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Conflicts between pharmaceutical patents and access to medicine during the pandemic

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ABSTRACT

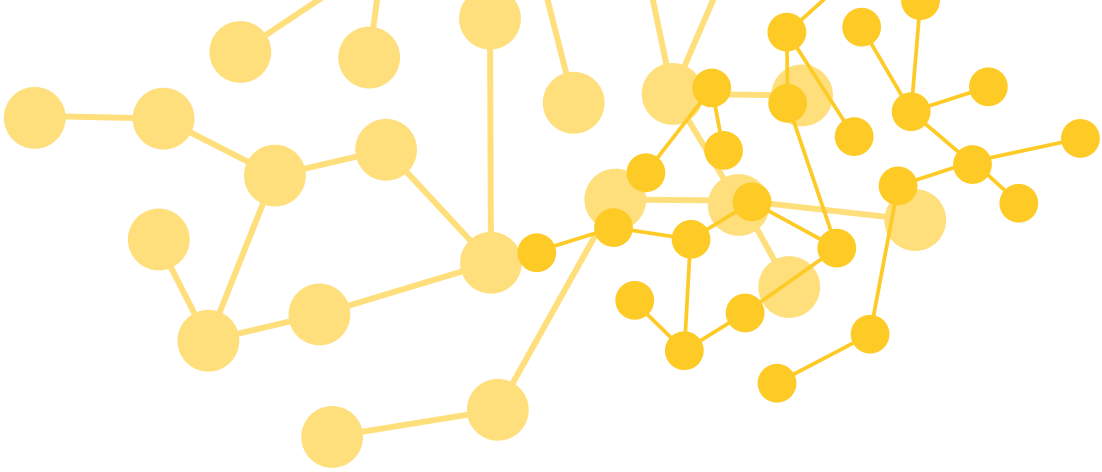
The coronavirus pandemic has changed many aspects of life. Revising contemporary laws and legal systems is inevitable to survive the current and future pandemics. The first paramount concerns are human life and health. An associated consideration is the financing of related medical solutions inter alia vaccines, antivirals, and antiretrovirals. These issues conflict with each other in the legal space intersecting between intellectual property (IP) and human rights. Humans have the legal right to 'access to medicine'. On the other hand, pharmaceutical industries have the right to patent their products, which unfortunately could make medicine prohibitively expensive. During pandemics, choosing to give the medicine/licenses for free sounds like the best ethical solution, but it comes with serious risks like compromising the existence of the sources of research and development (R&D) needed to prepare for future outbreaks. Therefore, a balance is needed. Consequently, more legal research is a requisite. Efforts by policymakers, practitioners, researchers, and related institutions are essential. The investigation tackles these issues on an international level, and it renders special focus on the EU in some sections. This paper locates the relevant problems that need attention, collects related provisions, and propounds recommendations.[1]

1. INTRODUCTION

A principal human right is that "to life," which is mentioned in international human rights legal instruments such as Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR)[2] and Article 2 of the European Convention on Human Rights (ECHR).[3] This right encompasses many related rights, *inter alia* access to essential healthcare services and products. However, significant growth in pharmaceutical patents has led to increased drug prices and may decrease people's ability to purchase medicine,[4] threatening "access to medicine." Disputes in this area, between states, pharmaceutical companies, patients, and investors, have occurred not only because of trade issues but also in relation to human rights, *inter alia the case of Novartis AG (Switzerland) v. Union of India & Others*[5] (discussed in subsection 5.2.2). During pandemics, the clash between patents and human rights can lead to unforgivable delays in delivering medicine, more suffering, and loss of lives. This is evident in the current worldwide trials regarding the IP rights of manufacturers of COVID-19 vaccines.[6] The legal regimes applicable in such conflicts are patent laws, such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS)[7] Agreement, domestic laws, international human rights laws (IHRL),[8] including the ECHR, and other human rights instruments. However, it is up to courts to decide whether to consider IHRL in a decision-making process. The reason for the growth in patent applications is the exclusivity right, which means that protection of inventions can generate large revenue. An important legal instrument that adds to the incentive for innovators is TRIPS, which sets minimum standards of legal protection for IP, to be provided by each signatory state.[9] Hence, TRIPS has an impact on the legal practices of states and unions (e.g., EU) in the field of patents.

The latest statistics show that pharmaceutical patent applications at the European Patent Office (EPO) grew by 4.4% between 2018 and 2019.[10] According to the Global Use of Medicines report from the IQVIA Institute for Human Data Science, the global pharmaceutical market grew to USD 1.2 trillion in 2018.[11] The report predicted the global market growth in the coming few years to be 4–5%, reaching USD 1.5 trillion (based on invoice pricing).[12] The pharmaceutical industry has huge costs for R&D processes, for which patents are meant to provide some compensation.[13] However, manipulations of the market exclusivity that comes with a patent raise ethical concerns, since patent-protected medicines have no price thresholds or competitors for about twenty years[14] (also protected by TRIPS). The Tufts Center for the Study of Drug Development estimates that around USD 2.6 billion and a ten-year commitment are needed for a new medicinal drug, from the research phase until its release to the market.[15] Hence, pharmaceutical companies need to set a suitable price to get a return on investment (ROI). This makes some medicines inaccessible to some populations, creating a dilemma.

The last seventy years have witnessed the development of human rights law, which has begun to touch new fields,



including patents. The general perception is that the problem of medicine costs exists only in developing countries. However, a study in the USA reveals 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."[16] One in four Americans is unable to fill prescriptions because of high medicine prices.[17] According to the study, this problem is due to "the patent system."[18]

When conflicts threaten the availability of a vital drug to a group of patients (e.g., HIV[19]/AIDS[20] victims) in a region, this calls for leveraging every possible way of managing this problem: healthcare (time to reach a decision and accessibility), legal issues (conflicts of law), policies (public interest and morality), economic considerations, and (pharmaceutical companies') business benefits and sustainability. When healthcare faces a pandemic (e.g., HIV/AIDS[21] , SARS[22], COVID-19[23]), conflicts related to patent rights for antiretrovirals,[24] antivirals[25] and vaccines[26] can have grave consequences. Human life must have the highest priority in such disputes. If prices soar, we would go against the policy of protecting medicine accessibility. Balancing patents against human rights in pandemic times is essential.

[1] Acknowledgement is made to Professor Marianne Levin at Stockholm University, Sweden, for fruitful advice and contributions through many discussions, the idea of including TRIPS Articles 8 and 31bis, and the analogy with the three cases at the Court of Justice of the European Union (CJEU): Funke, Pelham, and Spiegel.

[2] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976), 999 UNTS (ICCPR) art 6(1).

[3] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR), (4 November 1950) Art. 2.

[4] KT Richards, KJ Hickey, and EH Ward "Drug Pricing and Pharmaceutical Patenting Practices" CRS Report Prepared for Members and Committees of Congress, R46221 (Congressional Research Service 11 February 2020) 1.

[5] Novartis AG v. Union Of India & Others (Civil Appeal Nos. 2706–2716) arising out of SLP(C) Nos. 20539–20549 of 2009) Indian Supreme Court (1 April 2013).

[6] See Nasos Koukakis, "Countries worldwide look to acquire the intellectual property rights of Covid-19 vaccine makers" Our New Future - Special to CNBC (CNBC 22 January 2021).

[7] WTO, the TRIPS Agreement and the Conventions referred to in it (entered into force on 1 January 1995).

[8] OHCHR, "International Human Rights Law" (UN) 1996–2020.

[9] WTO, Overview: the TRIPS Agreement (1 January 1995).

[10] 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 February 2020) Market Watch.

[11] IQVIA, "Global pharma spending will hit $1.5 trillion in 2023" (29 January 2019) Pharmaceutical Commerce, para 1.

[12] Ibid.

[13] Bruce Lehman, "The Pharmaceutical Industry and the Patent System" (2003) International Intellectual Property Institute.

[14] Elle Mahdavi, "Patents and the Pharmaceutical Industry" (26 May 2017) California Review Management.

[15] Ibid.

[16] Tahir Amin, "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system" (2018) CNBC.

[17] Bianca DiJulio, Jamie Firth, and Mollyann Brodie, "Kaiser Health Tracking Poll" (20 August 2015) KFF.

[18] Amin (n 16).

[19] 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 (...)."

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

[21] WHO, Data and Statistics (HIV/AIDS, 12 April 2020), considers HIV/AIDS a pandemic – 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.

[22] 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 8,000 cases in 2003" https://www.who.int/ith/diseases/sars/en/ accessed 29 April 2020.

[23] 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 had caused a pandemic.

[24] See NIH, "Antiretroviral," (HIV/AIDS Glossary, 28 July 2020), definition as "A drug used to prevent a retrovirus, such as HIV, from replicating."

[25] 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."

[26] 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.

Pandemics strike by surprise, and if policies and laws are not prepared, trying to fix problems in "real time" may lead to more suffering and death. Some fields of concern include the resolution of conflicts between laws, whether exceptions to patents are needed, and the pros and cons of compulsory licenses (CL). In influenza and similar virus pandemics, vaccines are the principal measure for safe and effective mitigation.[27] Meanwhile, pharmaceutical companies have an interest in generating profit. The vaccine market share is very attractive to pharmaceutical industries, since it has increased six-fold over the past two decades (according to AB Bernstein) reaching a value of more than USD 35 billion today.[28] Moreover, the COVID-19 pandemic is increasing interest in the fast-growing vaccine industry.[29] Since 2020, some governments, *inter alia* those of Canada, Germany, France, and Chile, have started to adopt extraordinary measures such as amending laws and passing new legislation to allow for CL, to tackle the health crises created by COVID-19.[30] Moreover, South Africa and India have asked the World Trade Organization (WTO) to suspend IP protections for COVID-19 drugs, vaccines, and diagnostics for the duration of the pandemic.[31] The US President Biden was urged not to accept this request.[32] Political, economic and legal aspects all come into the picture, and CL cannot provide a global solution.

From the legal viewpoint, the aforementioned conflicts can be traced back to the rare intersections between patent laws and IHRL. We face the dilemma of choosing between two desirable laws, without any satisfactory solutions. Identification of provisions common to both patent law and human rights legal instruments is needed. The legal instruments in which such overlap should be investigated are TRIPS and IHRL (including relevant EU laws). The dilemma creates legal questions in pandemics, such as: (i) Is there a human right of "access to medicine," even though this phrase is not found in any provision of applicable laws? (ii) How can we choose between CL, patent exceptions or other methods? (iii) How do we ensure consistent court interpretations of the conflicting laws?

This paper does not consider instruments of international humanitarian law, which might sometimes be confused with IHRL, and does not include issues of compensation to patients or for pharmaceuticals. The legal instruments considered are: the ECHR;[33] the Universal Declaration of Human Rights (UDHR);[34] the ICCPR;[35] the International Covenant on Economic, Social and Cultural Rights (ICESCR);[36] the Convention on the Elimination of all forms of Racial Discrimination (CERD);[37] the WTO TRIPS Agreement;[38] and various EU norms.

2. THE HUMAN RIGHT "TO HEALTH"

The meaning of the phrase *right to health* is not difficult for most of us to grasp, but it can sometimes be confusing to interpret legally. There is no statement or rule in the human rights legal instruments on this, as such, or that includes wording that clearly articulates the right of a human to be healthy.[39] For many biological and behavioral reasons, such as genetics and accidents, it is not within the capacity of authorities to ensure that everyone lives in full health.[40] The word "medicine" is not found in any of the human rights provisions. However, IHRL protects *inter alia* the rights to security and safety of a human being, to own property, to private and family life, and to enjoying the "highest attainable standards of health."[41] Hence, we refer to the right "to health" as the right "to the highest attainable standards of health." Within IHRL, this research work investigates a smaller subset of instruments: the UDHR, the ICCPR, the ICESCR, the CERD, and EU conventions. The right to health is provided for in Article 25 UDHR and Article 12 ICESCR; the key phrases are underlined below. 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."[42] Some instruments, such as the ICESCR and the ICCPR, translate the UDHR principles into a legally binding form.[43]

[27] WHO, Vaccination (Health topics, Communicable diseases, Influenza 2020).

[28] Yun Li, "Coronavirus highlights the $35 billion vaccine market. Here are the key players" (23 February 2020) CNBC Markets.

[29] Ibid.

[30] Adam Houldsworth, "The key covid-19 compulsory licensing developments so far" Law Business Research (IAM 7 April 2020) para 1.

[31] Doctors Without Borders, "Governments make request to WTO for intellectual property waiver for all countries until herd immunity is reached" News and Stories (DWB 7 October 2020) https://www.doctorswithoutborders.org/what-we-do/news-stories/news/india-and-south-africa-propose-no-patents-covid-19-medicines-and-tools accessed 3 March 2021.

[32] The Economic Times, "President Biden urged not to accept India and South Africa proposal at WTO on COVID-19" Business News, International (6 March 2021) para 1.

[33] ECHR (n 3).

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

[35] ICCPR (n 2).

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

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

[38] WTO (n 7); WTO, A Handbook on the WTO TRIPS Agreement (WTO and CUP 2012).

[39] Daniel Moeckli, Sangeeta Shah, and Sandesh Sivakumaran, International Human Rights Law, 3rd ed (OUP 2018) 195.

[40] Ibid.

[41] Bruce Oswald, Helen Durham, and Adrian Bates, Document on the Law of UN Peace Operations (OUP 2011) 68–70; ECHR (n 3) Art 8.

[42] UNGA (n 34) Preamble.

[43] Ibid.

[44] ESC - European Social Charter (Revised), "The right to protection of health" (European Treaty Series no 163 Council of Europe) art 11; ECHR (n 3) Art 2; EC, Charter of Fundamental Rights of the European Union (2000/C 364/01) Art 35.

[45] Moeckli (n 39) 196; CESCR General Comment 14, para 12.

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 (...).

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 (...) 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.

ICERD Article 5(e)(iv)
In compliance with (...) article 2 of this Convention (...) 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; (...).

The major relevant EU provisions are Articles 11 and 13 of the European Social Charter, which form the basis for Article 2 ECHR on the right "to life" and Article 35 EU Charter of Fundamental Rights on "Health care" (below). Moreover, Article 2 ECHR discusses a similar right as that in Article 2 of the EU Charter of Fundamental Rights. Below are some excerpts of the relevant texts.

EU Articles[44]
- 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, (...) 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. (...)

Article 25 UDHR and Article 12 ICESCR rank highest, as they are conventions, at the top of the hierarchy of legal instruments. In Article 25 of the UDHR, we can make note of the important phrase "medical care." Although the UDHR is not legally binding, the phrase "medical care" gives a clear indication that medicine is part of such care. Moreover, ICESCR Article 12 gives no doubt about the human being – in a Member State – having the right to enjoy public healthcare, including medicine accessibility. In the EU, it is legally binding for a Member State to provide such access. Can legal reasoning lead to different interpretations of the right of "access to medicine"? Clearly, public health services and medical care cannot be delivered if there is a lack of medicine accessibility. Although there is no specific provision on *the right of "access to medicine,"* the above is enough to indicate that such access is part and parcel of human rights.

3. IHRL LEGAL OBLIGATIONS FOR THE RIGHT "TO HEALTH"

The right to health creates obligations on State Parties. The parties' fulfillment of such IHRL obligations is clearly stated in four steps in Article 12(2) ICESCR (above). The Committee on Economic, Social and Cultural Rights (CESCR) specifies, in General Comment 14, that the right to health involves four points that become obligations for State Parties.[45] The following four points define those legal obligations and examine their applicability in 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 sufficient quantities. Is this possible in pandemics? We have witnessed many states failing to provide for even simple needs, e.g., facemasks 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 have suffered tribulations and delays due to the lack of pandemic emergency laws and systems that aid governments in tackling outbreaks quickly. For instance, during the HIV/AIDS pandemic, it took many years before new laws and regulations saw the light. This paper identifies a problem in the issue of reducing the time-to-market (including R&D) for a vaccine (i.e., the length of time for it to become available). However, an available drug does not guarantee access for patients.

2. The second obligation is *accessibility* to health facilities, goods, and services for 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)."[46] An example of a problem is the high price for AIDS antiretroviral drugs protected by the patent system in the USA, EU, and most State signatories of TRIPS. The challenging problem is market-price regulation. It requires exceptions in thinking about pricing. In pandemic times, patent law exceptions must be reconsidered.

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."[47]

4. The fourth obligation is the *good quality* of health facilities, goods, and services.

The CESCR urges all State Parties to adopt, design, and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the entire population. Strategies and plans of action should be devised and continually reviewed on the basis of a participatory and transparent process.[48] They should encompass methods for follow-up, 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.[49]

In the current COVID-19 pandemic, we have witnessed a lack of medical goods like facemasks, personal protective equipment, 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 to only a few patients, since lupus and arthritis patients need it too, creating a shortage.[50] Another problem is the prevention of medical solutions resulting from prohibitive patents. An example is the inability to produce ventilators – which are urgently needed by some COVID-19 victims – because the original invention is protected by a valid patent. Thus, we have witnessed patent laws and legal systems causing a clash with the obligations of *availability* and *accessibility*. One example to learn from is provided by Medtronic and AmboVent, which shared their patented ventilator design without the need for manufacturers to pay for licenses via the issuing of special permissive licenses for the purpose of addressing the needs during the COVID-19 pandemic.[51] A similar problem arises when vaccines or antivirals with patent protection are ready to market. The US pharmaceutical company Moderna Inc. announced in October 2020 that it would not enforce patent rights in relation to its coronavirus vaccine during the pandemic.[52] However, the efforts of one company are not enough. The vaccine availability problem persists. How long will the delay in producing vaccines be allowed while lives are being lost? Should patents be allowed for such medicinal products during pandemics or should there be patent exceptions? The solution is not to depend on pharmaceutical companies to change their patent policies during pandemics, which would mean relying on private decisions. A responsibility also lies on governments and policymakers. There is a need to be legally proactive by learning from current needs and previous pandemics in order to design and implement legal provisions or system that are ready to invoke when pandemics strike.

4. PATENTS, PRICING, AND CLASH WITH THE RIGHT OF "ACCESS TO MEDICINE"

In the following, the focus is on the legal obligation of *accessibility* and its relation to the increased medicine pricing caused by patents. Tackling this requires application of some aspects of the *methodology of law and economics*. Based on Article 4 ICESCR and some national EU laws (e.g., German law), if a state cannot not fulfil its positive duty of protecting a human right, it can be construed as allowing other regimes to impair those fundamental rights.[53] This legal issue is relevant to patents from the economic viewpoint, since states must guarantee the economic *accessibility* of medicine. It translates to ensuring affordable medicines. The European Court of Human Rights (ECtHR) questions whether the balance between the public interest and the individual's interest is unfairly shifted.[54] To fully analyze this point, one would need study it on two planes: a theoretical economic dimension and an empirical dimension. This work does not indulge in mathematical analysis, but rather looks at the price levels from an economic viewpoint relating to interactions with law.

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 the first IHRL obligation of *availability*. However, the problem is that it goes against the second obligation of *accessibility*. The aim of IHRL instruments is to not separate the four obligations.

During pandemics like HIV/AIDS, pricing is critical.[55] The antiretrovirals are *available*, but the pricing policies hinder *accessibility* for many. The analysis of pricing requires a look at economic theory, to examine competition, the supply/demand curve, monopolies, and the governmental ability to support payments for medicines.[56]

In any business, the pricing process is one of the final

steps before launching a product. It is affected by many factors, e.g., supplied volume, number of customers, and market price. Pharmaceutical companies do not have complete influence over pricing, but sometimes have partial leverage. If a medicine is priced very highly, it will be hard to sell, since many patients cannot afford it. Hence, it will not bring the desired revenue due to fewer customers. On the other hand, if the price of a medicine is too low, it would not be profitable, no matter how many units are sold. Therefore, pharmaceutical industries play the game of balancing two factors: making a good profit, while ensuring patients can afford the medicine. Doing so at a global scale, with huge differences between the purchasing powers of nations and patients, has a very slim chance of success for drugs with high R&D costs. 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. For instance, Article 28 in Section 5 "Patents" of TRIPS[57] 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. (...)

With such rights, the patent owner can create a monopoly that allows them to choose whether to produce large quantities of the medicine at a lower price or smaller quantities at a higher price. Since it is a business for profit, a pharmaceutical company will select the market price promising the largest profit. Clearly, this market reasoning does not take into consideration the right of "access to medicine" and the ability of patients to purchase the medicine. Another legal problem that needs revisiting is the negligence of the right of every human being to enjoy scientific benefits. Article 15(1)(b) ICESCR recognizes the right of everyone "to enjoy the benefits of scientific progress and its applications."[58] UDHR Article 27(2) articulates "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."[59] However, those rights have – thus far – been neglected. An important issue is that the UN Member States, CESCR committee, and the UN (General Assembly and Human Rights Council and its Special Rapporteurs) have not yet emphasized this as a human right,[60] although it is clearly written to be interpreted as such. Another alarming issue is that the *travaux préparatoires* are taciturn on the UDHR provision.[61] From an empirical economic approach, prices for generic medicines are much lower than those for 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 have entered the market.[62] From a legal perspective, CL come into play in this economics and law interaction. The UK has practiced invoking CL. Canada also has a quite long experience of CL. The experiences of these two countries confirm the previous findings on pricing.[63] Not only does this economic analysis indicate that patent regimes affect the price of medicine, but there is also strong evidence supporting this. For instance, in situations when governments face pandemics, they threaten patent protection by imposing CL. This helps achieve large reductions on drug prices. Further evidence is found in the Brazil HIV/AIDS program to produce drugs locally, where a 70% price reduction was achieved during a period of the high demand in 2001.[64]

46 Moeckli (n 39) 196.
47 Ibid.
48 See p 10 in ICESCR (n 36) United Nations International Covenant on Economic, Social and Cultural Rights, United Kingdom, British Overseas Territories, Crown Dependencies 6th periodic report (2016).
49 Moeckli (n 39) para 43.
50 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.
51 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.
52 Moderna Inc. "Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic" Press Release (Moderna 8 October 2020) https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19 accessed 7 March 2021.
53 ICESCR (n 36) art 4; German law HD Jarass and B Pieroth, Grundgesetz für die Bundesrepublik Deutschland. Kommentar (ed 7, 2004) Vorb vor Art 1 para 24.
54 Mark P. Villiger, Handbuch der Europäischen Menschenrechtskonvention, 2nd ed (EMRK 1999) 344–345.
55 Holger Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine (OUP 2007) 148.
56 Ibid. 138–151.
57 WTO (n 7) Art 28.
58 ICESCR (n 36) Art 15(1)(b).
59 UNGA (n 34) Art 27(2).
60 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.
61 Hestermeyer (n 55) 143–144.
62 Jerry Stanton, "Comment: Lesson for the United States from Foreign Price Controls on Pharmaceuticals" (2000) 16 Conn J Int'l L 149, 158.
63 Fredric M. Scherer, "The Economic Effects of Compulsory Patent Licensing" in Ruth Towse and Rudi Holzhauer (eds), The Economics of Intellectual Property: Patents (Edward Elgar 2002) 315, 350.
64 Anne-Christine D'Adesky, Moving Mountains, The Race to Treat Global AIDS (Verso 2004) 28.

5. ANALYSIS OF THE CONFLICT

After analyzing the links between patent pricing and the legal conflict, I will revert to the dogmatic method by examining the applicable laws highest up in the hierarchy, namely treaties and legislations, and how they have been used in practice. Then, I will move on to case law.

5.1. Provisions

TRIPS is the most comprehensive agreement on IP rights (IPR). Not only does it harmonize patent rules in Member States, but it also provides a minimum standard for protection. In the EU, patent rights are the least harmonized of the IPR. In addition, the Court of Justice of the European Union (CJEU) has adopted a restrained approach in patent discipline.[65] This is particularly true in the CJEU case law on patent protection and where TRIPS is an applicable instrument.[66] After ratification of the Lisbon Treaty,[67] introducing Article 207 of the Treaty on the Functioning of the European Union (TFEU)[68] on "Common Commercial Policy," the CJEU took a clear stance on including TRIPS in its judgments as a harmonizing legal instrument for the patent system in the EU. *In the case of Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon,*[69] the CJEU mentioned that common commercial policy also concerned the commercial aspects of IP and that if the EU was intended to promote international trade, this fell within common commercial policy.[70] Regarding TRIPS, the CJEU 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.*[71]

In this respect, Section 5 of TRIPS (Articles 27–34) can be used to protect aspects of patents with specific power endowed in Article 28. Looking again at the interference with human rights instruments, Article 15(1) ICESCR and Article 27 UDHR were used a few years ago to try to justify patent collisions with the right of "access to medicine."[72] Thus, not only patent laws can be used to protect pharmaceutical patents, but also human rights laws. However, one cannot have high expectations on their use nowadays. They protect the moral and material interests of authors, but do not coexist with patents.[73] These articles do not protect patents as such, nor do they protect pharmaceutical companies. Article 15 ICESCR tries to strike a balance between protection of the interest of the inventor and public access to the invention. Usually, the practice is to protect the inventor's interests first. However, in cases when the right "to health" is seriously threatened, there would be greater support for protecting public access to pharmaceutical technologies and patents. Article 15(1)(c) ICESCR does not justify the interference of patent laws with the right of "access to medicine." Moreover, patent owners often 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.

In the context of pandemics, if they are considered to be 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 found in Article 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 I analyze in the discussion on balancing rights in subsection 9.4). By utilizing this option in the ICCPR, Member States' interference with the right can be justified.[74]

[65] Francesca Venerucci, A Comparative Study of the CJEU and ECtHR Approaches on Intellectual Property: Unity or Division? (thesis, UNIBOCCONI 2016) 72.
[66] Ibid.
[67] Treaty of Lisbon, EU (2007/C 306/01).
[68] TFEU (Treaty on the Functioning of the European Union) (entered into force on 1 December 2009) Part 5 Art 207 (e.g., Article 133 TEC).
[69] 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 CJEU (Grand Chamber 18 July 2013).
[70] Ibid. paras 45–48.
[71] Ibid. para 58.
[72] 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.
[73] Hestermeyer (n 55) 152–153.
[74] Manfred Nowak, Introduction to the International Human Rights Regime (RWI 2003) 56.
[75] Hestermeyer (n 55) 152.
[76] ICCPR (n 2) Art 6.
[77] WHO (n 27); Worldometer, "Coronavirus" https://www.worldometers.info/coronavirus/ accessed 19 May 2020.
[78] 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.
[79] 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.
[80] 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.
[81] 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.
[82] Zachary Brennan, "EMA and FDA Historically Agree on Just About Every New Drug Approval, but is That Slowly Changing?" (16 August 2019) Regulatory Focus.

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, col our, 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. (...).

This sends us back to ICESCR Article 4 to check the limitation obligation; some interpretations would justify 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.

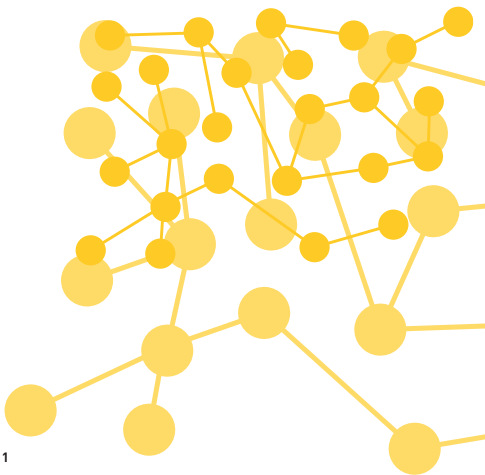
A word-by-word analysis of this article does not find reference to emergencies or survival (life-threatening issues). However, some have found justification through interpretation.[75] Furthermore, Article 6(1) ICCPR states the obligation to protect the right "to life" by law:

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. (...).[76]

However, other Article 6 provisions ((2)–(6)) make it obvious that this relates to death penalty regulations, refusal of authorization of genocide, and abolition of capital punishment. These life-threatening issues are specifically mentioned in the provisions of the article, 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 for or against this; however, the following analysis shows that there is a right to lifesaving medicine. The problem is that the right "to life" is not explained or further articulated in specific detail. It is left to judges to interpret it and decide to place on governments an *obligation* of *accessibility* "to lifesaving medicine." Going back to the interpretation, the article clearly states the legal obligation to protect the "inherent right to life." The rest of the article gives three instances of such protection (listed above), but does not limit the previous statement, since there is no phrase or wording indicating that the "right to life" is exhausted by those three instances. By deduction, the first two sentences encompass all instances of the right to protection of human life. This right relates to the obligation of a Member State to not end a life and to provide products that aid in decreasing or eliminating a threat of death. The relevant medical/medicinal products would include inter alia ventilators, pacemakers, and lifesaving medicine (e.g., HIV/AIDS antiretrovirals and COVID-19 vaccines).

In all these instruments, the right "to life" does not contain a limitation clause related to patent law. Most human rights articles can be limited under certain conditions. This means that a negative overlap – like that which patent law has with the right to "access to medicine" – could be justified under human rights law. On the other hand, patents protect revenue for pharmaceutical companies, thus motivating creation of new medicinal solutions. From a legal perspective, such an argument is used to protect patent owners' rights, as they support access to future needed medicine. This can create controversy when epidemics or pandemics occur, since there will be a fight against time, to save lives. A proof of this concept is evident in the current struggle to limit the number of deaths and infections from the COVID-19 outbreak.[77] The WHO declared the coronavirus outbreak a pandemic in February 2020.[78] The question that we need to be proactive about is access to vaccines/antiviral medicine.[79] Such medicinal products have been tested before approval for release,[80] and such testing processes will continue for new versions against new virus strains. The conflict requires an economic balance between the availability of research financing for developing new medicines and the prices of said medicines.

The only way to protect the "incentive to invent" is via patent protection. If exceptions to patent validity are favored in some areas due to life-threatening diseases, the incentive to innovate is lost in the area where it is most needed. Moreover, there is criticism of patent systems in general (e.g., a study shows that only 54% of patents are judged as valid in courts) even for a strong patent office like that in the USA.[81] The argument that patents motivate innovation does not say anything about patent limits. It favors patent law beyond all boundaries and is taciturn on how much profit is sufficient to incentivize inventors. The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) concur in their decisions to approve new drugs in more than 90% of cases, according to a new study from EMA and FDA officials who looked at 107 applications from 2014 to 2016.[82] No practical solution would be feasible without governments being involved. Hence, legal issues must be addressed by the policy-makers and legal specialists in governments, e.g., the EU Parliament.



5.2. Case law

In the pharma sector, it is not possible to consider domestic norms only, since medicinal products are needed worldwide. Moreover, as pandemics are global disease outbreaks, the mindset for legal analysis must be in harmony with international issues. Patents, in addition to being protected by domestic laws, can be listed and explained in treaties as investments to be protected.

5.2.1. Case law without expropriation

In many cases, 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., in the EU), pricing on one national market can affect that on another because of parallel imports. Hence, a medicine placed on a low-price market by the patent owner may be imported by some other company into a more highly priced market. This affects the patent owner's profit prospects.

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*.[83] GlaxoSmithKline and Boehringer Ingelheim were charged with excessive pricing of antiretrovirals in violation of the competition law of the Republic of South Africa, when the international best price offer of the branded product was compared with the price of a WHO prequalified generic. The court found that the branded drug was priced around 230% higher than the generic. This case revealed two important issues. First, the price difference between branded medicine and generics can be questionably large. Second, an argument arises on whether some profit can be made by branded drugs if they lower the marginal difference compared with cheaper medicinal products. In pandemic times, would governmental institutions and international organizations be able to pay such prices for branded medicine or vaccines when the number of patients is very high? The cost would certainly overstretch healthcare budgets. Court decisions like that in this case may help in identifying a problem that needs attention: marginal price differences and the need for governmental interference to lower prices during pandemics. This calls for a set of emergency laws that can be invoked when a pandemic strikes.

In the *Bayer AG v. Commission of the European Communities*[84] case, monopolies threatened to limit the supply on the market with a lower price – to prevent a medicine from leaving the country – or to set a unitary high price to prevent a loss of sales in a higher-priced country. At the same time, many of these drugs would have never been invented if not for patents. From a political viewpoint, it is a fact that monopoly incomes due to TRIPS' strengthening of patent legislation are commonly (but not always) transferred from less developed to more developed countries. Such threats have been used in debates on exporting cheaper drugs from Canada to elderly citizens in the USA, though it is hard to see how their realization would prevent the exportation of medicinal products.[85] Bayer acted in this way when sales of a drug (Adalat) in France and Spain grew dramatically, because the medicine was exported, at a much higher price, to the UK. Because its product was under governmental price control, Bayer reacted by filling orders only to a level determined by the orders of previous years. This shows that governmental interference and court decisions can play a major role in controlling access to medicine.

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

[84] Bayer AG v. Commission of the European Communities, (Case T-41/96) EU:T:2000:242 Judgment CJEU (26 October 2000).

[85] Hestermeyer (n 55) 160–181.

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

[87] AstraZeneca AB and AstraZeneca plc v. European Commission (T-321/05) EU:T:2010:266 Judgment CJEU (1 July 2010).

[88] AstraZeneca AB and AstraZeneca plc v. European Commission (C-457/10 P) EU:C:2012:770 Judgment CJEU (6 December 2012).

[89] "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.

[90] AstraZeneca (n 87) para 313.

[91] Ibid.

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

[93] Ibid., see para 3 on p 8 in "AS TO THE ADMISSIBILITY OF Application No. 12633/87" http://hudoc.echr.coe.int/app/conversion/pdf/?library=ECHR&id=001-738&filename=001-738.pdf&TID=ihgdqbxnfi accessed 5 March 2021.

[94] Centrafarm BV v. Winthrop BV (C-16/74) EU:C:1974:115 Judgment CJEU, 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 Judgment CJEU, ECR I-06285 (5 December 1996); IHT Internationale Heiztechnik GmbH v. Ideal-Standard GmbH (Case C-9/93) EU:C:1994:261 Judgment CJEU, ECR I-02789 (22 June 1994); SA CNL-Sucal NV v. HAG GF AG (Case C-10/89) EU:C:1990:359 Judgment CJEU, ECR I-03711 (17 October 1990).

[95] Treaty establishing the European Community (Nice consolidated version) - Part Three: Community policies - Title I: Free movement of goods - Chapter 2: Prohibition of quantitative restrictions between the Member States - Article 28 - Article 30 - EC Treaty (Maastricht consolidated version) - Article 30 - EEC Treaty.

[96] 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.

[97] Eli Lilly and Company v. Government of Canada, UNCITRAL, ICSID Case No UNCT/14/2, Award (16 March 2017).

[98] North American Free Trade Agreement (signed in 1992, entered into force on 1 January 1994) (NAFTA).

In the EU, there are interesting cases on seizures of generic medicines in transit[86] in the Netherlands and Germany, which were discussed by the TRIPS Council in 2009. On grounds of the Council Regulation (EC) No 1383/2003 of 22 July 2003 "concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights" the national customs officer in an EU Member State is given the task to protect – by police power – the IP laws on goods transiting through EU ports. This raises the issue of the doctrine of police powers. Using the powers bestowed on the custom personnel and based on unclear patent violation possibilities, the police initiated temporary seizures and delayed nearly 20 shipments of medicines in transit. The major issue was that the medicinal products were lifesaving (used to treat AIDS, Alzheimer's disease, heart conditions, and high blood pressure). The pharmaceutical corporations Sanofi-Aventis SA, Novartis AG, and Eli Lilly & Co requested that the shipments be detained. The Indian representative considered those actions "serious impediments to access to medicines" and a violation of core principles of the TRIPS Agreement. The case resulted in negotiations between 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. The case reveals a negative side to pharmaceutical patent owning in the EU.

Two cases, *AstraZeneca AB and AstraZeneca plc v. European Commission (Case T-321/05)*[87] and its appeal in *Case C-457/10 P,*[88] show how the CJEU has favored keeping medicine costs down and encouraging pharmaceutical innovation. AstraZeneca faced two charges: (i) misleading representation to the EU domestic patent offices, and (ii) an attempt to deregister the marketing authorizations for its drug (Losec) capsules in Sweden, Denmark and Norway and withdraw them from Scandinavia in order to launch another, similar drug (Losec MUPS tablets). The CJEU judged that AstraZeneca was to pay 60 million euros for misusing the patent system by unlawfully and in bad faith obtaining a Supplementary Protection Certificate (SPC) to block or delay generic competitors of Losec and keep its medicine price artificially high.[89] The judge stated that:

> *Patent 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.*[90]

An EU commissioner argued the following: (i) Support should be strong for patent protection of innovative products, so they get a satisfactory return on their R&D investment. However, the legislator should determine 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."[91] The appeal case was dismissed by the CJEU, upholding the previous decision.

One interesting case of the ECtHR on the issue of CL is *Smith Kline & French Laboratories Ltd. v. the Netherlands*.[92] The dispute was about CL granted by the Netherlands Patent Office, where there were two dependent patents, each owned by a disputing company. The ECtHR considered such an act to be lawful and supported the legitimate purpose of encouraging technological and economic development. The interesting issue is that the ECtHR applied the *proportionality principle* (discussed in subsection 9.4) 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."[93] Hence, a balanced CL was granted; this could be used, by analogy, in many other cases. In the following CJEU 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,*[94] the ECtHR prohibited EU Member States from banning parallel imports originating within the European Community under EC Treaty Articles 28 and 30.[95]

5.2.2 Case law under expropriation

Case law creates confusion in relation to when changes are made in domestic patent law and its interference with pharmaceutical patents granted before the patent law was changed (overlapping with access to medicine). This subsection investigates cases where such an act by a state was considered by pharmaceutical companies (defendants) tantamount to expropriation. Medicinal products are universal and pharmaceutical industries try to sell them on worldwide markets. Sometimes, this means that the pharmaceutical company is (legally speaking) to be considered an investor in a foreign state, with the patent registration in the foreign state being its foreign direct investment. Even within the EU, different Member States could be signatories of investment agreements. Although EU law functions as a supranational law for the EU States, such bilateral agreements cause controversy and debate. The EU government and CJEU have suggested cancelling such intra-EU agreements.[96]

An interesting case is *Eli Lilly and Company v. Government of Canada*[97] under the North American Free Trade Agreement (NAFTA),[98] where three Canadian courts (provincial, appeal, and supreme) made similar decisions. After having exhausted local remedies, Eli Lilly (a US pharmaceutical company) still wanted to file for an arbitration under NAFTA. Hence, there are four decisions, all with similar conclusions. Eli Lilly owned patents for the Zyprexa and Strattera drugs, which were registered in Canada before 1993. Until that year, the Canadian patent law allowed for CL. However, when Canada recognized TRIPS, the effect was large. Canada introduced the concept that an invention "must be useful" to grant a patent. Eli Lilly did not expect the new doctrine to take effect on existing patents. All courts invalidated the patents on

ground of not having a proof for the "must be useful" concept. Hence, the conflict was created by the intersection of three issues: (i) the investment agreement (NAFTA) protecting 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 patents were within their respective validity periods.

Accordingly, Novopharm (a Canadian pharmaceutical company) obtained regulatory approval to market a generic 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 (the patent registration) in Canada on the 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 (defendant) won all the cases, and the final tribunal decision took into consideration patent laws, the bilateral investment treaty (BIT), and human rights.

All the courts and the arbitration tribunal seemed to view patent law as the major applicable law, meaning that the changes were allowed. This raised a question regarding the three laws (patent law, BIT, and IHRL): whether or not they overlap in such cases. The courts, however, showed a mindset of considering the public interest. Comments mentioned keeping non-useful patents in Canada that would stop research in this field as the IPR could conflict with current and future research related to the right to health. For the sake of people's health and ordre public (better and faster research in healthcare products), the patents were invalidated on grounds of the new "usability" criteria. This case is applicable to pandemics in general, where any patent on a vaccine can hinder access to a new vaccine (timewise and research-wise). If there is a technical lack in "proving the usability of a patent," this should be corrected in a way where the courts have a chance to request amendment of the patent descriptions, without necessarily invalidating the patents. This case presented intriguing reasoning from judges on human rights within applicable laws.

In the judgment of the CJEU in *Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon*[99] on a similar issue regarding patents older than the Lisbon Treaty, the viewpoint of the CJEU was that:

> *[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.*[100]

Regarding the EU pharmaceutical industry, two of the famous clashes are those of *Novartis AG (Switzerland) v. Union Of India* case and the events when Novartis threatened to go to arbitration against Colombia.[101] Novartis held patents in many countries, including India and Colombia, for Glivec, a drug used to treat cancer. In the first case, the Indian Supreme Court upheld the Indian Patents Act against Novartis' patents and allowed for "access to medicine" in an affordable manner. In the latter conflict (against Colombia), Novartis threatened to resort to international arbitration on the grounds of an alleged violation of the Swiss-Colombian BIT. The question again was whether States should invalidate such critical patents or allow CL in case of a conflict with patent laws or BITs. The WTO has stated 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."[102] This is considered to create flexibility. Many countries allow for CL, but this issue was regulated under TRIPS, as discussed above in relation to the *Eli Lilly v. Canada* case.

Nonetheless, the type of disease and the relevant access to medicine is crucial to take into consideration when deciding on strong measures like CL. For instance, in the case of HIV/AIDS, millions of people were affected by the time the first HIV antiretrovirals were produced. Moreover, only one in a thousand of those patients had access to such antiretroviral medicines. More than eight thousand humans were dying of HIV/AIDS daily. Conflicts on HIV-related medical patents came after the adoption of TRIPS. Therefore, some nations revoked or invalidated patents and others reverted to CL in relation to the aforementioned decisions.

6. APPLICABLE LAWS AND HIERARCHY

The issue of the applicable laws to be considered by courts in such conflicts is complicated, because judges must decide which instruments are applicable and create a hierarchy based on the case at hand. First, regarding IHRL, it is within the powers of the court to neglect it, consider it as a fact, or leverage its value as the highest of legal instruments in the conflict. Second, the TRIPS Agreement could be part of the IP regime in a state. One possible way to better consider this applicable law is to view TRIPS within the conflict as falling partly within the IP regime and partly within the world trade regime. TRIPS is not only intended for patent protection, but it is one of the WTO agreements. Consequently, it falls 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) intersects with the IHRL regime (moral-based). When a clash occurs, current practices show that the organization of hierarchy between the two is underdeveloped.[103]

7. STRENGTHS AND WEAKNESSES OF TRIPS AS A WTO AGREEMENT

The WTO regime has a strength in its reach, which has two causes: many states are members, and trade touches most aspects of life. However, this strength becomes a weakness in case of conflicting interests, because when

the WTO touches upon other spaces, any other legal system becomes a potential colliding force, as many other systems affect trade. For instance, in the cases of seizure of generic medicines in transit[104] in EU ports, although the EU police doctrine (discussed in subsection 9.4) considered this act lawful, it did affect trade relations. Hence, trade rules and trade sanctions can touch on many aspects in many states.[105] How can pharmaceutical patents be enforced during wars or pandemics if IHRL requires fulfilment of the right to access medical goods in the best possible way? This involves ensuring speed and quality, without discrimination. Do we see this happening during the COVID-19 pandemic, among all the signatories to those two legal norms? Should not this pandemic lead to prioritization of IHRL over any other regime? The answer to the second question is yes, but how and to what extent?

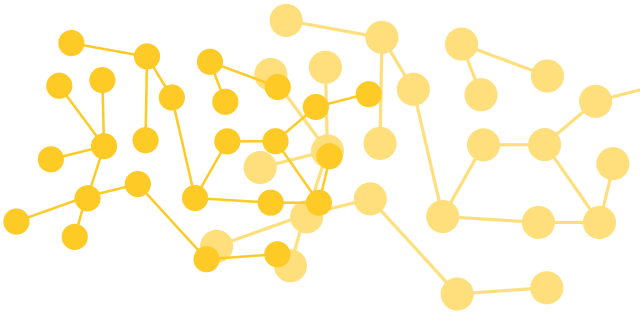
Although TRIPS obliges WTO Members to introduce patents, it allows them to make use of certain exceptions. As patents unjustifiably interfere with "access to medicine" during disasters and pandemics, nations and governments can only escape the violation of their IHRL obligations by invoking such exceptions. This flexibility of TRIPS is a strength for all parties. It generally does not provide for exclusion from patentability, but rather for a limitation of patent rights.

8. UNIFICATION OR REORGANIZATION OF REGIMES?

Unification of regimes refers to substantive uniformity, preventing conflicts between norms.[106] However, during pandemics, when we need quick decisions, it would not aid legislators or courts in faster and better understanding of the intersection of conflicting norms. The question then becomes if total divisibility (separation) of regimes, i.e., creation of special norms (lex specialis of IHRL and patent law) in the legal space would help. Total independence from the moral obligations of IHRL during pandemics would mean that only TRIPS applies. How do we reflect IHRL in legal decisions? IHRL must be considered as higher ranking, otherwise we would go against all the articles that protect the right to "life," "health," "access to medicine" and "prevent epidemics" (Article 11 European Social Charter).[107] For this reason, this paper proposes a reorganization of the overlapping laws in case of health emergencies and pandemics.

The proposed reorganization sheds light on the fact that TRIPS should not be considered to be only an IPR instrument, as it stems from a trade purpose (a WTO regime). Even in its protection of patents, TRIPS sets a minimum protection standard for invention owners (pharmaceutical companies) so that trade relations run more smoothly. Although TRIPS is used to harmonize EU patent legal systems, a large part of it is focused on trade. The proposed reorganization considers the trade part not intersecting (thus not conflicting) with IHRL and the right of "access to medicine." This does not mean that TRIPS and IHRL do not intersect at all. These two regimes intersect in the parts related to patents, i.e., Section 5 TRIPS (Articles 27–34).

Therefore, this paper considers the overlap with Section 5 TRIPS, where the most relevant point of intersection is Article 28 TRIPS, on patent protection. On the other hand, IHRL instruments intersect with this part of TRIPS in several parts: Article 4 ICESCR, Article 4 ICCPR, Article 6 ICCPR on protection of the right "to life," Article 15 ICESCR and Article 27 UDHR. If practitioners or courts focus on the aforementioned articles of TRIPS and IHRL instruments, a well-defined frame of intersection between the different laws would be constructed. This is a reorganization that includes placing the right of "access to medicine" as a human right of the highest rank when it comes to lifesaving medicine (vaccines, antivirals, and antiretrovirals) in pandemics. The case law discussed above, where claims of expropriation had been filed, shows us that the legal space would include bilateral agreements only when a patent is defined in such an agreement under the section relating to investment. This makes a pharmaceutical manufacturer that owns a patent an investor in the state where the patent is registered. In such cases, any bilateral treaty would become part of the reorganized legal space, in addition to all the aforementioned articles of TRIPS and IHRL. Although this model of thinking about the legal spaces shows a clear intersection of subsets (articles) of



[99] 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 CJEU (Grand Chamber 18 July 2013).

[100] Ibid. para 82.

[101] Business and Human Rights Resource Centre, "Colombia: Leaked documents reveal Novartis threatened govt. with intl. investment arbitration over licensing of pharmaceutical patents" (12 Apr 2017) https://www.business-humanrights.org/en/latest-news/colombia-leaked-documents-reveal-novartis-threatened-govt-with-intl-investment-arbitration-over-licensing-of-pharmaceutical-patents/ accessed 3 March 2020; Public Eye, "Compulsory licensing in Colombia: Leaked documents show aggressive lobbying by Novartis" Press Release (11 April 2017).

[102] See, TRIPS and Health Frequently Asked Questions https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm#:~:text=What%20is%20compulsory%20licensing%3F,the%20patent%2Dprotected%20invention%20itself.

[103] Hestermeyer (n 55) 206.

[104] WTO (n 86).

[105] 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.

[106] Mario Prost, The Concept of Unity in Public International Law (Hart Publishing 2012) 46–48.

[107] ESC (n 44) Art 11.

legal instruments, it does not mean that there would always be conflicts within the intersecting areas. For instance, the UDHR instrument does not necessarily always interact with patent definitions in BITs. In this way, the proposed model can be in harmony with the practical reasoning in the aforementioned case law. This is because the case law took into account both regimes of trade and human rights. In this respect, the proposed reorganization does not mean that there is a unification with no conflicts between the rules, or that there is divisibility with prevention of conflict. Rather, it means that there are overlapping areas that could clash in some cases.

Regarding priorities (hierarchy), case law observation shows that each case has its own hierarchy. For instance, Article 11 ESC is lower in hierarchy than any article in ICESCR or ICCPR because they are higher-ranking 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 is whether this could work with the Biotechnology Directive[108] in the EU. The answer, based on case law of the CJEU, is negative. Hence, this reorganization model calls for a stronger EU patent law: a unified patent law. Since the value of human life should be of highest rank, the unified patent law should ensure that the hierarchy prioritizes human life over monetary goals while keeping patent protection relevant, to achieve a balance.

9. BALANCING PHARMACEUTICAL PATENTS AND MEDICINE ACCESSIBILITY

Without a balanced view on TRIPS/WTO and IHRL during pandemics, nothing significant would be achieved. Some previous work has been done in this regard, which is presented below. This previous work paves the way for possible recommendations. In this respect, this paper investigates relevant instruments, *inter alia* TRIPS and ICESCR.

9.1. TRIPS flexibilities

The TRIPS Agreement allows flexible measures to limit the rights of patent owners. The right of access to medicine is one argument among many in the flexibility interpretation.[109] For instance, one flexibility lies in Article 6 TRIPS, which covers patent exhaustion:

> *For 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.*

Some courts interpret it as an "agreement to disagree," making each WTO member free to decide whether or not to observe the principle of international exhaustion of patents (in imports).[110]

Another flexibility is found 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 patent protection. As the heading of TRIPS Article 31 ("Other Use Without Authorization of the Right Holder")[111] and its footnote explaining the meaning of the phrase "Other use"[112] indicate, the exceptions in Article 30 apply without the authorization of the patent owners. Accordingly, they can limit the effects of a patent monopoly, i.e., lower product (medicine) prices. The wording is not precise, but it paves the way for an entry point to use the right of "access to medicine." The third point is in Article 27(1) TRIPS:

> *(...) 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.*

Some states argue that the non-discrimination rule is

[108] 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).

[109] Hestermeyer (n 55) 229 ff.

[110] See Mag Instrument Inc. v. California Trading Company Norway, Ulsteen (Case E-2/97) E1997P0002 EFTA (3 December 1997) and Bundesgericht (Switzerland), Kodak SA v. Jumbo-Markt AG, 31 IIC 1018, 1022 (2000).

[111] See Heading of Article 31 TRIPS which states, "Where the law of a Member allows for other use(7) 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 provisions shall be respected:" The reference to footnote 7 in this heading is explained in footnote 112, below.

[112] See footnote 7 in Section 5, Part II ("Standards concerning the availability, scope and use of Intellectual Property Rights") of TRIPS stating that "'Other use' refers to use other than that allowed under Article 30 [of TRIPS]."

[113] Hestermeyer (n 55) 237–238.

[114] Ibid.

[115] 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.

[116] Hestermeyer (n 55) 239 ff.

[117] WTO (n 7) art 31bis of the TRIPS Agreement as amended on 23 January 2017.

[118] Heading (n 111).

[119] Contra D Gervais, The TRIPS Agreement. Drafting History and Analysis (2nd ed 2003).

[120] F-K Beier, "Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law" (1999) 30 IIC 251, 259–260.

[121] Ibid. 260.

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

[123] 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.

[124] 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.

subject to the exception of Article 30 TRIPS, thus establishing separate rules for pharmaceuticals.[113] 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.[114]

The fourth point is TRIPS 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.*

Moreover, an important TRIPS flexibility is in Article 8 (below), allowing amendments to protect public health; hence, this adds a possibility to request amendments during a pandemic, 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.

9.2. International Human Rights Law (IHRL) provisions

Article 15 ICESCR tries to strike a balance between the protection of the interest of the inventor and public access to the invention, as indicated by both Article 15(1)(a), (b) and paragraph 2 of that provision.[115] The problem is that this article has been made dormant, and a practical solution is needed to put it in use again.

9.3. Compulsory licenses (CL)

The most appealing legal solution for states to lower medicine prices is CL granted by domestic courts. CL do not require any consent from the pharmaceutical companies (patent owners). With CL, the court does not invalidate patents, as in the *Eli Lilly* case, but authorizes other parties to produce drugs, so the government can fulfil its obligation of accessibility. The CL solution is threefold as it: (1) safeguards access to medicine; (2) promotes local competition, and (3) supports local industry.[116] The states that were for or against CL relied on TRIPS Article 31 and Article 31bis:[117]

TRIPS Article 31

According to this Article[118] (...) the following shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. (...)

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized (...)

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. (...)

(...)

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(...)

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

(...).

TRIPS was amended on 23 January 2017 by adding Article 31bis, an Annex and an Appendix. The amendments provided a legal basis for a WTO Member State to grant exclusive CL for producing generic medicines as well as for 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 under Article 30 TRIPS, it is checked through Article 31.[119] Nonetheless, most patent laws in industrial states (including the USA) include provisions to grant CL. Courts have granted CL in antitrust cases.[120] In some cases, CL push the pharmaceutical patent owners (companies) to lower their branded drug price.[121] Some researchers state that CL may only be granted in cases of patent abuse by the company, based on Article 5A(2) of the Paris Convention.[122] This is applicable via Article 2(1) TRIPS permitting members to grant CL to "prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent."[123] Moreover, Article 8(1) TRIPS (see above) requires members to show that CL are necessary for *ordre public*.[124] Even though CL lower drug prices, they have some weaknesses since they may discourage pharmaceutical companies from operating in a certain region or push them to find other ways (politically) to fix their prices. During the COVID-19 pandemic, if states were to inform pharmaceutical companies of a governmental will to grant CL, those companies would – most probably – stop their vaccine R&D programs. Hence, CL are not an optimal long-term solution during pandemics.

9.4. Principle of proportionality

The proportionality principle was initiated as an idea in Aristotle's Nicomachean Ethics (Book V): to serve human good and be just, by 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 striking a balance by finding the relationship between the end result and the means to reach it. The principle aids conflict resolution by balancing public interest arguments with the rights of the patent owners (e.g., pharmaceutical companies). It "demands there should be a reasonable relationship of proportionality between the means employed and the aim sought to be realized."[125] To apply this principle, three procedures need to be executed.[126] First, courts need to evaluate if a measure was suitable for its aim. The judges should check if there was a logical and acceptable link between what one party did and what its final goal was e.g., access to medicine. The second procedure is the evaluation of whether or not the goal could have been achieved with a less intense measure. The third and final procedure is the actual evaluation of the proportionality (balance estimate) between the measure and the benefit sought. Good examples include the two cases of *Azurix Corp. v. The Argentine Republic*[127] and *Biwater Gauff (Tanzania) LTD. v. United Republic of Tanzania*,[128] where the judges cited the ECtHR regarding the need for a reasonable relationship between the burden imposed on a foreign investor and the interest that the enforcement measures intended to achieve. Although this principle was applied by the ECtHR, its use causes confusion due to the practical difficulty of balancing the private interests of pharmaceutical companies against public interests.

9.5. Exception clauses

The use of exception clauses is an idea borrowed from the trade law instrument GATT.[129] Unfortunately, it does not refer to human rights, since it prioritizes business. Exception clauses may aid in achieving a balance between patent law and human rights by clearly explaining when a state can take exceptional regulatory measures to protect its public interest during pandemics without being held responsible for affecting the interests of pharmaceutical companies. It adds a maneuvering flexibility, which is crucial in cases of threats of legal obligations in relation to the right of "access to medicine." Nonetheless, there is not a wide implementation of exception clauses. Norway, Canada, and the USA include clearly articulated exception clauses in their agreement models. They mention that nothing in the agreement shall be construed as preventing a party from adopting measures "necessary to protect human, animal or plant life or health."[130] Such exception clauses achieve a kind of balance between the private interests of pharmaceutical industries and the public interest in the right of "access to medicine."

9.6. Doctrine of police powers

In this doctrine, police powers are viewed as "[t]he 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."[131] Health officials may use police powers to enforce a treatment and prevent a specific healthcare conduct.[132] Much like in the case of exception clauses, Canada and the USA have models that include clauses to allow for the police power doctrine to be considered and used in favor of the state. This doctrine is as useful as the exception clauses, but its application has been limited to a few cases.

9.7. Corporate responsibility

Pharmaceutical companies have a responsibility to people. Under the current critical need for a COVID-19 vaccine, the right of "access to medicine" cannot be achieved if the business/investor only sees monetary dimensions, without giving regard to the human side. Patients and governments would face a huge 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.[133] However, in life-critical matters, they should bear responsibilities. The important issue is for courts 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."[134] As a solution to this problem, this paper recommends clearer clauses for an obligation on pharmaceutical companies to give away the secrets to vaccines/antivirals in the case of a pandemic. Further, the clauses could state that after the pandemic, the company that revealed the secret would be granted a right to seek monetary compensation from states and specific organizations like the WHO and others. This issue – how pharmaceutical companies (as patent owners) could be given a monetary kickback after a pandemic – needs attention before the next COVID-19 vaccine/antiviral is ready to market and before another virus outbreak occurs.

9.8. Pricing vs. R&D

The crux of the matter lies in the high prices relative to the financial conditions of the patient (e.g., within the USA, the EU, and other countries). During pandemics, the cost for giving the vaccine to all the citizens at once can be higher than a budget may allow. If the R&D phase of pharmaceuticals (5–10 years, with hundreds of million EUR/USD being invested) is supported by large governmental budgets with clear legal provisions to protect pharmaceutical companies' interests and patients' lives, this can sooth the pandemic conflict. If not, imposing CL or obliging pharmaceutical companies to give away the secrets of their inventions (medicines) for free may shut down R&D entirely. Thus, the problems reside in the costs. If the costs of R&D in pharmaceutical industries are lowered with the help of governments and the WHO, the medicine prices can and would be lowered. Tackling this business issue is not easy – but it is feasible, especially with the strong interest and will created by a pandemic. Therefore, this paper suggests adding provisions that clearly require

states to invest in pharmaceutical industries during pandemics. New laws could make this an obligation, rather than a recommendation. This calls for international institutions to help creating or phrasing such new provisions to control prices and ensure access to vaccines against COVID-19 and in future pandemics.

10. PROBLEM IDENTIFICATION

Identifying problems that need attention is crucial before trying to find solutions. The first problem identified was in the justification used by pharmaceutical companies regarding the aim of patents. They indicate that highly priced medicine is the largest incentive for inventors to keep conducting pharmaceutical research, without which many medicinal products would not be *available*. Thus, high prices serve to satisfy the obligation of *availability* of medicine. The problem is that they go against the second obligation, that of *accessibility*. This issue needs to be addressed by judges and practitioners, and attention to this is needed on the part of governments, the EU, the WTO, and related organizations.

The *second problem* that needs revisiting is the *negligence* of the right recognized in Article 15(1)(b) ICESCR for everyone "To enjoy the benefits of scientific progress and its applications." This right has been dormant and not used for decades, and this problem requires attention to this, to support "access to medicine."

The *third problem* relates to *the divisibility* of laws in many cases, where the intersection between patent laws and IHRL instruments is not fully studied. There is a need to attend to this problem, perhaps through the reorganization discussed in section 8. It would promote an understanding of where to look for provisions in case of such conflicts. The proposal considers the intersection of the two regimes in a number of articles, outside the trade issues in WTO/TRIPS. Hence, practitioners and courts should focus on: (i) Section 5 TRIPS (Articles 27–34), with significant regard to Article 28 and (ii) a few IHRL instrument articles, namely Article 15(1) ICESCR with Article 27 UDHR, Article 2 ECHR (based on Article 11 of the ESC), Article 4 ICCPR on limitation clauses, Article 4 ICESCR, and Article 6 ICCPR protecting the right "to life" by law.

In addition to identifying problems, this section presents recommendations based on: (i) previous work discussed in this paper and (ii) new ideas. Before reading the recommendations, it is advisable to study the decisions made by the CJEU regarding copyright in relation to human rights, so as to understand – by analogy – how to strike a balance. The three CJEU cases are: *Funke Medien NRW GmbH v. Federal Republic of Germany,*[135] *Pelham GmbH, Moses Pelham, Martin Haas v. Ralf Hütter, Florian Schneider-Esleben,*[136] and *Spiegel Online GmbH v. Volker Beck*.[137] These cases had a common issue; they required the CJEU to balance between IPR (copyright) and fundamental rights. By analogy, this research relates to the balance between IPR (patents) and human rights. In the aforementioned three cases, the CJEU stated that the EU Charter of Fundamental Rights contains rights corresponding to those guaranteed by the ECHR. Moreover, Article 52(3) of the Charter seeks to ensure consistency between the rights contained therein and those guaranteed by the ECHR, without affecting the autonomy of EU law or the CJEU. The difference here is that with regard to patents, we have only the Biotechnology Directive, which is not very clear on the issue of the right of "access to medicine." However, we can – by analogy – try to give recommendations that do not harm either side of the balance and respect the autonomy of EU law.

[125] EDF Services Limited v. Romania, ICSID Case No ARB/05/13 Award (2009) 293.

[126] M Andenas and S Zleptnig, "Proportionality: WTO Law: In Comparative Perspective," Texas International Law Journal, vol 42, No 3 (2007) 371–427; N Diebold, Non-discrimination in International Trade in Services: 'Likeness' in WTO/GATS, (Cambridge University Press 2010).

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

[128] Biwater Gauff (Tanzania) LTD. v. United Republic of Tanzania, ICSID Case No ARB/05/22, Award (24 July 2008).

[129] General Agreement on Tariffs and Trade (1994) ("GATT").

[130] Ibid. Art XX(b).

[131] The Law Dictionary, "Police Powers" https://thelawdictionary.org/police-power accessed 1 June 2019.

[132] UNAIDS (Joint United Nations Program on HIV/AIDS) Criminal law, public health and HIV transmission: a policy options paper, Geneva, Switzerland (UNAIDS 2002).

[133] 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.

[134] OECD, Guidelines for Multinational Enterprises (OECD, 2000) Preface, para 1.

[135] Funke Medien NRW GmbH v. Federal Republic of Germany (Case C-469/17) EU:C:2019:623 Judgment CJEU (29 July 2019).

[136] Pelham GmbH, Moses Pelham, Martin Haas v. Ralf Hütter, Florian Schneider-Esleben (Case C-476/17) EU:C:2019:624 Judgment CJEU (29 July 2019).

[137] Spiegel Online GmbH v. Volker Beck (Case C-516/17) EU:C:2019:625 Judgment CJEU (29 July 2019).

11. RECOMMENDATIONS

This research adopts some previous solutions, adds some relevant recommendations, and also puts forward some new ideas as recommendations.

First, this work adopts use of the available TRIPS flexibilities from the patent law side and Article 15 ICESCR from the IHRL side.

Second, it adopts the principle of proportionality and recommends its use by practitioners. However, this principle needs leveraging in its practical use, enlisting the help of law experts and economists to formulate a benchmark method.

Third, this work adopts the solution of exception clauses and proposes that the EU parliament, governments, and the WTO create legal templates with specific and clear clauses for protecting the human right of "access to medicine" without threatening states of being accused of expropriation.

Fourth, it adopts the principle of police powers of states when protecting the right of "access to medicine," especially in critical situations like pandemics. However, the recommendation is made to add clearer clauses to limit these powers.

It is worth mentioning that regarding CL and pricing, this work does not entirely adopt this solution, since many issues remain hard to settle and are case-dependent. Although patent revocation is more difficult than CL, CL are tough on pharmaceutical companies, which can invest hundreds of millions of dollars in R&D (as has been the case during the COVID-19 pandemic).

The second set of recommendations stems from new ideas identified through this research and requires the attention of governments (including the EU), financial institutions (including the European Investment Bank), the WHO, the WTO, and pharmaceutical companies.

Fifth, this paper recommends a reorganization of laws, as discussed in section 8, especially during pandemic times. The current state of defragmentation clearly indicates which provisions must be looked at when there is a clash between patent laws and the right to "access to medicine." Doing so proactively could streamline solutions. We cannot expect to solve the problems of pandemics in real time. Pharmaceutical industries invest huge amounts of money to develop vaccines, with the incentive of large ROI, and humans need vaccines. To balance such issues, R&D costs must be lowered for pharmaceutical companies – but not by threatening with CL. Hence, governments (including the EU), the WHO, and other organizations must compensate pharmaceutical businesses. To do so, legal rules must be in place before a pandemic occurs. We cannot afford creating real-time solutions by legislating during a crisis. This calls for creating legislations and provisions to be used in case of a pandemic, i.e., provisions specifically made for pandemics. This could include amending TRIPS by invoking its Article 8(1) to reformulate or add provisions based on the public interest and need. In this respect, the recommendation is to include clauses for protecting the human right to "access to medicine," which could be invoked during pandemics. Examples of such amendments have occurred within the WTO: the Doha Declaration, the South Africa pharmaceutical trial, and the decision in 2005 to amend TRIPS.[138] This investigation also recommends adding WTO provisions to invest in pharmaceutical R&D departments at lower prices. Many states have affirmed commitments to including human rights in WTO instruments, but nothing has materialized. This paper recommends making use of the COVID-19 pandemic as a driver to make legislation – because it is currently up to judges' interpretations to oblige pharmaceutical companies or governments to fulfill their legal obligation of "access to medicine."

Sixth is a recommendation related to clauses for e*xceptions on patents*. This has been discussed in many IP circles since the COVID-19 outbreak. The paper recommends a provision related to pharmaceutical companies on patent exceptions (to be invoked in pandemic outbreaks only): (i) having R&D funded by governments (including the EU), the EU Investment Bank, and/or IP finance organizations, with a clear limit on how much the business can profit (to control drug prices) and (ii) being granted IPRs as special patent rights only *after* the pandemic. In the EU, we have recently witnessed a budget proposal from 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."[139] Moreover, the EC (on 27 May 2020) published 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."[140] Although this appears promising, especially as regards the goal to supply affordable medicines (considering the two obligations of *availability* and *accessibility*) and support pharmaceutical companies in Europe, the issue is that there is no clear funding strategy for research on legal provisions that support the fight against epidemics/pandemics when they occur. In addition, there is no clear view on how control of pricing could be practiced. This calls for a thorough study on how large an R&D fund percentage is needed by public institutions to control the price, so that the governments (including the EU) meet the legal obligation of medicine *accessibility*. Therefore, there is a need for work towards the goal of having provi-

[138] Hestermeyer (n 55) 255–287.

[139] Ben Upton, "National leaders to debate contentious budget increase for European research" (4 June 2020) Research Europe, Issue No 520.

[140] Ibid.

[141] WTO (n 86).

[142] Medicines Patent Pool (MPP) UNITAID (2020).

sions that aid in funding pharmaceutical R&D (with precise proposals on the percentages needed to control prices), as well as clearly written patent exception clauses that are set to invoke at the start of a pandemic.

Seventh, regarding the use of some police powers (like in the cases of seizure of generic medicines in transit[141] in the Netherlands and Germany), this may lead to trade agreement problems, especially when there are bilateral treaties that define a patent as an investment and the pharmaceutical company (patent owner) as an investor. The recommendation here is for governments (especially when the EU signs agreements with non-EU states) to have clear clauses in their agreements (BITs) that show exactly where the pharmaceutical obligations and rights reside and to clarify when the right of "access to medicine" may be invoked by governments. The time is ripe for including the phrase "access to medicine" in treaties, as well as clear provisions on what would be expected from each party in case of a pandemic.

Eighth, this work recommends pharmaceutical companies to use the Medicines Patent Pool (MPP)[142] licenses to negotiate public health-driven licenses with patent owners and to sublicense to generic manufacturers in some cases. The MPP has well-written agreements with clear articles to protect both the pharmaceutical companies and the licensee.

Ninth, this paper recommends governments and pharmaceutical industries to focus on the following *four objectives* in delivering a vaccine: (i) satisfying the obligation of *quality*, (ii) on *time*, (iii) within *budget* (provisions to aid R&D funds), and (iv) with *supportive applicable* laws. Currently, we can witness pharmaceutical companies focusing on the first three objectives, and governments focusing on the first two. In other words, there is no support for R&D from governments. The reason is that there are no previously existing clear provisions on this to invoke during pandemics. More importantly, point (iv) is ignored entirely, even though we need laws to control the process of vaccine production and pricing. During the next pandemic, we cannot create applicable laws in real time. Hence, we need to be proactive now and create suitable provisions regarding "access to medicine." This would help us in future pandemics.

Tenth, the final recommendation is based on the fact that without a unified patent regime in the EU, it is not possible to achieve the four objectives mentioned above: delivering a quality vaccine, on time, within budget, and with supporting applicable laws. COVID-19 should be a wake-up call for governments in the EU to create a unified EU patent law, since it would surely speed up the processes that will help us strike a balance in this matter.

12. CONCLUSIONS

This paper highlights problems that require attention and makes some recommendations, because the current pandemic and those of the future require proactive legal measures so that uncontrollable suffering will not devastate the world further. Unfortunate delays that have led to suffering and death could be minimized by resolving the conflict between pharmaceutical patents and the human right of "access to medicine" in the current COVID-19 crisis and in future outbreaks. We cannot amend or create applicable and appropriate laws in "real time" during pandemics. We need to be proactive with suitable provisions on "access to medicine." In the conflict between patent laws and the human right of "access to medicine," the applicable norms identified in this paper are mainly the TRIPS/WTO regimes and the IHRL instruments of UDHR, ICCPR, ICESCR, CERD, ECHR, the EU Charter of Fundamental Rights, and the ESC. One helpful result of this work is the identification of legal problems that require attention, through an investigation of the intersection of laws and the need for CL or patent exceptions. Another result is a proposition of reorganization of the provisions that play into the conflict, with the goal of striking a suitable balance. The focus on the patent side is on Section 5 TRIPS (Articles 27–34), with Article 28 being the most relevant. On the human rights side, the proposed reorganization calls practitioners, policymakers, pharmaceutical industries, and institutions to focus on the overlap of critical medicine patents with Articles 4 and 15 ICESCR, Article 27 UDHR, Article 11 ESC (also reflecting Article 2 ECHR and Article 35 EU Charter of Fundamental Rights), Articles 4 and 6 ICCPR on protection of the right "to life." The legal obligations that IHRL has upon patent law (regarding access to medicine) are: *availability, accessibility, acceptability, and quality*. The paper divides case law into two groups: (i) no filing for expropriation, and (ii) filing for unlawful expropriation. The research adopts some previous work on balance (TRIPS flexibilities, ICESCR Article 15, the proportionality principle, exception clauses, and the police power doctrine) and adds some new ideas to their application. One of the ten recommendations in this work 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 the human right of "access to medicine" and not be subject to attribution and responsibility. Another important recommendation is the use of MPP licenses for pharmaceutical companies. Lastly, to minimize the impact of the current pandemic and future disease outbreaks in the EU, this work recommends a unified EU patent law with specific provisions that can be invoked in the event of epidemics or pandemics, ensuring the right of "access to medicines."

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