



Patents and Human Rights:

Conflicts with Access to Medicine in Pandemics, and COVID-19 Recommendations

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Abstract

Since the last century, many wars and violations of Human Rights were direct reasons that set the pace to develop Human Rights laws, especially after the end of World War II and the holocausts associated with it. One of the critical Human Rights is that 'to life', relating to the right 'to health', hence the fundamental accessibility to healthcare services and products. Nonetheless, the last decades have witnessed a significant growth in pharmaceutical patents leading to increased drug prices. Overshoots in prices prohibit access to medicine. Disputes between States, pharmaceutical corporations, patients, and investors have occurred, some of which were not purely related to monetary aspects but also to Human Rights, such as the right to 'access to medicine'. These disputes are controversial. The applicable legal regimes are patent laws (e.g., the TRIPS Agreement) and International Human Rights Law (IHRL) including the European Convention on Human Rights (ECHR), European Social Charter, and more. However, it is up to the courts to decide on whether to consider IHRL in the legal decision process. The question turns to whether they consider the two regimes to be intersecting or independent. This thesis tackles the area of intersection between patent law and the right to 'access to medicine' in cases of pandemics such as *inter alia* HIV/AIDS and COVID-19. It investigates whether the right to 'access to medicine' exists as a human right by law, to jump to examine whether solutions like Compulsory Licenses (CLs) and patent exceptions are suitable. Then it answers the question whether there should be defragmentation of laws or not. The work analyzes available caselaw to seek a balance between patent laws and the human right to 'access to medicine' during pandemics. Caselaw shows that the conflict makes the overlap of laws confusing and in need of determining the set of relevant provisions in the applicable norms. The question on defragmentation is answered by focusing on Section 5 of the TRIPS Agreement and some provisions in IHRL instruments. The thesis proposes a defragmentation of applicable laws that aids in looking at previous solutions to reach the sought balance, and it sheds the light to give recommendations. The work finally recommends being proactive, for times of pandemics like the COVID-19 outbreak, and working on the realization of a unified and harmonized EU patent law to keep up to the objective of delivering quality vaccines/antivirals, on time, within budget, and with supporting applicable laws.

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“He who does not seek advice is a fool. His folly blinds him to Truth and makes him evil, stubborn and a danger to his fellow man.”
Kahlil Gibran (1883 – 1931 A.D.)

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Abbreviations

CDC	Centers for Disease Control and Prevention
CERD	Convention on the Elimination of all forms of Racial Discrimination
CESCR	Committee of the Economic, Social and Cultural Rights
EUCJ	European Union Court of Justice
CL	Compulsory License
ECDC	European Centre for Disease Prevention and Control (An agency of the European Union)
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
EMA	The European Medicines Agency
EPO	European Patent Office
EU	European Union
FDA	U.S. Food and Drug Administration
HRC	Human Rights Council (UN)
ICCPR	International Covenant on Civil and Political Rights
ICESCR	The International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
IHL	International Humanitarian Law
IHRL	International Human Rights Law
IP	Intellectual Property
IPR	Intellectual Property Rights
PCT	Patent Cooperation Treaty
R&D	Research and Development
RoI	Return on Investment
TRIPS	Trade-Related Aspects of Intellectual Property Rights Agreement
UDHR	Universal Declaration of Human Rights
UN	United Nations
WHO	World Health Organization (UN)
WIPO	World Intellectual Property Organization (UN)
WTO	World Trade Organization

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1 Introduction

*"I have no special talents. I am only passionately curious."
Albert Einstein (1879-1955)*

This chapter introduces the problem, motivation, purpose, research questions, legal methods, and scope of the thesis. The main problem stems from the interaction between patent regimes with Human Rights, where such an overlap leads to conflicts. One aim is to investigate the challenges and solutions and seek a balance that may inspire recommendations in cases of clashes between the Human Right to ‘access to medicine’ and patent laws. We focus on cases of pandemics and analyze them in order to propose what could be helpful for future similar cases, such as the current COVID-19 medicine (vaccine/antiviral) patents.

Section 1.1 describes the background and motivation. Section 1.2 presents the problem. Section 1.3 discusses the purpose and objectives of this thesis. Section 1.4 deliberates the research questions. Section 1.5 deals with the delimitations. Section 1.6 presents some terminology. Section 1.7 articulates the methods and materials, and section 1.8 introduces the organization of the remainder of the thesis.

1.1 Background and motivation

Staunch growth in patent applications and grants is evident in the last decade. According to the World Intellectual Property Indicators 2019 that uses data provided by national and regional IP offices, 3.3 million patent applications are globally filed in 2018. This number indicates a 5.2% increase in one year (see Figure 1).¹ The applications filed to the European Patent Office (EPO) alone have increased by 4% in 2019 including direct European applications and international (PCT) applications.² These facts show that the global economy is becoming increasingly innovative in nature.³ From the monetary viewpoint, the patent market is huge and continues to soar. According to Richardson Oliver Insights’ 2018

¹ WIPO, ‘World Intellectual Property Indicators 2019’ (WIPO, 2019) <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2019.pdf> accessed 30 April 2020.

² EPO, *European patent applications* (Patent Index, 2019).

³ Bridget Diakun, ‘A snapshot of the global patent landscape in eight charts’ (2020) IAM.

Patent Market Report, the cumulative sum of the asking prices for patents in the brokered and tracked private market reached over USD 16 billion (see Figure 2).⁴

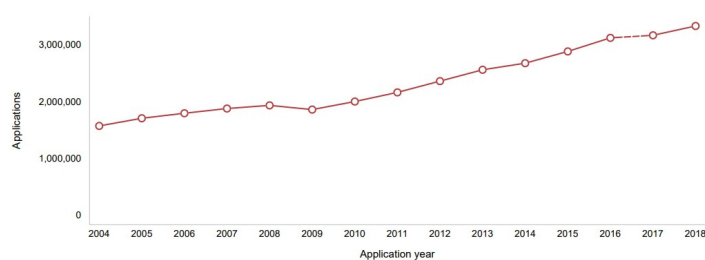


Figure 1. Global patent applications 2004–2018 shows 3.3 million in 2018 (2019 WIPO study).⁵

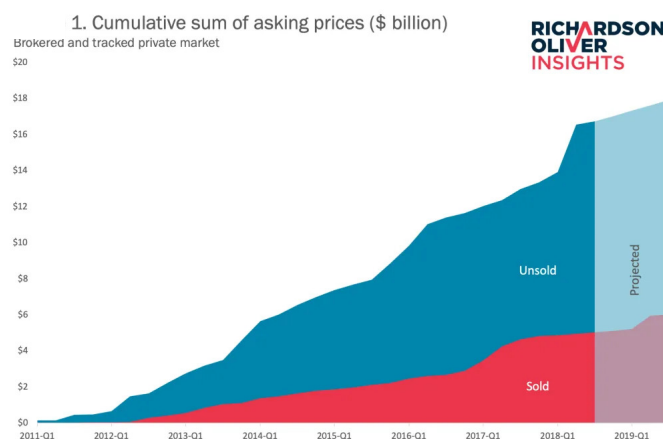


Figure 2. Cumulative sum of asking prices in billions of USD for the brokered patent market.⁶

The reason for the growth in patent applications is the exclusivity rights that a patent enjoys, thus allowing innovators a legal protection to generate the desired revenues. The World IP Organization (WIPO) defines a patent as “an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.”⁷ However, the WIPO adds that to be granted a patent, “technical information about the invention must be disclosed to the public in a patent application.”⁸ Hence, by revealing the technical information, there are risks of having the invention produced by some other entities. Therefore, many companies try other approaches to protect their products prices.

⁴ Kent Richardson, Erik Oliver, and Michael Costa, “The Brokered Patent Market Grows To \$353 Million In 2018” (IPWATCHDOG 7 May 2019).

⁵ WIPO (n 1) 12.

⁶ Richardson (n 4).

⁷ WIPO, “What is a patent?” (IP Patents) <<https://www.wipo.int/patents/en/>> accessed 30 April 2020.

⁸ Ibid.

An important legal instrument that adds to the incentive for innovators is the TRIPS⁹ (Trade-Related Aspects of Intellectual Property Rights) Agreement, which sets minimum standards of legal protection for Intellectual Property (IP) to be provided by each Member State.¹⁰ Hence, the TRIPS Agreement has an internal connection and effect on the legal practices of states and the EU in the field of patents.

At the same time, we witness more investments in innovation in the 21st century, where a large portion falls in pharmaceutical corporations¹¹. Patents are a way to prevent market failure and allow for greater investment in research.¹² The latest statistics show that pharmaceutical patent applications at the EPO continued to grow by 4.4% from 2018 till 2019.¹³ The EPO president António Campinos said in 2019 that:

*“The rapid growth of the number of patent applications in the life sciences area is highly indicative of the sheer amount of R&D work being undertaken in this field. It is encouraging to see that firms in this dynamic sector value the strength of the European market. Europe provides an encouraging environment for ambitious and entrepreneurial firms, and we will continue to deliver the best possible services to ensure that we have a competitive and effective patent system so that life sciences companies can keep up their research and innovation.”*¹⁴

According to the Global Use of Medicines report from the IQVIA Institute for Human Data Science, the pharmaceuticals global market grew to USD 1.2 trillion in 2018.¹⁵ The report predicted the global market growth in the coming few years to be 4-5% i.e., reaching USD 1.5 trillion (based on invoice pricing).¹⁶ These are very attractive numbers for investors, who- in the end- care about entering large markets to simply increase profits, regardless of medicinal ethical issues.

Patenting in the pharmaceutical industry differs in many aspects from other industries since its patents are the products themselves (e.g., a new medicinal drug). They are results of a very costly Research and Development (R&D) processes before extensive clinical testing.¹⁷ Patent protections encourage R&D of

⁹ WTO, The TRIPS Agreement and the Conventions Referred to in it (entered into force on 1 January 1995).

¹⁰ WTO, *Overview: the TRIPS Agreement* (entered into force on 1 January 1995).

¹¹ MarketWatch, ‘Pharma and OTC Market 2020 Growing Rapidly with Modern Trends, Development, Investment Opportunities, Size, Share, Revenue, Demand and Forecast to 2026 Says Industry Research Biz’ (27 Feb 2020) Market Watch.

¹² Elle Mahdavi, ‘Patents and the Pharmaceutical Industry’ (26 May 2017) California Review Management.

¹³ Ibid.

¹⁴ BIOENERGY International, ‘Life sciences sector records strongest patent application growth at the EPO’ (12 March 2019) BIOENERGY.

¹⁵ IQVIA, ‘Global pharma spending will hit \$1.5 trillion in 2023’ (29 January 2019) Pharmaceutical Commerce para 1.

¹⁶ Ibid.

¹⁷ Bruce Lehman, ‘The Pharmaceutical Industry and the Patent System’ (2003) International Intellectual Property Institute.

lifesaving medications. Nonetheless, manipulations of the market exclusivity that comes with patents raise ethical concerns since patent-protected medicines have no price caps or competitors for about twenty years.¹⁸ This 20-year period is even protected by the TRIPS Agreement. The Tufts Center for the Study of Drug Development estimates that around USD 2.6 billion and a ten-year commitment (including R&D and licensing) are needed for a new medicinal drug.¹⁹ This number proves that no small entity can render such processes and that such pharmaceutical corporations need to set a suitable price to get a Return on Investment (RoI). Thus, some medicines become inaccessible to some groups of human beings- a dilemma indeed.

Furthermore, in the last seventy years, the Human Rights Law development has been accelerating and gaining significant global endorsement, thus touching on other fields such as patents. The overlap between patent regimes and Human Rights Law can sometimes create conflicts, especially when a patent causes the price for a medicinal product to overshoot beyond the ability of patients or governments to pay. The general perception is that this problem exists only in developing countries. However, a study in the USA presents that “*Americans continue to suffer the highest prescription drug costs of anyone in the world (...) And even though drug prices tripled over the last decade, analysts predict they will double again in the next ten years.*”²⁰ One in four US Americans are unable to fill prescriptions because of high medicine prices.²¹ According to the study, this problem is due to “*the patent system.*”²²

When disagreements between patent laws/systems and access to medicine occur, they may cause difficulties, unacceptable sufferings, and even death of human beings. For instance, when conflicts strike the availability of a life-critical drug to a group of patients (e.g., HIV²³/AIDS²⁴ victims) in a region, the situation calls for leveraging the ways of thinking and dealing with this issue in all aspects: healthcare (time to reach a decision and accessibility), legal issues (law conflicts), policies (public interest and morality), economic considerations, and business (pharmaceutical companies) benefits and sustainability. In this respect, when the

¹⁸ *Mahdavi* (n 12).

¹⁹ *Ibid.*

²⁰ Tahir Amin, ‘The problem with high drug prices isn’t ‘foreign freeloading,’ it’s the patent system’ (2018) CNBC.

²¹ Bianca DiJulio, Jamie Firth, and Mollyann Brodie, ‘Kaiser Health Tracking Poll’ (20 August 2015) KFF.

²² *Amin* (n 20).

²³ See the HIV definition in WHO, *What is HIV?* (HIV/AIDS, 27 November 2017), stating that the ‘human immunodeficiency virus (HIV) targets cells of the immune system (...).’

²⁴ See the AIDS definition in WHO, *Is AIDS different from HIV?* (HIV/AIDS, 27 November 2017), stating that the ‘Acquired immunodeficiency syndrome (AIDS) is a term that applies to the most advanced stages of the HIV infection.’

healthcare situation faces pandemics (e.g., HIV/AIDS²⁵, SARS²⁶, COVID-19²⁷, etc.) the conflicts with patent rights for medicinal products can have grave consequences. Human beings are- without doubt- the most important in this dispute and their health and well-being shall be prioritized.

However, this means helping the human at the point (and time) of need (immediate aid) while trying to sustain the life of the companies that create and produce the relevant medicine. This is because without sustainability of such pharmaceutical corporations, when future pandemics hit hard, there would be no entity to research and develop the needed medicine (e.g., antivirals²⁸ and vaccines²⁹). In such a situation, there would be no possibility to provide the required medicine for humans, and we would end up with lower healthcare quality i.e., going against the main aim, policy, and Human Rights laws. Therefore, balancing between patent rights and Human Rights at times of pandemics is essential; otherwise, we lose on all sides.

Pandemics strike by surprise and if policies and laws are not prepared ahead for such emergencies, then trying to fix related issues in “real-time” may lead to terrible delays i.e., more sufferings and deaths. Looking back nearly a century ago till now, the human-race has suffered millions of deaths and periods of chaos (or lockdown/quarantines) due to pandemics such as the Spanish flu (1918)³⁰, Asian

²⁵ WHO, *Data and Statistics* (HIV/AIDS, 12 April 2020), considers HIV/AIDS as a global epidemic; Myron S. Cohen, Nick Hellmann, Jay A. Levy, Kevin DeCock, and Joep Lange, ‘The spread, treatment, and prevention of HIV-1: evolution of a global pandemic’ (April 2008) *The Journal of Clinical Investigation* 118 (4) 1244–54.

²⁶ See WHO, ‘SARS (Severe Acute Respiratory Syndrome)’ (WHO International travel and health, UN), stating that SARS is a type of CoronaVirus (SARS-CoV) identified in 2003 and that ‘An epidemic of SARS affected 26 countries and resulted in more than 8000 cases in 2003’ <<https://www.who.int/ith/diseases/sars/en/>> accessed 29 April 2020.

²⁷ See ECDC (European Center for Disease Prevention and Control), Stockholm, *Coronavirus disease 2019 (COVID-19) pandemic: increased transmission in the EU/EEA and the UK- seventh update* (Rapid Risk Assessment, 25 March 2020), stating that COVID-19 stands for COrona VIRus Disease 2019 and that it caused a pandemic.

²⁸ See WHO, *Antiviral drugs for pandemic (H1N1) 2009: definitions and use* (Emergencies preparedness, response, Diseases, 22 December 2009), defining antiviral drugs as ‘medicines that act directly on viruses to stop them from multiplying’.

²⁹ See para 2 in CDC, ‘Immunization: The Basics’ (CDC Vaccines & Immunizations), stating that a vaccine is ‘A product that stimulates a person’s immune system to produce immunity to a specific disease, protecting the person from that disease’ <<https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm>> accessed 29 April 2020.

³⁰ See WHO, *Past Pandemics* (Regional Office for Europe, Health topics, Communicable diseases, Influenza, Pandemic influenza, 2020) para 2, stating that the 20th century pandemics ‘the most severe of which was the so-called “Spanish Flu” (caused by an A(H1N1) virus), estimated to have caused 20–50 million deaths in 1918–1919’.

flu (1957)³¹, Hong Kong flu (1968)³², HIV/AIDS (1981)³³, SARS (2003)³⁴, the Swine flu also known as the H1N1 influenza (2009)³⁵, and COVID-19 (2019-currently)³⁶.

Observing this chronological sequence, one predicts that the hideous encounters with pandemics would continue, and preparedness in all fields would be necessary. One of the fields of concern to this research work is the resolution of conflicts between laws and whether exceptions to patents are needed, *let alone* investigating pros and cons of Compulsory Licenses (CL). During a pandemic, pharmaceutical corporations as well as governments and research institutions enter a race to produce a medical solution such as a vaccine/antiviral. In influenza pandemics, vaccines are the principal measure for a safe, effective prevention of infections i.e., reduction of the epidemic/pandemic impact.³⁷

On the other hand, pharmaceutical companies are businesses, which have a direct interest in generating profit. Governments also encourage such companies to generate large revenues since this supports further research for future medicines within the company, and taxation upon such revenues would help governmental programs to fund research in medicine and pharmacology. In this regard, within the pharmaceutical market the vaccine share is very attractive since it has increased by a factor of six (6X) over the past two decades (according to AB Bernstein) reaching a value worth more than USD 35 billion today.³⁸ Moreover, the COVID-19 pandemic is creating more attention to the fast-growing vaccine industry.³⁹ In this cycle of creating new medicinal products, generating profit for investors (RoI), and trying to provide patients access to the needed medicine, halting one point would cease solutions to exist for another. Therefore, balancing the cycle is crucial for guaranteeing good healthcare for now and the future.

Within these issues that affect human life, and with my passionate interests in law and economic growth while respecting Human Rights, my *motivation* rises.

³¹ Ibid, para 2 states that a milder pandemic occurred 'in 1957–1958 (the "Asian Flu" caused by an A(H2N2) virus)' that was 'estimated to have caused 1-4 million deaths.'

³² Ibid, para 2 states that another milder pandemic occurred 'in 1968 (the "Hong Kong Flu" caused by an A(H3N2) virus),' that was 'estimated to have caused 1-4 million deaths.'

³³ CDC (Centers for Disease Control and Prevention), 'The Global HIV/AIDS Pandemic' (MMWR, 11 August 2006), states that 'Since the first cases of acquired immunodeficiency syndrome (AIDS) were reported in 1981, infection with human immunodeficiency virus (HIV) has grown to pandemic proportions (...); UNAIDS, *Report on the global HIV/AIDS epidemic* (UNAIDS, 2000) Geneva.

³⁴ WHO (n 26).

³⁵ WHO (n 30) para 1, states that 'The first influenza pandemic of the 21st century occurred in 2009–2010 and was caused by an influenza A(H1N1) virus. (...) caused between 100 000–400 000 deaths in the first year alone.'

³⁶ WHO, 'Coronavirus disease (COVID-19) pandemic' (Emergencies, WHO Diseases, Coronavirus disease 2019, UN) <<https://www.who.int/emergencies/diseases/novel-coronavirus-2019>> accessed 29 April 2020; ECDC (n 27).

³⁷ WHO, *Vaccination* (Health topics, Communicable diseases, Influenza, 2020).

³⁸ Yun Li, 'Coronavirus highlights the \$35 billion vaccine market. Here are the key players' (23 February 2020) CNBC Markets.

³⁹ Ibid.

This motivation makes me very *curious* to learn more and investigate the conflicts to try proposing possible solutions and recommendations for a sought balance. During my search, I found that some of the abovementioned conflicts could be traced back to uncommon understandings of intersection between patent laws and International Human Rights Law (IHRL)⁴⁰, which includes the European Convention on Human Rights (ECHR)⁴¹. Hence, a new understanding on law divisibility or a re-fragmentation is suitable to investigate. The legal obligations and instruments that we investigate within the area of intersection of laws are patent laws (e.g., TRIPS Agreement and EU-related laws) and IHRL instruments.

In the following chapters, I discuss my investigation that goes through all the steps of background knowledge needed, legal obligations and instruments, interaction of laws, and caselaw. I focus on three aspects of the legal conflict: (i) IPR of patents, (ii) the human right ‘to life’ and ‘access to medicine’, and (iii) pandemics. Then I study the issue of defragmentation of applicable laws with the aim to seek a balance and present recommendations before concluding the work.

Reading this thesis would be easier if the audience have already garnered background knowledge in patent laws and relevant domestic issues as well as international agreements. Some familiarity with human rights from the legal viewpoint would make the reading smoother. However, it is not necessary for the reader to have thorough knowledge in Human Rights since Chapter 2 includes a section articulating the required background on this legal area (e.g., declarations, conventions, and covenants). Hence, examples of the thesis audience are: researchers in patent law and related conflicts, governmental legal personnel related to laws on ‘access to medicine’, international organizations experts in healthcare and patent laws (e.g., UN, WHO, and WIPO), patent lawyers/practitioners, inhouse lawyers (legal departments) in pharmaceutical firms, and development/investment experts in patent-funding organizations (e.g. Almi Företagspartner AB and Almi Invest AB⁴²).

1.2 Problem

The main problem is balancing between patent laws and Human Rights Law so that humans in need of medicine can have it and pharmaceutical companies that make those medicines do not lose their RoI. For instance, in cases of need for diabetic medicine or HIV medicine in a country, where the average patient does not have the means to pay large prices for medicine and healthcare, patents constitute a barrier to such a basic human right ‘to life’ and ‘to health’. This is because patents increase the prices for selling such medicine or even producing them locally. In tackling the problem, I focus on the cases of pandemics. A subproblem is understanding the relationship between three issues: the profit that motivates

⁴⁰ OHCHR, ‘International Human Rights Law’ (UN).

⁴¹ Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR) (4 November 1950).

⁴² Almi Företagspartner AB is a Swedish state organization.

companies, patent laws, and human rights law. Another subproblem is finding and proposing a solution to the presented challenges. Moreover, the work studies the subproblem of reorganizing the way we look at the relevant laws in order to investigate which provisions need to be taken into consideration (mainly in the context of intersection between patent legal instruments and IHRL). This challenge is complicated since we need to know where to draw the line in a conflict between patent IPR and Human Rights.

1.3 Purpose and objectives

The main purpose of the thesis is to fill the gap in understanding the overlap between patents and Human Rights in order to face the challenges of pandemics and have a balance. In this respect one objective is to investigate whether the right to ‘access to medicine’ is a human right by the applicable laws. The thesis investigates the right ‘to life’ and legally analyzes it to see if it leads to ‘access to medicine’.

Another objective is to study the challenges and solutions such as CL and patent exceptions during pandemics. The research locates legal problems that require direct attention. The thesis renders legal analysis of applicable laws provisions and caselaw to aid in providing recommendations for current and future pandemics such as the COVID-19 pharmaceutical patents (e.g., vaccine patents).

A third objective is to seek a balance between patent laws and the human right ‘to medicine accessibility’ in cases of pandemics.

1.4 Research questions

This research work entails delving in different areas of law, specifically patent law instruments (e.g., TRIPS) and Human Rights Law (e.g. IHRL, ECHR) with focus on ‘access to medicine’. The main aim is to seek a balance during pandemics. Two main research questions (each of which forks into three sub-questions) guide the study:

1.4.1 Can previous pandemic cases be comparatively used to *locate the legal right, obligations, and problems* to provide solutions for future similar dilemmas of the conflict?

The dilemma is the choice between two desirable laws that resists satisfactory solution. In patent law, many norms may be relevant such as the national patent laws, international agreements such as TRIPS (having highest hierarchy rank), economics laws, parties’ agreements, conventions, and customary law. It is up to the judges to decide the issues of applicable laws. In this conflict, Human Rights Law is relevant since the problem touches the right ‘to life’. This question forks to the following sub-questions:

- a- Is there a human right to ‘access to medicine’ even though this phrase is not found in any provision in the applicable laws?
- b- Can a right that is contained in the ICESCR justify the patent law interference with the human right to ‘access to medicine’ within the EU?
- c- Are patent CLs the right solution or are patent exceptions needed in times of pandemics i.e., what are the pros and cons?

1.4.2 Should there be fragmentation or unity of applicable laws to achieve a balance when a clash occurs between the right to ‘access to medicine’ in pandemics and patent rights?

To tackle this question, one needs a wide view on all relevant aspects of interpretations and understandings of relevant laws and their overlap. Thus, the focal point of the question addresses three sub-questions:

- a- How should courts interpret the need of multiple applicable laws in cases such as rights ‘to medicine accessibility’?
- b- How would giving regard to previous pandemics (e.g., HIV/AIDS) help us provide recommendations for balancing the COVID-19 vaccine dilemma and future similar cases?
- c- How could we use a defragmentation concept to improve solutions such as CL and patent exceptions for vaccines/antivirals to secure the balance in times of pandemics like COVID-19?

The two questions (1.4.1 and 1.4.2) are related, because to investigate achieving a balance, the research needs firstly to answer question 1.4.1.

1.5 Delimitations

This thesis discusses the instruments related to patent laws and IHRL including ECHR, but it does not consider instruments of International Humanitarian Law (IHL). Humanitarian law is sometimes confused with IHRL, but they cover different legal areas. IHL relates to the regulation conduct at times of war and armed conflicts⁴³, but it does not cover the basic rights for humans. Therefore, IHL is not within the thesis scope. This thesis considers the European Charter on Human Rights as one of Human Rights instruments. The thesis scope does not include issues of compensation to either patients or pharmaceutical companies. The thesis scope limits the consideration of legal instruments to the following:

⁴³ Bruce Oswald, Helen Durham, and Adrian Bates, *Document on the Law of UN Peace Operations* (OUP 2011) 195 para 2.

- a- The European Convention on Human Rights (ECHR)⁴⁴;
 - b- The Universal Declaration of Human Rights (UDHR)⁴⁵;
 - c- The International Covenant on Civil and Political Rights (ICCPR)⁴⁶;
 - d- The International Covenant on Economic, Social and Cultural Rights (ICESCR)⁴⁷;
 - e- The Convention on the Elimination of all forms of Racial Discrimination (CERD)⁴⁸;
 - f- The WTO TRIPS Agreement⁴⁹;
- and
- g- Other EU norms.

1.6 Terminology

The thesis considers business interests as those of pharmaceutical corporations and economic interests as those of governments. The thesis text uses the term “victim” to relate to a patient that has been infected by a disease. When the phrase ‘the conflict’ appears in the text without further description, it refers to the conflict between patent laws and Human Rights laws.

1.7 Methods and materials

In conducting the research in this thesis, the *legal dogmatic method* is adopted since we have different areas of law (patent law and Human Rights Law) with source-hierarchies. The research identifies and evaluates current legal material (sources) to designate a *lex lata (de lege lata)* or the legal condition *as it exists* in the conflict between the human right to ‘access to medicine’ and patent rights, especially during pandemics, where disputes as such may delay medicinal solutions. This delay-in turn- increases sufferings and deaths. It is a consequence that passionately awakens my conscious and curiosity about trying to better/change the future of humans and their rights in such tough circumstances.

In this thrust, the thesis renders the analysis of the current legal situation and laws with a view to the future (*lex ferenda*) in order to try to propose *what should be* by locating the legal problems, stating where solutions are needed and *could be* worked on, and trying to provide recommendations. The thesis looks at the con-

⁴⁴ ECHR (n 41).

⁴⁵ UNGA Res 217 A (adopted 4 November 1950, entered into force 3 September 1953) UDHR.

⁴⁶ International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR).

⁴⁷ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR).

⁴⁸ Convention on the Elimination of All Forms of Racial Discrimination (adopted 21 December 1965, entered into force 4 January 1961) 660 UNTS 195 (CERD).

⁴⁹ WTO (n 9); WTO, *A Handbook on the WTO TRIPS Agreement* (WTO and CUP 2012).

flicting laws interactions. Therefore, primary legal sources are applicable international and EU agreements, EU regulations and directives, local patent laws, and caselaw. Within this, treaties have a leverage to the highest value ‘*as binding formal agreements or written instruments establishing obligations between two or more subjects of international law (primarily states and international organizations)*’⁵⁰, thus affecting internal laws and legal regimes. Accordingly, it is very important to interpret applicable treaties for their internal connection to States and significant effects on legal interpretations and practices within nations and the EU.

Besides domestic legal instruments (as there is no unified European patent law), international agreements/instruments are applicable in both areas: patents (e.g., TRIPS Agreement) and Human Rights such as conventions (e.g., ECHR) and Covenants (e.g., ICESCR). All primary sources are underpinned by secondary legal sources of literature like journal articles, published papers, conference material, reports (e.g., WIPO material), encyclopedias, relevant magazine articles, and books.

Furthermore, when tackling the issue of patent prices and the interest of pharmaceutical corporations in generating profits, we use some aspects of the *law and economics methodology*. The conflict between patents and ‘access to medicine’ is related to the high cost of licenses incurred on a local company/government that wants to produce a patent-protected medicine. Such a high cost is projected to the end customers. Thus, the medicine price becomes prohibitively expensive and clashes with the right to ‘access to medicine’. In looking at some relations between pricing and laws, we adopt some elements of the methodology of *law and economics*.

The approach works on two levels: (i) human choice analyzed from an economic viewpoint, and (ii) goals that are attributed to legal systems.⁵¹ On the first level (human), the predominant mode is the rational choice theory, whose basic idea is that human behavior is analyzed as if persons and companies seek to maximize their expected utility.⁵² We do not use any other aspects of this methodology. However, using the described elements of law and economics helps our discussion on seeking a balance via comparing the two levels: human choices, and legal-system goals.

1.8 Organization of the thesis

The rest of the thesis falls in four chapters. Chapter 2 includes background knowledge of related Human Rights issues, surveys the relevant legal instruments and obligations of IHRL, analyzes the conflict between patent legal instruments

⁵⁰ Malcolm Shaw, ‘Treaty’ (International Relations, Politics, Law & Government, Encyclopedia Britannica, revised 27 August 2019) <<https://www.britannica.com/topic/treaty>> accessed 13 May 2020.

⁵¹ Alessio M. Paces and Louis Visscher, ‘Methodology of Law and Economics’ in Bart van Klink and Sanne Taekema (eds), *Law and Method. Interdisciplinary research into Law* (Series Politika 4 2011) 85.

⁵² Ibid.

and IHRL, and examines relevant caselaw. Chapter 3 presents the defragmentation principle within the conflict between patent law and ‘access to medicine’. Chapter 4 discusses seeking a balance, locates problems that require attention, and provides recommendations. Chapter 5 concludes the thesis, presents open issues, and discusses future work.

References in the bibliography section, except for the EUCJ caselaw, are listed alphabetically in the end of the thesis. The EUCJ cases in the bibliography section are ordered by their ECLI number in an ascending manner. Numbers between parentheses correspond to legal articles and provisions.

2 Interaction between patents and human rights

*"Use each interaction to be the best, most powerful version of yourself."
Marianne Williamson (1952- present)*

This chapter discusses the intersection between patents and IHRL to examine the conflict. It focuses on the TRIPS Agreement and the EU in respect of patents of medicinal products at times of pandemics. There is no unified legal patent law for the EU, and patent laws remain as domestic laws in each Member State. However, the TRIPS Agreement enjoys a high rank in the EU as a treaty that affects patent laws in all Member States. Section 2.1 introduces the topic. Section 2.2 presents some background on IHRL and its legal obligations and instruments, which is an essential step prior to analysis. Section 2.3 elaborates on the conflicts between patents and the right to 'access to medicine' and discusses related caselaw.

2.1 Introduction

One major aim is to find a balance and try to contribute to a solution that would help the sick get access to medicine especially in cases of pandemics while helping pharmaceutical corporations sustain needed finance to continue rendering medical research. For contrary reasons, Europe occupies a special part in the history of IHRL. At first, it was the birthplace, with the USA, for the political, legal, and economic modernization including liberty, democracy, marketing, and internationalization.⁵³ The paradox lies in the fact that Europe was also the site of the Holocaust and a place for World Wars I and II, which had serious violations of Human Rights.⁵⁴ From that point and on, there was large interest in progress towards Human Rights obligations. This motivation evolved over years into rules and regulations so now there is the Council of Europe and the EU, which have the legislative powers and the judicial functions for practicing and developing European Human Rights Law.⁵⁵ Hence, we look at how this evolution can give us lessons on the crucial right 'to medicine accessibility' especially at critical times such as pandemics. I see pandemic-time similar in many ways to wartime.

⁵³ Daniel Moeckli, Sangeeta Shah, and Sandesh Sivakumaran, *International Human Rights Law*, 3d edn (OUP 2018) 441.

⁵⁴ *Ibid.*

⁵⁵ *Ibid.*

I follow a top-down approach in describing the interaction between different areas of law, namely patent law and IHRL. Looking at caselaw and legal theory, we point out when tribunals could not have a clear vision on the intersection of different regimes. In this respect, the interface between patent laws and IHRL must be further analyzed since there is an increased complexity to resolve related disputes at times of pandemics.

2.2 Human Rights overview

The goal of this background section is to provide insight on a continuum of issues in relation to the application of IHRL. This section does not give a detailed study of IHRL. Firstly, it is important to define what Human Rights mean. I adopt the description of Rosalyn Higgins that they are “*rights held simply by virtue of being a human person. They are part and parcel of the integrity and dignity of the human being. They are thus rights that cannot be given or withdrawn at will by any domestic legal system. And although they may most effectively be implemented by the domestic legal system, that system is not the source of the right. International human rights law is the source of the obligation, albeit that obligation is reflected in the content of domestic law.*”⁵⁶

The Preamble to the Charter of the United Nations (‘the Charter’) reaffirms “*faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small.*”⁵⁷ Article 1(3) in the Charter Preamble explains that the purpose of the United Nations (UN) is “*to achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion.*”⁵⁸ To achieve these Human Rights goals, the UN set up missions. For instance, Article 55(c) in Chapter IX of the Charter reads that the UN shall promote “*universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.*”⁵⁹ Article 56 (in Chapter IX) of the Charter requires “*all Members pledge themselves to take joint and separate action in co-operation with the Organization for the achievement of the purposes set forth in Article 55.*”⁶⁰ Consequently, Articles 1(3), 55(c) and 56 of the Charter could affect the right to ‘access to medicine,’ because they commit all UN Member States to promote and encourage “*respect for, observance of, and implementation of Human Rights*” without distinctions. Moreover, this implementation/protection cannot be achieved without setting legal instruments in action. The thesis scope calls for a brief introduction on some Human Rights legal instruments.

⁵⁶ Rosalyn Higgins, *Problems and Process, International Law and How We Use It* (OUP: Clarendon Press 1994) 96.

⁵⁷ Charter of the United Nations (UN Charter) Preamble, s 1(2).

⁵⁸ Ibid Chapter I Purposes and Principles, art. 1(3).

⁵⁹ Ibid art. 55(c).

⁶⁰ Ibid art. 56.

2.2.1 International Human Rights Law (IHRL)

The IHRL has a wide reach. It encompasses all issues related to protecting humans and contains the fundamental rights and freedoms of individuals. It extends to prohibiting torture, slavery, and the arbitrary deprivation of life. It encompasses the right to liberty of the person, for women to be equal with men before the law, and for child's interests. IHRL protects the right to self-determination, to security and safety of the human being, to own property, to private and family life, and to enjoying the “*highest attainable standards of health*” (physical and mental).⁶¹ This research work needs a smaller subset of instruments to investigate namely, ICCPR⁶², ICESCR⁶³, and CERD⁶⁴. Other legal instruments that do not have the status of treaties exist, such as *inter alia* the Code of Conduct for the Law Enforcement Officials.⁶⁵ On the regional dimension, organizations have developed IHRL instruments such as the European Union (EU) among others. Out of these regional legal instruments, we consider only the ECHR.

2.2.2 The Bill of Rights

The foundation of the Human Rights law consists of three legal instruments namely, UDHR⁶⁶, ICCPR, and ICESCR. Together they form the *International Bill of Rights*⁶⁷, which is the starting point for many Human Rights legal instruments. The development of the bill came because of a real need and motivation to put in writing- some agreements to protect humans after the atrocities and the Holocaust of World War II. Therefore, we try to learn from previous lessons on real catastrophes in order to be proactive and locate problems that need attention/solutions. By learning from the history of Human Rights laws, we see that after World War II on 10 December 1948 the UDHR came to force. It includes civil, political, *economic*, and social rights. It was the first achievement of the UN after its formation in 1945.⁶⁸ Unfortunately, the UN Members did not vote for a legally binding convention at the adoption of the UDHR but rather a statement of ‘*common standard of achievement for all peoples of all nations*.’⁶⁹ The better lesson to learn is that some instruments such as the ICESCR and the ICCPR translate the UDHR principles to a legally binding form.⁷⁰

⁶¹ *Oswald* (n 43) 68-70; ECHR (n 41) art. 8.

⁶² *ICCPR* (n 46).

⁶³ *ICESCR* (n 47).

⁶⁴ *CERD* (n 48).

⁶⁵ *Oswald* (n 43) 68-69.

⁶⁶ *UNGA* (n 45).

⁶⁷ *Oswald* (n 43) 72.

⁶⁸ *Ibid.*

⁶⁹ *UNGA* (n 45) Preamble.

⁷⁰ *Ibid.*

2.2.3 The right 'to health'

The meaning of the phrase 'right to health' is not so difficult for most of us to grasp, however sometimes it could be confusing to interpret legally. There is no statement or rule in the Human Rights legal instruments that is entitled as such, or including exact wording that clearly articulates the right of a human to be healthy.⁷¹ Because of many biological and behavioral reasons such as genetics, risky endeavors, and accidents, it is not within the capacity of governments or state authorities to ensure that everyone lives fully healthy.⁷² This right should be granted in terms of an individual's potential, social preconditions, environmental situations, and health services.⁷³ We do not find the word 'medicine' in all the related provisions. We refer to the right 'to health' within the common sense and proper interpretation of the right '*to the highest attainable standard of health*'.⁷⁴ The right to health is provided for in Article 25 UDHR and Article 12 ICESCR. I underline the key phrases in them below.

UDHR Article 25(1)

"(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. (...)"⁷⁵

ICESCR Article 12

"1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(...)

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."⁷⁶

In addition, there are Human Rights standards on the 'right to health' like *inter alia* EU provisions (Articles 11 and 13 of the European Social Charter that are the basis for Article 2 ECHR on the right 'to life' and Article 35 EU Charter of Fundamental Rights on 'Health care'- below), Article 10 of the Protocol of San

⁷¹ *Moekeli* (n 53) 195.

⁷² *Ibid.*

⁷³ *Ibid* 195-196.

⁷⁴ *Ibid* 196.

⁷⁵ *UNGA* (n 45) art. 25.

⁷⁶ *ICESCR* (n 47) art. 12.

Salvador⁷⁷, and Article 16 ACHPR⁷⁸ (African Charter on Human and Peoples' Rights), Article 5(e)(iv) ICERD⁷⁹, Article 12(f) CEDAW⁸⁰, and Article 24 CRC (Convention on the Rights of the Child). Article 2 ECHR discusses the similar right as Article 2 of the EU Charter of Fundamental Rights. Below are some excerpts of the relevant texts of the articles.

EU Articles⁸¹

- European Social Charter- ESC (Revised)

Article 11 – “The right to protection of health

With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organisations, to take appropriate measures designed inter alia:

1. to remove as far as possible the causes of ill-health;

(...)

3. to prevent as far as possible epidemic, endemic and other diseases, as well as accidents”

- ECHR Article 2

“Right to life

1. Everyone’s right to life shall be protected by law. (...)”

- EU Charter of Fundamental Rights Article 35

“Health care

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. (...)”

ICERD Article 5(e)(iv)

“In compliance with the fundamental obligations laid down in article 2 of this Convention, States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of the following rights:

(...)

(e) Economic, social and cultural rights, in particular:

(...)

(iv) The right to public health, medical care, social security and social services;

(...)”⁸²

⁷⁷ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights ‘Protocol of San Salvador’ art. 10.

⁷⁸ ACHPR- African Charter on Human and Peoples' Rights (Adopted 27 June 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force 21 October 1986), art. 16 ‘Right to Health’.

⁷⁹ CERD (n 48) art. 5(e)(iv).

⁸⁰ CEDAW- Convention on the Elimination of All Forms of Discrimination against Women, OHCHR art. 12(f).

⁸¹ ESC- European Social Charter (Revised), ‘The right to protection of health’ (European Treaty Series no 163 Council of Europe) art. 11; ECHR (n 41) art. 2; EC, Charter of Fundamental Rights of the European Union (2000/C 364/01) art. 35.

⁸² CERD (n 48) art. 5(e)(iv).

The highest in rank are Article 25 UDHR and Article 12 ICESCR since they are conventions and come on the top of obligations. Interpreting Article 25 of the UDHR, we notice the important phrase “medical care”, which I underline in the above excerpt. Although the UDHR is not legally binding, but the presence of the phrase “medical care” gives a very clear indication that medicine is part of this care, and what follows it of ‘access to medicine’. Moreover, in the ICESCR comprehensive Article 12, reading the article gives no doubt about the provision giving the human being in a Member State the right to enjoy public health and medical care. In the EU, this becomes legally binding for a State to provide for such care. Can legal reasoning come with an interpretation that considers the right to ‘access to medicine’ outside the full meaning of the underlined phrases (above)? Clearly, the answer is “no,” and public health services as well as medical care may not be completely described if there is lack in access to medicine. I conclude that although there is not a specific provision entitled the right to ‘access to medicine’, the above is enough to include such an access to the rights of humans.

2.2.3.1 IHRL legal obligations

Like any law, its underlying philosophy relates to rights and obligations. The Human Rights, as they clearly explain themselves, are the rights of human beings, and the related obligations are then those of States and authorities. Under Article 12(1) ICESCR (above), Members (States Parties) clearly recognize all humans to enjoy the “highest attainable standards of physical and mental health,” and they are responsible to implement the required steps to assure such standards. The right ‘to health’ is interpreted to reach adequate healthcare, underlying health-preconditions, and fulfilment of social determinants of health.⁸³ The basic action by State Parties to fulfill their obligations is clearly stated in four steps in Article 12(2) ICESCR (above). For the scope of this thesis, we stress on two statements in this article, namely (2)(c) and (2)(d). In addition, the Committee on Economic, Social and Cultural Rights (CESCR) specifies in General Comment 14 that the right to health involves four constituents as being State Parties’ obligations⁸⁴. In what follows, I define those legal obligations and examine their applicability in cases of pandemics:

1- The first is the *availability* of healthcare and medicine. State Parties have an obligation to ensure availability of a functioning public health system and healthcare facilities, goods, and services in enough quantities. Is this possible in cases of pandemics? On the contrary, we witness many EU States failing to provide even the simplest of needs e.g., facemasks (influenza pandemics) and ventilators. Do State Parties’ politicians have enough time and resources to lead investments/projects on vaccines or antivirals? In the last hundred years, humans suffered tough delays due to the lack of *pandemic-emergency systems and laws* that aid governments to reach solutions more quickly. For instance, in the

⁸³ *Moeckli* (n 53) 196.

⁸⁴ *Ibid*; CESCR General Comment 14, para 12.

HIV/AIDS pandemic, many laws and regulations needed years to see the light. This thesis locates the problem of reducing the time-to-market (including R&D) for a vaccine/antiviral (time to availability). Having a drug available does not mean everyone has access to it.

- 2- The second is *accessibility* to health facilities, goods, and services to all humans. “*Accessibility has four overlapping dimensions: (1) non-discrimination; (2) physical accessibility; (3) economic accessibility (affordability); and (4) information accessibility (the right to seek, receive, and impart information and ideas concerning health issues).*”⁸⁵ An example of a problem is the high price for the AIDS antiretroviral drug protected by a patent-system in the USA, EU, and most signatories of the TRIPS Agreement. The challenging problem is market-price regulation. It requires exceptions in thinking about prices. Patent laws in times of pandemics need re-thinking about exceptions.
- 3- The third is *acceptability* i.e., “*all health facilities, goods, and services must be respectful of medical ethics and culturally appropriate, sensitive to gender and lifecycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.*”⁸⁶ This obligation is out of the thesis scope.
- 4- The fourth obligation is the *good quality* of health facilities, goods, and services. It requires experienced medical professionals, approved unexpired drugs, appropriate medical equipment, safe and potable water, and adequate sanitations. This obligation is out of the thesis scope.

The right ‘to health’ puts an obligation on States to plan, design, and implement measures to ensure access to health facilities, goods, and services. Moreover, this access is for all humans on the state-land, without any discriminatory basis, including vulnerable or marginalized groups that might not enjoy this access otherwise. Consequently, this puts the requirement on a fair and equitable distribution of all health facilities.⁸⁷ The CESCR articulated that a state would be in violation of its obligation to protect humans’ health if found failing to take all necessary measures to protect persons in its jurisdiction from infringements of the right ‘to health’ by any party.⁸⁸

2.2.3.2 Are obligations practiced?

Another issue is that obligations remain as ‘unused’ written rules if no realizations of the right ‘to health’ are practiced. Such a practice is directly attached to the materialization of some economic and social rights.⁸⁹ The CESCR urges all State Parties to adopt, *design* and *implement* a national-public-health strategy and *plan of*

⁸⁵ *Moeckli* (n 53) 196.

⁸⁶ *Ibid.*

⁸⁷ *Ibid.*

⁸⁸ *Ibid* 197.

⁸⁹ *Moeckli* (n 53) 197.

action, on the basis of *epidemiological evidence*, addressing the health concerns of the entire population, and that strategies and plans of action should be devised and always *reviewed* on the basis of a participatory and transparent process.⁹⁰ They should include methods, such as right-to-health indicators and benchmarks. Moreover, *everyone should be ensured access to essential drugs* as defined under the World Health Organization (WHO) Action Programme on Essential Drugs.⁹¹ The question remains on how to make sure that States keep up to those obligations during pandemic crises.

In the current COVID-19 pandemic, we witness lack of medical goods like facemasks, body shielding clothes, ventilators, and some medicines (e.g., Hydroxychloroquine). Some of these problems are caused by rules and policies such as the policy to provide the antiviral, Hydroxychloroquine, for only few patients since lupus and arthritis victims need it too i.e., causing shortage of the drug⁹². Another type of problems is the prevention of producing medical products at pandemic times due to prohibitive patents. An example is the inability to produce ventilators that are urgently needed for some COVID-19 victims in many EU States, because the original invention is protected by a valid patent. Therefore, in this COVID-19 outbreak we are witnessing patent legal systems and laws in the EU and other regions leading to a *clash with the obligations of availability and accessibility*.

One example to learn from for tackling this problem is what Medtronic and AmboVent practice by sharing their patented ventilators-design without the need for manufacturers to pay for licenses. They are issuing special *permissive-licenses* specifically for the purposes of addressing the needs of the COVID-19 pandemic.⁹³ By analogy, we foresee a similar problem arising when vaccines/antivirals for the COVID-19 are ready to market but with patent protection. How long shall this delay be allowed while lives are lost so that businesses have the relevant patents? Shall patents be allowed for such medicinal products during pandemics, or shall there be patent exceptions? The solution is to be legally proactive by learning from current needs and previous pandemics to *design and implement* the ready-to-invoke legal provisions/system when pandemics strike.

⁹⁰ *CESCR* (n 84).

⁹¹ *Moeckli* (n 53) para 43.

⁹² Elizabeth Cohen and Marshall Cohen, 'After Trump's statements about hydroxychloroquine, lupus and arthritis patients face drug shortage,' (7 April 2020) CNN Health <<https://edition.cnn.com/2020/04/07/health/hydroxychloroquine-shortage-lupus-arthritis/index.html>> accessed 7 April 2020.

⁹³ Darrell Etherington, 'Medtronic is sharing its portable ventilator design specifications and code for free to all,' (30 March 2019) TC Verison Media <<https://techcrunch.com/2020/03/30/medtronic-is-sharing-its-portable-ventilator-design-specifications-and-code-for-free-to-all/>> accessed 30 March 2020; Robert L. Read, "The Open Source Ventilator Game Has Changed: AmboVent and Medtronic COVID-19 Ventilators Open Sourced," (1 April 2020) Medium <<https://medium.com/@RobertLeeRead/the-open-source-ventilator-game-has-changed-ambovent-and-medtronic-covid-19-ventilators-open-d645bde594cc>> accessed 2 April 2020.

2.3 Patents clash with the right to ‘access to medicine’

In examining the conflict, the research focuses on the second legal obligation of *accessibility*. In the clashing overlap between the two regimes, a researcher cannot escape the issue of patent pricing and its interference with *accessibility* caused by high pricing. Tackling this point, I utilize some aspects of the *methodology of Law and Economics* (see section 1.7).

2.3.1 Pricing

From a legal viewpoint based on Article 4 ICESCR and some national EU laws (e.g., German Law), if a state could not fulfil its positive duty of protecting a human right, it is allowing other regimes (e.g., patent norms) to impair such rights.⁹⁴ This legal issue is relevant to patents from the economic viewpoint since States must guarantee the economic ‘accessibility to medicine.’ Consequently, this translates to assuring affordable medicine prices. The ECtHR questions whether the balance between public interest and individual’s interest shifts unfairly.⁹⁵ To fully analyze this point, one would need to work on verifications in two planes: theoretical economic dimension and empirical dimension. This work does not indulge into mathematical avenues of such analyses but rather looks at the price levels from an economic viewpoint relating to interactions with laws.

The usual claim to justify patent protection (with higher prices) is articulated by the aim of creating an incentive for inventors to keep conducting pharmaceutical research, without which many medicinal products would not be ‘available’. This justification creates a direct relation between legal patent protection and supporting the first IHRL obligation of ‘availability’ of medicine (see subsection 2.2.3.1). This relationship makes sense. However, *the problem located* in this rationale is that although it supports the first obligation (*availability*), it goes against the second obligation (*accessibility*). The aim of IHRL instruments is to not separate the four obligations.

In cases of pandemics such as HIV/AIDS, pricing is a life-critical problem⁹⁶. The antiretrovirals are ‘available’, but to many the pricing policies hinder ‘accessibility’. The same dilemma is feared in the COVID-19 outbreak when (and if) a vaccine becomes ‘available’. The analysis of pricing requires a look at the micro-economic theory to examine the competition in the market, the supply/demand curve, monopoly pricing, and governmental ability for medicine support.⁹⁷

Lawful pricing within national rules is also relevant. In any business, the pricing process is one of the final steps before launching a product. It is affected by many

⁹⁴ ICESCR (n 47) art. 4; HD Jarass and B Pieroth, *Grundgesetz für die Bundesrepublik Deutschland. Kommentar*, edn 7 (CH. BECK 2004)- German Law art. 1, para 24.

⁹⁵ Mark P. Villiger, *Handbuch der Europäischen Menschenrechtskonvention*, 2nd edn (EMRK 1999) 344-345.

⁹⁶ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (OUP 2007) 148.

⁹⁷ *Ibid* 138-151.

factors e.g., supplied volume, number of customers, critical need, etc. Pharmaceutical companies participate in two price issues, namely the taking and setting of market-values of medicinal products.⁹⁸ Hence, they do not have total influence on the price, but sometimes they impose partial leverage. If a medicine is priced very highly, it would be prohibitively expensive to sell. If its price is too low, it is not profitable. Pharmaceutical corporations play the game of balancing two factors: making good profit while patients can afford the medicine. Doing so on global-sales scale, with huge differences between purchasing powers of nations and patients, has a very slim chance to succeed for drugs that cost a lot in R&D (section 1.1). At the same time, the price is affected by the level of supply and demand. Legally, patent laws empower the patent-owner to prevent others from producing, marketing, using, selling, and importing the patented medicinal product e.g., Article 28 under Section 5 ‘Patents’ of TRIPS⁹⁹, which states:

TRIPS Article 28 - *Rights Conferred*

“1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. (...)”¹⁰⁰

With such rights, the patent owner can create a monopoly, where it can decide to produce large quantities of the medicine at a lower price or smaller numbers at a higher price. Since it is a business for profit, it will select the market price promising the highest profit. Clearly this market reasoning does not take into consideration the value of the human being, his/her right to ‘access to medicine’ and the ability to purchase the medicine. Another *legal problem location* that needs revisiting is the negligence of the right to enjoy scientific benefits by every human being. Article 15(1)(b) ICESCR¹⁰¹ recognizes the right of everyone ‘[T]o enjoy the benefits of scientific progress and its applications’. The UDHR Article 27(2) articulates rights for everyone to enjoy ‘the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’¹⁰². However, those rights have been so far neglected. An important issue is that the UN Member States, CESCR committee, the UN (General Assembly and Human Rights Council and its Special Rapporteurs) have not yet emphasized it as a Human Right¹⁰³, although it clearly is written to be interpreted as

⁹⁸ Ibid 139.

⁹⁹ WTO (n 9) art. 28.

¹⁰⁰ Ibid.

¹⁰¹ ICESCR (n 47) art. 15(1)(b).

¹⁰² UNGA (n 45) art. 27(2).

¹⁰³ UN, *Report of the High Commissioner for Human Rights, Economic, Social and Cultural Rights, ‘The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights* (UN, 27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, para 10 ff.

such. Another alarming issue is that the *travaux préparatoires* are taciturn on the UDHR provision.¹⁰⁴

From an empirical economic approach, the study checks the prices for generic medicines (priced much lower than branded ones). In the USA, the price of the first generic is around 60% of the branded medicine. It falls to 17% when twenty generics enter the market.¹⁰⁵ From a legal perspective, CLs take part in this economics and law interaction. In the EU, the UK has practiced CL. In addition, Canada has quite a long experience with CL. The related large experience in those two countries affirms the previous findings on pricing.¹⁰⁶ Not only does this economic analysis prove that patent regimes affect the price of medicine, but there is also strong evidence supporting it. For instance, in situations when governments face pandemics, they threaten the patent protection by imposing CL. CL helps them get large reductions on drug prices. Another evidence is the Brazil HIV/AIDS program to produce drugs locally, where 70% price reduction was achieved during the high need in 2001.¹⁰⁷

2.3.2 Legal analysis of the conflict

After analyzing the links between patent pricing and the legal conflict, the research reverts again to the dogmatic method by examining applicable laws with highest hierarchy and how they have been used in practice, namely the treaties and legislations. Then, the search moves to caselaw.

2.3.2.1 Provisions

Firstly, TRIPS is the most comprehensive agreement on IPR. Not only does it harmonize patent rules in Member States, but also provides a minimum standard for protection (see section 2.3.1). In the EU, patent rights, compared to other IPR, are the least harmonized. In addition, the EUCJ adopted a self-restrained approach for patent substantive discipline.¹⁰⁸ This was particularly true also in the EUCJ caselaw on patent protection and TRIPS as an applicable instrument.¹⁰⁹ After the Lisbon Treaty¹¹⁰, introducing Article 207 TFEU¹¹¹ on “Common Commercial Policy”, the EUCJ took a clear stance on including TRIPS in its judgements as a harmonizing legal instrument for the patent system in the EU. In the

¹⁰⁴ Hestermeyer (n 96) 143-144.

¹⁰⁵ Jerry Stanton, ‘Comment: Lesson for the United States from Foreign Price Controls on Pharmaceuticals’ (2000) 16 Conn J Int’l L 149, 158.

¹⁰⁶ Fredric M. Scherer, ‘The Economic Effects of Compulsory Patent Licensing’ in Ruth Towse and Rudi Holzhauser (eds), *The Economics of Intellectual Property: Patents* (Edward Elgar 2002) 315, 350.

¹⁰⁷ Anne-Christine D’Adesky, *Moving Mountains, The Race to Treat Global AIDS* (Verso 2004) 28.

¹⁰⁸ Francesca Venerucci, *A Comparative Study of the CJEU and ECtHR Approaches on Intellectual Property: Unity or Division?* (thesis, UNIBOCCONI 2016) 72.

¹⁰⁹ Ibid.

¹¹⁰ Treaty of Lisbon, EU (2007/C 306/01).

¹¹¹ TFEU (Treaty on the Functioning of the European Union) (entered into force on 1 December 2009) part 5 art. 207 (ex Article 133 TEC).

case of *Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon*¹¹², the EUCJ mentioned that common commercial policy also concerned the commercial aspects of IP and that if the EU is intended to promote international trade, it falls within common commercial policy.¹¹³ Regarding TRIPS, the EUCJ noted that:

*“[its] primary objective is to strengthen and harmonize the protection of intellectual property on a worldwide scale” and that “of reducing distortions of international trade by ensuring, in the territory of each member of the WTO, the effective and adequate protection of intellectual property rights (...) [it] contributes to attaining that objective by setting out, for each of the principal categories of intellectual property rights, rules which must be applied by every member of the WTO”.*¹¹⁴

In this respect, Articles 27-34 (Section 5) TRIPS can be used and interpreted to protect aspects of patents with specific power endowed in Article 28 (discussed in subsection 2.3.1). Looking again at the interference with Human Rights instruments, Article 15(1) ICESCR and Article 27 UDHR (discussed in subsection 2.3.1) have been used some years ago in practical situations to try to justify patent collisions with the right to ‘access to medicine’.¹¹⁵ Hence, not only patent laws can be used to protect pharmaceutical patents, but also Human Rights Law. However, nowadays one cannot bet on using them. They protect the moral and material interest of authors; however, they do not coexist with nowadays patents.¹¹⁶ These articles do not protect patents as such, nor do they protect pharmaceutical companies.

Article 15 ICESCR tries to achieve a balance between the protection of the interest of the inventor and public access to the invention. Usually, the practice is more to protect the inventors’ interests. However, if the rights ‘to health’ or ‘to food’ are threatened the support is more to access the benefits of the technology. Article 15(1)(c), therefore, does not justify the interference of patent laws with the right to ‘access to medicine’. Moreover, patent owners try to base their claims on regional instruments. For instance, in the EU, inventors depend on the Charter of Fundamental Rights of the European Union, and in the USA, they rely on the American Declaration of the Rights and Duties of Man. These instruments protect IP interests as property, hence giving them a forceful strength.

In the context of pandemics, and if they are considered as emergencies, another legal instrument to examine is the ICCPR, because it allows derogations in emergencies that threaten lives in a nation. The most relevant provisions are in Article

¹¹²*Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (Case C-414/11) EU:C:2013:520 Judgment EUCJ (Grand Chamber 18 July 2013).

¹¹³ Ibid paras 45-48.

¹¹⁴ Ibid para 58.

¹¹⁵ Werner Meng, ‘GATT and Intellectual Property Rights- The International Law Framework’ in Giorgio Sacerdoti (ed), *Liberalization of Services and Intellectual Property in the Uruguay Round of GATT* (Proceedings of the Conference on The Uruguay Round of GATT and the Improvement of the Legal Framework of Trade in Services, Bergamo 21–23 September 1989, published 1990) 57, 68.

¹¹⁶ *Hestermeyer* (n 96) 152-153.

4 ICCPR (below). An interesting issue is that it contains limitation clauses so Member States can limit the right in compliance with the clauses and the principle of proportionality (which we analyze in our discussion on balancing the rights in Chapter 4). By utilizing this option in ICCPR, Member States interference with the right can be justified with no violations.¹¹⁷

ICCPR Article 4.

“1. In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin.

2. No derogation from articles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16 and 18 may be made under this provision. (...)”¹¹⁸

This brings the search back to the ICESCR Article 4 to check the limitation obligation, where some interpretations support the justification of interference.

ICESCR Article 4

“The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.”¹¹⁹

In reading this article, a word-by-word analysis does not find reference to emergencies or survival (life threatening) issues. However, some have found justification within interpreting it.¹²⁰ Furthermore, Article 6(1) ICCPR states the obligation to protect the right ‘to life’ by law:

“1. Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life. (...)”¹²¹

However, the rest of Article 6 provisions (2)-(6) make it obvious that this article relates to death penalty regulations, no authorization of genocide, abolition of capital punishment. These life-threatening issues are specifically mentioned in the article provisions, but no other conditions related to life are listed. The question is whether Article 6(1) ICCPR can be used to protect the right ‘to lifesaving medicine’. Does not the right ‘to life’ include the right to ‘lifesaving’ products? One can argue with an affirmative answer or with a negation; however, the following analysis shows that there is a right to lifesaving medicine.

The problem we locate is that the right ‘to life’ is not explained or further articulated in any of the laws for what it exactly means. It is left to the judges to interpret it and decide to bring governments to their *obligation of accessibility* ‘to

¹¹⁷ Manfred Nowak, *Introduction to the International Human Rights Regime* (RWI 2003) 56.

¹¹⁸ ICCPR (n 46) art. 4.

¹¹⁹ ICESCR (n 47) art. 4.

¹²⁰ *Hestermeyer* (n 96) 152.

¹²¹ *Ibid* art. 6.

lifesaving medicine'. Back to the interpretation, this article clearly states the legal obligation to protect the 'inherent right to life,' hence I consider that the rest of the article would be giving three instances of this type of protection (death penalty regulations, no authorization of genocide, abolition of capital punishment), but they do not limit the previous statement since there is no phrase or wording reading that the right 'to life' is limited to three instances. I deduce that the first two sentences on this right include all instances of the right to have human-life protected. This right relates to the obligation of a Member State to not end a life and to provide products that aid in stopping the threat of death. The relevant medical/medicinal products include *inter alia* ventilators, pacemakers, and lifesaving medicine (e.g., HIV/AIDS and COVID-19 vaccines, antivirals, & antiretrovirals).

In all these instruments, the right 'to life' does not contain a limitation clause that is related to patent law. Most Human Rights articles can be limited under certain conditions. This means that the negative overlap that patent law has with the right to 'access to medicine' could be justified under Human Rights Law. On the other hand, patents protect the revenue for pharmaceutical companies, thus motivating the creation of new medicinal solutions. From a legal perspective, such an argument is also used to protect patent-owners' rights as they support the access to currently/future needed medicine. I see this as a controversial conflict that is awakened when epidemics/pandemics suddenly occur since the fight against time (to save lives) becomes severe. A proof of this concept is evident in the current struggle to decrease the number of global deaths (in hundreds of thousands) due to the concurrent COVID-19 outbreak and the exponentially increasing number of infections (millions)¹²².

The WHO declared it as a pandemic since February 2019.¹²³ The question that we need to be proactive in thinking about is the access to vaccines/antiviral medicines when they become available within a number of months.¹²⁴ A few of those medicinal products are currently under testing.¹²⁵ From this particular experience, we need to learn the lessons well, especially the legal ones, for current and future pandemics to seek a balance between the *right to access to medicine* (as a human right) and *patent laws that prevent this access*. This requires an economic balancing, as well, between the availability of research-finance for developing new medicines and

¹²² WHO (n 36); Worldometer, 'Coronavirus' <<https://www.worldometers.info/coronavirus/>> accessed 19 May 2020.

¹²³ WHO, *Summary* (Rolling updates on coronavirus disease, COVID-19, 17 May 2020) <<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen>> accessed 19 May 2020.

¹²⁴ Elizabeth Cohen, 'Early results from Moderna coronavirus vaccine trial show participants developed antibodies against the virus' (18 May 2020) CNN Health <<https://edition.cnn.com/2020/05/18/health/coronavirus-vaccine-moderna-early-results/index.html>> accessed 18 May 2020.

¹²⁵ WHO, 'Accelerating a safe and effective COVID-19 vaccine' (UN) <<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/accelerating-a-safe-and-effective-covid-19-vaccine>> accessed 29 April 2020.

regulation of their prices. This balance is so critical since it affects human lives on one side and economies on the other side (which indirectly but not as quickly and severely would affect lives and lifestyles). Hence, on whichever side of the balance we may stand, we would find fierce opponents of the position.

New medicinal products have high costs (e.g., in the range of hundreds of millions of USD) and consume several (5 to 10) years to be market ready (see section 1.1), making the balance more difficult to manage. Taking away the chances to recover this huge cost in time and money, the incentives of companies and inventors to innovate would fade away. The only way to keep the 'incentive to invent' is via patent protection. If exceptions to patent validity is favored in some area due to life-critical diseases, the incentive to innovate is lost in the area where it is mostly needed. There would be dependency on solutions from outside which would be of higher costs. In this respect, we witness criticism of patent systems in general even for a strong patent office like the USA one (e.g., a study shows that nearly 54% of patents only are judged as valid in courts)¹²⁶. Even if the quality of patent examinations were better, there is much debate whether the innovations made because of patents compensate for the welfare losses. The argument that patents motivate innovation does not say anything about patent limits. It favors patent law beyond all bounds and is taciturn on how much profit is enough for inventors' incentives. This is an issue that pharmaceutical companies consider to be most profitable, which is usually all what they care about.

A very important fact that adds to this conflict is that the patent-life period was never decided based on thorough economic studies nor was the factor of pandemics taken into consideration. For instance, the twenty-year patent life-period in the TRIPS Agreement and other patent law instruments does not rely on business or economic investigations; it came from a historic coincidence and goes back to the Belgian patent legislation passed in 1854.¹²⁷ This calls upon legislators to ponder if a very important rule on time periods from year 1854 would still fit our current needs in the 21st century. Some reformists agree that patent systems need to be revisited for a change.¹²⁸

At the same time, we must be able to see the issue from the viewpoint of businesses (pharmaceutical companies) that are- in the end- profit hungry. They conduct research only where they see an opportunity with little risk and high probability for cash-in. Basic R&D for medicine are produced with government involvement.¹²⁹ The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) concur more than 90% of the time in their decisions to approve new drugs based on a new study from EMA and FDA officials that

¹²⁶ James Love, *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord* (UNDP, 2001) para 8.

¹²⁷ S Lapointe, 'L'histoire des Brevets' (2000) 12 *Les Cahiers de Propriété Intellectuelle* 633, 649.

¹²⁸ *Hestermeyer* (n 96) 160.

¹²⁹ NIH, *Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies: Workshop Summary*, Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation (2009) National Academies Press.

looked at 107 applications from 2014 to 2016.¹³⁰ Hence, practical solutions could not be thought of without governments being involved. Consequently, legal issues must be addressed by the political and legal specialists in governments e.g., EU parliament.

2.3.2.2 Caselaw

For pharmaceutical cases, it is not possible to think of domestic basis only since medicinal products are needed and sold globally. Moreover, pandemics are global outbreaks of diseases, so the mindset for legal analysis goes in harmony with global (i.e., international) outbreaks. The work here entails thinking “out of the box” and out of any provincial mentality. IPRs, besides being protected by domestic laws, can be listed and explained in treaties for their protection. They have also been placed within definitions of investments in many international treaties. Protecting IPR is surely a very positive goal since it protects inventors’ rights. However, it may lead to problematic situations especially in the cases when the IP (owned by a foreign investor) is related to a topic that touches upon Human Rights obligations (“access to medicine”).

To explain the intensity of such issues, in the case when a treaty signatory (Member State) suspends the health-related IP (e.g., patent) that is owned by a pharmaceutical company acting as a Foreign Direct Investor (FDI), this measure is sometimes construed as equivalent to unlawful expropriation. The dilemma starts when States try to meet their legal obligation of medicine ‘accessibility’ (a life-critical obligation in pandemics). This work partitions caselaw into cases not related to expropriation claims, and cases under expropriation claims.

2.3.2.2.1 *Caselaw without expropriation*

Many cases exist where the conflict between IPR and Human Rights is evident, without the need for a pharmaceutical company to file for compensation based on allegations of a State having practiced unlawful expropriation. When national markets are interconnected (e.g., EU), the price of one national market ‘leaks’ into another one. Such leakage may occur because of parallel imports. Hence a medicine placed on a low-price market by the patent owner may be imported by a 3rd-party into a more highly priced market. This ruins prospects for profit for the original company.

In relation to the price of medicine, a good case to learn from is *Hazel Tau et al v GlaxoSmithKline, Boehringer Ingelheim et al, Competition Commission*.¹³¹ The filing was based on charging GlaxoSmithKline and Boehringer Ingelheim with excessive pricing of antiretrovirals to the detriment of consumers in violation

¹³⁰ Zachary Brennan, ‘EMA and FDA Historically Agree on Just About Every New Drug Approval, but is That Slowly Changing?’ (16 August 2019) Regulatory Focus.

¹³¹ *Hazel Tau et al v GlaxoSmithKline, Boehringer Ingelheim et al* (CC) Republic of South Africa (RSA), Statement of Complaint in Terms of Section 49B(2)(b) of the Competition Act 89 of 1998; See also CC (Competition Commission), *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim: A Report on the Excessive Pricing Complaint to South Africa's Competition Commission* (RSA, 2003).

of the State Competition Act comparing the international best price offer of the branded product with the price of a WHO prequalified generic medicine. The court found that the branded drug was priced around 230% higher than the generic medicine. This case shows two important issues. Firstly, that the margin of difference between branded medicine and generics can reach questionable overshoots. Secondly, an argument arises on whether some profit can be made by branded drugs if they lower the marginal difference with cheaper ones. At times of pandemics, would governmental institutions and international organizations be able to handle such prices of branded medicine or vaccines when the number of patients is very high? At least it would cost beyond budget limits on healthcare systems. Such court decisions may help in locating a problem that needs attention: marginal differences in prices, and the need for governmental interference to lower prices during pandemics. This problem calls for a set of *pandemic-emergency laws* that can be made ready to invoke when pandemics strike.

In the *Bayer AG v Commission of the European Communities*¹³² case, monopolies threatened to limit the supply for the market with a lower price to prevent the medicine from leaving the country or it might simply set a unitary high price to prevent a loss of sales in the high-price country. At the same time, we shall keep in mind that without patents many of these drugs would never have been invented. From a political viewpoint, it is a fact that monopoly income due to TRIPS-induced strengthening of patent legislation are commonly transferred from less-developed to a more-developed country such as *inter alia* from India and Brazil (less-developed) to USA and Germany (more developed).

Even though it is hard to see how the realization of the threat would prevent the exportation of medicinal products, such threats have been put on the tables in debates on exporting cheaper drugs from Canada to elderly citizens in the USA.¹³³ Bayer took up this action when the drug (Adalat) sales in France and Spain began growing in huge amounts for exporting the medicine with much larger prices to the UK. Bayer reacted by fulfilling orders only to a level determined by the orders of previous years because its medicinal product was under governmental price control. This case shows a very important point, that governmental control and court decision in that favor have a major role in controlling the access to medicine.

In the EU, there are interesting cases on *seizure of generic medicines in transit*¹³⁴ in the Netherlands and Germany, which went to the TRIPS council in 2009. The EC Regulation 1383/2003 gives the national customs officer the task to protect by police power the IP laws on goods going via transit through EU ports. This brings up the issue of the doctrine of police powers (Chapter 4). Using the powers bestowed on the custom-personnel and based on unclear patent-violations

¹³² *Bayer AG v Commission of the European Communities* (T-41/96) EU:T:2000:242 Judgement, ECR II-03383 (26 October 2000).

¹³³ *Hestermeyer* (n 96) 160-181.

¹³⁴ WTO, *Minutes of Meeting of the Council for TRIPS* (27–28 October & 6 November 2009).

possibilities, the police initiated temporary seizures and delayed nearly 20 shipments of medicines in transit. The major issue, as I see it, is that the medicinal products were lifesaving-medicines (AIDS, Alzheimer's disease, heart conditions, and blood pressure like losartan potassium), and the pharmaceutical corporations Sanofi-Aventis SA, Novartis AG, and Eli Lilly & Co requested that the shipments be detained. The Indian representative considered these actions "serious impediments to access to medicine" and a *violation of core principles of the TRIPS Agreement*. The case went to negotiations amongst the parties, where an understanding was reached with the EU over the pending complaint before the Dispute Settlement Body. The medicines were sent back to the source after months of delay. This case shows a very negative image of the pharmaceutical patent holding in EU.

The *AstraZeneca AB and AstraZeneca plc v European Commission (Case T-321/05)*¹³⁵ case and its appeal *C-457/10 P*¹³⁶, show how the ECJ favored keeping the medicine cost down and encouraging pharmaceutical innovation. AstraZeneca faced two charges: (i) misleading representations to the EU domestic patent offices, and (ii) the attempt to deregister the marketing authorizations for its drug (Losec) capsules in Sweden, Denmark, and Norway, and withdraw them from Scandinavia to launch another similar drug (Losec MUPS tablets). The ECJ judged that AstraZeneca was to pay 60 million Euros for misusing the patent system by unlawfully obtaining an SPC done with bad faith to block/delay generic competitors to Losec and keep its medicine price artificially high.¹³⁷ The judge stated:

*"[p]atent protection is central to the encouragement of innovation in economically viable conditions and it is therefore necessary to recognise a public policy imperative that undertakings should not be unduly deterred from registering patents in the pharmaceutical sector under the SPC scheme."*¹³⁸

An EU commissioner argued that: (i) support should be strong for patent protection of innovative products so that they get a return on the R&D investments; however, the legislator decides the length of the suitable protection period, (ii) generic medicines "*keep costs down*," and "*(...) competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals*."¹³⁹ The appeal case was dismissed by the ECJ upholding the previous decision.

One interesting case of the ECtHR is on CL in the EU; the *Smith Kline & French Laboratories Ltd. v. the Netherlands*¹⁴⁰ case, where the dispute was about a

¹³⁵ *AstraZeneca AB and AstraZeneca plc v European Commission (T-321/05)* EU:T:2010:266 Judgement ECJ (1 July 2010).

¹³⁶ *AstraZeneca AB and AstraZeneca plc v European Commission (C-457/10 P)* EU:C:2012:770 Judgement ECJ (6 December 2012).

¹³⁷ Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs' (15 June 2005) Press Release IP/05/737 Brussels 1.

¹³⁸ *AstraZeneca* (n 136) para 313.

¹³⁹ *Ibid.*

¹⁴⁰ *Smith Kline & French Laboratories Ltd. v the Netherlands* (decision No 12633/87) CE:ECHR:1990:1004DEC001263387 European Commission of Human Rights (4 October 1990).

CL granted by the Netherlands Patent Office, and there were two dependent patents, each owned by a disputing company. The ECtHR considered that such an act was lawful and supported the legitimate purpose of encouraging technological and economic development. The interesting issue is that the ECtHR applied the proportionality principle when deciding that “(...) *the owner of the dominant patent is entitled to royalties in respect of each compulsory licence granted under the legislation and receives reciprocal rights under the dependent patent.*” Hence, a balanced CL was granted, which could be used by analogy in many other cases.

In the EUCJ cases, (1) *Centrafarm BV v Winthrop BV, Merck & Co. Inc.*, (2) *Merck Sharp & Dohme Ltd. and Merck Sharp & Dohme International Services BV v Primecrown Ltd., Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd.*, (3) *Beecham Group plc v Europharm of Worthing Ltd.*, (4) *IHT Internationale Heiztechnik GmbH v Ideal-Standard GmbH*, and (5) *SA CNL-Sucal NV v HAG GF AG*¹⁴¹, the ECtHR prohibited the EU Member States’ banning of parallel imports originating within the European Communities under EC Treaty Articles 28 and 30.

In general, in EU cases and in cases involving EU pharmaceutical companies with businesses in other countries, we learn that there are considerations of two major regimes: patent law and Human Rights Law. However, reading the cases carefully (now after a period) with current life-demands in pandemics, one sees unclear arguments on why a law was favored over the other and the areas of intersection of regimes are still confusing for the reader. There is no practice of full mentioning of the Articles and provisions, where the two norms intersect i.e., in which set of provisions the conflict occurs. This is an issue I tackle via the defragmentation principle in Chapter 3.

2.3.2.2.2 *Caselaw under expropriation*

Caselaw provides a confusing issue in relation to changes in a domestic patent law and its interference with pharmaceutical patents granted before the patent law has changed (overlapping with access to medicine). In this subsection, I investigate the cases, where such an act by a State was considered by defendants (pharmaceutical corporations) tantamount to expropriation. As discussed in section 1.1, medicinal products are universal, and pharmaceutical corporations try to sell them in worldwide markets. This, sometimes, legally turns the pharmaceutical company to be considered as an investor in a foreign State, with the patent registration in the foreign State being its Foreign Direct Investment (FDI). Even within the EU, different Member States could be signatories of investment agreements. Although the EU law functions as a supranatural law for the EU states,

¹⁴¹ *Centrafarm BV v Winthrop BV* (C-16/74) EU:C:1974:115 Judgement EUCJ, ECR 01183 (31 October 1974); *Merck & Co. Inc., Merck Sharp & Dohme Ltd. and Merck Sharp & Dohme International Services BV v Primecrown Ltd., Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd.* and *Beecham Group plc v Europharm of Worthing Ltd.* (Joined Cases C-267/95, C-268/95) EU:C:1996:468 Judgement EUCJ, ECR I-06285 (5 December 1996); *IHT Internationale Heiztechnik GmbH v Ideal-Standard GmbH* (Case C-9/93) EU:C:1994:261 Judgement EUCJ, ECR I-02789 (22 June 1994); *SA CNL-Sucal NV v HAG GF AG* (Case C-10/89) EU:C:1990:359 Judgement EUCJ, ECR I-03711 (17 October 1990).

these bilateral agreements cause a huge controversial debate. The EU government and EU CJ stands on this are to cancel such intra-EU agreements¹⁴².

When it comes to the issue of pharmaceutical patents, the best case to learn from is *Eli Lilly and Company v Government of Canada (under NAFTA)*¹⁴³ that happened outside the EU, but it is important to analyze as it became famous, and one can learn from it for future EU conflicts. Three Canadian courts (provincial, appeal and supreme) had similar decisions. Then, the US pharmaceutical company, Eli Lilly, still wanted to file for an arbitration under NAFTA. Hence, there are four decisions that converge to similar conclusions. Eli Lilly owned patents for the Zyprexa and Strattera drugs that were registered in Canada before 1993. The Canadian patent law used to allow for CL until 1993. However, the effect of the TRIPS Agreement was large when Canada recognized it. Then, Canada introduced the concept of a ‘must-be useful’ invention to be patented, which was a controversial issue for pharmaceutical products. The company did not expect that the new doctrine would take effect on previously registered patents. All courts invalidated the patents on ground of no proof for the ‘must-be useful’ concept. Hence, the conflict was created by the intersection of three issues: (i) the investment agreement (NAFTA) protecting both, investment and patents in Chapters 11 and 17, respectively, (ii) the patent claims related to access to medicine, and (iii) the change in Canadian patent law while the patent was within its validity period.

Accordingly, the Canadian pharmaceutical company, Novopharm, obtained regulatory approval to market a generic medicine based on Zyprexa. Eli Lilly considered this retroactive effect of the court decisions on the previously granted patents as equivalent to an unlawful expropriation of its investment (patent registration) in Canada on grounds of the investment and patent definitions under NAFTA. Eli Lilly claimed that the court decisions were attributed to the Canadian State. The Canadian State (respondent) won all the cases, and the final tribunal decision took into consideration the applicable laws as: patent laws, the bilateral investment agreement/treaty (BIT), and Human Rights Law without much articulation.

The largest consideration by all the courts and arbitration tribunals seem to take patent law as the major applicable law including the changes being allowed. This poses a question on the fragmentation of the three laws (patent law, BIT, and IHRL) to be ‘not overlapping’. The thesis analyzes this fragmentation issue and its effect on court decisions in Chapter 3. The courts, however, show a mindset considering the public interest (‘everyone’) rights (for health). In fact, some comments were mentioned about the fact that keeping non-useful patents in Canada would stop research in this field as the IPR may conflict with current and future research related to the right ‘to health.’ For the sake of people’s health and *ordre*

¹⁴² EC ‘EU Member States sign an agreement for the termination of intra-EU bilateral investment treaties’ (5 May 2020) Financial Stability, Financial Services and Capital Markets Union.

¹⁴³ *Eli Lilly and Company v Government of Canada*, UNCITRAL, ICSID Case No UNCT/14/2, Award (16 March 2017); North American Free Trade Agreement (signed in 1992, entered into force on 1 January 1994) (‘NAFTA’).

public for better and faster research in healthcare products, the patents were invalidated on grounds of the new ‘usability’ criteria.

This is a very inspiring case for the EU now and in pandemics in general, where any patent for vaccines can hinder the access to the vaccine (timewise and research-wise). In my opinion, if a technical lack ‘to prove usability of a patent’ exists, then this should be corrected in a way where the courts have a chance to request amending patent descriptions, and not just directly invalidate the patents. This case presented intriguing reasoning from judges to dig deep for Human Rights goals within the fragmentation of legal instruments. On the long run this creates a problem of revenue for pharmaceutical companies i.e., lack of encouragement and less ability to conduct new research.

In comparison with the judgement of the EUCJ in the *Daichii Sankyo*¹⁴⁴ case on a similar issue on patents older than the Lisbon Treaty, one sees a different viewpoint of the EUCJ than the Canadian courts, where it did not take the decision with retrospective effects stating:

*“[T]he TRIPS Agreement obliges members of the WTO to make it possible to obtain patents for inventions of pharmaceutical products. That obligation cannot, however, be understood as meaning that members of the WTO which, in a period anterior to the date of that agreement’s entry into force, excluded protection of inventions of pharmaceutical products claimed in patents granted for inventions of processes of manufacture of those products must, from that date, regard those patents as covering those inventions of pharmaceutical products.”*¹⁴⁵

For EU pharmaceutical companies, some of the most famous cases are the Novartis (Switzerland) cases: *Novartis AG v Union of India & Others*, and *Novartis AG warning the Colombian government about the investment treaty*.¹⁴⁶ Novartis owns patents for the Glivec drug to treat cancer in many countries including India and Colombia. In fact, in the latter case, Novartis threatened to resort to international investment arbitration on grounds of an alleged violation of the Swiss-Colombian BIT.

The patents put a huge increase on prices. The question again is whether States should invalidate such critical patents or allow CL? The WTO states that CL “*is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.*” It is considered a flexibility. Many countries allow for CL, but under the TRIPS Agreement this issue was regulated as discussed above in the *Eli Lilly v Canada* case. Millions of people were affected, where only one in a thousand had access to the antiretroviral medicines against HIV. More than eight-thousand humans died of HIV/AIDS daily. Conflicts on HIV-related medical patents came after the adoption of the TRIPS Agreement. Some nations went on with revoking/invalidating

¹⁴⁴ *Daichii Sankyo* (n 112).

¹⁴⁵ *Ibid* para 82.

¹⁴⁶ *Novartis AG v Union of India & Others* (CA no. 2706-2716) Supreme Court of India (1 April 2013); Public Eye, ‘Colombia: Leaked documents reveal Novartis threatened govt. with intl. investment arbitration over licensing of pharmaceutical patents’ (12 April 2017) Business & Human Rights Resource Center.

patents, and others reverted to the CL. With all this in mind, one way to try to tackle this challenge would be to defragment international law so that it may aid tribunals to reach a balance, which is discussed in the next chapter.

3 Indivisibility or not of applicable laws?

“Divide each difficulty into as many parts as is feasible and necessary to resolve it.”
Rene Descartes (1596-1650)

To serve the purpose of the thesis, this chapter investigates whether there should be full unity or a level of divisibility between applicable laws in the realm of the conflict. It examines the reorganization of the interaction between the TRIPS Agreement and IHRL. Section 3.1 discusses applicable laws within the conflict. Section 3.2 explains unity and fragmentation of laws. Section 3.3 presents reorganizing the understandings of the legal issues under the proposed defragmentation.

3.1 Applicable laws hierarchy

The issue of the applicable laws to be considered by courts in this conflict is complicated because judges must decide which instruments are applicable and then form a hierarchy based on the case. In practice, defendants of the right to ‘access to medicine’ depend on the obligations to protect the right ‘to life’ and ‘to healthcare/public health’ in arguing against patent-owners (pharmaceutical companies). It is within the powers of the court to neglect IHRL, consider it as a fact, or leverage its value to the highest of legal instruments in the conflict. Acting in one of these different ways of consideration, the applicable regimes automatically garner a degree of unification or separation.

As discussed in section 2.3.2, the TRIPS Agreement could be part of the IP regime in a State. One possible way to better consider this applicable law is to defragment TRIPS understanding within the conflict to be partly falling within the IP regime and partly in the world trade regime. The TRIPS Agreement is not totally for patent protection nor IPR. The legal justification is clear in the fact that the TRIPS Agreement is one of WTO agreements. Consequently, it is under the rules of the WTO, which is to a large part concerned with trade. In the interaction with Human Rights, the WTO order (trade-based regime) intersects with a regime that is moral-based (IHRL). When the clash occurs as such, invalidating current practice shows that an agreement on (or an organization of) hierarchy between the two is underdeveloped.¹⁴⁷

¹⁴⁷ Hestermeyer (n 96) 206.

Previous research on this hierarchy considers *inter alia* two levels: normative (prioritizing morals and IHRL), and factual (prioritizing business interests). It leads to complications. Up till now, in most cases, the claim of a leveraged normative of IHRL raises emotional but not legal support. States oftentimes look at the economic aspects more than Human Rights. I consider a defragmentation of laws so IHRL could be valued parallel to the WTO regime.

3.2 Strengths and weaknesses of WTO and TRIPS

The WTO regime has a strength in its far reach due to two reasons: (i) many States are members, and (ii) trade touches most life aspects. At the same time, this strength becomes a weakness in conflicting interests, because when the WTO touches upon other spaces, any other legal system becomes a potential collision. This is because other systems also affect trade. For instance, in the cases of *seizure of generic medicines in transit*¹⁴⁸ in EU ports, although the EU police doctrine considered this act as lawful, it did touch on the WTO regime and affect trade relations. Hence, trade rules and trade sanctions can touch on many aspects in many States.¹⁴⁹

One of the problems in court decisions over the past decades is that there are sometimes total disconnection and other times some linkage between TRIPS/WTO and IHRL. This thesis deduces that they are not totally disconnected nor are they totally coinciding. As the previous chapter shows in the provisions from both regimes, they do interest in some areas discussing similar protections and obligations. A governmental or business understanding of IPR might not go in harmony with ‘access to medicine’ obligations or investment law (pharmaceutical companies being investors). Within the IHRL, the UN Charter Chapter VII of the Security Council has the right to question actions of businesses and States under Human Rights or Humanitarian Law.

Due to the delimitations of this thesis, we only consider legal regimes and not pharmaceutical companies’ rules. Many states are bound by legal instruments to be applied at the same time in the same place. How can pharmaceutical patents be enforced at times of war/pandemics if IHRL requires full attention to the right ‘to access medical goods in the best attainable way’? Best attainable ways include speed and quality without discrimination. Do we see this happening now in the COVID-19 pandemic, in all signatories to these two legal norms? Should not this prioritize IHRL over any regime? The answer is ‘yes,’ but how and to which extent?

To come to a solution, these regimes need defragmentation under pandemics. A good start is that although the TRIPS Agreement obliges WTO Members to introduce patents, it allows them to make use of certain exceptions. The TRIPS

¹⁴⁸ *WTO* (n 134).

¹⁴⁹ Steve Charnovitz S, ‘Trade Measures and the Design of International Regimes’ in Steve Charnovitz (ed), *Trade Law and Global Governance* (Cameron May 2002) 27; David W. Leebron, ‘Linkages’ (2002) 96 *AJIL* 5.

Agreement gives its signatory an option. As patents unjustifiably interfere with access to medicine at times of disasters/pandemics, nations and governments could only escape the verdict of violating their IHRL obligations by invoking the exceptions. This flexibility of the TRIPS Agreement is a strength for all parties. The TRIPS Agreement flexibilities generally do not provide for the exclusion from patentability, but rather for a limitation of patent rights.

3.3 Unity, fragmentation, and defragmentation of the regimes

3.3.1 Unity

Unity in the context of unification of regimes refers to the substantive unity preventing conflicts between norms.¹⁵⁰ Prost divides it to six types of unity: (i) material unity, (ii) formal unity, (iii) cultural unity revolving around two subtypes of (iii.1) a common narrative/postulate and (iii.2) grammatical rules, and (iv) logical unity that encompasses (iv.1) axiological unity and (iv.2) epistemological unity.¹⁵¹ Given the breadth of laws globally and even within the EU States with the variations within bilateral agreements in different languages, it makes unification prohibitively hard for all applicable laws. I find the concept of Unity interesting for theoretical discussions. However, in practical cases especially in pandemics, where we need quicker decisions, it would not aid legislators or courts for faster and better understanding of the intersection of conflicting norms. The unification under any of Prost's concepts would not serve the goal of the thesis.

3.3.2 Fragmentation

The understanding that this thesis discusses for fragmentation is the divisibility of regimes i.e., creation of special norms (*lex specialis*) in the legal space of the conflict. The *lex specialis* are: IHRL and patent law. A lot of research work on fragmentation has been conducted. If there were no differences between norms, then one big document can include them all. It is not possible to prove whether the regimes converge to the same big legal space without differences. Divergence exists. There should be a balance made between diversity and uniformity, where we can keep the norms as units. If practitioners consider there is total independence between the special norms, then we talk about full fragmentation, which goes again with what we see in some case-law (Chapter 2). Total independence from moral obligations at times of pandemics means that only the TRIPS Agreement and national patent laws apply.

How do we reflect IHRL in legal decisions? In caselaw in Chapter 2, some judges seem in favor of one regime over the other. In pandemics, IHRL must be

¹⁵⁰ Mario Prost, *The Concept of Unity in Public International Law* (Hart Publishing 2012) 46-48.

¹⁵¹ *Ibid* Chapters 2, 4-7.

considered of the higher rank, otherwise, we go against all the Articles that protect the right to ‘access to medicine’ and to ‘prevent epidemics’ (Article 11 European Social Charter)¹⁵². For such a reason, the thesis proposes a defragmentation of the applicable laws.

3.3.3 Defragmentation

Defragmentation is reorganizing the overlapping laws. Caselaw shows decisions sometimes in favor of one law over the other without any consistency in the hierarchy considerations or the explanations of the judgements. One of the reasons is that many tribunals have experience in one law more than the other, or an inclination to a regime or policy. However, as shown above, Articles in the TRIPS Agreement and IHRL instruments exist for the cases of the right to ‘access to medicine’ even though they require some interpretation. Chapter 2 provides clear interpretation and deduction on this right from the specific provisions.

Using these detailed explanations, the proposed defragmentation sheds the light on the fact that the TRIPS Agreement should not be considered as only an IPR instrument, nor should it be thought of as originating from the legal concept of protecting patents, but rather stemming from a trade purpose. The TRIPS Agreement is a WTO regime, so even in its protection for patents, it is protecting the minimum standard for authors (pharmaceutical corporations) so that trade relations go more smoothly. Although it is used to harmonize EU patent legal systems and EUCJ decisions, a big part of the TRIPS Agreement is still a trade part. Defragmentation considers the trade part not intersecting (thus not conflicting) with the IHRL and the right to ‘access to medicine’. This does not mean that the TRIPS Agreement and IHRL are not intersecting at all. These two regimes intersect in the part related to patents in the TRIPS Agreement, which is Section 5 TRIPS (Articles 27-34). Therefore, the defragmentation considers intersection with Section 5, where the most relevant point of intersection is Article 28 on patent protection.

On the other hand, IHRL instruments intersect with this part of the TRIPS Agreement in the following few Articles: Articles 4 ICESCR, Article 15 ICESCR and Article 27 UDHR, Article 4 ICCPR, Article 35 EU Charter of Fundamental Rights, Article 2 ECHR (related to Article 11 ESC), and Article 6 ICCPR on protection of the right ‘to life’. If practitioners/courts focus on the abovementioned Articles of the TRIPS Agreement and IHRL instruments, then a well-defined frame of intersection between the different laws is constructed. This defragmentation includes the colossal thinking of these specific articles within putting the right to ‘access to medicine’ as a Human Right at the highest rank when it comes to lifesaving medicine (vaccines, antivirals, and antiretrovirals) in pandemics. Caselaw, where claims of expropriation are filed teaches that in such cases, the legal space would include bilateral agreements only when a patent is

¹⁵² *ESC* (n 81) art. 11.

defined in this agreement under the section of investment. This makes a pharmaceutical company (that owns patents) an investor in the State, where the patent is registered.

In such cases, besides all the above TRIPS Articles and IHRL, the bilateral agreement (BIT) becomes part of the defragmented legal space. Although this model of thinking about the legal spaces shows a clear intersection of subsets (Articles) of the regimes, it does not surely mean that within the intersection areas there would always be conflicts. For instance, the UDHR instrument does not necessarily always interact with patent definitions in BITs. In this way, the defragmented model can go more in harmony with the practical reasoning in caselaw since it does not theoretically say there is a 'unification with no conflicts between the rules' or there is 'fragmentation with prevention of regimes to conflict'. Nonetheless, it says there are overlapping areas.

Regarding priorities (hierarchy), caselaw observation shows that each case considers its own hierarchy. For instance, Article 11 of the European Social Charter (ESC) is given less hierarchy than any Article in ICESCR or ICCPR due to that they are higher international conventions. However, Article 11(3) ESC considers protection in cases of epidemics, which means a new look at this Article should be considered. The next issue to consider is if this could work well with having the Biotechnology Directive¹⁵³ alone in the EU. The answers based on caselaw of the EUCJ, is 'no.' Hence, this defragmentation calls upon the need for a stronger EU patent law, namely a unified patent law. This defragmentation would make the factual hierarchy prioritize the value of a human over monetary value while keeping patent protection relevant i.e., achieving a balance. We discuss other issues to seek a balance in Chapter 4.

¹⁵³ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (6 July 1998).

4 Balancing pharmaceutical patents and medicine accessibility

*“There's a way to do it better - find it.”
Thomas A. Edison (1847 – 1931)*

This chapter seeks a balance. Section 4.1 introduces the topic. Section 4.2 discusses previous work on ways to better Human Rights protection. Section 4.3 articulates located problems and recommendations for the sought balance.

4.1 Introduction

The balance between patents and IHRL is not possible to achieve when one side of the scale is prioritized. We, humans, create those priorities. There could be a better way to do it; we just need to ‘find it.’

One hard reality is changing the behavior of governments or investors (pharmaceutical corporations). The UN has conducted initiatives since the 1970s to address the issue of Human Rights and innovation (patents). Its General Assembly struggled (from 1970s to 1980s) discussing the Code of Conduct for Transnational Corporations.¹⁵⁴ To try to better the behavior of governments on one side and businesses on the other, the UN adopted the Global Compact¹⁵⁵ principles to encourage businesses to work towards globalization in a ‘responsible way.’¹⁵⁶ Nearly ten thousand companies accepted the ten principles of Global Compact by 2018, with the motto ‘business as a good force.’¹⁵⁷ The first two principles are of interest to this work:

“Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and

Principle 2: make sure that they are not complicit in human rights abuses.”¹⁵⁸

¹⁵⁴ Ibid.

¹⁵⁵ See the UNGC, ‘The Ten Principles of the UN Global Compact’ (UN) <<https://www.unglobalcompact.org/what-is-gc/mission/principles>> accessed 30 April 2020.

¹⁵⁶ See Hurst Hannum, *Rescuing Human Rights, A Radically Moderate Approach* (Cambridge University Press, 2019), where the 1999 Global Compact Principles were announced by the UN Secretary-General at the time, Kofi Anan.

¹⁵⁷ Ibid.

¹⁵⁸ UNGC (n 155).

Without a balanced view on TRIPS/WTO and IHRL in the conflict during pandemics, nothing significant would be achieved. Hence, it is good to utilize the defragmentation concept addressed in Chapter 3. Some previous work was done in this regard and presented below.

4.2 Previous methods to leverage Human Rights protection in the conflict with patents

The previous work paves the way for possible recommendations.

4.2.1 Legal instruments

This section investigates two main instruments namely, the TRIPS Agreement and ICESCR.

4.2.1.1 TRIPS flexibilities

The TRIPS Agreement allows flexible measures to limit the rights of patent owners. The right to ‘access to medicine’ can be used as an argument in the interpretation of the flexibilities.¹⁵⁹ The right to access to medicine is one argument amongst many in the flexibility interpretation.¹⁶⁰ For instance, the first flexibility point is in Article 6 TRIPS that covers the patent exhaustion:

“[f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”¹⁶¹

Some courts interpret it as an ‘agreement to disagree’ making each WTO-Member free to decide whether to follow the principle of international exhaustion of patents (in imports) or not. A good example is in the two cases: *Mag Instrument Inc. v California Trading Company Norway, Ulsteen* (in the EFTA court), and *Bundesgericht (Switzerland), Kodak SA v Jumbo-Markt AG*.¹⁶²

The second flexibility is in Article 30 TRIPS:

“Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

This article allows exceptions to protect patents. As the heading of Article 31 of the TRIPS (“Other Use Without Authorization of the Right Holder”) and its

¹⁵⁹ *Hestermeyer* (n 96) 229 ff.

¹⁶⁰ *Ibid.*

¹⁶¹ *WTO* (n 9) art. 6.

¹⁶² *Mag Instrument Inc. v California Trading Company Norway, Ulsteen* (E-2/97) E1997P0002 EFTA (3 December 1997); *Bundesgericht (Switzerland), Kodak SA v Jumbo-Markt AG*, 31 IIC 1018, 1022 (2000).

footnote (“Other use”) indicate, the exceptions of Article 30 apply without authorization of the patent holder. Accordingly, they can limit the effects of a patent monopoly, hence lower the product (medicine) prices. The wording is not precise, but this imprecision paves the way for an entry point to use the right ‘access to medicine’.

The third point is Article 27(1) TRIPS, which states,

“(...) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”¹⁶³

Some States argue that the non-discrimination rule is subject to the exception of Article 30 TRIPS, thus establishing separate rules for pharmaceutical companies.¹⁶⁴ The *travaux préparatoires* show that this non-discrimination rule was adopted to prevent automatic CL on pharmaceuticals and must be applicable to Article 31 TRIPS, hence to Article 30 due to their link.¹⁶⁵

The fourth point is the TRIPS Agreement allowing revocation of patents via Article 32:

“[A]n opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.”¹⁶⁶

An important TRIPS flexibility is Article 8 allowing amendments to protect public health; hence this adds a possibility to ask for amending the TRIPS Agreement in cases of pandemics to protect the obligation of ‘access to medicine’:

TRIPS Article 8

“Principles.

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

4.2.1.2 IHRL provisions

Article 15 ICESCR tries to achieve a balance between the protection of the interest of the inventor and public access to the invention as indicated both by Article 15(1)(a), 15(1)(b), and paragraph 2 of the provision.¹⁶⁷ However, Article

¹⁶³ WTO (n 9) art. 27.

¹⁶⁴ Hestermeyer (n 96) 237-238.

¹⁶⁵ Ibid.

¹⁶⁶ WTO (n 9) art. 32.

¹⁶⁷ Committee on Economic, Social and Cultural Rights, General Comment No 17, para 2; Peter Drahos, ‘The Universality of Intellectual Property Rights: Origins and Development’ in WIPO (ed), *Intellectual Property and Human Rights* (Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights, Geneva, November 9, 1998, published 1999) 24.

15(1)(c) ICESCR enjoys less legal support than the other provisions of the Article. This issue does not support a hierarchy. The *problem location* here is that this Article has been made dormant, and a practical solution is needed to put it in use again.

4.2.2 Compulsory License (CL)

The most appealing legal solution for States to lower medicine prices are CLs granted by domestic courts. CLs do not require any consent from the pharmaceutical corporations (patent owners). With a CL the court does not invalidate the patent as in the *Eli Lilly* case, but it authorizes other parties to produce drugs, so the government meets its obligation of accessibility. The CL solution advantages are threefold: (i) safeguards the drug supply (access to medicine), (ii) promotes local competition, and (iii) supports local industry.¹⁶⁸ States that have large pharmaceutical corporations take a restrictive approach such as *inter alia* the USA proposing a ban on CLs.¹⁶⁹ The States with and against CL depended on TRIPS Article 31 and Article 31 *bis*,¹⁷⁰ as follows:

TRIPS Article 31

“Where the law of a Member allows for other use (7) [than that permitted by Article 30 of the TRIPS Agreement] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following shall be respected: (...)”

The TRIPS Agreement was amended on 23 January 2017 by adding Article 31 *bis*, an Annex, and an Appendix. The amendments provided legal basis for a WTO Member State to grant exclusive CLs for producing generic medicines as well as exporting them to other WTO Member States, which do not have the possibility to purchase the branded medicine or produce them locally.

When a measure is not justifiable by Article 30 TRIPS, it is checked with Article 31.¹⁷¹ Nonetheless, most patent laws in industrial States (including USA) include provisions to grant CLs. Courts already granted CLs in antitrust cases.¹⁷² In some cases, CLs push the pharmaceutical companies to lower their branded-drug price.¹⁷³ Some researchers see that CLs may only be granted in cases of patent

¹⁶⁸ Hestermeyer (n 96) 239 ff.

¹⁶⁹ Focke Höhne, ‘TRIPS’ in Jan Busche and Peter T. Stoll (eds), *TRIPs - International and European Intellectual Property Law, Commentary* (Carl Heymanns Verlag 2007) art. 31 para 3.

¹⁷⁰ WTO (n 9) art. 31, art. 31 *bis* of the TRIPS Agreement as amended on 23 January 2017.

¹⁷¹ Contra D. Gervais, *The TRIPS Agreement. Drafting History and Analysis* (2nd ed 2003).

¹⁷² F-K Beier, ‘Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law’ (1999) 30 IIC 251, 259-260.

¹⁷³ *Ibid* 260.

abuse by the business based on Article 5A(2) of the Paris Convention¹⁷⁴, applicable via Article 2(1) TRIPS permitting Members to grant CLs to ‘prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent’.¹⁷⁵

Moreover, Article 8(1) TRIPS (see above) requires Members to show that CLs are necessary for *ordre public*.¹⁷⁶ Even though CLs lower drug prices, they suffer weaknesses and lead to problems since they may discourage pharmaceutical companies from dealing with a certain region or push them to find other ways (political avenues) to fix their prices. If, during the COVID-19 outbreak, States inform pharmaceutical corporations of their will to render CLs, such companies would stop their R&D programs to produce vaccines. Hence, a CL is not an optimal and ‘always right’ solution on the long run for pandemics.

4.2.3 Principle of proportionality

The principle of proportionality stems from justice and Human Rights and it is borrowed to seek a balance. It was initiated as an idea in Aristotle’s Nicomachean Ethics (Book V) in order to serve human-good and be just via applying the right ratio. It evolved to the concept of balancing interests and became a general principle of law. In patent law it aids in seeking balance by finding the relationship between the end-result and the means to reach it. The principle helps conflict resolution to be conducted with less difficulty via balancing public interest arguments with the investors’ (pharmaceutical companies) rights. It ‘demands there should be a reasonable relationship of proportionality between the means employed and the aim sought to be realized.’ To apply this principle, three procedures need to be executed.

First, courts need to evaluate if the measure was suitable for the aim. The judges would check if there was a logical and acceptable link between what one party conducted and what its final goal was e.g., access to medicine.

The second procedure is the evaluation if the goal could have been accomplished in a less intense measure or not.

The third (final) procedure is the actual evaluation of the proportionality between the measure and the sought benefit.

Good examples to follow are the *Azurix Corp. v The Argentine Republic*¹⁷⁷ and *Bivater Gauff (Tanzania) Ltd. v United Republic of Tanzania*¹⁷⁸ cases, where the judges cited the ECtHR on the need of a reasonable relationship between the burden

¹⁷⁴ Paris Convention for the Protection of Industrial Property, 21 UST 1583, 828 UNTS 305 art. 5A(2).

¹⁷⁵ Richard P. Rozek and Renee L. Rainey, ‘Broad-Based Compulsory Licensing of Pharmaceutical Technologies. Unsound Public Policy’ (2001) 4 J World Intell Prop 459, 468.

¹⁷⁶ ER Gold and DK Lam, ‘Balancing Trade in Patents- Public Non-Commercial Use and Compulsory Licensing’ (2003) 6 J World Intell Prop 5, 22–23.

¹⁷⁷ *Azurix Corp. v The Argentine Republic*, ICSID Case No ARB/01/12, Award (English) (14 July 2006).

¹⁷⁸ *Bivater Gauff (Tanzania) Ltd. v United Republic of Tanzania*, ICSID Case No ARB/05/22, Award (24 July 2008).

imposed on the foreign investor and the interest that the enforcement measures intend to achieve.

Although this principle was utilized in ECtHR, still its use causes confusion for some disputing parties or judges due to the practical difficulty of balancing between private interests of patent-owners (pharmaceutical companies) and public interests.

4.2.4 Exception clauses

Exception clauses in the TRIPS Agreement stem from an idea borrowed from the trade law instrument GATT¹⁷⁹. Unfortunately, it does not refer to Human Rights since it prioritizes business. Exception clauses may fill this gap by writing clear clauses when a State can take exceptional regulatory measures to protect its public interest during pandemics without being held responsible for affecting interests of pharmaceutical corporations. It adds a maneuvering flexibility, which is crucial in cases of threats of legal obligations towards Human Rights e.g., the right to ‘access to medicine.’ Nonetheless, there is not a wide implementation of exception clauses.

In the EU only Norway utilizes them. Outside the EU, Canada and USA clearly include articulated exception clauses in their investment agreement models. They mention that nothing in the Agreement shall be construed to prevent a party from adopting measures “*necessary to protect human, animal or plant life or health.*” This type of exception clause achieves a kind of balance between the private interests of pharmaceutical companies and the public interest in the right to ‘access to medicine’.

4.2.5 Doctrine of police powers

In this doctrine, Police Powers are viewed as the powers granted by the Constitution of the State “*in order to govern, establish, adopt as well as enforce laws that are designed for the protection as well as preservation of the public health.*”¹⁸⁰ In a similar way of the exception clauses, Canada and the USA have Model treaties that include clauses to allow for the police powers doctrine to be considered and used in favor of the State. This doctrine is as useful as the exception clauses, but it is limited till now to falls under some cases.

4.2.6 Corporate responsibility

Based on the UN Principles mentioned in section 4.1, pharmaceutical corporations have responsibilities towards people. In the current COVID-19 vaccine critical-need, invoking the right to ‘access to medicine in pandemics’ as such cannot be achieved if the company/investor only sees monetary dimensions without

¹⁷⁹ General Agreement on Tariffs and Trade (1994) (“GATT”).

¹⁸⁰ The Law Dictionary, “What is Police Power” Free Online Legal Dictionary 2nd ed, Featuring Black’s Law Dictionary <<https://thelawdictionary.org/police-power/>> accessed 12 May 2020.

giving regard to the human value. Patients and governments, then, would face a huge life problem.

There is still debate on whether a business can bear responsibilities like humans do. According to UN representatives, “*it does not seem that the international human rights instruments discussed here currently impose direct legal responsibilities on corporations.*”¹⁸¹ I believe that in life-critical matters they do bear responsibilities. However, the important issue is for tribunals to see this point too. The OECD Guidelines for Multinational Enterprises have “*recommendations addressed by governments to multinational enterprises [and] provide voluntary principles and standards for responsible business conduct consistent with applicable laws.*”¹⁸²

To solve this problem, this research recommends clearer clauses for obligations of pharmaceutical corporations in pandemics, like COVID-19, to give away the secrets of the vaccines/antivirals. At the same time, the clause can provide that after the pandemic threshold is passed, the company that gave the secret would be granted rights to seek monetary refunds from States and specific organizations like the WHO. This needs attention before the next COVID-19 vaccine/antiviral is out.

4.2.7 Pricing vs R&D

The crux of the matter lies in high prices relative to the financial conditions of patients (e.g., USA), EU States, and other countries. In cases of pandemics, the time and cost needed for giving the vaccine to all patients at once can be higher than budgets might allow. If the R&D phase of pharmaceutical company (around 5-10 years with hundreds of million Euros/USD spending) is supported by large governmental budgets with clear legal provisions to protect pharmaceutical corporation interests and patients’ lives, then this can sooth the pandemic holocaust. If not, imposing CLs or obliging pharmaceutical corporations to give it away for free may shutdown the whole R&D. Thus, the problems are the time and cost.

If pharmaceutical R&D costs are lowered by help from the government and the WHO, the price could and would be lowered. Tackling this business issue is not easy, but it is doable especially with the interest and strong will during pandemics. Hence, I suggest provisions that clearly oblige States in cases of pandemics, such as the Coronavirus outbreak, to invest in pharmaceutical corporations. This means the new laws will make it an obligation and not a recommendation. This calls for international institutions also to help creating or phrasing such new provisions for the COVID-19 and future pandemics.

¹⁸¹ See John Gerard Ruggie, *Business and Human Rights: Mapping International Standards of Responsibility and Accountability for Corporate Acts* (OCHR, 2007) UN Document A/HRC/4/035 para 20.

¹⁸² OECD, *Guidelines for Multinational Enterprises* (OECD, 2000) Preface, para 1.

4.3 Locating problems and recommendations

Locating a problem is crucial before trying to find solutions. This section deduces ideas from all the previously discussed points in the conflict and presents the location of some problems that need attention.

The *first problem location* is in the *justification* used by pharmaceutical companies, in many cases, that patents for highly priced medicine aim at creating the incentive for inventors to keep conducting pharmaceutical research, without which many medicinal products would not be ‘available’ (see Chapter 1). They refer to having fulfilled the obligation of ‘availability’ of medicine. The problem here is the rationale. Although it supports the first obligation (*availability*), it goes against the second obligation (*accessibility*). This issue needs to be addressed by judges and practitioners, and an attention to it is needed from governments, the EU, WTO, and other organizations.

The *second problem location* that needs revisiting is the *negligence* of the right recognized in Article 15(1)(b) ICESCR for everyone “[t]o enjoy the benefits of scientific progress and its applications.” This right has been dormant and not used for decades. This problem needs attention to support ‘access to medicine’.

The *third problem location* is related to *fragmentation* of laws in many cases, where patent laws and IHRL instruments are not totally studied for their intersection/overlap. There is a need to attend to this problem by the proposed defragmentation principle (discussed in Chapter 3). It simplifies the understanding on where to look in this conflict. The proposed defragmentation considers the two regimes intersecting in few articles taking away all the trade issues in WTO/TRIPS. Hence, practitioners and courts better focus on: (i) Section 5 TRIPS (Articles 27-34) with significant regard to Article 28, and (ii) Articles in IHRL instruments namely, Article 15(1) ICESCR with Article 27 UDHR, Article 2 ECHR (based on Article 11 of the ESC), Article 35 EU Charter of Fundamental Rights, Article 4 ICCPR on limitation clauses, Article 4 ICESCR, and Article 6 ICCPR protecting the right ‘to life’ by law.

Besides locating problems, this section presents further *recommendations* based on: (i) previous work that this thesis adopts, and (ii) new ideas. Before articulating the recommendations, it is advisable to study the recommendations made by the EUCJ for copyright in relation to Human Rights, so we learn- by analogy- how to strike a balance. The three EUCJ cases *Funke Medien NRW GmbH v Federal Republic of Germany*¹⁸³, *Pelham GmbH, Moses Pelham, Martin Haas v Ralf Hütter, Florian Schneider-Esleben*¹⁸⁴, and *Spiegel Online GmbH v Volker Beck*¹⁸⁵, have a relevant common issue. They requested the EUCJ to balance between Copyright (IPR) and fundamental rights. By analogy, this thesis researches the balance between patents (IPR) and fundamental Human Rights. In these three cases, we learn the recommendation of the EUCJ that the EU Charter contains rights corresponding

¹⁸³ *Funke Medien NRW GmbH v Federal Republic of Germany* (C-469/17) EU:C:2019:623 Judgement EUCJ (29 July 2019).

¹⁸⁴ *Pelham GmbH, Moses Pelham, Martin Haas v Ralf Hütter, Florian Schneider-Esleben* (C-476/17) EU:C:2019:624 Judgement EUCJ (29 July 2019).

¹⁸⁵ *Spiegel Online GmbH v Volker Beck* (C-516/17) EU:C:2019:625 Judgement EUCJ (29 July 2019).

to those guaranteed by the ECHR. Moreover, Article 52(3) of the Charter seeks to ensure consistency between the rights contained in it and those guaranteed by the ECHR, without affecting the autonomy of the EU law or ECJ. The difference here is that in patents, we only have a Biotechnology Directive in the EU, which is not so clear on the issue of the right to ‘access to medicine’. However, we learn- by analogy- to give recommendations that do not harm any side of the balance and that respect the autonomy of the EU laws. Accordingly, from the *previous work on solutions* discussed in section 4.2, the I adopt some solutions and add relevant *recommendations* that are discussed below.

First, I adopt utilizing the available TRIPS flexibilities from the patent law side and Article 15 ICESCR from the IHRL side.

Second, I adopt the principle of proportionality and recommend its use by practitioners. However, I add my own view on the matter leveraging the practical use of the principle via the help of law experts and economists to formulate a benchmark method.

Third, I adopt the solution of exception clauses and propose that the EU parliament, government, and WTO create legal templates with specific clear clauses for protecting Human Rights without threatening a State to become attributed to expropriation.

Fourth, I adopt the principle of police powers of States when protecting Human Rights, but I recommend adding clearer clauses to control it.

It is worth mentioning that regarding CLs and pricing, I do not fully adopt this solution since many issues remain hard to decide on, and they are case-dependent. My take on this method is that although patent revocation is harder than a CL, CL is tough on pharmaceutical corporations in cases of pandemics since pharmaceutical companies invest hundreds of millions in one year sometimes (as happening with the COVID-19 investments). With this, I move to the *second part of recommendations* coming from new ideas in this research and calling on governments (including the EU), financing institutions (including the European Investment Bank), WHO, WTO, and pharmaceutical corporations to give them attention.

Fifth, I recommend utilizing the proposed defragmentation of laws as discussed in Chapter 3, especially during pandemics. This defragmentation clearly lists the provisions needed to look at when there is a clash of laws. Thus, it would speed up the solution time. We cannot wait to solve problems during pandemics in real-time. Pharmaceutical corporations invest huge amounts to get the vaccine with their incentive of a large RoI, and humans need the vaccine/antiviral. To balance these issues at such times, like the COVID-19 outbreak, R&D costs must be lowered for pharmaceutical companies, and not via threatening with CLs. Hence, governments (including the EU), WHO, and other organizations must compensate pharmaceutical companies. To do so, legal rules must be in place before a pandemic occurs. We cannot afford having real-time solutions by creating laws during the crisis. This calls for creating legislations and provisions that are ready to invoke in times of pandemics i.e., provisions that are specifically made for pandemics. This could include amending the TRIPS Agreement via

invoking Article 8(1) TRIPS to reformulate/add provisions based on public interest and need. In this respect, I recommend including clauses to invoke- *during pandemics*- for protecting the human right to ‘access to medicine’. Examples of such amendments have occurred within the WTO such as *inter alia* the Doha Declaration and the South Africa pharmaceutical trial with the decision in 2005 to amend the TRIPS Agreement.¹⁸⁶ I also recommend WTO provisions to invest in pharmaceutical R&D processes to lower prices. Many States affirmed commitments to including Human Rights in WTO instruments, but nothing has materialized yet. I recommend that the current COVID-19 pandemic to be used as a motivation to put it in law, because it is still up to the judges’ interpretation to bring pharmaceutical corporations or governments to their legal obligation of ‘access to medicine’.

Sixth, this recommendation relates to clauses for *exceptions on patents*. This has been a discussion in many IP circles since the COVID-19 outbreak. I recommend the following solution of a needed provision for pharmaceutical companies (ready for invoking *during pandemics* only): (i) to have their R&D funded by governments (including the EU), the EU Investment Bank, or IP finance organizations (e.g. Almi Företagspartner AB and Almi Invest, Sweden) with a clear indication on how much the business can profit (to control drug prices), and (ii) to be given IPRs as special-patent rights granted *after* the pandemic critical-time has passed. What we witness nowadays in the EU is a budget proposal by the Commission (Horizon Europe) that should “*scale up the research effort for challenges such as the coronavirus pandemic, the extension of clinical trials, innovative protective measures, virology, vaccines, treatments and diagnostics, and the translation of research findings into public health policy measures*”.¹⁸⁷ Moreover, the EC published (on 27 May 2020) a roadmap for a pharmaceutical strategy for Europe, soliciting that the “*overall goal of this strategy, scheduled for adoption by the end of the year [2020], is to help ensure Europe’s supply of safe and affordable medicines to meet patients’ needs and support the European pharmaceutical industry to remain an innovator and world leader*.”¹⁸⁸

Although this looks promising, especially from the viewpoint mentioning the goal to supply affordable needed medicines (abiding by the two obligations of *availability* and *accessibility*) and to support pharmaceutical corporations in Europe, the issue is that there is no clear funding for research towards legal provisions that support the fight against epidemics/pandemics *when they occur*. In addition, there is no clear view on how the control of pricing would be practiced. This calls for a thorough study on how much R&D fund percentage is needed to control the price so that the EU meets the legal obligation of medicine ‘*accessibility*’. Therefore, I reiterate the need to work towards the goal of having provisions to aid in funding pharmaceutical corporations in their R&D phases (with precise proposals on the finance-percentages to control prices) and where clearly written *patent exception clauses* are set to invoke during a pandemic.

¹⁸⁶ Hestermeyer (n 96) 255-287.

¹⁸⁷ Ben Upton, ‘National leaders to debate contentious budget increase for European research’ (4 June 2020) Research Europe, Issue No 520.

¹⁸⁸ Ibid.

Seventh, regarding the use of some police powers (like in the cases of *seizure of generic medicines in transit*¹⁸⁹ in the Netherlands and Germany), it may lead to trade-agreement problems especially when there are bilateral treaties that define patents as an investment and the pharmaceutical corporation as an investor. The recommendation here is to governments (especially when the EU signs agreements with non-EU States) to have clear clauses in such agreements (BITs) that show exactly where the pharmaceutical company obligations and rights reside and to clarify when the right to ‘access to medicine’ may be invoked. It is about time to write the exact phrase ‘access to medicine’ in treaties, especially for times of pandemics inasmuch as it is time to start including well written provisions on what would be expected from each party in cases of epidemics.

Eighth, I recommend to pharmaceutical companies, disputing parties, and courts to hire experts that have multidisciplinary and international knowledge in IP law and in the relevant technologies/art. For instance, in the *Eli Lilly* case, the expert report was not helpful and had negative effects on the Claimant, because Eli Lilly hired US experts, who knew the US patent law but not the Canadian patent law. This calls for the below ninth recommendation.

Ninth, I recommend to education ministries and parliaments (including the EU) to call for new educational programs that include people from different disciplines (IP, Human Rights, international business, biotechnology, and engineering).

Tenth, I recommend to pharmaceutical corporations to utilize the licenses provided by the Medicines Patent Pool (MPP)¹⁹⁰ to negotiate public-health driven licenses with patent holders and in cases to sublicense to generic manufacturers. The MPP has well thought-of agreements with clear articles to protect both parties, the pharmaceutical corporation, and the licensee.

Eleventh, I recommend to governments (including the EU) and pharmaceutical corporations to focus on the following concurrent *four objectives* to deliver a vaccine/antiviral: (i) with good *quality* (satisfying the obligation on quality; see Chapter 2), (ii) on *time* (since pandemics push us for a fight with time), (iii) within *budget* (provisions to aid R&D funds), and (iv) with the relevant and *supportive applicable laws*. Nowadays, we witness pharmaceutical companies focusing on the first three objectives and governments focusing on the first two only. Hence, they leave no well-studied support for R&D by governments. The reason is that there are no previously existing clear provisions to invoke during pandemics. More importantly, point (iv) is left totally unattended, while we need laws to control the processes of going about the vaccine production and prices. In a next pandemic outbreak, we cannot work on applicable laws in real-time, we need to be proactive now for the COVID-19 outbreak suitable provisions on ‘access to medicine’ and for future pandemics.

Twelfth, my final recommendation is based on the reality that without a *unified patent regime* in the EU, it is not possible to achieve the four objectives of delivering quality vaccines, on-time, within-budget, and with supporting applicable laws.

¹⁸⁹ WTO (n 134).

¹⁹⁰ Medicines Patent Pool (MPP) UNITAID (2020).

The COVID-19 pandemic should be a reason for governments in the EU to call for a *unified and harmonized EU patent law* since it would surely speed up the processes to find a better balance.

5 Conclusions and future work

“We have not taken the final step of our journey, but the first step on a longer and even more difficult road.”

Nelson Mandela (1918-2013)

This chapter presents concluding remarks in section 5.1. In Section 5.2 it discusses the research points that have been left without investigation, and it looks at the open issues to suggest specific future research tasks.

5.1 Conclusions

The work follows a top-down approach in discussing the conflict between patent laws and Human Rights. It starts with the motivation (in Chapter 1) driven by a curiosity to look for reasons behind the conflict. It goes further down to check applicable norms, mainly TRIPS/WTO regimes and IHRL. Then it goes further down in the approach to locate the relevant IHRL instruments (UDHR, ICCPR, ICESCR, CERD, ECHR, EU Charter of Fundamental Rights, and the European Social Charter). Then it goes on answering the two research questions on: (i) locating legal problems that require attention via investigating the existence of the right to ‘access to medicine’, the intersection of laws, and the need for CLs or *patent exceptions*, (ii) whether there should be defragmentation of laws in the conflict in order to reach a balance.

Afterwards, the thesis conducts investigations (in Chapter 2) on exact related provisions to the right ‘to health’ to deduce the right ‘to access to medicine’ and answer the first research sub-question. The work examines the legal obligations that IHRL has upon patent laws (in cases of access to medicine) leading to four obligations: *availability*, *accessibility*, *acceptability*, and *quality*. The search goes down to the pricing issue of patents and its relation to the conflict by using the *methodology of law and economics* looking at TRIPS Article 28 and ICESCR Article 15, and UDHR Article 27. The work branches down the legal analysis to provisions of legal instruments (TRIPS, ICESCR, ICCPR, ECHR, etc.) and caselaw. It partitions the cases to two sets: (i) without filing for expropriation, and (ii) with filing for unlawful expropriation. The search examines the relevant caselaw, and nearly all cases do not show common knowledge on the exact provisions that lead to the conflict i.e., there is a lack of organization of Articles in legal instruments applicable to the conflict. This calls for examining the intersection of laws and locating specific provisions that aid practitioners and courts for quicker decisions

on the cases related to ‘access to medicine’. The diversity between the applicable laws leads to natural fragmentation rather than unification of laws.

The thesis proposes defragmentation (in Chapter 3) where patent laws and IHRL are envisioned as separate but intersecting in specific provisions. For instance, the best way to look at the TRIPS Agreement is not as a whole agreement since a huge part of it is dedicated to monetary purposes and trade i.e., making the application of this instrument confusing for Human Rights issues. The defragmentation principle focuses on Section 5 TRIPS (Articles 27-34) with Article 28 being the most relevant.

On the Human Rights side of the balance, the defragmentation focuses on the overlap with Articles 4 and 15 ICESCR, Article 27 UDHR, Article 11 European Social Charter (also reflecting Article 2 ECHR and Article 35 EU Charter of Fundamental Rights), and Articles 4 and 6 ICCPR on protection of the right ‘to life’. With this, a part of the second research question is answered, where defragmentation is shown to aid in achieving a balance.

The search moves (in Chapter 4) to answer the question of seeking a balance after all the analysis. The thesis adopts some previous work on balance (TRIPS flexibilities, ICESCR Article 15, proportionality principle, exception clauses, and the police powers doctrine) and adds new ideas to their application. It also investigates CLs, pricing, and R&D. This chapter answers the research sub-question that a CL is not always a suitable solution for the sought balance. Then it calls for templates for exclusion clauses that judges could become familiar with.

Finally, the research discusses twelve recommendations. Of these recommendations that I would like to stress on is amending WTO instruments, on grounds of TRIPS Article 8(1), to allow WTO Member States to include IHRL as an applicable law to protect Human Rights of its citizens and not be subject to attribution, responsibility, and submissions to remedy.

Another recommendation to reiterate is the use of MPP licenses for pharmaceutical corporations.

I also staunchly stress on the recommendation for an *EU unified and harmonized patent law* with specific provisions to invoke in cases of pandemics assuring the right to ‘access to medicine’.

5.2 Open issues and future work

Some issues in this thesis remain open such as the level of diversity of applicable laws within the WTO and the free trade agreements as well as setting the threshold between fragmentation and separate regimes. Shall further regimes be fragmented as well? Another open issue is the relevance of *Amici Curiae* and NGOs in such disputes, which this work did not touch upon. From these open issues, the thesis suggests some future work that needs attention by scholars, researchers, governments (including the EU), practitioners and pharmaceutical corporations:

- ✓ Designing templates for exclusion clauses and make them available for use.
- ✓ Investigating specific clauses in the MPP licenses.
- ✓ Studying specific clauses for the amendments/addition in the TRIPS Agreement on grounds of its Articles 7 and 8.
- ✓ Working on the implementation of tools and education program plans to leverage the understanding of defragmentation. On this final note, I end this part with *Nelson Mandela's* statement:
“Education is the most powerful weapon which you can use to change the world”.

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