer, 2016).
[112] ibid.
[113] It is possible to consulate the states members of the WTO at <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> accessed 11 June 2018.
[114] Christopher J. Meyers, 'European Union Competition Law and Intellectual Property Licensing: Trans-Atlantic Convergence and Compulsory Licensing' in 11th Annual Institute On Intellectual Property Law, 135, 149 (Practising Law Institute 2005)
[115] Martin Khor, *Patents, compulsory license and access to medicine: some recent experiences*, Intellectual property rights series (2nd Edition, Third World Network 2009).
[116] Autoritá Garante Della Concorrenza a Del Mercato, 'Case A364' Glaxo-Principi Attivi Provvedimento n. 16597, 21 March 2007 <http://www.agcm.it/concorrenza/intese-e-abusi/download/41256297003874BD/EE6153D52C3DB5CCC12572B300343157.html?a=p16597.pdf> accessed 12 June 2018
[117] Rita Coco and Paolisa Nebbia; 'Compulsory licensing and interim measures in Merck: a case for Italy or for antitrust law?' (2007) 2 7 Journal of Intellectual Property Law & Practice 452
[118] TAR Lazio Decision n. 1713, 7 March 2006. Law n. 287/90 empowers the Regional Administrative Tribunal of Lazio to review all decisions of the AGCM on points of law only.

Dobfar first negotiated with MSD to try to produce the drug for export to generic manufacturers outside the EU so as to avoid the possibility of community exhaustion of patent rights.[119] Nevertheless, even with the mediation of the Ministry of Industry, negotiations failed and the request for the compulsory license was sent to the AGCM.[120]

The TAR (and AGCM) considered MSD's refusal to license the intellectual property as abusive since it prevented Dobfar from producing the medicines and enabled MSD to maintain its dominance of certain pharmaceutical markets, cutting out potential competitors.[121]

The compulsory license for MSD was royalty-free. The AGCM stated refusal to license as the pillar for the license itself and mentioned anticipated price reductions for the medicine, promotion of more widespread use of generics, and benefits for consumers when it announced its decision.[122]

In addition to MDS, in 2005, another pharmaceutical group, the Glaxo Group's (GSK) denied a license to Fabbrica Italiana Sintetici SpA (FIS), a chemical industry, for the manufacturing of an active ingredient *Sumatriptan Succinate* inside the territory of Italy for export other countries in the EU, particularly Spain.[123] Sumatriptan is a medicine used in the production of migraine medicines.[124]

After the failure of negotiations, FIS applied to the AGCM. On February 8, 2006, the AGCM closed the investigation into the GSK. According to the AGCM, the license primarily targeted exporting the medicines to Spain.

Since this case is about two countries inside the EU, the GSK had to avoid parallel trade by adopting a dual pricing strategy for 82 products in Spain, selling drugs to wholesalers at higher prices for export purposes and lower prices for local supply.[125]

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[119] According to the *community exhaustion principle*, once a product with an IP right is allocated into the EEA area with the consent of the right holder, the circulation succeeded cannot be stop and parallel imports must be allowed into the area under Article 7, paras 1 and 2, of Directive 89/104; under Article 13, paras 1 and 2, of EC Regulation 40/94; in Italy (for all IP rights), under Article 5 of Legislative Decree, n 30/05. See also Coco (117).
[120] Coco (n 117).
[121] ibid.
[122] 't Hoen, '*Private Patents and Public Health'* (n 28) 54.
[123] Cherian (n 52) 38.
[124] Xavier Badia and others, 'The burden of migraine in Spain: beyond direct costs' (2004), 22 9 PharmacoEconomics 591.
[125] Inno-Group 'Analysis of the Impact of Dual Pricing in Spain' (2014) 4(44), <http://www.inno-group.com/system/projects/attached_files/000/000/147/original/Analysis_of_dual_pricing_in_Spain_final_version_20140701.pdf?1427327440> accessed 10 June 2018.

In 2001, the European Court of Justice considered this practice illegal and ordered the GSK to remedy its behavior.[126] Studies demonstrate that parallel trade in the EU has a detrimental effect on overall welfare, as it forces the convergence of prices across markets with varying abilities and different levels of willingness to pay, making a case for differential pricing in the EU.[127]

In order to make the decisions for the legality (or lack thereof) of the compulsory license, the AGCM used TFEU article 102, which describes a situation of abuse[128] (By the time of the decision, the TFEU was not yet established, so the article used was 82 of the TEC).[129] According to the judgment that issued the compulsory license (A363 - GLAXO-PRINCIPI ATTIVI *Provvedimento* n. 15175, dated as of February 8, 2006), the AGCM states that Italy was the only European country with a patent for the medicine Sumatriptan, and according to paragraph 41 of the decision, the GSK retained a 58% share of Spanish sumatriptain sales at the time, despite patent expiry, and 96% of Italian market.[130] Ultimately, the AGCM pointed out that the GSK controlled a larger market share than its neighbor countries due to the extended protection under the supplementary protection certificate system that was set until 2008.

Supplementary Protection Certificates (SPC) are extensions of patent validity, granted as a form of compensation for a regulatory lag from the date of the petition for the patent to date of approval for a maximum of five years under EU law. For example, in Italy, the Law No. 112/02 establishes a compulsory licensing framework for the export of pharmaceuticals under Supplementary Protection Certificates as 'only valid for export to countries in which patent protection has expired of its active ingredients, including any supplementary protection certificate, and in accordance with regulations in force in the destination countries.'[131]

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[126] European Commision Press Release Database 'Commission prohibits Glaxo Wellcome's dual pricing system in Spain' (Brussels, 8 May 2001) <http://europa.eu/rapid/press-release_IP-01-661_en.htm?locale=en> accessed 11 June 2018

[127] Patricia. M. Danzon, 'The Economics of Parallel Trade' (1998) 13 Pharmaeconomics 301.

[128] Autoritá Garante Della Concorrenza a Del Mercato, 'Case A363' Glaxo-Principi Attivi Provvedimento n. 15175, 8 February 2006 < http://www.agcm.it/concorrenza/intese-e-abusi/download/41256297003874BD/F6DE3DE75F12767CC12571220055E7E1.html?a=p15175.pdf> accessed 12 June 2018

[129] The TEC has been renamed the 'Treaty on the Functioning of the Union' By the time of the decision, the AGCM used article 82 of the TEC, but now it is the article 102 of the TFEU.

[130] AGCM - CASE A363 - Glaxo-Principi Attivi Provvedimento n. 15175, dated as of February 8, 2006

[131] Cherian (n 52) 40.

In the press release, the AGCM stated:

> 'To remedy the earlier refusal to license, Glaxo granted the licenses originally requested by FIS, but also set conditions such as to allow the time to be made up which had been lost because of the original refusal. Those conditions include the granting of a number of additional procedural licenses, whereby Glaxo has allowed FIS to save the time otherwise required to research and test an efficient manufacturing process for Sumatriptan Succinate. FIS will thus be enabled to offer the active ingredient to manufacturers of generics as early as if Glaxo had never refused the original request for a license.'[132]

In the decision above, the AGCM wanted to prevent delays in bringing generic pharmaceuticals to the market, looking for price reductions. In the beginning, FIS used the compulsory license for the export market only, supplying generic pharmaceutical companies that were selling the medicines in markets outside of Italy (for example Spain), where the patents had already expired.

After the decision and under threat of penalty, the GSK issued a non-exclusive license to FIS for export to neighboring markets at a confidential royalty rate.[133]

In 20017, the *Comité de Evaluación de Medicamentos* reported that the generic version of the Sumatriptan entered the Spanish Market by February 2006 and was exported to Spain by Universal Farma SL.[134] In 2007, the GSK reported having lost 25% of the sales of the medicine after the entry of the generic into the market.[135] Del Fresno & Lopez explain that the generic was not hugely adopted by European citizens because of the price convergence.[136] While Imigran® 50mg by the GSK cost € 5.63 in 2010, the generic cost € 4.40 (a small difference of 1.23 euros). In 2013 the prices became exactly the same: € 3.067.[137]

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[132] Autorità Garante della Concorrenza e del Mercato, 'Pharmaceuticals: Antitrust says Glaxo has made amends and abuse of dominant position discontinued Granting of licence opens way for manufacture of generic migraine drugs' AGCM (Roma, 21 Febreuary 2006) <http://www.agcm.it/en/newsroom/press-releases/1267-glaxo-principi-attivi.html> accessed 12 June 2018.
[133] Cherian (n 52) 40.
[134] Agencia Española de Medicamentos Y Productos Sanitarios – AEMPS, 'Comité de Evaluación de Medicamentos (CODEM) New Drug approvals March 2007' (2007)<https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/comiteEvaluacion/2007/docs/codem_marzo-2007.pdf> accessed 10 June 2018.
[135] GlaxoSmithKline 'GSK Annual Report 2007' (39) <https://www.gsk.com/media/2682/annual-report-2007.pdf> accessed 3 April 2018
[136] Miguel del Fresno Garcia and Antonio López Paláez, 'Social work and netnography: The case of Spain and generic drugs. Qualitative social work' (2014) 13 1 Qualitative Social Work 85.
[137] Data of 2010 by the Spanish medicines agency

Ultimately, the Italian cases in which the AGCM had to assess the abusive nature of unjustified refusals to grant licenses by the patent holder benefited competition and consequently, consumers.[138] These licenses were necessary for the production of active ingredients in quantities sufficient to allow wide distribution of generic drugs.

In addition, in Europe in 2008, the European Commission began an exhaustive investigation into pharmaceutical company practices, which, if found to be anticompetitive, could have led to additional compulsory licenses.[139]

5.2.3 Rwanda-Canada (2007) – The Waiver Mechanism

The first and only country to issue a compulsory license under article 6 and article 31bis, the waiver mechanism under the export provision, was Rwanda on July 17, 2007. According to the jurist Jessica L. Greenbaum, the fact that Rwanda is the only country since 2003 that has made use of article 6 may indicate that the waiver mechanism has not achieved its desired results.[140] This is what this paper aims to discuss in this section.

Rwanda is one of the few countries in Africa that has implemented a Universal Healthcare Coverage system (UHS), which also includes access to full treatment of antiretroviral therapy (ART). Even with only 5% of its GDP being spent on health, the Rwandan healthcare system can be considered an example of successful healthcare limited resources. Its system ensures basic care to 90% of the population of the country, primarily targeting 60% of the population living below the poverty line.[141] Rwanda notified the WTO that it wanted to purchase 260,000 package of the triple drug mentioned above, which was enough to treat 21,000 people in the period of one year.[142]

Canada was one of the first countries that ratified the WTO's Waiver Decision in 2003. In 2004, the country amended its national law, creating The Canadian Access to

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[138] Third World Network 'Info Service on Intellectual Property Issues' (7 April 2007) <http://www.twn.my/title2/intellectual_property/info.service/twn.ipr.info.040701.htm > accessed 10 June 2018.

[139] S. Castle and J. Kanter, 'European Antitrust Regulators Raid Drug Companies' (2008) International Herald Tribune; also European Commission 'Pharmaceutical Sector Inquiry: Preliminary Report DG Competition Staff Working paper' (28 November 2008) <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf> accessed 12 June 2018.

[140] Jessica L. Greenbaum, 'Trips and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication n the Wake of Paragraph 6 Waiver' (2008) 25 J Contemp. Health L. & Pol'y 142, 143.

[141] Cherian (n 52) 33.

[142] Unnati Gandhi, 'Generic Drug Problem strangled by Red Tape' (2007) The Globe and Mail 1.

Medicines Regime (CARM).[143] according to the Canadian government, the CARM is meant to 'provide a way for the worlds developing and LDC to import high-quality drugs and medical devices at a lower cost to treat the diseases that bring suffering to their citizens to allow generic manufactures to produce and export medication to developing countries'.[144]

Nevertheless, before Canada could issue the compulsory license, the CARM required that a generic company obtain the permission - voluntary license - from the patent holder. Only after that permission was met, could Canada obtain a compulsory license from the Canadian Commissioner of Patents.[145] Finally, after those steps, the generic manufacturer could start the process with the government of the LDC.

Rwanda had made an agreement with the Canadian manufacturer of patented medicine from the pharmaceutical company Apotex to supply a fixed dose of the mix Zidovudine, Lamivudine, and Nevirapine (AZT/3TC/NVP) for the Rwandan National AIDS Program. Since the country relied on imported medicines and others pharmaceutical products, the waiver mechanism was used to procure a first line regime from Canada,[146] according to the law.

After all the requirements and steps were met, the Canadian Federal Commissioner of Patents granted Apotex a royalty-free compulsory license for export of only two years on a humanitarian basis.[147] In this case, Rwanda was not required to issue a license to import the medicine based on article 31bis, which exempts the LDC from issuing a license under the waiver mechanism. The medicines were finally delivered to Rwanda in September 2008.

From the end of 2008 until the beginning of 2009, two shipments of the medicine, with a total of 240,239 bottles (60 tabs), were delivered to WHO Rwanda.

Despite the humanitarian reasons included in the CARM and in the legislation of the waiver mechanism, it was clear that the rules were overly complicated and imposed

[143] Holger P. Hestermeyer, 'Canadian-made Drugs for Rwanda: The first Application of the WTO Waiver in Patents and Medicines'(2007) 11 28, ASIL Insight Home 1.
[144] Government of Canada, 'Canada's Access to Medicines Regime' <https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime.html> accessed 2 March 2018.
[145] Unnati Ganhdi, 'Supplying Generic AIDS drugs called pricey process' (2008) the Globe and Mail.
[146] Cherian (n 52) 34.
[147] ibid 35.

tough requirements to be accomplished.[148] After the two year licensing, Apotex refused to renew the settlement, since it was 'costly and complicated', unless it was amended with less bureaucratic procedures.[149] Canadian civil society also tried to amend Canadian law in order to facilitate the waiver mechanism and the production of medicines under compulsory licenses, but so far, there has not been success.[150]

In March 2010, a WTO Council meeting was held to discuss the lack of use of the Doha Declaration and its waiver mechanism, which proved the system was ineffective, but developed countries disagreed, arguing that there were other means available to provide affordable medicines to LDC.[151]

The main complication in the waiver mechanism and the reason that it has only been used once can be clearly summarize by MSF's Dr. Felipe Garcia de la Vega, an AIDS doctor from the MSF in 'Neither Expeditious, Nor A Solution: The WTO August 30th Decision is Unworkable' (Toronto August 2006):

> 'When we order medicines normally, all we need to do is type up a form, send it to the supplier and pay the bill–then we receive the shipment. With this system we have to persuade a government to notify the WTO, find a company willing to produce, push to get a drug on the list of eligible medicines, wait for voluntary license negotiations to be completed, wait for the compulsory license application to be made, and then granted**… For a disease that kills 8,000 people a day, not only is this not a solution, it's unacceptable.**'

Although Greenbaum, as mentioned in the beginning, indicated that the waiver mechanism is fragile and has problems,[152] Ellen 't Hoen states that it is not correct to assume failure only because of the case of Rwanda, the only one that used the system and failed in providing low-cost medicines, especially antiretroviral medicines. The author explains that the lack of use of the waiver mechanism is complex and that antiretroviral medicines are not patented in India and could be produced without the intellectual property barriers.[153]

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[148] Greenbaum (n 140) 160.
[149] 't Hoen, '*Private Patents and Public Health'* (n 28) 46.
[150] Michael Geist, 'Easing the passage of AIDS medicines to Africa' *The Star* (13 April 2009).
[151]Donald Harris, 'TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing' (2011) 18 Journal of Intellectual Property Law 367, 391.
[152] Greenbaum (n 140) 161.
[153] 't Hoen, '*Private Patents and Public Health'* (n 28) 46.

To conclude Rwanda case, despite the waiver mechanism indeed provided the medicines to the country (a LDC) after a long delay of two years, the waiver mechanism demonstrated to be complex and bureaucratic. The waiver mechanism could not maintain itself, so the others countries did not use it again since, proving that by international level, the legislation of the waiver mechanism needs to enhance to support itself.

5.2.4 Brazil (2007) – The Brazilian Model

The Brazilian constitution of 1988 declared that health was the 'right of all persons and the duty of the State' in article 196[154] and created the *Sistema Unico de Saúde* (SUS) or in English, the Unified Health System. Brazil extended free health coverage to all its citizens[155] with no discrimination. It was the first country in the world to provide complete treatment of HIV with ARV in the National HIV and AIDS Program (NAP), incorporating the program inside SUS.[156] President Fernando Henrique Cardoso published the law n. 9.313 in November 13, 1996 to ensure the provision and free supply of HIV medicines to the population.[157]

In 2001, still before the patenting law was active in Brazil, approximately one-fifth of the people were estimated to be infected with HIV and received ARV treatment inside the SUS.

As already mentioned in this study, the treatment for HIV in Brazil was successful before the patenting of medicines, but since the increase of prices, the country faced a need to issue its first compulsory license in 2007 for the import and manufacture of the medicine efavirenz (EFV), a first-line HIV medicine patented by Merck, Sharpe and Dohme (MSD) at the time.[158]

In the first half of the first decade of 2000, Brazil had an estimated of 63% of ARV produced by local manufacture generics industry and 37% by imported patent drugs. It was able to achieve discounts of 40-70% through its negotiations.[159] During that period,

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[154] Brazilian Federal Constitution (1988) Art. 196: *Da Saúde* <http://dtr2004.saude.gov.br/susdeaz/legislacao/arquivo/01_Constituicao.pdf> accessed 23 April 2018.
[155] Jairnilson Paim and others, 'The Brazilian health system: History, advances, and challenges' (2011) 26 3 Lancet 461, 463.
[156] Amy Nunn '*The Politics and History of AIDS Treatment in Brazil'* (1st Ed. Springer. 2009).
[157] Brazilian Law n. 9.313/1996 Preamble: <http://www.planalto.gov.br/ccivil_03/Leis/L9313.htm> related to the providing of HIV medicines to the population
[158] Cherian (n 52) 23.
[159] Nunn (156).

Brazil had mastered combining negotiations, local manufacturing, threats of CL to obtain discounts, which earned the name "the Brazilian Model."[160]

However, the negotiations resulted in minimal discounts in 2005, and Brazil issued a compulsory license for medicines EFV and tenofovir under the public non-commercial use category of the TRIPS Agreements,[161] since Brazil adopted it in 1996, without the period of *vacatio legis*.[162]

Furthermore, Brazilian industrial property law n. 9.279 from 1996, Section III, Chapter 7, provides several provisions for the concession of certain types of compulsory licenses. Between articles 68 and 74 of the law, one can find the obligations, procedures, exceptions, and the circumstances under which a compulsory license can be issued in Brazil. The circumstances include local non-working (art. 68, paragraph 4), dependent patents (art.70), and public interest (Art. 71).

The unit price of the EFV was US$ 1.59 and had not changed over the three years before 2007.[163] After two years of negotiations between Brazil and MSD and the refusal to reduce the price of the drug efavirenz 600mg by more than 2%,[164] which would have been equivalent to US$ 42.071.400,00 - Forty-two million, seventy-one thousand, four hundred - (US$ 568.4 per patient per annum, or US$ 1.536 per tablet).[165] The Ministry of Health took into account that the discount of 2% would be insufficient given the price reductions published in the media and prices by MSD on the international market.[166]

First, price considerations were a major factor in prompting the use of compulsory licensing.[167] Thus, in 2007, Brazil issued the compulsory license based on the necessity of public interest under article 71 of the industrial property law: "In cases of national

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[160] Cherian (n 52) 23.
[161] Feldman (n 86) 142.
[162] Gabriela Costa Chaves and others, 'Strategies for price reduction of HIV medicines under a monopoly situation in Brazil' (2015) 49 Rev Saúde Pública, 86.
[163] Brazilian Ministry of Health 'Targets and Commitments made by the Member Sates at the United Nation General Assembly Special Session on HIV/AIDS' (2008) 89 <http://data.unaids.org/pub/report/2008/brazil_2008_country_progress_report_en.pdf> accessed 10 June 2018.
[164] Renata Reis and others 'Access To Medicines And Intellectual Property In Brazil: A Civil Society Experience' in Renata Reis and others (eds) *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South* (Brazilian Interdisciplinary AIDS Association 2009).
[165] Brazilian Ministry of Health (n 163).
[166] ibid.
[167] Eric Bond and Kamal Saggi 'Compulsory licensing, price controls, and access to patented foreign products' (2012) 109 Journal of Development Economics 217, 224.

emergency or public interest declared by the Federal Executive Power, in case the patent holder does not meet the need, a compulsory license - temporary and non-exclusive - may be granted *ex officio* for the exploitation of the patent, without prejudice to the rights of the truly holder."

Since Brazilian law accepts the concession of the compulsory license without the consent of the holder, the public declaration[168] requesting the compulsory license was announced on April 24, 2007[169] and duly signed (decree 6.108) by President Luiz Inácio Lula da Silva on May 7, 2007 to "take care of the health of the Brazilian people."[170]

According to decree 6.108, the compulsory license of the EFV was issued for the NAP's non-commercial, non-exclusive use for a term of five years with the possibility to renew if necessary[171]. It was established that the price to be paid to the patent holder, as royalties, would be 1.5% of the purchase value (invoice amount) of the drug sold by the MoH.[172]

The drug started to be imported through the multilateral international organizations Pan American Health Organization (PAHO) and UNICEF. The drug was produced by two Indian laboratories, the Aurobindo and Ranbax. While UNICEF was responsible for the process of purchasing the drug from Aurobindo, PAHO was responsible for purchasing it from Ranbaxy. The WHO pre-qualification ensures the

[168] Brazil Minitry of Helath 'Ministério da Saúde. Portaria MS-GM nº 886' de 24 de abril de 2007 Brazilian Ministral Ordinance n. 886 (24 April 2017): <ftp.saude.sp.gov.br/ftpsessp/bibliote/informe_eletronico/2007/iels.abr.07/iels79/U_PT-MS-GM-886_240407.pdf.> accessed 10 June 2018.

[169] The patent holder was notified in April 24, 2007 to present a public proposal within 7 days according to law, but this did not in fact happen through the appropriate formal channels. Brazilian Ministry of Health and Health Surveillance Secretariat 'Brazil – Country Progress Report - Targets and Commitments made by the Member Sates at the United Nation General Assembly Special Session on HIV/AIDS' (2008), 89 <http://data.unaids.org/pub/report/2008/brazil_2008_country_progress_report_en.pdf> accessed 10 June 2018.

[170] Marília Juste 'Após licenciamento compulsório, Brasil vai fabricar remédio contra Aids' *Globo* (São Paulo, 30 November 2007) <http://g1.globo.com/Noticias/Ciencia/0,,MUL198787-5603,00-APOS+LICENCIAMENTO+COMPULSORIO+BRASIL+VAI+FABRICAR+REMEDIO+CONTRA+AIDS.html> accessed 10 April 2018.

[171] Brazilian Decree 6.108 'on the compulsory license' art. 1, paragraph 1 <http://www.planalto.gov.br/ccivil_03/_ato2007-2010/2007/decreto/d6108.htm> accessed 10 June 2018.

[172] ibid. Art. 2, caput

quality, safety, and effectiveness of the drug for Brazil.[173] In this case, the WHO approved the bioequivalence and bioavailability tests and pre-qualification.[174]

The drug had to be imported from India, since the Brazilian pharmaceutical company Farmanguinhos was unable to manufacture EFV in 2007 as it lacked the technological knowhow.[175]

The final cost of the drug, including shipping costs and royalties, was US$ 0.4594 for EFV 600mg and US$ 0.2173 for EFV 200mg. By that time, it was estimated that this would be a reduction in expenditure by some US$ 30,000,000 per annum on EFV 600mg alone for the Brazilian government.[176] It is estimated that Brazil had saved US$ 236.8 million in 2012, at the time of the patent's expiration.[177]

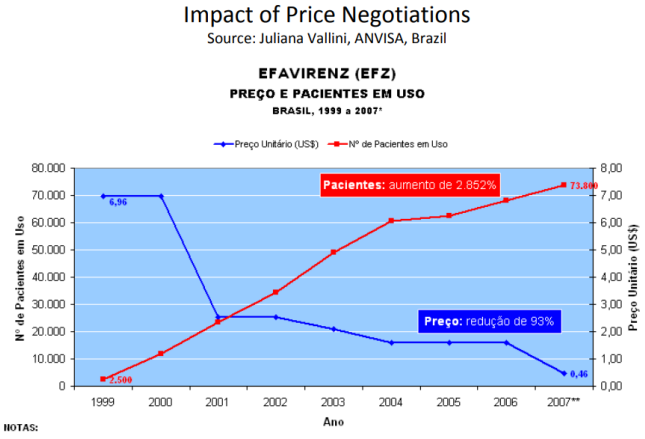
The Brazilian Ministry of Health reported having saved around US$ 104 million between 2007 to 2012 because of the import and compulsory license for the EFV.[178] After 2012, the EFV started being produced domestically by five national pharmaceutical companies: Globe Quimica S.A, Nortec Quimica S.A., Cristália Produtos Químicos Farmacêuticos Ltda., Instituto de Tecnologia em Fármacos Farmanguinhos, and Laboratório Farmacêutico do Estado de Pernambuco (Lafepe).[179] However, the final cost turned out to be more than the imported ones from India, because of the cost of R&D.[180]

On May 7, 2012, President Dilma Rousseff renewed the compulsory license for a period of five years.

Ultimately, Brazil can be considered one of the most successful cases of issuing a compulsory license since 2001. The Brazilian Government knew how to use their leverage, and how to use the threats of the compulsory license (for the others cases listed in the Appedix I, which the Brazilian Government obtained discounts). As a result, the number of patients increased, the price of medicines decreased, and it was possible for

[173] Brazilian Ministry of Health (n 169) 89.
[174] Regina Ferro do Lago e Nilson Rosário Costa 'Antiretroviral manufacturers and the challenge of universal access to drugs through the Brazilian National STD/AIDS Program' (2009) 25 10 Cad. Saúde Pública 2273.
[175] Bond (n. 167) 219 quoting Daemmrich and Musacchio, 2011
[176] Brazilian Ministry of Health (n 169) 89.
[177] Amy S. Nunn and others, 'Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment', (2007) 4 11 PloS Medicine 1804.
[178] Cherian (n 52) 26.
[179] Lago (n 174).
[180] ibid.

the government to bring medicines to communities with HIV, as can be analyzed in the graphic below by the Brazilian Health Surveillance Agency (ANVISA) from 2010.



However, there is criticism of the Brazilian compulsory license of EFV. Some critics argue that the compulsory license set a negative precedent in the sense that this case encourages overuse of the mechanism of the compulsory license, because Brazil[181] is an upper-middle-income country and also had a relatively low rate of HIV[182] infections. Being able to pay for the medicines with the discount provided by MSD at the time of the negotiations, Brazil was criticized by the media on this matter.[183] However, in the matter of providing medicines to the population, the case was a success, as the SUS was able to provide medicines to the population for free, and was also able to incentivize the domestic pharmaceutical company to improve and produce medicines without international help.

5.2.5 Thailand (2007 and 2008) – Governmental Use License

Between the years of 2006 and 2008, Thailand's Ministry of Public Health (MOPH) granted governmental use licenses for seven patented drugs in order to improve access to essential treatments, not only focusing on HIV, but also on oncological and heart disease medicines.[184] These specific compulsory license are hereafter referred to as GUL.

[181] Feldman (n 86) 150.
[182] International Centre for Trade and Sustainable Development, 'Brazil Issues Compulsory Licence For Aids Drug' *Reuters* (8 May 2007) < https://www.ictsd.org/brazil-issues-compulsory-licence-for-aids-drug> accessed 12 June 2018.
[183] Vera Zolotaryova, 'Are We There Yet? Taking "TRIPS" to Brazil and Expanding Access to HIV/AIDS Medication' (2008) 33 Brooklyn Journal of International Law 1099.
[184] Amanda Glassman and Miriam Temin, *Millions Saved: New Cases of Proven Success in Global Health* (Brookings Institution Press, 2016).

Thailand introduced its universal health coverage system in 2002 under the National Health Security Act with the ambition of securing medical care for 64 million citizens.[185] The Universal Coverage Scheme (UCS) was a public insurance system that aimed to achieve universal access to healthcare, including essential medicines. It also aimed to influence primary care centers and hospitals to use resources efficiently via capitated payment for outpatient services and other payment policies for inpatient care.[186] Thailand's health system included patients' access to drugs for the HIV, since those were under the National List of Essential Medicines (NLEM).

After 2003, the number of treatment sites for HIV with ARV increased from 112 in 2001 to 841 by February 2005. The successful rise in access to ARV therapy resulted in the number of patients growing from 27,000 in 2003 to 52,593 by 2005.[187]

The GUL are legal under Thailand regional law in accordance with Section 51 of the Thai Patent Act B.E. 2522 from 1979, which allows the government *ex officio* – without consent of the Ministry of Commerce and the Cabinet - to issue licenses in the general public's interest by "*any ministry, bureau or department of the Government*" and to exercise the rights of any patent "*to carry out any service for public consumption.*"[188] The supra-mentioned act allows the compulsory license on the following grounds: local non-working of patents (Sec 46), dependent patents (Sec 47), public non-commercial use (Sec 51), and national emergency (Sec 52). The TRIPS Agreement was adopted by Thailand in 1996, with an amendment to the Thai Patent Act.

Thailand justified the GUL as a necessity to ensure medical healthcare and access to medicines for the population.

The first license granted to Thailand in November 2006 was for EFV, a medicine by MSD. The second and third were granted a few months later in January 2007 for the lopinavir/ritonavir (LPV/r), an ARV combination from Abbott Laboratories, and clopidogrel, a drug used in the treatment of coronary artery disease, from Sanofi-Aventis. Finally, four licenses were granted in January 2008 for cancer drugs, letrozole, docetaxel,

[185] Inthira Yamabhai and others 'Government use licenses in Thailand: an assessment of the health and economic impacts' (2011) 7 28 Globalization and Health, 1.
[186] Laura Faden Garabedian and others, 'Impact of universal health insurance coverage in Thailand on sales and market share of medicines for non-communicable diseases: an interrupted time series study' (2012), 28 2(6) BMJ Open 1.
[187] Glassman (n 184) 65.
[188] Yamabhai (n 185) 2.

erlotinib, and imatinib (oncological medicines use in the treatment of breast and lung cancers, gastrointestinal stromal tumor (GIST), and leukemia).[189]

In 2008, one of the drugs that Thailand issued for licensing was imatinib (Glivec), patented by the Switzerland pharmaceutical Novartis, using price as the main justification.[190] While the full price of Novartis could rise up to US$ 29.30, the generic version that could be produced with the compulsory license would be US$ 1.59-2.23.[191] For letrozole, the compulsory license reduced the cost per pill from US$7.35 to US$0.19 to US$0.22 per pill.[192] The prices are presented in the table below.

Thailand: Comparison of prices before and after the government-use authorization

Medicine	Price (US$)			
	Patented drug before GU	Patented drug after GU	Generic drug	Percentage of cost/price reduction
Efavirenz	58/month	24/month	7.5/month	87%
Lopinavir/ritonavir	1,800/year	1,000/year	600/yr	67%
Clopidogrel	3	1.3	0.06	98%
Docetaxel	900	450	37	96%
Letrozole	7	2.2	0.1	98%

Source: Dr Suwit Wibulpolprasert, Ministry of Public Health, Thailand.

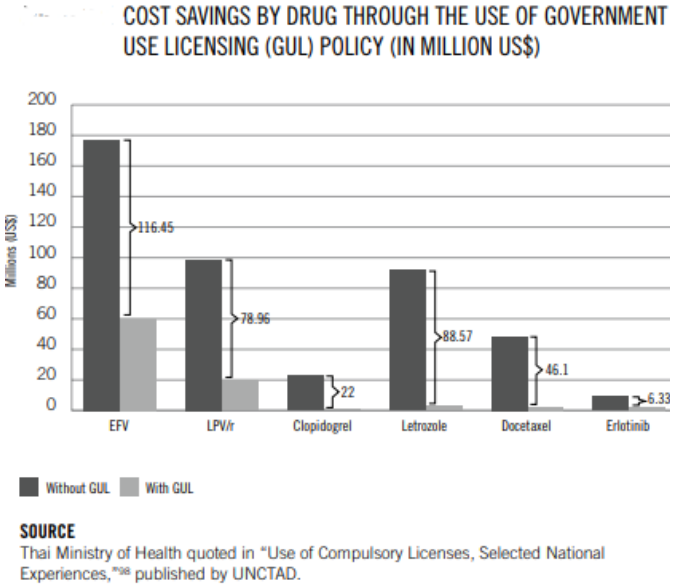
As for drugs' cost to the government, letrozole was estimated to save US$88 to US$102 million per year, docetaxel was estimated to save US$46 to US$53 million per year, and erlotinib was estimated to save US$6 to US$8 million per year.[193]

A government assessment in 2009 analyzing the compulsory license of imatinib concluded that the increased availability of the drug resulted in a gain of 2.435 in terms of Quality-Adjusted Life Years (QALYs). For the third of the first licenses, a study by

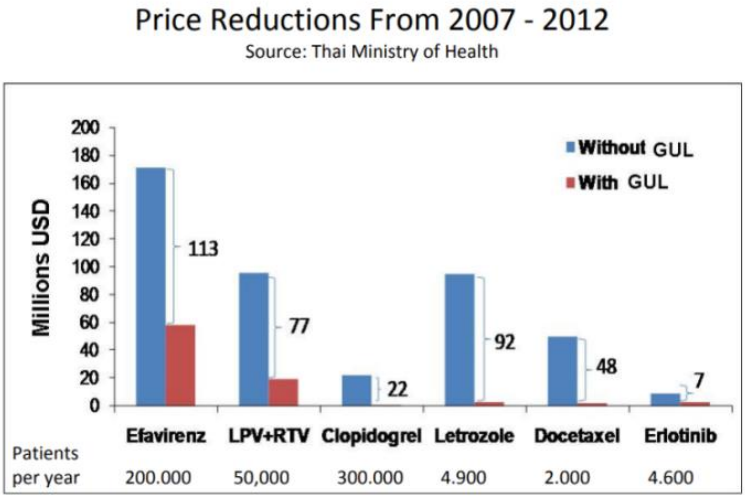
[189] Ministry of Public Health and The National Health Security Office. 'Facts and Evidences on the 10 Burning Issue Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand' (2007) Nonthaburi: Ministry of Public Health.
[190] The Ministry of Public Health and the National Health Security Office Thailand, The ten burning questions on the government use of patents on the four anti-cancer drugs in Thailand, 2008, <http://www.essentialaction.org/access/uploads/2d.Thai.CL.whitepaper.pdf>
[191] 't Hoen, '*Private Patents and Public Health'* (n 28) 66.
[192] Ellen 't Hoen 'Access to cancer treatment: A study of medicine pricing issues with recommendations for improving access to cancer medication' (2014) A report prepared for OXFAM, Medicines Law & Policy.
[193] Adum Mohara and others, 'Impact of the introduction of government use licenses on the drug expenditure on seven medicines in Thailand' (2012) 15 Value Health S95.

Yamabhai et al. resulted in n terms of QALYs gained as follows: letrozole gain of 3.656 QALYs; EFV 2.694 QALYs gained; clopidogrel 2.457 QALYs gained; and docetaxel: 1.251 QALYs gained.[194]

Below, two graphics based on two sources display the savings in the prices of medicines in Thailand, once from Ellen 't Hoen and another from the Thailand Government.



SOURCE
Thai Ministry of Health quoted in "Use of Compulsory Licenses, Selected National Experiences,"[98] published by UNCTAD.



The compulsory license issued under governmental use had a positive impact on national productivity due to increased access to treatment in Thailand. The Yamabhai and others study indicated that the level of benefits varied according to the type of drug.[195]

However, the decision to grant compulsory licenses for the medicines related to cancer and heart disease was strongly criticized,[196] due to the idea that the compulsory license was only supposed to be used in case of national emergencies.[197] However, it is clearly possible under the Doha Declaration, which stipulates that 'each Member has the

[194] Yamabhai (n 185).
[195] ibid.
[196] The criticism came from Office of the United States Trade Representative
[197] Yamabhai (n 185).

right to grant compulsory license and the freedom to determine the grounds upon which such licenses can be granted'.'[198]

Once again, similar to Brazil, the issuance of the compulsory license in Thailand was also criticized. However, the system proved once again to be useful in providing access to medicine and considerably reducing prices.

5.2.6 India (2012 and 2013) – The Case of Compulsory License for Cancer Medicines

After 2010, the new generation of cancer medicines made it challenging for several countries to provide medicine to its citizens.[199] Therefore, The Controller General of Patents Designs and Trademarks of India ("Patent Controller") granted the Indian drug manufacture a compulsory license for the drug sorafenib, dully patented by the German pharmaceutical company Bayer and named Nexavar®. Sorafenib is used in palliative treatment for hepatic and renal carcinomas. Bayer sold Nexavar at INR 280.428 (US$4100) for a month of treatment.[200]

India implemented the TRIPS Agreement in 2005, taking the entire transition time provided by the TRIPS Agreement to developing countries. Then, India amended its internal legislation, the Indian Patent Act, to recognize patented medicines.[201]

Thus, section 84 of the Indian Patent Act regulates the use and possibilities for compulsory licenses as follows:

> '(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely: (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India'.[202]

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[198] Doha Declaration (n 46) art. 5(b).
[199] 't Hoen, '*Private Patents and Public Health'* (n 28) 68.
[200] Cherian (n 52) 29.
[201] ibid.
[202] Indian Patent Law, S84 free translation <http://www.mondaq.com/india/x/435044/Patent/Compulsory+License+The+Most+Happening+Section+Of+The+Patents+Act+1970> 30 March 2018.

Natco Pharma tried to negotiate with Bayer in 2010 to manufacture the drug and make the price more affordable for Indian society. After not obtaining a proper answer from the Germany pharmaceutical over six months, according to the Indian law, Natco Pharma, issued a request for a compulsory license for the drug on July 29, 2011 on the grounds that the pharmaceutical company refused to deal. Despite this, Bayer claimed that Natco Pharma did not make enough of an effort to negotiate as well.[203]

The Patent Controller found Nexavar eligible for compulsory licensing on March 9, 2011 under Section 84 of the Indian Patent Act because (1) the drug was not meeting the reasonable requirements of the public, (2) the drug was not reasonably affordable, and (3) the patent was not being sufficiently used in India because it was not being locally manufactured.[204] This brought the price of the patented drug down from over Rs 357,629 (US$ 5,500) per month to Rs 8,880 (US$ 136) per month – a reduction of 97%. Under the terms, Bayer is being paid a 6% royalty on sales by Natco.[205]

However, Bayer appealed to the Intellectual Property Appellate Board (IPAB) against the Patent Controller's decision. The board upheld the grant of the compulsory license, but increased the royalty payable by Natco to Bayer from 6% to 7% of the sales of the drug.[206]

Despite the incredible discounts provided by the compulsory license of 97%, the price might still be unaffordable for the general Indian population, whose monthly per capita income is only US$ 142 per month.[207]

The compulsory license for sorafenib in India led to a huge controversy and brutal responses from the industry and policy makers in developed countries that are part of multinational pharmaceutical companies, especially at the United States. In 2013, 170 members of Congress wrote to President Obama complaining about the compulsory

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[203] Cherian (n 52) 32.

[204] White & Case, 'Indian Patent Office Grants Compulsory License for Bayer's Nexavar: Implications for Multinational Drug Companies' *Client Alert* (March 2012) <https://www.whitecase.com/sites/whitecase/files/files/download/publications/alerts-indian-patent-office-grants-compulsory-license.pdf> accessed 30 March 2018.

[205] Mohan D Nair, 'TRIPS and Access to Affordable Drugs' (2012) 17 Journal of Intellectual Property Rights 305, 312.

[206] Khaitan & Co 'Compulsory license granted for Nexavar to continue, holds Supreme Court' *Lexology* (India 15 December 2016) <https://www.lexology.com/library/detail.aspx?g=382da65e-855a-4e1d-a263-bad4b7032b8a> accessed 11 June 2018.

[207] Trading Economic, 'India - GDP per capita' (2016) <https://tradingeconomics.com/india/gdp-per-capita-us-dollar-wb-data.html> accessed 12 June 2018.

license for sorafenib and communicating concerns for the possible issuance of more compulsory licenses in the near future. Forty senators also wrote to Secretary of State John Kerry to express similar fears, and business groups established a new coalition, named *the Alliance for Fair Trade with India,* which focuses on India's IP policy. This policy was called "unfair" and harmful to the American business plan. Since then, India's IP policy has been the subject of discussions between India and the US. This has provoked an out-of-cycle review by the US Trade Representative.[208]

In 2013, after the case of sorafenib, the Ministry of Health recommended (based on Sections 82 and 92 of the Patent Act) the compulsory license for three anti-cancer drugs: desatinib, trastuzumab, and ixabepilone, from the pharmaceutical companies Bristol-Myers Squib ("BMS"), Roche, and BMS, respectively. In July 2015, there was also a request for the compulsory license for the medicine saxagliptin, a diabetes drug by AstraZeneca.[209]

Desatinib, the anticancer drug for leukemia, faced several judicial problems in 2013, when Natco Pharma Ltd. started selling a generic version of desatinib for 95.54% cheaper than BMS. The original price was US$ 52.20 instead of the US$ 2.33, which Natco was selling at the time[210]. The High Court in India prohibited Natco from continuing to sell the product, and the Department of Industrial Policy and Promotion (DIPP) finally denied the compulsory license in October 2014.

Along the same lines, Roche relinquished its patent for trastuzumab, named Herceptin® and used for the treatment of breast cancer, despite a request for a compulsory license because of the pressure, saying that the request for a compulsory license unfounded.[211]

In summary, sorafenib was India's first granted compulsory license, and only one so far. The license proved itself to be useful, reducing the prices of the medicine Nexavar. However, the lack of a useful public system or insurance still made it impossible for the Indian population to make use of the medicine because of the low salaries and per capita income of the population.

[208] 't Hoen, '*Private Patents and Public Health'* (n 28) 68.
[209] ibid.
[210] ibid 69, quoting mims.com (2013))
[211] t Hoen, '*Private Patents and Public Health'* (n 28) 70

5.3 Concluding remarks of case studies

Each case was analyzed because of the different types of compulsory licenses, different countries, and different outcomes. Cases such as Brazil and Thailand had the most success in providing citizens with access to medicine, since both countries had (and still have) a decent public health system with complete treatments for HIV for its citizens. Both licenses were issued as GUL. Rwanda, on the other hand, for example, was incapable of manufacturing its own medicines and had to make use of the waiver mechanism set out in the law, which proved to be ineffective because of the bureaucracy and delays. It took more than two years for the medicines to be provided in the country.

India had the same request as Brazil and Thailand, and the issuance of the license made the prices of the medicines decrease considerably. However, with the basic income of the Indian population, citizens were still incapable of affording the medicines. Therefore, even with positive effects of the compulsory license as described in the law, the Indian population continued to be unable to receive the medicines.

India, Brazil and Thailand were all GUL, but the three countries negotiate in different manners under the requirements of the law. The TRIPS Agreement is not clear how the companies or countries are supposed to negotiate, generating barriers and difficult and absence of standards.

Despite the fact that the compulsory license was issued to provide medicines in case of a lack of medicine, mainly in LDC, Italy had to use the compulsory license because the pharmaceutical company was using the competitive law in bad faith and the anti-trust mechanism to increase the prices. Italy's case was completely different from the others, since the main reason for issuing the compulsory license was not related to provide access to medicines (even so, the prices continued to be the same between the generic and the patented drug. In addition, Taiwan, which planned to achieve the Avian Influenza medicines for its population, despite the issuing of the patent, it was not necessary in the end, since the pharmaceutical Roche was able, in the end, to attend the population with the related medicine.

After the deep analysis of these case studies, one can understand that the law, *per se*, is not enough to achieve the right to health and make medicines accessible indiscriminately to the population. There have been some improvements and positive

outcomes, such as Brazil and Thailand, but only countries that already had some wealth and structured public healthcare systems were able to achieve the full capacity of the compulsory license. On the other hand, countries which needed the most help, the least developed countries are still lacking medicines, even with the waiver mechanism, which has been designed especially to them, but it still hasn’t achieved its full capability.

6. CONCLUSION:

This thesis made some conclusions regarding the questions raised during the introduction. However, it is far from exhaustive due to the length, novelty, and complexity of the study. It is impossible to cover all aspects of the matter.

The main points that this thesis was looking to discover are as follows: (i) the effectiveness of the compulsory license in providing access to medicines to the population; (i) whether the compulsory license works better in low-, medium- or high-income countries (Italy against Brazil, Thailand, India, Taiwan against Rwanda); (ii) whether the populations of countries that have better health coverage systems benefit more from with the issuances of compulsory licenses compared to those countries that do not have a structured health system (Brazil, Thailand and Italy against India and Rwanda); (iii) whether the possibility of granting compulsory licenses has or not affected innovation; (iv) the different types of requests for compulsory licenses (government use license, emergency use, anti-trust), the different outcomes of the license, the skepticism of it, whether the law needs to clarify requests for and reasoning behind the license; (v) the effectiveness of lowering prices for the medicines subject to the compulsory license.

First, it is possible to make small conclusions based on the cases specified during the thesis regarding the compulsory license and access to medicines. The Rwanda-Canada case, for example, was the only case in which the waiver mechanism was used. One of the reasons was that the process requirements seemed excessively complex for the license. The negotiations and bureaucracy delayed the medicines for two years, proving the waiver mechanism to be a complicated mechanism. The pharmaceutical company itself denied to continue with the process because of this. Article 31bis has, in international level, to undergo some modifications in order to reduce these cumbersome elements, make the mechanism more applicable, and promote cooperation in order to the maintain the system itself.

Regarding access to medicines because of the compulsory license, Thailand and Brazil made proper use of the compulsory license and maintained a robust and decent health care system and programs for HIV. The compulsory licenses were used to decrease the cost of the medicines and aid the production of generic medicine, improving and encouraging manufacturing of medicines domestically. Despite the criticism of the

governmental use of the license, the two cases are prime examples of successful cases of the compulsory license providing populations with access to medicines (especially because of the universal healthcare coverage of both countries). On the other hand, India, despite its successful use of the compulsory license to lower the prices of the cancer medicine sorafenib, the price remained high compared to the monthly per capita income of the Indian population. For the compulsory license to be successful today, the lowering of medicine prices should not be enough to ensure the population's access to the medicine, as was proved in the Indian case.

One conclusion regarding the requesting of compulsory licenses, either GUL or not, is that the TRIPS Agreement is clear that the parties have to negotiate with the patent holder prior the request of compulsory license. However, the agreement is not clear how the companies or countries are supposed to negotiate. Thailand and Brazil each had different approaches to the negotiations because of how broad this interpretation is. The law should set the requirements and standards for these negotiations in order to facilitate the procedure the parties and make it faster, without involving the judicial and often slow courts.

The main answer of the thesis is that the compulsory license legislation **by itself** is not effective in providing access to medicines indiscriminately to the population, since it depends on how the country dealing with the mechanism, as well as its wealth, internal laws, and mainly, based on the case studies, a universal health system. As mentioned in the introduction and the research questions, it was only possible to analyze the effectiveness of the mechanism between 1995 and 2001. The compulsory license is indeed a way to reduce the barrier to access to medicines, but there are vast reservations.

Regarding the effects of the license mechanism on innovation, despite the creation of exceptions to patents, the compulsory license ultimately did not affect the cost expended on innovation and R&D for new medicines. There are several reasons for that, but the main finding was that companies would rather lose their monopoly in LDC than lower prices in the high-income countries, since western societies would still pay full prices for discovered new medicines. The issuance of the compulsory license in LDC ultimately does not disturb pharmaceutical companies. The statement by the CEO of Bayer in 2013 proves that the company is intentionally maintaining high prices, prejudicing populations of mainly LDC (without the decrease of the prices, it would take

longer for the patients to have the medicines in the LDC because of the wait for the compulsory license).

Moreover, the reasons for issuing the compulsory license can be defined based on the capability of the country (high-,medium-, or low-income countries). Medium-income countries used the mechanism of governmental use license (Thailand, Brazil) to provide more medicines to their healthcare systems or programs, India also used the government use license, bur in order to make the medicines more available and in lower prices . More robust countries, such as Italy, used compulsory license as a competition law to avoid parallel trade. Governmental use license is criticized more for the states' lack of transparency and the prior negotiation (on which the law is not clear regarding how negotiations are supposed to proceed), as in Brazil or Thailand. One policy suggestion, in international level, is to clarify better means for the TRIPS Agreement regarding the transparency of transactions in requests for compulsory licenses and in the negotiations.

In all cases except Italy's, the lowering of prices resulted in an advantage. The case of Italy involves a different use of the compulsory license, anti-trust, to prevent anticompetitive problems and parallel trade between companies in the EU. The law of the EU should prohibit parallel trade and other trade agreements with clauses that may affect the population's access to health. The license itself was focused on bringing generic medicines to the market to avoid parallel trades, but in the end, there was not effect in the prices of the medicine itself.

Taiwan, the conditional compulsory license was in the end not used be the country since Roche pharmaceutical was able to attend with the request of the medicines. However, the conditional license demonstrated to be useful in emergency pandemic status, creating a relief for the Taiwanese citizens and avoiding panic.

In conclusion, the compulsory license was effective in a few cases, where the countries had implemented decent universal healthcare coverage, which helps with the full disclosure and effectiveness of the compulsory license. Despite some cases having lowered the prices of medicines with the license, most of the population still lacked access to medicines. This demonstrates how the countries with better health systems benefited themselves (Thailand and Brazil against India). Therefore, not all countries can benefit themselves from the mechanism, especially LDC, such as Rwanda, which had the opportunity to achieve access to medicines with the Doha Declaration and article 31bis,

but was not able to continue with the process because of the bureaucracy of the waiver mechanism. This demonstrates that the compulsory license still needs some modifications, in international level, considering low and medium income countries with don't have the capacity to pay for the medicines, produce internally and those which don't possess a good health care system.

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APPENDIX I

Year	Country	Drug	Indication	Results
1995	Israel	hepatitis B vaccine	Hepatitis B	CL (Public interest)
2001	USA	ciproflaxin	Anthrax	Discount
2001	Canada	ciproflaxin	Anthrax	Discount
2002	Dominican Republic	clopidogrel	Heart Disease	Rejected
2002	South Korea	imatinib	Chronic Myeloid Leukemia	Rejected
2002	Egypt	Sildenafil	Erectile Dysfunction	CL (Public interest)
2003	Malaysia	didanosine; zidovudine	HIV-AIDS	CL (Government Use)
2003	Zimbabwe	All ARVs	HIV-AIDS	CL (Emergency)
2004	Mozambique	lamivudine/stavudine/nevirapine	HIV-AIDS	CL (Emergency)
2004	Zambia	lamivudine/stavudine/nevirapine	HIV-AIDS	CL (Emergency)
2005	Indonesia	lamivudine/ nevirapine	HIV-AIDS	CL (Government Use)
2005	Ghana	All ARVs	HIV-AIDS	CL (Emergency)
2005	Argentina	oseltamivir	Avian Influenza H5n1	Rejected
2005	Taiwan	oseltamivir	Avian Influenza H5n1	Conditional CL
2005	Italy	imipenem cilastatin	Bacterial infections	CL (Anti-trust)
2006	India	Imatinib	Renal and lung cancers	Rejected
2006	Italy	sumatriptan	Migraine	CL (Anti-trust)
2006	Thailand	Efavirenz	HIV-AIDS	CL (Government Use)
2007	Italy	finasteride	Prostatic Hypertrophy	CL (Anti-trust)
2007	Thailand	lopinavir/ritonavir	HIV-AIDS	CL (Government Use)
2007	Thailand	clopidogrel	Heart Disease	CL (Government Use)
2007	Brazil	Efavirenz	HIV-AIDS	CL (Government Use)
2007	Nepal	sunitinib and erlotinib	Renal and lung cancers	Rejected
2007	Brazil	atazanavir	HIV-AIDS	Discount
2007	Brazil	lopinavir/ritonavir	HIV-AIDS	Discount
2007	Rwanda	zidovudine; lamivudine; nevirapine	HIV-AIDS	CL (Waiver mech.)

2008	Thailand	letrozole; docetaxel; erlotinib	Breast and lung cancers	CL (Government Use)
2008	Brazil	Brazil	HIV-AIDS	Discount
2008	Thailand	imatinib	Chronic Myeloid Leukemia	Discount
2010	Ecuador	lopinavir/ritonavir	HIV-AIDS	CL (Government Use)
2012	Indonesia	LPV/r ; TDF/ETC/NVP; 3TC ; EFV	HIV-AIDS	CL (Government Use)
2012	Índia	Sorafenib	Hepatic and Renal Carcinoma	CL (Government Use)
2012	Ecuador	abacavir/lamivudine	HIV-AIDS	CL (Government Use)
2012	India	Ertotinib	Renal and lung cancers	Canceled
2012	Thailand	rituximab	Non-Hodgkin's Lymphoma	None
2012	China	Tenofovir	HIV-AIDS	Discount
2013	Ecuador	ritonavir , lamivudine , abacavir	HIV-AIDS	CL (Government Use)
2013	India	trastuzumab	Breast cancer	Canceled
2013	India	dasatinib	Chronic Myeloid Leukemia	Rejected
2013	India	ixabepilone	Breast Cancer	Rejected
2014	Ecuador	sunitinib	Cancer	CL (Government Use)
2014	Ecuador	sodium micophenolate	Renal transplant	CL (Government Use)
2014	India	indacterol	COPD	Rejected
2014	Ecuador	etoricoxib, certolizumab	Rheumatoid arthritis	CL (Government Use)
2015	India	saxagliptin	Diabetes	Rejected
2015	Columbia	imatinib	Chronic Myeloid Leukemia	Rejected
2015	Peru	atazanavir	HIV-AIDS	Rejected
2017	Germany	raltegravir	HIV-AIDS	CL (Emergency)