Interpretation of Article 27(2) of the TRIPS Agreement: Better way to reconcile innovation and equitable access to essential medicine

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1. INTRODUCTION

1.1. Background

Patent laws are designed to encourage inventors to make innovations that require time and money, and those innovations are supposed to enhance discoveries and developments in every field of science.[1] The aim to create incentives has a long history in this field.[2] Related to this, Ayn Rand argues that the "Human mind itself is the source of wealth and survival and that all property at its base is intellectual property."[3] Many individuals believe that their ideas could make a change in the world and bring important benefits to themselves through their ideas. In this regard, individuals and companies tend to innovate and get patents on medicines among other things to invent new methods of treatments and drugs to cure diseases. On the other hand, it has been recognised by the Universal Declaration of Human rights and explained by the International Covenant on Economic, Social and Cultural Rights that every human has the right to enjoy the highest standard of mental and physical health.[4] As can be expected, having access to essential medicines is one of the elements that provide an adequate standard of health for individuals. Furthermore, as Article 1 of the Universal Declaration states, the right to health is derived because all humans are equal in dignity.[5] Therefore, making essential medicines accessible to the public while also encouraging inventors' progress[6]becomes a vital task.

As mentioned, the purpose of patents is to give an exclusive right to the patent holder so that no other competing supplier could enter the market with the same invention.[7] Hence, patents create a legal monopoly in favour of the patent holder and eliminate competition. Consequently, when competition is eliminated; high prices start to emerge in the market.[8] Since high prices would make it harder for many people to access medicines, several instruments, such as compulsory license method, generic drugs and patent waivers are used to resolve this issue. Further, WTO is aware of this fact as well and as a result, they included compulsory licenses in the Doha Declaration as a solution. Article 31 of the Doha Declaration states that "a third party or the government can use a patent without the authorization of the right holder in cases of public interest, such as cases of public health emergencies when it is necessary to

[1] World Health Organization, *Advancing the Right to Health: The Vital Role of Law* (World Health Organization 2016) <https://apps.who.int/iris/handle/10665/252815> accessed 16 June 2022.
[2] 'Founders Online: Thomas Jefferson to Isaac McPherson, 13 August 1813' <http://founders.archives.gov/documents/Jefferson/03-06-02-0322> accessed 16 June 2022.
[3] Extended Learning Institute (ELI) at Northern Virginia Community College (NOVA), "Introduction to Computer Applications and Concepts" (Lumen)
[4] UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A (III), available at: https://www.refworld.org/docid/3ae6b3712c.html, UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, available at: https://www.refworld.org/docid/3ae6b36c0.html
[5] Article 1 Universal Declaration of Human Rights
[6] Philippe Cullet, 'Patents and Medicines: The Relationship between TRIPS and the Human Right to Health' (2003) 79 International Affairs (Royal Institute of International Affairs 1944-) 139, 140.
[7] World Health Organization (n 1) 231.
[8] Ibid 232

lower the prices of medication."[9] Although this license aims to make it easier to access medicine, it is regarded as an unsuccessful attempt in several sources due to bureaucratic impediments, still having high prices which are hard for LDCs to afford, and long periods for approval of the licence.[10] Further, in the TRIPS agreement, exceptions to patentability are provided in Articles 27(2) and 27(3)[11] but they are not necessarily used in essential medicines. Nevertheless, it is important to link the concepts under the provision with the accessibility of medicines to have a deeper understanding of the notions mentioned.

Firstly, to be exempted, commercial exploitations of inventions should be contrary to "ordre public" and/or "morality" or they should be listed under Article 27(3). Defining morality or "ordre public" could not be done without referring to different sources which indicate that these concepts prevent actions that would be against social structure or humanity.[12] When focusing on the concepts in the field of pharmaceuticals, the distribution of medicines becomes important, because, as said in UDHR, everyone should be treated equally. For instance, "About one-third of the world's population does not have access to basic drugs"[13] and only 10% of the current research on pharmaceuticals focuses on the diseases that affect 90% of the global disease burden[14]: the problem of neglected diseases. One reason for this problem is that drug companies tend to develop drugs that can be sold at high prices and do not invent medicines for diseases that affect only the poor countries because they incur expenses on R&D and need to recoup the money they spent on this process. This can be seen as only "One new drug has come on the market in the last half-century to treat tuberculosis, a disease which killed 1.5 million people in 2013"[15], however, "more money is invested in research of drugs against baldness than in research of all tropical diseases combined".[16] Looking at these statistics, one could be inclined to think that tropical diseases are rare around the world. However, more than one billion people are struggling with neglected tropical diseases and millions of people are dead or disabled because of these diseases.[17] Therefore, it is possible to conclude that these

[9] Rivka Shaindla Ajzental, "Compulsory license: analysis of the effectiveness in providing access to medicines" (LLM Thesis, Universiteit van Tilburg European and International Public Law 2018) 16

[10] Cullet (n 6) 79; Ajzental (n 10); "D4 The Trips Agreement: Two Decades of Failed Promises" [2014] Global Health Watch 4; Visanko HHE, "Pharmaceutical Patent Monopolies' Effect on Access and Availability of Medicines: Problems and Solutions" (Dissertation Universiteit van Tilburg Business Law 2016), also see supra note 37

[11] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]

[12] Viola Prifti, 'The Limits of " Ordre Public" and "Morality" for the Patentability of Human Embryonic Stem Cell Inventions' (2018) 22 The Journal of World Intellectual Property 4.

[13] Cullet (n 6) 143.

[14] Thomas Pogge, 'The Health Impact Fund: How to Make New Medicines Accessible to All' (2011) 246.

[15] Fran Quigley, 'Making Medicines Accessible: Alternatives to the Flawed Patent System' (Social Science Research Network 2015) SSRN Scholarly Paper 3496793 <https://papers.ssrn.com/abstract=3496793> accessed 16 June 2022 citing World Health Organization, Tuberculosis Fact Sheet (Geneva: WHO, 2015). Available at http://www.who.int/mediacentre/factsheets/fs104/en/

[16] Sigrid Sterckx, 'Patents and Access to Drugs in Developing Countries: An Ethical Analysis' (2004) 4 Developing World Bioethics 58, 69.

[17] World Health Organisation, Department of Neglected Tropical Disease. "Ending the neglect to attain the sustainable development goals: a road map for neglected tropical diseases 2021–2030" (2021), WHO/UCN/NTD/2020.01. 2

types of diseases are neglected not because they are rare, but because innovation does not reach out to the developing or least developed countries to provide a solution to current medical problems. Since there would be no return on the investments in the case of neglected diseases, patents could not be used as an incentive for those diseases and medicines.[18]

Hence, this distribution of attention and importance are given to different kinds of diseases observed in real-life statistics should be examined by considering the combination of morality and ordre public with the right to health to see whether this distribution is against the public interest in enhancing social well-being. Eventually, it is visible that the current patent regime only incentivises inventors to invent drugs that could be sold at a high price to developed countries.[19] Therefore, there is a need for different incentive mechanisms, which encourage innovation in medicine while preventing the lack of access to drugs and ensuring the right to health.

1.2. Connecting Literature

There are opposing views on patent rights and the accessibility of medicines. One view suggests that medicines should be free from patenting while others think that patent rights are vital for the progress of innovation in medicine. Considering these opposing views, this thesis aims to analyse the different perspectives on the topic and present a new way of looking at Article 27(2) of TRIPS by combining the Article with the concept of "right to health."

To understand how people think differently on this topic and problem, the matter needs to be approached from different perspectives. To start with, Indira Gandhi says, "The idea of a better world is one in which medical discoveries would be free from patent and there will be no profiteering from life and death."[20] Although this is a valid point of view, it might also be argued that patents are a must for innovation in the field of medicine.

As this is an ongoing issue, the philosophy of patent rights is still discussed by scholars.[21] Patents and other intellectual properties are intangible assets and regular property rules do not apply to them. Recognition of intellectual property (IP) rules is accepted since granting rights to the ones who have intangible assets helps them to gain a competitive advantage [22] It is argued that patents can be justified under various philosophical arguments, namely natural rights, distributive justice, utilitarianism, and fundamental human rights.[23] There are valid and important counterarguments against these philosophical approaches, which will be discussed in detail in Chapter 2. While this is the general overview of the philosophy

[18] World Health Organization (n 1).
[19] Ibid 2
[20] 'Patent Regime And Right To Health: National and International Perspective' <http://www.legalservicesindia.com/articles/pg.htm> accessed 16 June 2022.
[21] See John Perry Barlow, "The Economy of Ideas" (Wired March 1, 1994) accessed October 1, 2021, Extended Learning Institute (ELI) at Northern Virginia Community College (NOVA), "Introduction to Computer Applications and Concepts" (Lumen), Tom G. Palmer, "Are Patents and Copyrights Morally Justified - the Philosophy of Property Rights and Ideal Objects" (1990) 13 Harvard Journal of Law & Public Policy 817 - 867
[22] Peter Drahos, *A Philosophy of Intellectual Property* (Routledge 1996) 28
[23] Sigrid Sterckx, 'Can Drug Patents Be Morally Justified?' (2005) 11 Science and Engineering Ethics 81, 84-87–88; Peter Drahos, 'The Universality of Intellectual Property: Origins and Development' 21 <https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=7604> accessed 16 June 2022.

of patents, there are implications of these justifications. Garrett Hardin introduced the notion of the tragedy of the commons and the need for privatization by stressing that private ownership could improve innovation by maximizing 'good' for each person.[24] However, 'good' differs from one to another. Therefore, as the tragedy of the commons shows, everybody should make their own decisions on what to earn and how to benefit, which is linked to privatization. On the other hand, excessive privatization could lead to the tragedy of the anticommons. The tragedy of the anticommons happens when there is too much ownership that nobody can benefit from resources effectively and people are driven to underuse resources.[25] For example, if the amount of the money paid as royalty to patent holders for a drug is higher than the price of sales, there would not be an incentive to produce that product again in the future. Michael Heller explains the effects of the commons and the anticommons in his article, giving examples from different disciplines.[26] Moreover, in their research, Rebecca S. Eisenberg and Michael Heller ask questions, regarding pharmaceuticals patents, on whether they can create a tragedy of anticommons.[27] As this is a delicate subject, it is also important to point out Heller's argument as he explains that various potential drugs cannot enter the market, and the reason behind this is patent anticommons.[28][29] Consequently, the implications of moral justifications for patents can create problems, therefore it is vital to examine these justifications and objections to them.

Secondly, the importance of access to medicine has been an important focal point for society, scholars, governments and organizations.[30] A major challenge emerged during the 90s. Nearly 14 million people died (8.000 people per day) because of AIDS and the lack of access to drugs.[31] In this regard, the Doha Declaration on the TRIPS agreement was introduced by WTO, WIPO, and WHO.[32] These three bodies decided to bring new rules on IP considering public health issues while keeping in mind why IP rights exist. The 'compulsory license' method was also created by the WTO for this aim. The goal of this method was to supply drugs to states and their citizens who cannot afford medicine. Related to this, Carlos María Correa and South Center explain the effects of the Doha Declaration on public health, access to medicine and the compulsory license method.[33] However, Helene Henrietta Emilia Visanko, Rivka Shaindla Ajzental, and Global Health Watch in their separate research explain the failure of the Doha Declaration and the compulsory license method due to bureaucratic impediments

[24] Garrett Hardin, 'The Tragedy of the Commons' (1968) 162 Science 1243, 1243–1248.
[25] Heller M, "The Tragedy of the Anticommons: A Concise Introduction and Lexicon" (2013) 76 The Modern Law Review 7.
[26] Ibid.
[27] MA Heller and RS Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science (New York, N.Y.) 698.
[28] ibid 21.
[29] Also, in the same article it is stated that a drug which could be a potential treatment for Alzheimer could not have the chance to enter to the market, because company needed access to dozens of patents and all the patent holders demanded high royalties.
[30] WTO WIPO WHO, *Promoting Access to Medical Technologies and Innovation - Second Edition* (2020) <https://www.who.int/publications-detail-redirect/9789240008267> accessed 16 June 2022.
[31] "History of HIV and AIDS Overview" (Avert October 10, 2019) accessed October 3, 2021, citing World Health Organisation (WHO) (1999) 'The World Health Report 2009'
[32] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN (01)/DEC/1, 41 ILM 746 (2002)
[33] Carlos Correa, 'The TRIPS Agreement and Developing Countries' (2005) 2010–2046.

such as the long process of recognizing a license, importing and exporting problems, slow communication between WTO, WIPO, WHO and states.[34] Although this process is aimed to help LDCs, all these bureaucratic processes fall upon LDCs which are already in a vulnerable position. Therefore, they must demonstrate again that compulsory license is a necessity for them, while the acceptance of this was already the leading reason for Doha Declaration. As an example of this problem in a real-life case, in December 2004 a Canadian company agreed to produce and export a new anti-retroviral drug (Apo-TriAvir), however, the first shipment of the drug took place in September 2008 due to the slow technical and bureaucratic recognition process.[35] Besides, after this example, different situations arose as to the use of the compulsory license, however, in all three instances use of the compulsory license is withdrawn since a much lower price for the same drug was available in the market as a generic version. Nevertheless, generic versions are not usually available for essential medicines at all such as Type 2 diabetes, breast cancer, lung cancer, prostate cancer, and multiple myeloma or generic versions cannot be used because of patents.[36] Therefore, to assure essential medicines are accessible to everyone in the world, their patentability should be re-evaluated.

To see the problem on a deeper level, as explained in the earlier paragraphs, this thesis also gives great importance to interpretations of morality and ordre public, which is mentioned under the exceptions to patentability, Article 27(2) of TRIPS and their connection with the right to health. To explain these terms more broadly, Viola Prifti, Schellekens, M.H.M.; Vantsiouri, P., and Kathleen Liddell's interpretations of morality and ordre public are beneficial to examine.[37] Kathleen Liddle says that to understand whether an invention is immoral, an intersection between IP and philosophy should be considered.[38] As Liddle's explanation is an abstract one and since it depends on the context, it is necessary to analyse these concepts case-by-case. Likewise, Prifti provides a general definition of these terms and writes, "The concept of morality has been related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong"; ordre public expresses the issues that threaten the values of society and its structure.[39] While examining the connection between the right to health and these concepts, linking them to real-life situations is crucial. In addition to given perspectives on the aforementioned concepts, CESCR General Comment No. 14 states that non-discrimination and equality are important parts of the right to health and "Inappropriate health resource allocation can lead to discrimination that may not be overt."[40] It is stated that if only the privileged class

[34]Cullet (n 6); Ajzental (n 11); Global Health Watch 4 (n 11), Visanko (n 11)
[35] "THE TRIPS AGREEMENT AND ACCESS TO ESSENTIAL MEDICINES" (LLM thesis, University of Amsterdam, International and European Law: International Trade and Investment Law)
[36] Tolulope Adekola, 2020. Has the Doha Paragraph 6 system reached its limits?, Journal of Intellectual Property Law & Practice, 15(7), 527.
[37] Kathleen Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary to *Ordre Public* and Morality' (Social Science Research Network 2016) SSRN Scholarly Paper 2865820 <https://papers.ssrn.com/abstract=2865820> accessed 16 June 2022.; Maurice Schellekens and Petroula Vantsiouri, 'Patentability of Human Enhancements' (2013) 5 Law, Innovation and Technology
[38] Ibid 1-2
[39] Prifti (n 13) 4.
[40] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), 11 August 2000, E/C.12/2000/4, available at: https://www.refworld.org/docid/4538838d0.html 7-8

of the population has access to medicines rather than a comprehensive health care system around the world it would end up with discrimination.[41] However, discrimination can happen in ways that try "to promote equal opportunities, particularly in government and educational spaces for groups who have been historically discriminated."[42] For example, in South Africa, to increase the participation of black people in the country's economy; the Black Economic Empowerment policy is adopted which uses fair, non-arbitrary, and positive discrimination.[43] Nevertheless, as unfair discrimination which relies on arbitrary grounds is prohibited for moral and social reasons, examination of exceptions in line with the right to health is necessary.[44]

In this thesis, the examination of moral justifications for the patent system and evaluation of whether current innovation in medicine still follows these moral justifications will be conducted. Further, this examination and evaluation will be combined with morality and ordre public's connection with the right to health, and the current interpretation of morality provision (Article 27(2)). Finally, this will lead revisiting Article 27(2) of TRIPS which has never been interpreted in a way that includes patenting essential medicines that would be immoral or contrary to ordre public. Shortly, this thesis aims to recommend a new way of looking at the provision with the help of the philosophy of patents, the right to health, prohibition of discrimination, the process of innovation and recommend new mechanisms to develop innovation and prevent lack of access to medicines.[45]

1.3. Research Questions

The controversy between patent rights and accessibility of essential medicine is discussed by several scholars which illustrate the need to find an authoritative way to reconcile them.[46] The aim of this research is to examine the exceptions to patentability in the light of several elements of the patent regime, and eventually recommend a new system which includes new incentive mechanism and legislative changes to Article 27(2) of TRIPS.

Hence, this research will ask the question:

How can Article 27(2) of the TRIPS Agreement be interpreted in a manner that reconciles patent rights with the right to health with the aim of improving equitable access to medicines on a global scale?

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[41] Ibid 8

[42] D Sanchez, 'The Economic Empowerment of African Descendents: Lessons from South Africa's Black Economic Empowerment Strategy' <https://repository.hsrc.ac.za/handle/20.500.11910/3806> accessed 16 June 2022.

[43] Antonio Andreoni and others, Structural Transformation in South Africa: The Challenges of Inclusive Industrial Development in a Middle-Income Country (Oxford University Press 2021)

[44] As stated in the background section, issue with allocation of medicines and research in the current medicine inventions are called 10/90 gap which creates discrimination among humans

[45] As Thomas Pogge recommended Health Impact Fund as a new incentive mechanism in his article, it is going to be discussed in the last chapter of this research. Also, other types of incentive mechanism among patent rights will be provided. These discussions will help to resolve practical implication of the recommended changes in legislations.

[46] Jørn Sønderholm, 'A Critique of an Argument against Patent Rights for Essential Medicines' (2014) 7 Ethics & Global Politics 119; Thomas Pogge, M Rimmer and Kim Rubenstein, 'Incentives for Global Public Health: Patent Law and Access to Essential Medicines' (2010) 1.

To answer this question various sub-questions should be answered, namely:

1- To what extent are patent rights essential incentives for innovation in the field of pharmaceuticals considering current inventions and patents in this field?

2- What is the application, interpretation, and importance of the exceptions to patentability for real-life situations as laid down in Article 27(2) of the TRIPS agreement, and to what extent do these exceptions cover pharmaceuticals?

3- What could be the possible ways and benefits of including essential medicines as exceptions for patentability under the TRIPS agreement?

4-What are the sensible recommendations to better reconcile inventors' rights and the public's access to medicine on a global scale when interpreting Article 27(2) of TRIPS to pharmaceuticals?

1.4. Methodology

During this research, a reform-oriented approach will be used. While this approach is a form of doctrinal legal research, it also includes recommendations for further changes and interpretations while evaluating the sufficiency of current rules. To evaluate the current rules, while bearing the transnational scope of the issue in mind, the TRIPS agreement, reports and materials of WIPO, WTO and WHO will be used. In addition, academic literature will be analysed in these reports as well to understand the concepts and explanations in the agreements, articles, and reports. Moreover, implementations and outcomes of the methods that were used to reconcile IP law with lack of access to medicine are going to be focused on by referring to dissertations, theses, and NGO reports. Finally, decisions made by the European Patent Office (EPO) will be used to illustrate the scope and interpretation of elements of Article 27(2) such as "morality" and "ordre public." Mentioned elements would possibly show that there is a need for new rules in this field and those same elements will be helpful while designing a legal framework.

After explaining the legal framework of patents on pharmaceuticals, this research will examine the existing empirical evidence on access to medicine to see the current issues of lack of access to medicine. Mainly, reference will be had to the data provided by WTO, WIPO, WHO and NGOs. In addition, academic literature will be used to understand what those statistics mean and how they should be interpreted. When analysing statistics, the current situation of medicines, patents and innovation will be compared between developed, developing and least developed countries to show whether discrimination occurs in terms of accessibility to medicine. This research will use interpretations from diverse cultural and economic regions and authorities to see the issue from a transnational perspective. Eventually, comments of scholars and mentioned data on the topic will help to explain whether current patents are effective for innovation and if not, new recommendations will be asserted to reconcile the accessibility of medicines with patent rights.

To examine the exceptions to patentability; the philosophy of patents, morality and discrimination, benefits and risks of preventing essential medicines to be patented will be evaluated. This requires looking at the issue from different perspectives and reconciling them

to incentivize innovation while ensuring adequate levels of access. Eventually, to answer the research question, these perspectives and interests will be used while deciding what could be presented as new recommendations about the disparity between patent rights and incentive mechanisms considering the lack of access to medicine.

1.5. Chapter Overview

This thesis will be divided into four chapters in line with sub-questions. After this introduction, firstly, the philosophy of patent will be summarised. Firstly, arguments in favour of intellectual property law will be examined. Secondly, the disparity between justifications and the current situation of innovation in medicine will be discussed. In the end, the second chapter will be finalized with the presentation of conflicting arguments on whether patent rights are justified in terms of essential medicines, considering the findings from the previous sections.

In the third chapter of this paper, definitions, context, scope and interpretation of exceptions to patentability will be explained while focusing on the conceptualism of "morality" and "ordre public" and their connection with the right to health. Article 27(2) of the TRIPS was interpreted for different cases, such as new chemicals that pose detrimental risks to human life and health. Linked with this, the second chapter will show the aim and current interpretations of Article 27(2) and examine its application, if any, to medicines.

Then, as this thesis adopts a reform-oriented research method, possible ways and benefits of altering the current legal framework will be discussed. Due to the radical nature of excluding essential medicines from patentability to altering the legislation, different views and arguments will be presented to have a grasp of the possible future effects.

Lastly, considering the information explained in the first four chapters, possible recommendations will be provided that aim toward a reinterpretation of Article 27(2) of the TRIPS to remedy the lack of access to medicine while protecting the rights of inventors. In this chapter, new incentive mechanisms, such as Health Impact Fund, will be explored more deeply.

2. PHILOSOPHY OF PATENTS

2.1. Different Philosophical Approaches

Evaluating the foundations of IP rights requires analysing opposing arguments. Despite heated debates on this topic, IP still has an essential place for protecting ideas and innovation in most legal systems. However, this essential place of IP law has been tried to be balanced with other interests such as competition, high prices, and the right to health. For example, in 1624, the English patent statute stated "that 'they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient'" that of which Article 27(2) of TRIPS agreement finds its roots.[47] Moreover, recognition of IP rights enables the development and innovation while imposing restrictions on the rest of the society by not letting them reproduce the patented invention without the permission of the owner.[48] Therefore, justification for patents and challenges to these arguments will be evaluated to see whether patent rights create encouragement to the industry.

Trying to justify the patent system comes with its challenges since this system incentivises innovation by creating monopolies. As patents are portrayed as property, they also appear as restrictions to liberty since "monopolies are a profound interference in the liberty of subjects."[49] This also applies to the medicine patent system in general. However, it is essential to evaluate the philosophical justification attempts against the medicine patent system because if the restrictions that arise from medicine patents are bigger than the system's benefits, the damage inflicted on society would be more devastating than the possible negative outcomes of many other technological areas since medicines and medical technologies are directly linked with people's life or death. As this is a delicate topic, there are several moral justifications for patents too, namely natural rights theory, personal autonomy, fairness, and utilitarianism.

To continue, even though those justifications are cited countlessly, almost all scholars believe that utilitarianism is more important than other arguments since the main aim of this theory is to enhance innovation and maximize welfare by creating incentives with patents.[50] However, there are objections to this approach as well which question whether this system substantiates the promises of its philosophy/justification and whether there is a better option to achieve the goals of the current system. Since the focus of this thesis is the patentability of inventions, equitable access to medicine, and morality, examples from the meeting points of these fields will be provided to determine whether this theory is still efficient and beneficial for medicine patents, or whether there should be a different approach.

2.2. Utilitarian Grounds for Justifying Patent System

The common ground for the justifications for IP systems is utilitarianism because it aims to maximize the benefit to society while enhancing the development of innovation by

[47] Liddell (n 38) 142.
[48] Stephen R Munzer and Kal Raustiala, 'The Uneasy Case for Intellectual Property Rights in Traditional Knowledge' (2009) 27 Cardozo Arts & Entertainment Law Journal 37, 45.
[49] Palmer (n 22) 818, Drahos (n 23) 42
[50] Alan Devlin and Neel Sukhatme, 'Self-Realizing Inventions and the Utilitarian Foundation of Patent Law' (2009) 51 William & Mary Law Review 897, 901.

creating a solid and balanced IP system. To start with, utilitarian arguments aim to weigh the negative and positive aspects of different parties and to choose the option that maximizes the benefit for the highest possible number of people.[51] Under this theory, in the short run patents confer 20 years of monopoly which precludes others to use the patented invention, but in the long run, after the expiration of the patent, the invention becomes freely available to the public.[52] Meaning that, after the inventor recoups her investments and R&D costs, the invention becomes common good. Therefore, both encouragement of innovation and the right to innovation are satisfied according to this theory.

Even though this theory seems to balance two sides, why is there a necessity for conferring 20 years of monopoly right? If there were no patents, the inventor could be inclined to keep her invention a secret, because "once the information is disclosed, that information becomes a public good, which in economic terms means that it is non-excludable and non-rivalrous."[53] So, patent law tries to solve "public good" problem by providing 20 years of exclusive right to inventors and by requiring full disclosure of the invention to the public. Furthermore, sustaining development and innovation is as important as justifying incentives. Therefore, under this system to sustain the progress of innovation, patent law should ensure the existence of three elements: firstly contribution brought to innovation through the system, secondly, the current system is the best option among other systems, and lastly, it brings optimal benefits to the greatest number of people.[54] To assess whether these requirements are achieved, utilitarian theory mostly conducts "weighing" activity to maximise wealth.[55] While conducting the weighing activity, different interests should be carefully evaluated. For example, for medicines, the interest at stake would be the right to health of the ones who do not have access to essential medicines and the financial profits and values of companies.[56] Therefore, questions for this theory are: would market failure occur in the absence of patenting essential medicines and whether patenting essential medicines would bring more benefits than harm to society?[57]

Notwithstanding ongoing consideration of utilitarian weighing activity, utilitarian justification for patents as being an incentive to innovation and a *quid pro quo* for the disclosure are still popular among scholars and courts.[58] There are also opposing views to this justification

[51] William W Fisher, 'THEORIES OF INTELLECTUAL PROPERTY' [2000] 9
[52] Michele Svatos, 'Biotechnology and the Utilitarian Argument for Patents*' (1996) 13 Social Philosophy and Policy 113, 118.
[53] Devlin and Sukhatme (n 51) 914.
[54] Svatos (n 53) 166
[55] There are many questions regarding how this "weighing" activity can practically take place in the context of patents. These questions mostly regard to economical perspectives rather than ethical ones. See, e.g., Fisher W.W., "Theories of Intellectual Property." (2000)
[56] Emma Perot, "Maximising Utility: Applying Utilitarian Theory to International Patent Law" (2014) 5 King's Student Law Rev 68
[57] David Olson, 'Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter' (2009) 82 Temple Law Review 181, 4.
[58] Ted Sichelman, 'Commercializing Patents' (2010) 62 Stanford Law Review 341; Lisa Larrimore Ouellette, 'Do Patents Disclose Useful Information?' (Social Science Research Network 2011) SSRN Scholarly Paper 1762793 <https://papers.ssrn.com/abstract=1762793> accessed 16 June 2022.

both to its reasonings and consequence, so in the next section, those objections will be evaluated.

2.3. Challenges and Objections to Utilitarian Grounds

2.3.1. Introduction and Overall Objections

Every philosophical argument constitutes counterarguments within itself. So, it is not surprising that there are several counterarguments for the utilitarian justification of patents and these counterarguments can be supported by real-life examples of medicine patents. Therefore, throughout this section, this simple question will become important: is this patent system the best option to incentivize innovation or could there be a better alternative to obtain this aim?

The main conflict between utilitarian theories' goal of wealth maximization and the overall view of challenges can be summarised with those lines of arguments: Accepting "wealth-maximisation" as the goal leads to challenges for the sense of justice since "wealth-maximisation is not the goal of law; rather, the goal is justice."[59] For instance, the question of how to value and compare A's and B's interests becomes important. According to utilitarianism, the "end" is increasing wealth and happiness, and on this road "everyone's preferences count equally."[60] However, as an example, monopolies increase prices, and companies do not usually produce drugs for people who cannot afford high prices. Moreover, the wealth of the inventors is increasing due to this system, and the happiness of wealthy countries' citizens are increasing as drugs for their diseases are being produced rapidly. Notwithstanding, the problem is not about the system bringing more harm to poor people who is more populous than the rich, rather, it is about the fact that the interests of these two categories cannot be evaluated on the same level. Likewise, even if the end result increases the overall wealth of certain people, comparing people who suffer from such a system with the benefits of a specific wealthy group would be immoral, since people who suffer might be facing serious health problems.

2.3.2. Challenges for Application of Utilitarian Arguments to Medicine Patent System

The monopoly right is conferred in return for inventive, novel, and useful inventions and their disclosure leads to social costs as well.[61] The monopoly of patented inventions makes it possible for the inventors to determine the price of their products. However, the inventor's price is usually higher than the price of the normal functioning competitive market.[62] The consequence of the gap between the price of the competitive market and the price determined by monopoly is economically named "deadweight loss."[63] Therefore, whether patents are

[59] Stephan Kinsella, 'The Case Against Intellectual Property', *Journal of Libertarian Studies*, vol 15 (2013) 12.
[60] Micheal Sandel, Justice (Flammarion 2017) 41
[61] Devlin and Sukhatme (n 51) 917.
[62] ibid
[63] ibid

beneficial for society, regarding the comparison of the harms and benefits of this monopoly, can be asked.

Even though this comparison might seem logical from the utilitarian point of view, many difficult questions need to be answered in the context of medicines. For example, at one point Milton Reynolds set the price for a ballpoint pen as $12.50[64] while the actual cost was 80 cents, and his profits were 19 times higher than his investment.[65] As can be imagined, it is easy to compare the benefits and costs of an invention when a ballpoint is at stake. However, if the case was about a life-saving drug, this comparison would become so much harder since while people have the chance to not buy a ballpoint, people with deadly diseases cannot choose to not buy a drug.

Further, it is vital to point out the negative sides of granting monopolies with patents. Utilitarianism seemingly aims to make sure that there are enough drugs on the market, and they focus on the users rather than the producers themselves. However, Joan Robinson argues that:

> "A patent is a device to prevent the diffusion of new methods before the original investor has recovered profit adequate to induce the requisite investment. The justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse..."[66]

For example, in 2016, AIDS Healthcare Foundation sued Gilead Sciences for manipulating the patent system.[67] Even though the case is still pending in the Supreme Court of the United States decision alongside other cases against Gilead Sciences, it is argued that Gilead Science intentionally slowed down the research process for a less harmful form of tenofovir, which is listed under essential medicines by WHO against HIV, to gain more money from the first form, before the patent expired.[68] After 6 years, in 2010, the new form of the mentioned medicine, which is less harmful to kidneys and bones, was approved under the name of Genvoya.[69] As can be seen from this example, the question of whether this system is the best option to increase utility since it is vital, could be raised and becomes quite important to answer.[70]

2.3.3. Tragedy of Anti-Commons on Medicines

Utilitarian theory gives a chance for every individual to come up with a novel invention, and benefit from it. Therefore, it aims to use the resources of the world efficiently both for the inventors and society. According to this system, when an inventor gets 20 years of exclusivity on an invention, other inventors working on it need the permission of the patent holder.

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[64] This is equal to $195.25 for 2022
[65] Svatos (n 53) 18.
[66] Joan Robinson, The Accumulation of Capital (London: Macmillan, 1956) 87; quoted in Dorothy Nelkin, *Science as Intellectual Property (New York: Macmillan)* 19
[67] Melody Peterson, 'A Question of Timing: A Lawsuit Claims Gilead Sciences Could Have Developed a Less-Harmful Version of Its HIV Treatment Sooner' (*Los Angeles Times*, 29 May 2016) <https://www.latimes.com/business/la-fi-gilead-20160529-snap-story.html> accessed 16 June 2022.
[68] ibid
[69] ibid
[70] Edwin C Hettinger, 'Justifying Intellectual Property' (1989) 18 Philosophy and Public Affairs 31.

However, when this requirement for permission comes to a point that prevents the diffusion of new products to the market, effective usage of the resources cannot be ensured.[71]

To focus on examples from the real world, an example of a drug to cure diseases originating from schizophrenia can be used. Inventors discovered that drugs which target dopamine receptors would cure these types of diseases since they resemble Parkinson disease which is about dopamine receptors.[72] However, inventors were not able to develop the drug because compounds that were to be used in it were patented, and funds for the research were not able to cover all licensing agreements.[73] To continue, the second example would be the "golden rice" which is modified rice that was aimed to stop children to go blind since "250,000 to 500,000 children" are affected and go blind due to lack of Vitamin A.[74] However, inventors had to license "seventy U.S Patents… and negotiate with more than thirty companies, universities, and other institutions."[75] In the end, it was not possible for the inventors to produce and market the Golden Rice too, because of the same reasons as the first example[76]. One of the inventors describes:

> "It seemed to me unacceptable, even immoral… Fortunately, I did a bit of further thinking and became aware that "Golden Rice" development was only possible because there was patenting. Much of the technology I had been using was publicly known because the inventors could protect their rights. Much of it would have remained secret if this had not been the case. If we are interested in using all the knowledge to benefit the poor, it does not make sense to fight against patenting. It makes far more sense to fight for a sensible use of intellectual property rights."[77]

2.4. Conclusion

In this chapter, it is observed that systems for the protection of patents and other IPs proved their necessity over the decades. However, the starting point of this chapter was to understand whether current innovations in the field of medicines are in line with the historical justification of patents. On this, utilitarian arguments are the most common accepted ground for both justifying patent systems and for being the most efficient way of sustaining innovation. It is also observed that even though the utilitarian ground is still valid for some parts of the industry, there are noteworthy objections to this, especially in the field of medicines. Despite the utilitarian patent system aims to maximize the benefits for society, there are significant drawbacks of it which possibly decrease its efficiency. First, with this system prices of the

[71] Michael Heller, 'The Tragedy of the Anticommons: A Concise Introduction and Lexicon' [2013] The Modern Law Review, Vol. 76, p. 6, 2013 <https://scholarship.law.columbia.edu/faculty_scholarship/1778>.
[72] Michael Heller, The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives (Basic Books 2010) 53
[73] ibid 53
[74] ibid 55
[75] ibid 55
[76] There are other examples in the same book such as one Malaria vaccine was covered by 93 patents. Another one is "Several years ago an official at a major pharmaceutical corporation said that it could not research about 100 potential cancer treatments its scientists wanted to test, because it could not obtain the rights at all, or could not negotiate an affordable price."
[77] Heller (n 73) citing Potrykus, "The Golden Rice 'Tale,'" In Vitro Cellular and Developmental Biology Plant 37 (2001): 93–100, 97

medicines would go so high that only a limited portion of the society can afford them, which causes real harm to millions of people. Besides this harm, it is laid down that interests and preferences that are affected by the medicine patent system cannot usually be evaluated at the same level. Generally, there are different categories of interests that should be diligently and, on a case-by-case basis dealt with.

Another point was the diffusion of innovation might decrease as companies would wait to innovate a new medicine till the expiration of the ongoing patents. Linked with this, novel and promising medicines cannot always find ways to enter the market since transaction costs regarding existing patents might be very high that innovators cannot afford. Therefore, the basic underlying argument of utilitarian grounds which is to maximize benefits for the greatest portion of the society by creating a legal monopoly as an incentive can be challenged as to either not every portion of society has the same level of interest that can be compared easily, or development and innovation can slow down as a result of this design. Nevertheless, these debates do not argue that the IP system should be fully abolished. Rather, these moral considerations along with counterarguments to justifications should be taken into consideration when deciding the future of the patents. The TRIPS agreement and other relevant national legislations have a provision for immoral inventions, it is still unclear how it should be interpreted.[78] Therefore, in the next chapter, interpretation of the Article 27(2) of the TRIPS agreement will be discussed to see how these moral objections are being used.

[78] Justine Pila, 'Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies' (2020) 38 Nature Biotechnology 555, 555; Amanda Warren-Jones, 'Vital Parameters for Patent Morality—a Question of Form' (2007) 2 Journal of Intellectual Property Law & Practice 832, 832; Aisling McMahon, 'Patents, Governance and Control: Ethics and the Patentability of Novel Beings and Advanced Biotechnologies in Europe' (2021) 30 Cambridge Quarterly of Healthcare Ethics 529, 529.

3. EXCEPTIONS TO PATENTABILITY: EVALUATION OF ARTICLE 27(2) OF TRIPS

3.1. The Objective and Purpose of the Article 27(2)

3.1.1. What is Article 27(2) of TRIPS

Concepts of trade, protection of IP rights, and social values are discussed under the TRIPS agreement which came into force in 1995.[79] Related to this thesis, Article 27(1) provides patent rights for novel, non-obvious, and useful inventions.[80] Besides this protection, it has been accepted in the agreement negotiations that recognition of members' right to take measures to "protect public morality, national security, public health and nutrition" is necessary.[81] Therefore, balancing technological developments with social and economic interests was a critical objective for drafters throughout the TRIPS agreement. One result of this objective can be seen in Article 27(2), which provides exceptions to the broad protection provided in Article 27(1). The article reads as follows:

> "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."[82]

Patent protection for inventions in all fields of technology raises concerns on whether patents should be available for inventions that are against morality. Therefore, when drafting this article, the main aim was to ensure the protection of public interests, social and moral values by allowing MSs to exclude inventions from patentability. However, one country's morality/values are not identical, even similar, to other countries' morality/values. Therefore, the last draft of this article was a product of controversies regarding different understandings of what the Article should mean. To understand the real purpose of this article it is useful to explain different arguments on the agreement's negotiations.

3.1.2. The path to the Current Provision

The meaning and objective of the article were different for wealthy and poor countries. While the former ones were recommending flexible provisions, the latter ones were insisting on overarching ones. To start with, in 1989, India brought the situation of resource-poor countries into question by stating, "patent system can have serious adverse effects in sectors of critical importance to" developing and LDCs, "such as food production, poverty alleviation,

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[79] Watal J and Taubman A (eds), The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations (World Trade Organization 2015) 15

[80] Article 27(1) of TRIPS Agreement provides "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, 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."

[81] Watal and Taubman (eds) (n 80) 250

[82] Article 27(2) of TRIPS Agreement

nutrition, health care and disease prevention."[83] Specifically, on drugs, the communication states that "ample evidence" indicates, with the effect of patent monopolies, essential drugs' prices are at "abnormally high levels in industrialised as well as developing countries" and consequently reduce poorer communities' access to them. Therefore, India, with the support of other developing countries, suggested that "inventions … whose use would be … injurious to public health" should be excluded from patentability.[84] Therefore, in light of the comments of 14 developing countries, the following provision for the exceptions to patentability was included in the 1990 draft of TRIPS:

> "Inventions, [the *publication* or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [*public health*,] [or the basic principle of human dignity] [or human values]."[85]

However, the US drew attention to the possible abuse of detailed provisions on morality and suggested a more flexible form of the provision that only focuses on the 'commercial exploitation of the invention.[86] Further, Switzerland was also cautious on this article due to the pressure of the Swiss pharmaceutical industry and possible patent application rejections related to different understandings of morality/ordre public.[87] Hence, Switzerland proposed a provision, which is a combination of Article 53(a) of EPC and the Paris Convention on environmental considerations.[88] Eventually, an extent of flexibility was added to the provision by changing "publication or use" to "commercial exploitation" and including "ordre public" rather than having categories of interests such as the basic principle of human dignity or generally accepted standards.

Eventually, the last version of the article aims that some inventions should not be incentivised by being granted a patent because they can conflict with moral values and/or public interests. Therefore, MSs use their power to indirectly regulate technological development, since not incentivising would decrease investment and innovation. However, as the TRIPS agreement does not provide any definition for the broad words, the scope and meaning of the article, and consequently which type of inventions will be disincentivised is open and left to interpretations of national courts.

3.2. Meaning of the Article

3.2.1. Methodology of examination

After this background of how the provision has been shaped, it is time to analyse what this provision is about and how it is being interpreted. First of all, this provision is believed to be a 'safeguard' for society against the monopoly of harmful inventions.[89] However, as the

[83] GATT Document MTN.GNG/NG11/W/37
[84] ibid para 17, Watal and Taubman (eds) (n 80) 245
[85] GATT document MTN.GNG/NG11/76 (emphasis added)
[86] Watal and Taubman (eds) (n 80) 141
[87] ibid 174
[88] ibid 174
[89] Louise Clarke, 'Should the Courts Be Moral Censors of Biotechnological Innovation? An Analysis of the Morality Provisions of Patent Law with Specific Reference to Rule 28(1)(c) of the Implementing Regulations to

Article is shaped in a flexible form, elaborating its exact scope is needed. When adopting this flexible version, WTO members "borrowed" the terms from Article 53(a) of the EPC.[90] Therefore, there are some significant similarities between these provisions. For example, three major words in Article 53(a) are directly included in the TRIPS. Both articles emphasize that if *commercial exploitation* of inventions is contrary to "ordre public" or morality, they will be excluded from patentability. Moreover, both articles try to protect moral values but as those values might differ in every country, their objective is to ensure some degree of flexibility with their words. However, it should be kept in mind that there is a major difference between these articles. While the TRIPS includes categories of health, environment, human and plant life as guidance for deciding what should be protected, EPC 53(a) does not. Nevertheless, since the main elements and objectives of these provisions are the same, EPO cases and CJEU's guidance are the best references to explain current interpretations of Article 27(2). Moreover, despite "the EPO is not a party to and not bound by the TRIPS", it is accepted that EPC should be "in conformity with the TRIPS" because contracting states to EPC are signatories to TRIPS agreement and TRIPS agreement "is aimed at setting common standards and principles" regarding IP rights.[91] Therefore, some articles including 53(a) have been shaped following TRIPS, and some EPO cases stated that TRIPS should be taken into consideration when deciding the issue.[92] Therefore, explanations stated in the EPO cases regarding components of the provision are helpful to understand the scope of Article 27(2).

3.2.2. Components

First of all, there is no internationally accepted definition of morality. Ethical discussions reflect the values of each society and culture, so interpretation of morality depends on the context and culture.[93] On this, Britannica Encyclopaedia asserts that morality is "beliefs about what is right behaviour and what is wrong behaviour.[94] Moreover, the Board of Appeal of EPO in Plant Genetic Systems repeats this definition and says, "this belief founded on the totality of the accepted norms which are deeply rooted in a particular culture."[95] In the jurisdiction of the EPO, an invention is considered immoral only if real and plausible

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the EPC Concerning Embryonic Stem Cell Patents Dissertations' (2021) 11 Southampton Student Law Review 114, 118.

[90] Joseph Straus, 'Ordre Public and Morality Issues in Patent Eligibility' [2013] Intellectual Property in Common Law and Civil Law 19, 22.; EPC 53(a) provides: "European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."

[91] Frédéric Bostedt et al (eds.) "Case Law of The Boards Of Appeal Of The European Patent Office" (9th edn, European Patent Office Legal Research Service of the Boards of Appeal 2019) 786-787

[92] G 00002/02 Priorities from India/ASTRAZENECA EPO (2004); G 00003/02 Priorities from India/ASTRAZENECA EPO (2004)

[93] Straus (n 91) 26–27.

[94] "Morality" (Encyclopædia Britannica) https://www.britannica.com/dictionary/morality#:~:text=m%C9%99%CB%88r%C3%A6l%C9%99ti%2F-,noun,and%20what%20is%20wrong%20behavior accessed April 5, 2022

[95] Plant Genetic Systems v Greenpeace [1995] EPOR para 6

risks/harm to society could be determined.[96] Furthermore, EPO states it should be "revoked only in rare and extreme cases" and will be applied when "public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable."[97]

Secondly, there is also no universally accepted definition of *ordre public*. However, the wording '*ordre public'* is preferred upon 'public order', since the former is narrower than the latter.[98] Of course, as the term is 'borrowed' from European jurisdiction, it would be helpful to consider how European institutions interpret the wording. CJEU indicates that it covers "genuine and sufficiently serious threat to the requirements of public policy affecting one of the fundamental interests of society," and adds that its meaning "may vary from one country to another and from one period to another."[99] However, in European jurisdiction, it is stated that *ordre public* covers 'major principles of legal order' "including human dignity and the right to life."[100] Moreover, EPO guidelines suggests *ordre public* is about inventions that contravene with public security or lead to "offensive behaviour."[101] These offensive behaviours are exemplified as human cloning, "antipersonnel mines", destruction of embryo and "avoidance of unwanted offspring." In all these points, ordre public reflects that societies have interests and values as well, and technological development might conflict with those. For example, destructing human embryo for the sake of creating treatment for pancreas cancer would be excluded from patentability since it is regarded as contrary to human dignity and morality/ordre public.

To elaborate, real life examples are as necessary as the theoretical framework to understand the application of morality and ordre public to inventions. In the EPO's jurisdiction, this provision is triggered by, but is not limited to, genetically modified mice,[102] human embryos,[103] genetically engineered plants,[104] gene coding, [105] and stem cells.[106] At first, the EPO was willing to balance innovation and morality/ordre public while suggesting a utilitarian approach by stating "careful *weighing* up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other."[107] As can be seen, morality would depend on whether benefits prevail over risks of the invention. However, with time, this utilitarian approach became exceptional. With the PLANT GENETIC SYSTEMS N.V vs. Greenpeace case[108], EPO has first asserted that the priority of the patent is

[96] Maureen O'Sullivan "Morality Patently Matters: The Case for a Universal Suffrage for Morally Controversial Biotechnological Patents" (Ph.D thesis, University of Edinburg, 2017) 54
[97] Guidelines for Examination in the EPO (2022) Part G-II 4.1
[98] Straus (n 91) 21
[99] C-30/77, Regina v Pierre Bouchereau, [1977] ECLI-1977 para 35
[100] Straus (n 91) 22 citing German Federal Supreme Court (BGH), 18 October 1967, 48 BGHZ 327 (at 330)
[101] Guidelines for Examination in the EPO (2022) Part G-II 4.1
[102] T 19/90 EPO Harvard/Oncomouse (1990)
[103] C-34/10 Oliver Brüstle v Greenpeace eV [2011] ECR I-9821.
[104] Lionel Bently and Brad Sherman, 'The Ethics of Patenting: Towards a Transgenic Patent System' (1995) 3 Medical Law Review 275, 278.
[105] T 0272/95 EPO Relaxin/HOWARD FLOREY INSTITUTE (2002)
[106] T1374/04 Wisconsin Alumni Research Foundation (WARF) (2007) OJ EPO 313
[107] T 19/90 EPO Harvard/Oncomouse (n 150) para 5 (emphasis added)
[108] T 0356/93 PLANT GENETIC SYSTEMS N.V., et al v Greenpeace (1995)

not evaluating morality, but assessing scientific details, then underlined that patent offices cannot determine whether an innovation is moral by their own decision, other bodies and institutions are also involved in this process. This was an indicator that the EPO might move into a more different approach when morality/ordre public is considered. Therefore, in the Relaxin case[109], a narrow interpretation of the provision is explicitly asserted. Nevertheless, in the Brüstle Case[110], perception of what is immoral has changed in a way to embrace innovation's effects on the society, which showed the EPO's willingness to broaden their approach when they are dealing with morally controversial innovations. Therefore, the EPO tried to show that there are some core moral values and public interests, such as human dignity, that will be protected in the face of morally controversial inventions which conflict with those core values.

The second element is the phrase 'commercial exploitation.' It is clear from the wording that, for the provision to be triggered, commercial exploitation of the invention should be against morality/*ordre public,* and not the invention itself. To start with, only commercial exploitation is touched upon in the provision, so non-commercial exploitation is not included in the article. Although the provision does not define what 'commercial' means, common accepted meaning is that inventors' intention to make profit.[111] In other words, this article only includes "economic activities carried out with the intention of realizing a profit."[112] More importantly, the question 'what the Member States intended when restricting the provision only to 'commercial *exploitation'* could be asked. As an answer, there are four different readings expressed in the literature: utilization of invention, consequences of granting a patent to the invention, conducted research for the invention, and invention's unworthiness to patent regarding novelty, obviousness, and usefulness.[113] First ground covers the "intended use" of the invention and the means to create that invention. On the other hand, the second ground also focuses on the ethical considerations of the consequences of patent monopoly and exclusive rights.[114] All four grounds are raised in the Onco-Mouse case; however, EPO only accepted the first ground, which refers that conflict with morality will be decided with examining only the intended use of the invention.[115]

In addition to how Article 53(a) and its components are explained by the authorities, scholarly opinions on the words and their meanings might make easier to interpret the article despite the fact that majority of the scholars thinks lack of definition in the article leads to obscureness and makes the article more controversial.[116] Because it is observed that EPO and EPC's guidance are not sufficient to apply this article to the real-life examples,[117] and therefore

[109] See supra note 153
[110] C-34/10 Oliver Brüstle v Greenpeace eV (n 151)
[111] Peter-Tobias Stoll, Jan Busche & Katrin Arend (eds), "WTO—Trade-Related Aspects of Intellectual Property Rights" (2009) Koninklijke Brill NV. 496
[112] ibid 497
[113] Liddell (n 38) 10.
[114] ibid 149
[115] Ibid, T 19/90 EPO Harvard/Oncomouse (1990)
[116] Pila (n 79) 555, Liddell (n 38)
[117] Prifti (n 13) 4, Liddell (n 38) 5

it needs more elaboration. Since these words have broad meanings, first tendency by the lawyers is to interpret them narrowly.[118] As also this view can be observed in the EPO's decision, first, morality had a narrow role which was to ensure "the grant of a patent would not be universally regarded as outrageous."[119] However it is stated that this view should be expanded to ensure not patenting immoral inventions.[120] Eventually, ethics and morality is seen as a means to define what is good and harmful invention for the society. For example, while helping humanity is an important criterion to understand whether the invention is morally good, it is also important that whether these inventions threaten social interests and structures.[121] Consequently, since most of the technological development might help the humanity and at the same time might threaten social structure, it is recommended that interpretation of morality/ordre public should be evaluated on a case-by-case basis regarding "religious, social and moral values and world views of society."[122]

Even though Article 53(a) sheds light on the scope of the Article 27(2), there are still major differences which limits the use of 53(a) as a model for determining the scope and the interpretation of Article 27(2). For example, one of the major differences between the Article 53(a) of EPC and Article 27(2) TRIPS agreement is that, while the latter includes 'health' to the provision the former does not mention it. Since the TRIPS was adopted 21 years after the EPC, and values of society evolve in time and impacts of inventions to those values significantly change, it is significant to know that WTO Member States explicitly included 'health' when their reference legislation does not. While knowing this, it should also be kept in mind that patent rights try to encourage inventions that enhance society and technology, immorality provision should try to prevent any harm that could happen to them. Otherwise, the patent system would encourage inventors to work on inventions to which granting a patent creates immoral consequences.[123] Therefore, in the next section, further opinions and possible interpretations in accordance with right to health will be examined.

3.2.3. Further Opinions on determining the scope

Full understanding and transposition of the Article 27(2) depends not only the words in the Article, but also other articles provide important information to make clear possible interpretations. For example, Article 8 indicates, "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health." As observed, Article 27(2) includes "health", which points out that some inventions may conflict with "health." Therefore, Article 8 creates opportunity for the MSs to read Article 27(2) in light of public health considerations. Hence, the objective of the Article 27(2) can be fully reached when it is interpreted while taking account the letter and the spirit of the whole agreement rather than analysing only the Article 27(2).

[118] Liddell 2
[119] Schellekens and Vantsiouri (n 38) 14
[120] ibid 14-15
[121] Prifti (n 13) 4
[122] Peter-Tobias Stoll, Jan Busche & Katrin Arend (eds), (n 112) 493
[123]Liddell (n 38)159

To continue with how public health considerations can take place under the Article 27(2), it is necessary to underline that WTO members were also cautious regarding the issue when drafting the TRIPS agreement. However, after the adoption of the TRIPS, the AIDS outbreak has changed the perception on the public health. MSs who were cautious before, realized the extreme dangers to the right to health since just in 1995, 62% of people who acquired AIDS died in the US.[124] Likewise, in 2001, 3 million people died because of AIDS in Africa.[125] Therefore in the same year, WTO members have adopted Doha Declaration on the TRIPS agreement.[126] This Declaration asserts "the gravity of the public health problems" in its first paragraph for developing and least-developed countries, and in the third paragraph, IP rights' effect on prices is stated.[127] After this declaration public health became one of the categories that interpretation and implementation of the whole TRIPS should take into account. For instance, paragraph 4 of the Doha declaration states:

> "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[128]

After the adoption of the Doha Declaration, compulsory licenses became an important topic for promoting access to medicine. However, as described in the first chapter, it has been considered a "failure" since its practical application was completely unsuccessful in promoting access to medicine.[129] Despite unsuccessful attempts, compulsory license is a step that TRIPS agreement can be shaped in accordance with right to health. While underlying the significance of public health considerations, this also leads to a question how Article 27(2) can have a role on this debate. On this, United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD)'s resource book on the TRIPS agreement clearly indicates Article 27(2) "includes the protection of 'human, animal or plant life or health or to avoid serious prejudice to the environment", thus it refers to 'health' on the article to "encompass not only medical care but also the satisfaction of basic requirements such as adequate food, safe water, shelter, clothing, warmth and safety."[130] Therefore, exception to patentability will be triggered "when any of these interests may be negatively affected by patent grants."[131] Consequently, when millions of people's lives are at stake due to diseases such as AIDS, Malaria, Tuberculosis, it is important to consider whether patenting essential medicines are contrary to morality/ordre public as much as considering patenting a human embryo is immoral due to its effect on human dignity, body, and life.

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[124] 'First 500,000 AIDS Cases -- United States, 1995' <https://www.cdc.gov/mmwr/preview/mmwrhtml/00039622.htm> accessed 16 June 2022.
[125] 'The Status of the HIV/AIDS Epidemic in Sub-Saharan Africa' (*PRB*) <https://www.prb.org/resources/the-status-of-the-hiv-aids-epidemic-in-sub-saharan-africa/> accessed 16 June 2022.
[126] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].
[127] ibid
[128] ibid (emphasis added)
[129] See supra note 35
[130] Resource Book on Trips and Development (Cambridge University Press 2005) 376
[131] ibid

3.3. Summary

Aside from hesitancy that patent system would be unsuitable for making ethical judgments, current interpretation of Article 27(2) of TRIPS still has some controversies. This chapter has shown that it is designed to be safeguard for immoral inventions which might harm public interest and social values. The drafters of the article intentionally left the Article in a flexible form that every state can implement it in accordance with their national values and interest. Since the Article is vague and flexible, the best way to analyse its' objective and components was to look its' reference provision, EPC 53(a), and Article 53(a)'s interpretations by the competent authorities. The EPO in its decisions and guidelines provides that morality means cultural beliefs regarding the good and bad behaviour and "ordre public" is correlated with public interest and security, which would be intervened with any offensive behaviour. However, it is certainly underlined that only "commercial exploitation" of the invention can trigger this article, so not the invention itself. On this, EPO has accepted that only the indented use of the invention will be considered under this requirement. So far, this Article is triggered by mostly biotechnological innovations such as gene editing and embryonic stem cell research.

This chapter also observed that while the similarities between Article 53(a) and Article 27(2) helped to explain the main components of the Article, there are still significant differences which possibly leads extra interpretation to Article 27(2) of the TRIPS. Foremost among them is Article 27(2) explicitly provides protection of "health" as a one category that will be considered under morality/ordre public. Furthermore, Article 8 of the TRIPS and Doha Declaration adds that TRIPS agreement can and should be interpreted with taking public health into consideration. This is also supported by the Resource Book of the TRIPS by stating inventions which negatively affect health would trigger this Article to be applied. All things considered, the next chapter will discuss possible ways and benefits of interpreting this Article to exclude essential medicines from patenting.

4. POSSIBLE WAYS AND BENEFITS OF EXCLUDING ESSENTIAL MEDICINES

4.1. Introduction

Having explained the current interpretation of Article 27(2) and possible further opinions on it, this chapter will present the interpretation of the Article in accordance with the right to health. To do this, this chapter will evaluate the differences between EPC 53(a) and TRIPS 27(2) as well as other articles in the TRIPS, which guide MSs on implementing the whole TRIPS agreement. Moreover, the following pages will analyse Article 27(2) and its components to explain how essential medicines can be included in the interpretation of the Article. Lastly, practical implementation of re-interpretation of the Article will be provided with examples to explain why this interpretation is more beneficial than other solutions suggested to ensure equitable access to essential medicines.

4.2. How to understand essential medicines

Before analysing the Article, questions about the categorization of essential medicines and how they are determined should be explained since these medicines will be the primary subject of the re-interpretation that will be suggested. WHO explains that "essential medicines are those that satisfy the priority health care needs of a population."[132] The list of these medicines is published every two years and "intended as a guide for countries or regional authorities."[133] Their selection criteria include public health considerations, "disease prevalence", "efficacy", and "safety."[134] For example, the list includes drugs such as sofosbuvir for Hepatitis C, imatinib for leukaemia, isoniazid and rifampicin for tuberculosis.[135] Having this list is aimed to "result in better quality of medical care, better management of medicines and cost-effective use of health care resources,"[136] because the amount, quality and price of medicines listed are "intended" to be appropriate for all healthcare systems in the world.[137] Therefore, essential medicines are for the basic needs of humans in the context of medical care and drugs.

4.3. Re-interpretation

4.3.1. Insufficiency of EPC's interpretation

Having clarified what drugs are categorized as essential medicines, it would be useful to explain why EPC 53(a) is insufficient to fulfil this duty while analysing their place in Article 27(2). One of the reasons for this is because there are significant differences between these two

[132] WHO Model List Of Essential Medicines - 22Nd List, 2021' (Who.int, 2022) <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02> accessed 24 July 2022.
[133] ibid
[134] ibid
[135] World Health Organization, "Model List of Essential Medicines – 22nd List, 2021." Geneva: World Health Organization;)2021) (WHO/MHP/HPS/EML/2021.02) 15-20-30
[136] Ministry of Health & Family Welfare (MOHFW) Government of India, "Report of the Core-Committee for Revision of National List of Essential Medicines" (2015) 12
[137] Jonathan D. Quick and others, 'Twenty-Five Years of Essential Medicines' (2002) 80 Bull World Health Organ 913

articles which change their meaning within the context of the right to health. This is because the protection of health is explicitly mentioned in Article 27(2) as a further explanation for the terms. However, the meaning of Article 53(a) is to be explained by the authorities since there is no further explanation/guidance in the Article as to the meanings of the morality/ordre public. There is even no explanation in the EPC 53(a), it is not possible to understand the intentions of the drafters. Moreover, nothing in the EPC 53(a) directly means that the Article should be "revoked in extreme cases" or no such word refers to that public, in general, should find the inventions "so abhorrent." More importantly, the Article is designed to have a flexible form so that it can be construed according to individual cases. Therefore, EPO's interpretation, which implies this article is to be applied in a narrow sense and refers to topic-related (biotechnological inventions) limitations, is nothing more than a policy choice which is in line with European culture and values. However, the TRIPS agreement involves different cultures and interests, which makes the interpretation of TRIPS on its own merits necessary.

4.3.2. TRIPS agreement as a whole

Given the international and multicultural aspects of TRIPS agreement, interpretation of the provisions should be instructed as part of the agreements' objectives. Since the main objective of this Article is to find a balance between technological development and public interests, there are two instruments that provide clarification for this balance. First of them is the Doha Declaration which sheds light on the importance of the right to protect public health. In the Doha Declaration, it has been "affirmed" that MSs can and should interpret and implement the provisions to "protect public health and, **in particular**, to promote access to medicines for all."[138] Moreover, "the right of WTO members to use, **to the full**, the provisions in the TRIPS Agreement" has been 'reaffirmed.'[139] Also, paragraph 5 provides a non-exhaustive list of flexibilities - the word used in the agreement is "include"- to be used to this end. All things considered, it is observed that Doha Declaration might change the perception of the interpretation of the TRIPS, especially in the context of finding a balance between the right to health and development.[140] For example, "a possible practical impact of the Doha insistence" might underline the importance of Article 8's effects on other provisions of the TRIPS.

Considering this, Article 27(2) should be evaluated accordingly with the information provided in Article 8 because Article 27(2) involves the protection of health while Article 8 assists MSs in the protection of public health. Therefore, an interpretation of Article 27(2) made without considering Article 8 would be inadequate. As mentioned, Article 8 expands the interpretation of the TRIPS by stating that the adoption of necessary measures to protect public health is also part of the TRIPS agreement and "elaborates the socio-economic policies in question, with particular attention to health."[141] Therefore, considering Article 8 and Doha Declaration together might lead to flexible interpretations by avoiding previous judgements. It

[138] Doha Declaration paragraph 4 (emphasis added)
[139] ibid
[140] Peter K Yu, 'The Objective and Principles Of The Trips Agreement' (2009) 46 Houstan Law Review 999 citing Daniel Gervais, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 3-26 (2d ed. 2003)
[141] ibid 993

is vital to bear in mind that Article 8 emphasises "necessary" measures, therefore the interpretation of Article 27(2) which include measures to fulfil the right to health should be "necessary" to be consistent with the Agreement. Hence, the next section will address the necessity of measures to ensure the right to health and equitable access to medicines.

4.3.3. Necessity

The necessity of considering essential medicines in the context of Article 27(2) arises from a few interdepended elements. The first element is linked with the effects of patent system's current design on medicines. To start with, when companies spend millions of dollars and many years of research on a new drug, 20 years of monopoly might seem insufficient for companies that aim to make a profit from this process. Therefore, instead of developing new drugs, they sometimes change the active ingredients of an existing drug without changing its core functionality to get a patent for this "new" drug (me-too drugs). For example, between 2000-2014 in Europe, only 2% of the new patented drugs brought real advancement to the field, and only 7% of them offered real advantages; while 51% of them were not different from existing drugs concerning their active ingredients and success of the treatments they provide.[142] Moreover, it is observed that pharmaceutical companies' high expenses occur because they "spend twice as much on marketing as research."[143] Consequently, this is reflected in the price of the medicines in the market which leads to the second element.

High prices of medicines make it impossible for certain people to access the medicines they need due to their financial situation. This does not only affect LDCs and DCs' access to medicines but impacts developed countries' citizens in some instances as well. As an example, a medication called sofosbuvir for hepatitis C entered the market for "$84,000 per course of treatment."[144] Likewise, a cancer drug called Imatinib was introduced at $30,000 for a year, but afterwards, it became a blockbuster drug and its price went up to $92,000 while the generic version had 45 times lower prices.[145] Of course, many people do not have or cannot have this amount of money and they were unable to access these drugs.

Besides high prices, the current system makes innovators strongly consider the possible economic consequences of developing new drugs and getting patents for it. Consequently, innovators tend to produce profitable drugs, which can be sold at high prices to recoup their investments. Hence, innovators are "disincentivised" to develop medicines for diseases which affect poorer parts of the world. For example, companies do not tend to produce "child-friendly formulations" of HIV medicines.[146] It's clear that there is a real necessity for these types of drugs as "without treatment, 50% of HIV-positive children will die before their second

[142] Ellen F. M. 't Hoen, *Private Patents And Public Health* (Health Action International) 126.
[143] Amy Ford, 'THE CONCEPT OF EXCEPTIONALITY: A LEGAL FARCE?' (2012) 20 Medical Law Review 304; Joseph E Stiglitz, 'Scrooge and Intellectual Property Rights' (2006) 333 BMJ 1279; Michael Ravvin, 'Incentivizing Access and Innovation for Essential Medicines: A Survey of the Problem and Proposed Solutions' (2008) 1 Public Health Ethics 110, 113; James Love and Tim Hubbard, 'Prizes for Innovation of New Medicines and Vaccines' (2009) 18 Annals of Health Law 155, 1524.
[144] 'Equitable Access to Innovative Pharmaceuticals – PEAH – Policies for Equitable Access to Health' <http://www.peah.it/2022/04/equitable-access-to-innovative-pharmaceuticals/> accessed 16 June 2022.
[145] Ellen (n 143) 5
[146] Ellen (n 143) 120

birthday, and four-fifths before their fifth birthday."[147] Under these circumstances, the right to life and health is crucial for people in poor countries who are fighting malaria, cancer, HIV, tuberculosis, Hepatitis C and other life-threatening diseases daily.[148]

4.3.4. The Outcome

As a result of these circumstances, Article 27(2) should be, ideally, provided with new interpretations by extending Article 53(a)'s interpretation. Firstly, the meaning of commercial exploitation should not be limited to intended use and means to create, but it should also cover the consequences of patents for several reasons. The first reason is about the direct link between "commercial exploitation" and the consequences of a patent. As mentioned, commercial exploitation arises as a result of the inventor's intention to make a profit, which is highly affected by the determination process of understanding which drug could be sold at high prices. In other words, while innovators are entitled to think about the consequences of their newly found drugs, they might simply seek a way to make profit rather than working for a beneficial medicine for all. In such cases, the consequences of the patents are shaped according to the innovators' wish to make money and not by a desire to provide medicine for the sick. Therefore, the consequences of patenting such medicines directly affect the medicine's market price.

The second reason is consequences of granting a patent to medicines are more likely to reflect the negative and harmful effects of the patent than the utilization of the invention. The latter makes it harder to analyse immoral consequences and thus, the risk of not being able to see such harmful effects becomes an important issue. For example, the intended use of an invention could be beneficial to society, but its actual effects can only be measured by looking at its real use in society. If one drug is intended to bring a cure to tuberculosis but granting a patent to it makes it impossible to access for the majority of people who suffers from tuberculosis, the real use of the drug is de facto restricted, which stops millions from getting treatment. Consequently, intentions of profit of the innovators are linked to the consequences of granting patents which is the most overarching way to assess inventions' harmful and immoral effects on social values.

To continue, the Article states that if an invention's commercial exploitation is contrary to morality/ordre public, it can be excluded from patentability and it continues to on elaborate what morality is. On this, the word "including" is used in the Article to demonstrate the protection of health is included in the determination of the spectrum of morality. Contrary to EPC 53(a), the words "including protection of health" clarify the scope of Article 27(2). Therefore, if commercial exploitation of invention (including consequences of granting a patent) leads to situations which can affect "health" in a negative and immoral way, it should be directly examined under this Article. Consequently, essential medicines are undoubtedly a part of "health" as they "satisfy the priority health care needs of a population." Incentivising the development of essential medicines leads to either high prices that affect the affordability of the essential medicines or underdevelopment as innovators choose to develop a medicine which can be sold at high prices. As a result, commercially exploiting an essential medicine

[147] ibid

[148] See Cullet (n 6); Also, to recall there are more drugs for baldness or for erection problems than all tropical diseases, see supra note 17.

should be ideally regarded as contrary to morality/ordre public as it both restricts millions of people's access to drugs and negatively affects public health and the right to health.

4.4. Practical implementations and future possibilities

Practical implementations of public health measures and interpretations are vital since protecting the right to health is not an option but an obligation brought by Article 12 of ICESR by saying states should respect the right to health which compromises not only being healthy but also access to the "treatment of diseases."[149] Linked with this, General Comment 14 of CESCR bring interpretations to the right to health and mentions its four dimensions: "availability, ***accessibility***, acceptability, and quality" and all these also apply to essential medicines.[150] Furthermore, the CESCR also asserts that one of the core obligations under the right to health is for states "to provide essential drugs" to people in need.[151] Therefore, re-interpretation of Article 27(2), which includes that patenting essential medicines is contrary to morality due to the lack of accessibility caused by the high prices, is the best way possible for states to comply with the obligation.

To demonstrate the necessity of this, an example would be beneficial. Monkey pox virus is currently spreading around the world and, in particular, it is critical in Africa.[152] Of course, health care systems are now more developed and well-equipped to fight with monkey pox virus and vaccines are available in most developed countries; however, "it takes years, sometimes decades, for new health solutions to reach people in" developing and least-developed countries.[153] As a solution to this, Article 31 of the Doha Declaration can be used but as it will require different bodies' approval and reconciliation with the producers, which took 4-5 years in the real example, medicines would not be available to people for a long time. On the other hand, the interpretation under Article 27(2) would prevent this medicine to face the consequences of patents, which would decrease the prices and consequently LDCs would focus more on their healthcare infrastructure than on spending money on highly-priced medicines. Nevertheless, if protection for intellectual inventions is not sufficiently placed, most firms and individuals who produce innovative medicines could be hesitant to invest in research since they would not be able to recoup their investment. In such a situation, the public would not be able to find sufficient and necessary medicines in the market because companies would simply stop producing new drugs as they would not gain any profit out of them without patents. Therefore, Chapter 5 will provide alternative incentive mechanisms to make sure essential medicines are being produced even if patenting system changes.

[149] Jennifer Anna Sellin, 'Does One Size Fit All? Patents, the Right to Health and Access to Medicines' (2015) 62 Netherlands International Law Review 445, 450.
[150] UN Committee on Economic, Social and Cultural Rights (CESCR), "General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)", E/C.12/2000/4 (2000) General comment 14, ibid (emphasis added)
[151] CESCR General Comment 14, para 43
[152] Monkeypox' (Who.int, 2022) <https://www.who.int/news-room/fact-sheets/detail/monkeypox> accessed 26 July 2022.
[153] Global Health Program Overview' [2010] Bill & Melinda Gates Foundation 16

4.5. Conclusion

This chapter started with providing interpretations of insufficient applications of EPC 53(a) the Article 27(2) of TRIPS because of their basic differences. Therefore, the TRIPS agreement on its own merits should be taken into consideration in the interpretation of Article 27(2). To this end, Article 8 and Doha Declaration were the main instruments. All things considered, these two suggested that public health considerations and promoting access to medicines have importance in the interpretation of Article 27(2). To re-interpret this Article, the first aim was to suggest words "commercial exploitation" should ideally involve not only the intended use of the invention but also the consequences of granting a patent since the latter represents the reality of the medicine patent system more sufficiently. Secondly, it has been observed that protection of "health" is also part of morality, therefore, it has been concluded the best way to secure the right to health within the context of an IP system is that any invention that poses negative and immoral affects to the "health," including the accessibility of essential medicines, should be excluded from patentability.

5. RECOMMENDATIONS

5.1. Incentive Mechanisms

The last chapter of this thesis aims to focus on recommendations that would make it possible to exclude essential medicines from patenting while also incentivising the researchers. Until this point, it was pointed out that me-too drugs and excessive marketing costs stifle real innovation. However, when talking about essential medicines, innovation means not only producing novel products but also saving millions of lives. Hence, this thesis argues that the focus of the incentive mechanism should shift from the price of the medicines to the success rate of these products.

In this respect, several alternative methods can be asserted to incentivize firms working on medicines, one of which is the Medical Innovation Prize Fund Act introduced by Bernie Sanders in the US.[154] Related to this fund, push and pull mechanisms have been a topic of debate. In the most general sense, push mechanisms to grant funds before the research is done to decrease R&D costs and herewith prices.[155] Government-funded research, university research grants, and other sponsors are examples of this mechanism. However, this system has negative aspects too since it grants money before the research is done. Thus, this method funds not only successful attempts but failed experiments too.[156] Moreover, determining who will get the grant can be "biased" as the future of the improvements and developments of the research are still unknown in the first steps, when the grants are being given. In contrast, it is known that pull systems work according to the success of the medicine. Through this method, the medicine will be rewarded with a prize only if it is beneficial.[157] The idea behind this method is to delink price from innovation and tie innovation and reward with success.[158] Thus, it can be said that pull mechanisms have more positive aspects compared to push mechanisms. For example, pull mechanisms do not reward failures as push mechanisms do, and pull mechanisms urge innovators to produce and create medicines that are helpful, successful, and impactful.[159] On the other hand, pull mechanisms also have negative sides such as some medicines for several diseases which require more time and money to generate more success can still be neglected since innovators might choose to produce medicines that are easy to generate impact. Therefore, alternative incentive mechanisms can be advanced by providing several improvements to prevent neglecting those types of diseases under pull mechanisms. Further on the negative sides of the pull mechanisms, it can be seen that the patent system is also a pull mechanism since it grants a monopoly for novel inventions, however, as stated it only fosters innovation(!) in the markets that can afford monopoly prices, which creates accessibility and

[154] James Love and Tim Hubbard, 'The Bid Idea: Prizes to Stimulate R&(and)D for New Medicines' (2007) 82 Chi-Kent L Rev 1519, 1532
[155] Ravvin (n 144) 115.
[156] ibid.
[157] ibid 116.
[158] Love and Hubbard (n 155) .
[159] Thomas Pogge, 'The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices' (Social Science Research Network 2009) SSRN Scholarly Paper 1431180 193 <https://papers.ssrn.com/abstract=1431180> accessed 14 June 2022.

discrimination problems.[160] Other examples of pull mechanisms are Advance Purchase Commitment, Advance Market Commitment, Medical Innovation Prize Fund Act, Medical R&D treaties and Health Impact Fund which will be the main focus of this section.

To start with, Health Impact Fund is a promising method to provide equitable access to medicines by preventing the occurrence of monopoly prices. It is a voluntary "pay-for-performance mechanism" to incentivise innovation in the medical field.[161] "Voluntary" means that it improves the existing patent system rather than repealing it. Firms can either choose to follow the conventional patent system or HIF.[162] However, under this system, firms would recoup their investments in accordance with the impact of the drug they produced.[163] Also, the reward money would be sponsored by the "states international taxation and/or charitable funders."[164] The rationale behind this method is to provide rewards to successful medicines which "will be assessed by reduction on human morbidity and premature morality it achieves."[165] The success of the drug will be accepted based on its *actual* impact in the real world.[166] One of the essential principles of this system is when firms use this method, medicine would "be provided as a public good that all pharmaceutical manufacturers may use free of charge," which prevents monopoly prices and allow generic companies to produce it all over the world while the innovator recoups their investment based on the impact of the medicine and not on the prices.[167] As Pogge explains, firms can choose this method provided that they accept to sell the drug "no higher than the lowest feasible cost of production."[168]

Further, the benefits of this system can be the solution to the problems of the patent system explained in this thesis. First, since me-too drugs do not have an actual impact or contribute to the field, they would be de-incentivised through this method.[169] Secondly, the problem of neglected diseases can be resolved through this method as the main concern of this problem is people who suffer from these diseases and cannot pay monopoly prices. As it will be explained further in the following paragraphs, giving different amounts of prizes to medicines found in different categories of diseases can be the solution to this. Linked with this, firms would be willing to take their medicines available throughout the world and inform the patients about this medicine to increase its impact and work on especially necessary drugs to get the highest prize possible.[170]

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[160] Ravvin (n 144) 116.
[161] 'Health Impact Fund' <https://healthimpactfund.org/en/> accessed 14 June 2022.
[162] Thomas Alured Faunce, 'Three Proposals for Rewarding Novel Health Technologies Benefiting People Living in Poverty: A Comparative Analysis of Prize Funds, Health Impact Funds and a Cost-Effectiveness/Competitive Tender Treaty' (Social Science Research Network 2008) SSRN Scholarly Paper 1402389 149 <https://papers.ssrn.com/abstract=1402389> accessed 14 June 2022.
[163] Frank Mueller-Langer, 'Neglected Infectious Diseases: Are Push and Pull Incentive Mechanisms Suitable for Promoting Drug Development Research?' (2013) 8 Health Economics, Policy and Law 185, 193.
[164] 'Health Impact Fund' (n 162).
[165] Pogge (n 160) 196.
[166] ibid.
[167] Faunce (n 163) 150.
[168] Pogge (n 160) 197.
[169] Ravvin (n 144) 120.
[170] ibid; Mueller-Langer (n 164) 194.

Of course, even though this method has benefits, it is still open to improvements. This is because the system does not currently categorize diseases. Thus, it simply gives rewards to any new impactful medicine made for any disease. Thus, drugs that are made for non-fatal diseases would get a similar prize as the drugs made for deadly diseases. [171] Therefore, this thesis suggests several improvements and changes to HIF. Firstly, HIF is a voluntary incentive mechanism right now, meaning that innovators can choose the traditional patent system or the HIF system as their incentive mechanism. However, this thesis suggests it should be mandatory when essential medicines are the case. As essential medicines are more vital than other medicines considering humans' health, leaving the choice to the innovator would still create barriers to the accessibility of essential medicines since the traditional patent system could be still chosen by companies aiming for profit. Secondly, high prices are dangerous when essential medicines are the concern as people directly face death because of a lack of medicines. Therefore, when deciding the "prize incentive" for essential medicines, instead of having a "price incentive," criteria should be focused on the diseases themselves. As asserted in the original proposal, higher impacts (medicines that save more people's lives) should get higher rewards than the ones that work on diseases that have milder effects on people. Through this method, health impact will be assessed by the method "Quality-Adjusted Life Years" which differentiates "perfect health" and "poor health" impact for a year by giving "1" point to perfect health and giving a point between "0-1" to poorer health impacts.[172] These points will be given by taking the combination of morbidity and mortality changes of the diseases.[173] Therefore, medicines that "collect" more points would be said to have a greater health impact, and get higher amounts of money, and this would lead companies to seek solutions for deadlier diseases. Thus, the severity of the diseases that medicines try to cure should be considered to understand the importance of medicines for certain diseases such as AIDS, tuberculosis, and malaria. Thus, as explained, when firms produce successful diseases for severe diseases, they should get bigger rewards. The severity of the diseases might be determined by several factors: the number of the patients affected by mortal diseases, the mortality rate of the diseases regardless of how many patients there are (such as SMA), the infection rate of the disease, severity of the effects other than mortality such as blindless and body paralysis. Lastly, to prevent large prize gaps between the maximum and minimum prize, rates should be determined beforehand. All these criteria should be diligently considered by professionals. Overall, this method would lead researchers to work on neglected diseases as much as they spend time and money on "rich country" problems, such as baldness. Of course, even though every system would have its flows, this method would both continue to incentivise the researchers and lead companies towards diseases that kill people who are unable to afford medicine.

[171] ibid 120.
[172] Aidan Hollis and Thomas Pogge, The Health Impact Fund: Making New Medicines Accessible for All (Incentives for Global Health, 2008) 28
[173] ibid

6. CONCLUSION

This thesis aimed to analyse Article 27(2) of the TRIPS, which asserts exclusion from patentability on morality grounds. The main goal was to find a balance between equitable access to medicines and patent rights. The starting point of the thesis was people around the world do not have equal access to essential medicines, which is a result of patent rights. As patent rights create a legal monopoly, and high prices; accessibility of medicines is jeopardized for poor countries' citizens since either sufficient essential medicine are not produced or placed in the market at excessive prices that those people cannot afford. On the other hand, it has been accepted that patents are an essential tool to incentivise innovation in every field of science. Therefore, diligent research and determination are needed.

To understand whether there is a better way to reconcile equitable access to essential medicines and patent rights, the topic was approached from several aspects such as the philosophy of patents, negotiations on Article 27(2), interpretations of the morality clause, effects on the right to health and better alternative methods to incentivise innovation.

In Chapter 2, the important point to analyse was why and how patent rights are created, The most cited ground for justifying patent rights was the utilitarian ground, which brings incentives for innovators to create beneficial and novel innovations for society. With this, society would benefit from these innovations, and consequently, the greatest good for the greatest number would be generated. After understanding their rationale, the next step is to determine whether this rationale was still applicable to modern innovations in medicines. In this step, it has been observed that there are sound challenges to utilitarian ground. First, it has been asserted that the system was open to abuse by big firms as they can use monopolies for their goods only and disregard the needs of the societies. Slowing down the innovation and tragedy of anticommons, which asserts innovations cannot come into the market because of early patent monopolies transaction costs, had significant importance in the field of medicines because every negative side of the step might lead to the death of millions.

Chapter 3 went into examining the current interpretation of morality provision. The first was to understand the objectives and purpose of the Article by looking historical background and MSs comments on the meaning of the Article. After this meaning of the article has been examined. To this end, Article 53(a) of EPC was primarly used as a reference point to understand basic interpretation of the Article 27(2), since they have similarities as to the words used in the Articles. On this, it is observed that morality and ordre public have been interpreted in a narrow sense, which is triggered in rare and extreme cases. They suggest good and bad behaviours, which threaten public security and social values. Moreover, critical point was to determine what commercialisation means to the morality of the innovation. EPO interpreted as utilisation of the product is the only consideration under commercial exploitation. The last part of the chapter provided that there are differences between EPC 53(a) and TRIPS 27(2), which might lead to different interpretation while considering other articles in the TRIPS.

Chapter 4 started with the premise of re-interpreting Article 27(2) while taking its own components and TRIPS agreement into account. The reason was to understand whether essential medicines should be included in the interpretation. On this, essential medicines are

defined as basic needs of human in the context of health-car. The important point to determine on what conditions the Article would include essential medicines. To this end, first insufficieny of EPC 53(a)'s interpretation is explained. Then, other instruments (article 8 and Doha Declaration), which clarify and guide interpretation of TRIPS provisions, are evaluated. Considering this information, it has been, first, concluded that commercial exploitation should also cover consequences of granting patent because the utilisation of the product might be one aspect of morality, but consequences of every action are important to assess whether the product leads to immoral situations. Secondly, it is observed that essential medicines are important part of protection of health, which is threatened by the current design of patent system's incentive mechanism. Consequently, lack of equitable access to essential medicines negatively affects right to health, causing millions to die and suffer. Therefore, it is suggested that including essential medicines to the exclusion from patentability is the best way to ensure right to health.

Chapter 5 was dedicated to recommending different incentive mechanisms which do not create the same problems with the patent system. The most significant one was Health Impact Fund which promises prizes as a reward for medicines following their health impact. This thesis went one step further by modifying HIF. Distinguishing essential medicines from other medicines and creating different prize layers in accordance with the severability of the diseases. Lastly, Ethics and Health Committee is briefly suggested to assess ethical questions and determine the reward.

All things considered, the answer to the research question is to exclude essential medicines from patentability to ensure equitable access to medicines because patenting them created immoral consequences for the public and to create different incentive mechanisms to still foster innovation in medicines. It is believed that this system could generate more innovation than the patent system and at the same time ensures equal access to essential medicines.

BIBLIOGRAPHY

PRIMARY SOURCES

International Treaties

UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), 11 August 2000, E/C.12/2000/4,

UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A (III)

UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993

TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

Guidelines for Examination in the EPO (2022)

WTO, WHO, WIPO and Other Documents

GATT document MTN.GNG/NG11/14

GATT document MTN.GNG/NG11/76

GATT document MTN.TNC/W/35/Rev.1 Uruguay Round – Trade Negotiations Committee – Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations – Revision, 3 December 1990

GATT document MTN.GNG/NG11/W/37

Ministry of Health & Family Welfare (MOHFW) Government of India, "Report of the Core-Committee for Revision of National List of Essential Medicines" (2015)

Office of United Nations High Commissioner for Human Rights and WHO, 'The Right to Health' (Fact Sheet No. 31) (2008)

Peter Drahos, 'The Universality of Intellectual Property: Origins and Development' https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=7604

Stoll PT., Busche J. & Arend K. (eds), WTO—Trade-Related Aspects of Intellectual Property Rights. © 2009 Koninklijke Brill NV

Watal J and Taubman A (eds), The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations (World Trade Organization 2015)

World Health Organization, *Advancing the Right to Health: The Vital Role of Law* (World Health Organization 2016)

World Health Organisation, Department of Neglected Tropical Disease. "Ending the neglect to attain the sustainable development goals: a road map for neglected tropical diseases 2021–2030" (2021), WHO/UCN/NTD/2020.01. 2

World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN (01)/DEC/1, 41 ILM 746 (2002)

WTO Analytical Index: Guide to WTO Law and Practice "TRIPS Agreement – Article 8 (Jurisprudence)" (2012) ("WTO Analytical Index").

WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation - Second Edition* (2020)

Case Law

C-34/10 Oliver Brüstle v Greenpeace eV [2011] ECR I-9821.

G 00002/02 Priorities from India/ASTRAZENECA EPO (2004)

G 00003/02 Priorities from India/ASTRAZENECA EPO (2004)

Plant Genetic Systems v Greenpeace [1995] EPOR

T 0272/95 EPO Relaxin/HOWARD FLOREY INSTITUTE (2002)

T1374/04 Wisconsin Alumni Research Foundation (WARF) (2007) OJ EPO 313

T 19/90 EPO Harvard/Oncomouse (1990)

SECONDARY SOURCES

Books

Antonio A and others, Structural Transformation in South Africa: The Challenges of Inclusive Industrial Development in a Middle-Income Country (Oxford University Press 2021)

Bostedt F. et al (eds.) “Case Law of The Boards Of Appeal Of The European Patent Office” (9th edn, European Patent Office Legal Research Service of the Boards of Appeal 2019)

Drahos, Peter, *A Philosophy of Intellectual Property* (Routledge 1996)

Ellen FM., *Private Patents And Public Health* (Health Action International)

Heller M., The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives (Basic Books 2010)

Hollis A. and Pogge T., The Health Impact Fund: Making New Medicines Accessible for All (Incentives for Global Health, 2008)

Resource Book on Trips and Development (Cambridge University Press 2005)

Robinson J., The Accumulation of Capital (London: Macmillan, 1956) 87; quoted in Dorothy Nelkin, *Science as Intellectual Property (New York: Macmillan)*

Sandel M., Justice (Flammarion 2017)

World Health Organization, “Model List of Essential Medicines – 22nd List, 2021.” Geneva: World Health Organization;)2021) (WHO/MHP/HPS/EML/2021.02)

Articles

Adekola, T., 2020. Has the Doha Paragraph 6 system reached its limits?, Journal of Intellectual Property Law & Practice, 15(7),

Ajzental RS, “Compulsory license: analysis of the effectiveness in providing access to medicines” (LLM Thesis, Universiteit van Tilburg European and International Public Law 2018)

Bently L and Sherman B, ‘The Ethics of Patenting: Towards a Transgenic Patent System’ (1995) 3 Medical Law Review 275

Clarke L, ‘Should the Courts Be Moral Censors of Biotechnological Innovation? An Analysis of the Morality Provisions of Patent Law with Specific Reference to Rule 28(1)(c) of the Implementing Regulations to the EPC Concerning Embryonic Stem Cell Patents Dissertations’ (2021) 11 Southampton Student Law Review

Correa C, ‘The TRIPS Agreement and Developing Countries’ (2005)

Cullet P, ‘Patents and Medicines: The Relationship between TRIPS and the Human Right to Health’ (2003) 79 International Affairs (Royal Institute of International Affairs 1944-) 139

Devlin A and Sukhatme N, ‘Self-Realizing Inventions and the Utilitarian Foundation of Patent Law’ (2009) 51 William & Mary Law Review 897

D4 The Trips Agreement: Two Decades of Failed Promises” [2014] Global Health Watch 4

Perot E., “Maximising Utility: Applying Utilitarian Theory to International Patent Law” (2014) 5 King's Student Law Rev

Faunce TA, ‘Three Proposals for Rewarding Novel Health Technologies Benefiting People Living in Poverty: A Comparative Analysis of Prize Funds, Health Impact Funds and a Cost-Effectiveness/Competitive Tender Treaty’ (Social Science Research Network 2008) SSRN Scholarly Paper 1402389

Fisher WW, ‘THEORIES OF INTELLECTUAL PROPERTY’ [2000]

Fran Quigley, ‘Making Medicines Accessible: Alternatives to the Flawed Patent System’ (Social Science Research Network 2015)

Ford A., ‘THE CONCEPT OF EXCEPTIONALITY: A LEGAL FARCE?’ (2012) 20 Medical Law Review.

Global Health Program Overview' [2010] Bill & Melinda Gates Foundation

Hardin G, ‘The Tragedy of the Commons’ (1968) 162 Science

Heller M, ‘The Tragedy of the Anticommons: A Concise Introduction and Lexicon’ [2013] The Modern Law Review, Vol. 76

Heller MA and Eisenberg RS, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ (1998) 280 Science (New York, N.Y.)

Hettinger EC, ‘Justifying Intellectual Property’ (1989) 18 Philosophy and Public Affairs

Kinsella S, ‘The Case Against Intellectual Property’, *Journal of Libertarian Studies*, vol 15 (2013)

Liddell K, ‘Immorality and Patents: The Exclusion of Inventions Contrary to *Ordre Public* and Morality’ (Social Science Research Network 2016) SSRN Scholarly Paper 2865820

Love J and Hubbard T, ‘Prizes for Innovation of New Medicines and Vaccines’ (2009) 18 Annals of Health Law 155

——, 'The Bid Idea: Prizes to Stimulate R&(and)D for New Medicines' (2007) 82 Chi-Kent L Rev

McMahon A, ‘Patents, Governance and Control: Ethics and the Patentability of Novel Beings and Advanced Biotechnologies in Europe’ (2021) 30 Cambridge Quarterly of Healthcare Ethics 529

Monkeypox' (Who.int, 2022) <https://www.who.int/news-room/fact-sheets/detail/monkeypox> accessed 26 July 2022.

Mueller-Langer F, ‘Neglected Infectious Diseases: Are Push and Pull Incentive Mechanisms Suitable for Promoting Drug Development Research?’ (2013) 8 Health Economics, Policy and Law 185

Munzer SR and Raustiala K, ‘The Uneasy Case for Intellectual Property Rights in Traditional Knowledge’ (2009) 27 Cardozo Arts & Entertainment Law Journal 37

Olson D, ‘Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter’ (2009) 82 Temple Law Review 181

Ouellette LL, ‘Do Patents Disclose Useful Information?’ (Social Science Research Network 2011) SSRN Scholarly Paper 1762793

O’Sullivan M., “Morality Patently Matters: The Case for a Universal Suffrage for Morally Controversial Biotechnological Patents” (Ph.D thesis, University of Edinburg, 2017)

Palmer TG, “Are Patents and Copyrights Morally Justified - the Philosophy of Property Rights and Ideal Objects” (1990) 13 Harvard Journal of Law & Public Policy

Pila J, ‘Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies’ (2020) 38 Nature Biotechnology

Pogge T, ‘The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices’ (Social Science Research Network 2009) SSRN Scholarly Paper 1431180 <https://papers.ssrn.com/abstract=1431180> accessed 14 June 2022

——, ‘The Health Impact Fund: How to Make New Medicines Accessible to All’ (2011)

Pogge T, Rimmer M and Rubenstein K, ‘Incentives for Global Public Health: Patent Law and Access to Essential Medicines’ (2010)

Prifti V, ‘The Limits of “ Ordre Public” and “Morality” for the Patentability of Human Embryonic Stem Cell Inventions’ (2018) 22 The Journal of World Intellectual Property

Quick J. and others, 'Twenty-Five Years of Essential Medicines' (2002) 80 Bull World Health Organ

Quigley F, ‘Making Medicines Accessible: Alternatives to the Flawed Patent System’ (Social Science Research Network 2015) SSRN Scholarly Paper 3496793 <https://papers.ssrn.com/abstract=3496793> accessed 16 June 2022

Ravvin M, ‘Incentivizing Access and Innovation for Essential Medicines: A Survey of the Problem and Proposed Solutions’ (2008) 1 Public Health Ethics

Sanchez D, ‘The Economic Empowerment of African Descendents: Lessons from South Africa’s Black Economic Empowerment Strategy’ <https://repository.hsrc.ac.za/handle/20.500.11910/3806> accessed 16 June 2022

Schellekens M. and Vantsiouri P ., 'Patentability of Human Enhancements' (2013) 5 Law, Innovation and Technology

Sellin JA, ‘Does One Size Fit All? Patents, the Right to Health and Access to Medicines’ (2015) 62 Netherlands International Law Review

Sichelman T, ‘Commercializing Patents’ (2010) 62 Stanford Law Review

Sønderholm J, ‘A Critique of an Argument against Patent Rights for Essential Medicines’ (2014) 7 Ethics & Global Politics

Sterckx S, ‘Patents and Access to Drugs in Developing Countries: An Ethical Analysis’ (2004) 4 Developing World Bioethics

——, ‘Can Drug Patents Be Morally Justified?’ (2005) 11 Science and Engineering Ethics

Stiglitz JE , ‘Scrooge and Intellectual Property Rights’ (2006) 333 BMJ

Straus J, ‘Ordre Public and Morality Issues in Patent Eligibility’ [2013] Intellectual Property in Common Law and Civil Law

Svatos M, ‘Biotechnology and the Utilitarian Argument for Patents*’ (1996) 13 Social Philosophy and Policy

“THE TRIPS AGREEMENT AND ACCESS TO ESSENTIAL MEDICINES” (LLM thesis, University of Amsterdam, International and European Law: International Trade and Investment Law)

Visanko HHE, “Pharmaceutical Patent Monopolies’ Effect on Access and Availability of Medicines: Problems and Solutions” (Dissertation Universiteit van Tilburg Business Law 2016)

Warren-Jones A, 'Vital Parameters for Patent Morality—a Question of Form' (2007) 2 Journal of Intellectual Property Law & Practice

Yu P.K., 'The Objective and Principles Of The Trips Agreement' (2009) 46 Houstan Law Review

Online

Barlow JP., "The Economy of Ideas" (1 March 1994) https://www.wired.com/1994/03/economy-ideas/

"Declaration on the TRIPS Agreement and Public Health" (WTO) <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.html> accessed April 1, 2022

'Equitable Access to Innovative Pharmaceuticals – PEAH – Policies for Equitable Access to Health' <http://www.peah.it/2022/04/equitable-access-to-innovative-pharmaceuticals/> accessed 16 June 2022

Extended Learning Institute (ELI) at Northern Virginia Community College (NOVA), "Introduction to Computer Applications and Concepts" (Lumen)

'First 500,000 AIDS Cases -- United States, 1995' <https://www.cdc.gov/mmwr/preview/mmwrhtml/00039622.htm> accessed 16 June 2022

'Founders Online: Thomas Jefferson to Isaac McPherson, 13 August 1813' <http://founders.archives.gov/documents/Jefferson/03-06-02-0322> accessed 16 June 2022

'Health Impact Fund' <https://healthimpactfund.org/en/> accessed 14 June 2022

"History of HIV and AIDS Overview" (Avert October 10, 2019) https://www.beintheknow.org/351/pdf accessed October 3, 2021

Melody Peterson, 'A Question of Timing: A Lawsuit Claims Gilead Sciences Could Have Developed a Less-Harmful Version of Its HIV Treatment Sooner' (*Los Angeles Times*, 29 May 2016) <https://www.latimes.com/business/la-fi-gilead-20160529-snap-story.html> accessed 16 June 2022

"Morality" (Encyclopædia Britannica) https://www.britannica.com/dictionary/morality#:~:text=m%C9%99%CB%88r%C3%A6l%C9%99ti%2F-,noun,and%20what%20is%20wrong%20behavior accessed April 5, 2022

'Patent Regime And Right To Health: National and International Perspective' <http://www.legalservicesindia.com/articles/pg.htm> accessed 16 June 2022

Quigley F.,‘Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes’ (*Health and Human Rights Journal*, 6 December 2013) <https://www.hhrjournal.org/2013/12/incorporating-a-right-to-health-perspective-into-the-resolution-of-patent-law-disputes/> accessed 10 June 2022

‘The Status of the HIV/AIDS Epidemic in Sub-Saharan Africa’ (*PRB*) <https://www.prb.org/resources/the-status-of-the-hiv-aids-epidemic-in-sub-saharan-africa/> accessed 16 June 2022

WHO Model List Of Essential Medicines - 22Nd List, 2021' (Who.int, 2022) <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02>