VIEWS ON THE TRIPS AGREEMENT TO FIND AN APPROACH TO INCREASE THE ACCESS TO PHARMACEUTICAL PRODUCTS IN DEVELOPING COUNTRIES

A NEED FOR TRANSFORMING THE GLOBAL MEDICINE REGIME?

Intellectual Property Shaping Society

Master's Thesis

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Lack of access to pharmaceutical products in developing countries is major problem due to strict patent protection. The aim of the thesis is to find out whether one of the suggested approaches could increase the access to pharmaceutical products by analyzing the TRIPS Agreement and discussing few ways to view it. The views are from the perspectives of public health, right to health as well as generic medicines. The analyzed approaches are the Medicine Patent Pool, Open-Source model and Orphan medicines. An analysis of whether the global medicine regime needs transforming will be discussed before concluding the thesis that in order to increase access to pharmaceuticals in developing countries, it is essential to choose the right view on the TRIPS Agreement and then chose the right approach for practical application that supports the chosen vision.

The theoretical analysis and discussion are conducted by examining the TRIPS Agreement and Doha Declaration as well as by critically analyzing and commenting on the books and articles written by legal scholars on the similar topics.

Key words: Pharmaceutical product, access, developing countries, patent protection, TRIPS

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Kehitysmaiden pääsy farmaseuttisiin tuotteisiin johtuu tiukoista patenttisuojauksista. Analysoimalla TRIPS sopimusta ja keskustelemalla sen eri tulkintatavoista, tämän tutkielman tavoite on selvittää, josko yksi ehdotetuista lähestymistavoista voisi lisätä farmaseuttisten tuotteiden saatavuutta. Tulkintatapoja ovat kansanterveyden, oikeus terveyteen sekä geneeristen lääkkeiden perspektiivit. Lähestymistavat, joita analysoidaan ovat lääkkeiden patenttipooli, avoimen lähdekoodin malli ja orpolääkkeet. Analysoinnista, josko maailmanlaajuinen lääkejärjestelmä tulisi muuttaa, keskustellaan, ennen kuin tutkielma lopettaa toteumaan, että jotta farmaseuttisten tuotteiden saatavuutta kehitysmaissa voidaan parantaa, on tärkeää valita oikea tulkintatapa TRIPS sopimuksesta ja sitten valita oikea lähestymistapa käytännön toteutukseen, joka tukee valittua näkemystä.

Teoreettinen analysointi ja keskustelu on toteutettu tutkimalla TRIPS sopimusta, Dohan julistusta sekä kriittisesti analysoimalla ja kommentoimalla kirjoja ja artikkeleja samanlaisista aiheista, jotka ovat kirjoittaneet oikeustieteilijät.

Avainsanat: Farmaseuttiset tuotteet, saatavuus, kehitysmaat, patenttioikeudet, TRIPS

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ABBREVIATIONS

Doha Declaration	Doha Declaration on the TRIPS Agreement and Public Health, WT, MIN(01)/DEC/W/2, 14 November 2001
GATT 1994	The General Agreement on Tariffs and Trade 1994
MPP	Medicines Patent Pool
MRDT	Medical Research and Development Treaty
Orphan Medicinal Products Regulation	The European Union Regulation (EC) No141/2000 on orphan medicinal products
PPP	Public-private partnership
TRIPS	The 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)
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. INTRODUCTION

The lack of access to pharmaceutical products due to the strong patent protections has for a long time been a major problem in the world, especially among developing countries. It has been estimated that roughly one-third of the world's deaths is because of a serious disease which, consequently, stems from the lack of access to medicines or right treatments.[1] Access problems, especially relating to pharmaceutical products has gradually grown more pressing and there have been various approaches that all have tried to solve how to increase access to pharmaceutical products in developing countries. As one could assume, developing countries fall behind on various areas when compared to developed countries, and accessing pharmaceutical products is not an exception. Many different approaches for solution have been introduced and analyzed over time but nothing has yet been agreed on being the most suitable one for lifting developing countries to meet the level of developed ones. The debate on which approach is the most effective and the most suitable continues.

The Agreement on Trade Related Aspects of Intellectual Property Rights (hence forth 'TRIPS', 'Agreement' or 'TRIPS Agreement'), a legal agreement between members of the WTO established in 1994, aims at ensuring that every member country has the adequate rules on the protection of intellectual property and every member country apply them as guided. The TRIPS Agreement sets the minimum standards concerning the availability, scope and use of intellectual property rights.[2] These minimum standards are set for countries when they regulate intellectual properties of every sort, but countries can themselves decide on the implementation measures as long as they still follow the TRIPS and will not breach its provisions. These measures can be greater than those set in the TRIPS which explains the word of 'minimum standards.'[3]

For developing countries, the TRIPS Agreement did not meet the desired outcomes due to various high costs towards them as countries, and the pressure from developed countries towards high intellectual property protection standards, hence patent rules that might restrict access to affordable medicines for people in developing countries were among these concerns. Furthermore, developing countries were not fully satisfied with the TRIPS Agreement, and

[1] Cox, K. L. (2012). The medicines patent pool: promoting access and innovation for life-saving medicines through voluntary licenses. *Hastings Sci. & Tech. LJ, 4*, p 292.
[2] World Trade Organization, Uruguay Round Agreement: TRIPS, Part I – General Provisions and Basic Principles
[3] World Trade Organization, TRIPS: FAQS. Accessible: https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm

rather viewed it as something that had to be agreed to since the access to market for developing countries came with a condition of more strict intellectual property protection of products. The specific concerns about the TRIPS Agreement towards developing countries were not solely the reason why the Agreement did not meet the hoped outcome. The TRIPS Agreement caused uncertainty among the member countries which led to both variety of interpretations and new perspectives on how to view it.

Because of the number of uncertain scenarios, in 2001 Doha Declaration on the TRIPS Agreement and Public Health (hence forth 'Doha Declaration') was adopted. It was designed to be the respond to concerns of developing countries in situations where they struggle with implementing measures to foster access to pharmaceuticals in the interest of public health, whilst not limiting any specific diseases.[4] The Doha Declaration, as the TRIPS Agreement, was thought to be a solution for the issues of intellectual property standards.[5] The Doha Declaration together with compulsory licensing will be discussed in the chapter 2.2.1 and in the chapter 2.2.2. in this thesis. The focus of that discussion is inter alia analyzing its positive and negative effects since there is room for countries to interpret the Article 31 in the TRIPS Agreement that relates to compulsory licensing and how compulsory licensing caused more conflicting benefits between developing countries and pharmaceutical companies.

Due to the many existing interpretations and views on the TRIPS Agreement, there occurred new approaches towards decreasing the lack of access to pharmaceutical products in developing countries. Among other reasons, finding the most effective method or approach to the issue is important because access to medicine has been recognized as part of a right to health which is a fundamental human right itself.[6] Various approaches exist, all trying to achieve the same goal of increasing the access to pharmaceutical products in developing countries, but there also exist suggestions that focus more on challenging and reforming the current patent system, especially relating to pharmaceutical patents. The new suggestions stem from the idea of medicines and other pharmaceutical products would be accessible for all easier and more affordable than before. In addition, the reform would also relate to research and development and how to further promote and protect it. The transforming of the global medicine regime will be discussed in the chapter 5 of this thesis.

[4] World Health Organization, Essential medicines and health products, The Doha Declaration on the TRIPS Agreement and Public Health
[5] Birkbeck, C. D. Intellectual Property, Development, and Access to Knowledge. In *The Oxford Handbook of Intellectual Property Law*. p 2.
[6] Cox, K. L. (2012), *supra nota* 1, p 293.

This thesis will discuss few of the many approaches and suggestions, some mainly aiming at increasing the access to pharmaceutical products in developing countries, but also some that suggest the wholesome reform to the intellectual property system. In addition, suggestions on how to view the TRIPS Agreement will be discussed in the third chapter and various approaches are analyzed in the fourth chapter of this thesis. Furthermore, the proposal for Medical Research and Development Treaty will be discussed with the question of whether to change the current patent system completely or not. Among many approaches trying to increase access to pharmaceutical products, prior mentioned compulsory licensing, the Medicine Patent Pool as well as Open-Source model were the most successful options compared to the others.

Medicine Patent Pool has been trying to solve access issues of pharmaceutical products in developing countries with its unique perspective: creating patent pools that could increase access to pharmaceuticals by allowing third parties to obtain non-exclusive licenses in order to develop the products. The chapter 4.1 discusses the Medicine Patent Pool's division into three different phases of operation: working as a 'home country' where the administrator is based in, a country where manufacture happens and a country that imports and exports the medicine. In addition, the chapter discussed more in detail how the Medicine Patent Pool works, the achievements of the Medicine Patent Pool as well as the reasonings of it and for it.

As the last-mentioned approach, also Open-Source model, focusing on availability and sharing of knowledge, has been suggested to enhance access to pharmaceutical products in developing countries. This model does not offer exclusive rights, rather aims to reach each and every country to share the knowledge relating to pharmaceutical products and the process of creating them. Open-Source model has received critique of being too uncertain and lacking motives to be participated in which are introduced in the chapter 4.3.

Because the theories, methods and mechanisms are not created for solving the problem specifically in developing countries and their lack of access to pharmaceutical patents, the analysis in this thesis is not aiming to prove that one or all the discussed approaches would be the most suitable but merely just to bring out more options and give a fresh perspective to look at the problem at hand. To solve the access issues developing countries are facing, or at least to get closer to a possible solution, is important not only because of fundamental human rights but also because of the fair balance of international intellectual property rights. As access problems form a quite broad topic and many issues relate to it, a few good questions will be asked and answered, as well as some already known approaches will be challenged in this thesis. Is compulsory licensing helping developing countries to have better access to

pharmaceutical products and if not, is one of the other discussed methods better? Should the intellectual property rights system, or global medicine regime be reformed in the world to better take the perspective of developing countries into account? Should the TRIPS Agreement be interpreted differently to better understand the issue relating to it and the consequences of it?

In this thesis the term 'developing countries' covers countries on the 'least-developed countries' -list concluded by World Trade Organization (hence forth 'WTO'), such as Cambodia, Rwanda and Mozambique, but these countries are not solely the countries that will be discussed about. The discussion about developing countries and their situations related to the lack of access to pharmaceutical products concentrates to all countries, no specific division will be made. The term 'pharmaceutical product' covers any product that is subjected to being regulated as medicine or a drug, including vaccines and so on. These will be referred as 'pharmaceutical products' or only as 'pharmaceuticals.'

Choosing the right methodology allows us to outline the topic correctly as well as to help guiding the topic and research into the right direction. Because one of the wished aims in this thesis, and its topic, is to find a suitable solution that would not only allow better access to pharmaceutical products but also to further balance the global intellectual property rights system and its aspects relating to promoting research and development as well as the right to health, the methodology stems from comparative law. Comparative law methods are suitable here because of their nature of seeking common themes among different legal systems as simultaneously aiming at harmonizing laws, reforming them and solely just analyzing whether an idea of a certain law is true within different legal systems. Because widely conducted comparing of various approaches and views gives a broader vision of every topic, such as the one in this thesis, comparative method gives the perfect base for analyzing the issues discussed. Comparison will be made between different approaches relating to the access of pharmaceutical products and between different views of the TRIPS Agreement. Furthermore, considering different perspectives also helps to get a deeper understanding of the issues and although being different, those perspectives can accommodate each other.[7]

Furthermore, comparative method is also suitable when European Union and international laws are under an analyze.[8] Especially, in this thesis the reason for choosing comparative method comes useful because of the comparative nature when analyzing, discussing or

[7] Hervey, T., Cryer, R., Sokhi-Bulley, B., & Bohm, A. (2011). *Research methodologies in EU and International law*. Bloomsbury Publishing. p. 23.
[8] *Ibid.,* p. 28.

arguing different aspects of European Union law or other international laws. Comparative law and international law together can offer a chance for deeper analysis and new perspectives. Also, when suggesting new approaches, perspectives or reforms, it is important to use quite a simple and clear methods so that the readers will have a better understanding of what the situation is now and how it will change and what the situation will be later on; to have something to reflect on helps with understanding the reasons behind the change or behind the need for a change. Worth noting is that, although comparative law method compares different legal systems between countries, that type of comparison is excluded here. There will not be comparison between civil law and common law even if the countries in discussion have different legal systems.

For analyzing and observing the pressing access issue relating to pharmaceutical products in developing countries, as well as the discussed approaches and suggestions in this thesis, the materials are gathered from different articles written by legal scholars who have touched upon the same subject and analyzed it or presented their perspective and arguments towards or against certain issues. Moreover, EU legislation used in this thesis include The TRIPS Agreement, Doha Declaration and other decisions concluded. In addition, international intellectual property law and the framework of it will be used. What also has been used to gather information about the subject of this thesis were information from websites of relevant organizations to the subject, such as WTO and World Health Organization (hence forth 'WHO'). Although, the information gathered from these Organizations were merely just to either clarify definitions or to support more complex analyses, or just to bring out and discuss the statements of these Organizations.

As it is stated in the WHO Constitution: "*the enjoyment of the highest attainable standard of health as a fundamental right of every human being without distinction of race, religion, political belief, economic or social condition*"[9] the right to health, which access to pharmaceutical products is part of, should not be left without attention in so far that there is such a difference and fragmentation between countries and their abilities to access pharmaceuticals: equality among countries and right to health must both be valued and respected in the world.

[9] UN General Assembly, Entry into force of the constitution of the World Health Organization, 17 November 1947, A/RES/131

2. EN ROUTE TO ACCESSING PHARMACEUTICAL PRODUCTS

Imagining one's life with life-long, or even deadly, disease and knowing that there exist medicines for its cure or to ease the symptoms but having no access to it. It is self-evidently frightful. Within European Union, there were approximately 822 people who died due to AIDS-related illnesses in 2018 according to the data gathered.[10] Compared to developing countries, for instance only to Mozambique, there were 54 000 persons who died because of it within the same year.[11] The difference is enormous especially when compared to inhabitants of the both: in European Union, there were approximately 512 million inhabitants in 2018,[12] and in Mozambique there were approximately 29 million inhabitants in 2018, which has increased by then.[13] Although, being a global issue, HIV and AIDS, among other serious diseases, are most met in developing countries where those diseases spread more rapidly and widely also because of the lack of medicine which is caused by poverty and poor economic stand. Within these developing countries, there do not exist incentives of other motives for pharmaceutical companies to produce medicines or other products such kind.[14]

There exist numerous reasons why lack of pharmaceutical products is still a pressing issue in the world, especially in the developing countries, but there are few reasonings why the situation is such as it is at the moment which all need to be altered or developed more to better accessibility. These three are research and development, costs and health infrastructure within a country.[15] Firstly, developing countries are not as wealthy as more developed countries which is quite a simple reason why developing countries cannot purchase pharmaceutical products that have been strictly patented and due to it costs can get high compared to the average income. Secondly, developing countries have difficulties to provide incentives for research and development due to their lack of knowledge as well as lack of research

[10] European Centre for Diseases Prevention and Control/WHO Regional Office for Europe. (2019). HIV/AIDS surveillance in Europe 2019-2018 data. p 11.
[11] UNAIDS, Mozambique – Overview. Accessible: https://www.unaids.org/en/regionscountries/countries/mozambique
[12] European Commission, *Eurostat*. Accessible: https://ec.europa.eu/eurostat/web/products-press-releases/-/3-10072018-BP
[13] Worldometer, Mozambique Population 1950-2020.
[14] Grover, A., Citro, B., Mankad, M., & Lander, F. (2012). Pharmaceutical companies and global lack of access to medicines: strengthening accountability under the right to health. *The Journal of Law, Medicine & Ethics, 40*(2), p 234.
[15] *Ibid.,* p 235.

institutions to name a few.[16] And lastly, overall, the health infrastructure in developing countries is lacking many parts such as resources, qualified and skilled employment.[17]

2.1 From the establishment of the TRIPS Agreement to uncertainty

International intellectual property law has always been focusing on unifying and harmonizing countries' domestic intellectual property systems. It has been a coordinated response to the problematic issues that domestic intellectual property territoriality has caused.[18] Although the problems with intellectual property territoriality, such as situations where the intellectual property subject matter passes beyond the territorial boundaries of the rights granting state, have been somewhat solved with international intellectual property systems, the issue with pharmaceutical patents and its consequences to access to medicines still remains. As known, the issue with accessing pharmaceutical patents has been problematic for developing countries quite a long time. Moreover, as mentioned in the introduction, there have been suggestions of alternative solutions aiming at solving this problem but even if there are many approaches none of them have fully succeeded.

One of the core problems relating to the lack of access is the high prices of pharmaceutical products, such as medicine. High prices that developing countries cannot afford, result from strong intellectual property protection that patent holders of such products enjoy.[19] What makes the situation problematic, and causes conflict, is that patent protection is needed for ensuring compensation for innovators' research as well as to promote further research and development of products.[20]

Over the decades, different milestones relating to increasing the access to pharmaceutical products have been achieved and some of them already before the TRIPS Agreement. During the TRIPS Uruguay Round between the years of 1989-1994, the standpoint of developing countries was taken into deeper discussion when other countries, including strong countries such as the United States and Japan together with European Union, pressured the developing countries to take higher levels of intellectual property protection as well. Moreover, during the Uruguay Round not all problematic issues were solved that were meant to be solved there and consequently, there were a 'built-in-agenda' gathered for future when more negotiations were

[16] UNESCO Institute for Statistics (UIS). (2010). Measuring R&D: Challenges Faced by Developing Countries.
[17] Orach, D., & Garimoi, C. (2009). Health equity: challenges in low-income countries. *African health sciences, 9*(s2), S49-S51.
[18] Pila, J., & Torremans, P. (2019). *European intellectual property law.* Oxford University Press, USA. p 28.
[19] 'T Hoen, E. (2003*) TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*. p 39.
[20] Kumari, M. K., & Sharma, A. (2019). Doha Declaration: Compulsory Licensing and Access to Drugs. Global Journal of Medical Research. p 17.

meant to happen.[21] These negotiations that were planned to happen later did, but the outcomes of them did not make any significant changes to access problems nor did they solve it.

Although nothing significant solutions regarding access issues came out from the Uruguay Round, some steps were taken forward. During the Uruguay Round in 1994, The TRIPS Agreement was established. It was established in order to unite intellectual property rights within the WTO's scheme.[22] Furthermore, the TRIPS is believed to be the key in easing trade both in creativity and in knowledge and in addition, believed to have the most impact on the pharmaceutical sector and access to medicine as WTO has stated.[23] The TRIPS Agreement sets the minimum standards for intellectual property protection as well as safeguards to remedy in case of abuse of patents for instance. Because the TRIPS holds such a significance, it can be understood that it covers large amounts of aspects concerning intellectual property and trade. What is included in it, are five sections concerning roughly the following: general provision and its principles, minimum standards to protection of intellectual property, dispute settlement, transitional arrangements and guidelines for enforcement of intellectual property rights.[24] Only the provisions of the TRIPS that concern patents will be discussed in order to maintaining the scope of the discussion in this thesis. For patents, the Agreement provides prior mentioned minimum rights for the patent holder as well as allows Members to the Agreement to grant compulsory licenses, which will be discussed later on.

A few years further, during the 1999 Seattle Ministerial Conference, additional few concerns arose relating to developing countries view on the TRIPS Agreement and its effects. Developing member countries saw the TRIPS Agreement granting other, more developed and wealthier, countries access to their markets as well as that these same countries would take advantage of the chances to interpret the TRIPS Agreement as they like in order to better their own position while leaving developing countries behind. This was due to the usage of the non-violation nullification or impairment causes of action.[25] To understand this better, the General Agreement on Tariffs and Trade 1994 (hence forth 'GATT 1994'), that was replaced in 1995 by WTO, included provisions about consultation and dispute settlement. More specifically, in its Article XXIII, titled as Nullification or Impairment, the conditions for Member countries for requesting a dispute settlement are laid out in XXIII:1. Regarding the

[21] Abbott, F. M. (2000). TRIPS in Seattle: The Not-So-Surprising Failure and the Future of the TRIPS Agenda. *Berkeley J. Int'l L, 18,* p 2.
[22] Pila, J., & Torremans, P. (2019), *supra nota* 18, p 33.
[23] World Health Organization, WTO and TRIPS Agreement. Accessible: https://www.who.int/medicines/areas/policy/wto_trips/en/
[24] World Trade Organization, *Intellectual property: protection and enforcement*. Accessible: https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
[25] Abbott, F. M. (2000), *supra nota* 21, p 5.

conditions for a country to request the dispute settlement, the Article XXIII:1 reads as follows:

"1. If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of

(a) the failure of another contracting party to carry out its obligations under this Agreement, or
(b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or
(c) the existence of any other situation,

the contracting party may, with a view to the satisfactory adjustment of the matter, make written representations or proposals to the other contracting party or parties which it considers to be concerned. Any contracting party thus approached shall give sympathetic consideration to the representations or proposals made to it."[26]

As seen, there are mainly three types of complaints that could be made: violation complaint, non-violation complaint and situation complaint. The WTO has dispute settlement systems for these three types of complaints, although there are typically only violation complaints made, and small number of non-violation complaints.[27] To put it simplest possible, dispute settlement is needed when there is an argument or other disputes relating to a member country's belief that another member country has violated an agreement or other obligations that it has committed to the WTO. Before, dispute settlement procedures were stated in the GATT 1994 but because there were many lacking parts, an improved model for dispute settlement process was introduced during the Uruguay Round. The procedure that was in the GATT 1994 inter alia had long settling times for cases and did not have timetables which were all improved. The agreement that was concluded during the Uruguay Round had rules for the length of the cases as well as clear steps along the way of the dispute settlement procedures. Moreover, one of the significant changes was that the given rulings were not as easy to block as it was before. After the improvements, rulings were able to be blocked only if the opposing member country could get every member country to agree on to its views.[28]

As developing countries had expressed their concerns before, also the dispute settlement option for the non-violation cause was as not wanted during the Uruguay Round as an option.

[26] World Trade Organization, The General Agreement on Tariffs and Trade, *Article XXIII:1*
[27] World Trade Organization, Legal basis for dispute, 4.2 Types of complaints and required allegations in GATT 1994. Accessible: https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c4s2p1_e.htm
[28] World Trade Organization, Understanding the WTO: Settling disputes, A unique contribution. Accessible: https://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm

The perspective of developing countries was the concern of misusing the option of non-violation cause by certain companies, such as pharmaceutical companies for instance. Another concern that developing countries had, common with European Union, (then European Community 'EC'), was that the Agreement could possibly be used as a way to gain access to market.[29] This concern stemmed from the fact that the United States could argue that the restrictions towards its audio-visual sector market prevents them to gaining the benefits from copyrights and other intellectual property right protection, if they would allow copyrights to authors who cannot show their works, such as films within the EC (now the EU).[30]

Moreover, developing countries had concerns already before any improvements were made to the dispute settlement procedures, and although the dispute settlement procedure was now better and more effective, developing countries still were doubtful about it. Since negotiations were handling cross-retaliation to trade, developing countries were afraid that their position would weaken even more. Due to developing countries typically being "weaker" countries, they were afraid that for them to place a complaint to press trade barrier to imports. If done so, it could result to increased prices of them which then could negatively affect producers and consumers of such imports. The supply for those imports could also be reduced.[31] Other concerns relating to suspensions to obligations existed also, but because the subject would go on for quite some time, the rest has been left out from discussion in this chapter. Overall, developing countries could not practice suspense of obligation procedure because by doing so, developing countries could end up having trade barriers.

Although the concerns presented by developing countries, the same concerned countries have taken part to the dispute settlement quite actively over the years and most of the cases it is the developing countries who initiate cases against more developed ones.[32] From this, it could be concluded that there has been and still remains to be significant imbalance between developing and developed world but also, it could be also said that even if there were doubts about the dispute settlement and about the extents it reaches, developing countries are still partly, or without any other option, contented with it.

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[29] Abbott, F. M. (2000), *supra nota* 21, p 5.
[30] Abbott, F.M. (2003). Non-violation nullification or impairment causes of action under the TRIPS Agreement and the Fifth Ministerial Conference: A warning and reminder. Quaker United Nations Office (Geneva) (QUNO), *Occasional Paper*, (11). p 2.
[31] World Trade Organization, The process – Stages in a typical WTO dispute settlement case, 6.10 Countermeasures by the prevailing Member (suspension of obligations). Accessible: https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c6s10p1_e.htm
[32] World Trade Organization. Developing countries in WTO dispute settlement. Accessible: https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c11s1p1_e.htm

The TRIPS Agreement has received critique by concentrating too much on profits, for instance with its incentives towards the development of pharmaceuticals. In addition, it has been argued that the TRIPS Agreement also priorities commercial interest rather than public health which is alarming since right to health is one of fundamental human rights.[33] Although the TRIPS Agreement started off well, the critique towards it increased as the years went by and still, there are debates over the Agreement and its Articles. A few of these Articles are being discussed next.

2.1.1. Clarifying misunderstandings of the TRIPS Agreement or increasing the number of interpretations?

As it is more difficult for developing countries to enhance their technologies and use their knowledge to its fullest potential as well as stay equal to developed countries in the field of intellectual property rights, the Article 7 of the TRIPS was established. The purpose of the Article is to give developing countries support from more developed ones by transferring technologies. In addition, the obligation of developed countries to provide incentives for technology transferring in their areas and then transfer technologies to developing countries has been established so that also the developing countries could achieve and then further maintain more coherent and stable base for technologies.[34] This is stated in the Article 66.2 of the TRIPS Agreement.[35]

As will be disclosed, there is no standard and clear definition for technology transfer in the TRIPS Agreement. Since a standard definition of technology transfer is missing, countries could interpret the word broadly, and include different activities to be acceptable for suitable program to help with encouraging technology transfers. These activities have entailed inter alia training, supporting educational systems and providing incentives for foreign direct investments in which some of them were missing the actual transfer part. Countries have also not been clear on what that transferring parts were.[36] Moreover, according to WHO,

[33] Bloemen, S., Mellema, T., & Bodeux, L. (2014). Trading Away Access to Medicines-Revisited: How the European trade agenda continues to undermine access to medicines.
[34] World Trade Organization, Uruguay Round Agreement: TRIPS, Part IV – Transitional Arrangements, Article 66.2, Accessible: https://www.wto.org/english/docs_e/legal_e/27-trips_08_e.htm
[35] 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) Article 66.2
[36] Moon, S. (2008). Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs?. *Retrieved January*, 30, 2010. p 6.

technology transfer not only refer to the process of procedure movement but also movement of people with certain skills, material as well as licensing.[37]

The idea and purpose of technology transfers might have been appealing to some but there have been different studies concluded where the success of the Article 66.2 have been under examination. For instance, there has been doubts on whether the obligation stated in the Article has resulted in the hoped increase of incentives in countries and the actual steps taken towards it. One of such studies is by Suerie Moon.[38] Suerie Moon aims at better understanding the compliance of developed countries to the mentioned obligation because it is seen important for a few reasons. Inter alia, having knowledge on this subject can tell a lot about the impacts that the TRIPS Agreement has had on developing countries. Of course, there a many other factors that have weaken the position of developing countries as well. Moreover, gathering knowledge on the compliance of develop countries also tells something about the possible need for better and more effective obligations and other aspects that need a closer examination and possibly altering.[39]

What Suerie Moon concluded in her study was that although the obligation set in the Article 66.2 of the TRIPS Agreement was aiming at promoting innovation (and technology transfer), the motivation to provide incentives was not in its full potential among countries. Worth noting is that there are not many studies that have examined the extent to which the obligation is carried out. In addition, it is not studied as much as the reasons of why countries are or are not complying. Because not every developed country submitted their reports on the topic, it can be quite difficult to get a clear picture about the measures to comply with the obligation.[40] What was missing from the reports, due to some countries leaving the information out, were also detailed explanations about how certain incentive will eventually result in technology transfer.[41] From my point of view, for a developed country to not to leave a report only shows that the commitment for the obligation might not be strong, hence there is a question of motives also.

Technology transfer could be viewed from the perspective of developing countries also. Incoming knowledge, skills and needed materials would seem to be wished for. Despite the obligation in the Article 66.2, developing countries want that obligation to be more effective. In fact, in 2003 there was a decision *(IP/C/28)* made about the incentives provided by

[37] World Health Organization, Public health, innovation, intellectual property and trade. Local production and technology transfer. Accessible: https://www.who.int/phi/implementation/tech_transfer/about/en/
[38] Moon, S. (2008), *supra nota* 36.
[39] *Ibid*., p 1-2.
[40] *Ibid.,* p 2-5.
[41] *Ibid.,* p 6.

developed countries and how those incentives have worked in practice[42], but as discussed by Suerie Moon previously, these reports came back quite vague, not going into concrete examples. But there were other aspects also that could have been better prepare in addition to the reports. If technology transfer as a term would have been defined clearly in so far that every country follows it, it could have significant impact on developing countries and their local productions, especially relating to medicine production. When thinking the lack of access to pharmaceuticals that developing countries face, technology transfer could be seen having a lot of enhancing factors. But because such definition, a standard one, is not laid down in the TRIPS Agreement to begin with[43] there are challenges relating to helping developing countries better their position among developed countries as well as with their access issues with using technology transfer as one of the options. But what could be done? Suggestions include proposals to have improved multilateral mechanisms that would increase the transfer of technology together with information and knowledge to developing countries.[44]

Although the whole TRIPS Agreement, as well as its Articles 7 and 66.2, among others, were aimed at bettering coherence among countries and keeping the balance within countries relating to rights and other obligations, it came with conflicting issues such as alternative ways of interpreting it and uncertainty how to for instance use the mentioned safeguards.[45] Especially some of the articles included in the Agreement caused the most interpretation problems and differing views on them. To demonstrate this, couple articles are worth mentioning. Both the Article 7 and Article 8 of the TRIPS Agreement caused fragmentation due to their unclear wording. Firstly, the Article 7 of the TRIPS states:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conductive to social and economic welfare, and to balance of rights and obligations."[46]

Here, the focus is on the wording that both the protection and enforcement of intellectual property rights have to promote social as well as economic welfare.

Moreover, and secondly, the Article 8 of TRIPS concentrating on principles, states:

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[42] Decision of the Council for TRIPS of 19 February 2003, IP/C/28, Implementation of Article 66.2 of the TRIPS Agreement.
[43] Moon, S. (2008), *supra nota* 36, p 2.
[44] Abbott, F. M. (2000). *supra nota* 21, p 2.
[45] 'T Hoen, E. (2003*) supra nota* 19, p 39.
[46] 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) Article 7.

"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement"[47]

Here, focus is on the sentence concerning the free determination of member countries on the measures they want to take in order to protect public health and nutrition. What was problematic and unclear was the scope of the measures that member countries could take in so far, they would not breach the provisions of TRIPS because there are no alternatives that could be used in comparison on what would be the suitable measure. In addition, the lack of explanation of the measures themselves caused conflicting interpretations.[48]

As for my opinion, it could be seen problematic that the TRIPS Agreement might give too much of a freedom to Member countries to alter their own approaches to both intellectual property protection and to the enforcement of them. Because members to the TRIPS Agreement are allowed to do so, the motives behind their actions toward the protection and enforcement might be tilted more to their own needs and aims. This leads to these wealthier countries, that typically are those who can have heavier outcomes that impact negatively other countries than their own, to make decisions that do not serve nor help less wealthier countries in any way and in contrary could end up pulling less developed countries further away from their desired goal. One of the most known examples of this is very strict patent protection that was demanded by developed countries that led to the current situation where developing countries lack access to certain patents because of the high prices of the patented products.

In addition to both Article 7 and the Article 8, also the Article 41.5 of the TRIPS Agreement has caused fragmentation. The Article 41.5 states no obligation to member countries to set a 'separate' judicial system for the enforcement of the intellectual property rights.[49] Whether this is seen as a problem or not depends on the perspective from which this is considered. From the perspective of less developed countries, this was seen to have positive outcome since they do not have enough resources to set up or maintain a separate intellectual property groups, courts nor supervisory party. From the perspective of developed countries, this could

[47] 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) Article 8.
[48] World Intellectual Property Organization (2012*) Implications of The TRIPS Agreement on Treaties Administered by WIPO*. Accessible: https://www.wipo.int/edocs/pubdocs/en/intproperty/464/wipo_pub_464.pdf p 9.
[49] World Trade Organization – Module VII. Enforcement. Accessible: https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules7_e.pdf

be seen unfair and creating more imbalance between the countries and their enforcement issues.[50]

Moving further from the mentioned Articles, the TRIPS Agreement has also caused developing countries to have other difficulties and social costs. Developing countries faced and are still facing barriers maintaining their supply of public goods, such as public health and scientific research, especially research relating to medicines. In addition, developing countries have increasing of lack of resources to maintain their traditional provisions relating to public goods. This is because prior to the TRIPS, they were not protected as strictly, or they were in the public domain and the prices were more competitive.[51] The TRIPS Agreement affected not only the traditional public goods in developing countries but also the access to pharmaceutricals as discussed before.

Before the TRIPS Agreement was ever concluded, countries could themselves determinate which medical innovation got patent protection depending on where their level of development was at the time but after the TRIPS Agreement was adopted, patents were and are globalized through it. This changed how patents were granted because now the motives might revolve around sales and market shares which results negatively to developing countries who typically are also the poorest countries.[52] Because of the ability of manufacture of low-cost generic medicine in some countries such as India, it was possible for least developed countries also to have access these low-cost medicines. Since the TRIPS Agreement, the possibility to get these medicines, and other pharmaceutical products, depends on patent holders and their pricing plans as well as the current regulations within a country as well as international agreements.[53] For instance, pharmaceutical companies that are part of the Organization for Economic Co-operation and Development pressured more strict rules of the TRIPS so that it would not be as flexible towards member countries and to prevent these countries from authorizing parallel trade of pharmaceutical products that are patented.[54] In addition, before the TRIPS Agreement was adopted, countries could also by themselves decide on the type and length of patents which enabled various different type of patents to exist. The length of the patents varied depending on the country, for instance less developed

[50] Peter, K., Y. (2014) Why are the TRIPS enforcement provisions ineffective? In *Research Handbook on Cross-border Enforcement of Intellectual Property.* Edward Elgar Publishing. p 8.
[51] Abbott, F. M., & Reichman, J. H. (2007). The Doha Round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of international economic law, 10*(4), p 925.
[52] Dentico, N., & Ford, N. (2005). The courage to change the rules: a proposal for an essential health R&D treaty. *PLoS medicine, 2*(2). p 96.
[53] Abbott, F. M., & Reichman, J. H. (2007), *supra nota* 51, p 928.
[54] Abbott, F. M. (2000), *supra nota* 21, p 3.

countries could have shorter terms for their patents which could be seen as a positive effect to their innovation landscape. Also, prior to the TRIPS Agreement there were also exceptions to certain type products that got patent protection. These patent products related for instance to medicines. When the TRIPS Agreement was adopted, it is clear that every country had to harmonize their patent systems and reform them at the level of wealthier, more developed countries where patent protection goes on at least 20 years. (Although, some exceptions relate to this and least-developing countries) Paul A. David, who is a historian of economics has described the current patent system as: *"a product of centuries of evolution but poorly suites as a policy tool for modern innovation".*[55]

High level of protection of pharmaceutical products and from it resulted access problems are not the only concerns that were an issue for developing countries, but also the intellectual property protection to their traditional knowledge. For many developing countries, there have always existed innovations that stem from prior inventions but have been passed on through generation to the next. One example of this type of traditional knowledge is the traditional practice of medicines. This caused concerns because there were conflicting perspectives relating to the view on terms of 'new' and 'original' of the TRIPS Agreement in comparison to those of developing countries. Although the TRIPS does not view products of traditional knowledge new nor original, developing countries have wondered why it should not be protected to some level in order to prevent any exploitation by other countries without receiving any pay.[56] Advocates who are against TRIPS Agreement, are supporting the old ways and time prior the TRIPS Agreement when countries were more capable for determine their own patent granting[57] in a way as explained with for instance traditional knowledge.

To conclude, as seen among other problematic issues, the TRIPS Agreement has flaws in its wordings and lack of standard definitions. Although, this could be seen a rather small issue, standard definitions provide a solid base for interpreting the TRIPS Agreement and supports the coherence among Member countries which is important in the light of further balance in the field of intellectual property between countries in the world. The fact that the TRIPS Agreement has many unclear definitions and Articles, due to lack of clear and universal definitions, results to differing interpretations and further fragmentation rather than unifying Member countries and balancing rights and respecting equity and equality.

[55] Moon, S., Bermudez, J., & Hoen, E. T. (2012). Innovation and access to medicines for neglected populations: could a treaty address a broken pharmaceutical R&D system? *PLoS medicine*, *9* (5). p 1.
[56] Abbott, F. M. (2000), *supra nota* 21, p 4-5.
[57] Dentico, N., & Ford, N. (2005), *supra nota* 52, p 96.

2.2. Towards coherent interpretations and the consideration of public health aspects

2.2.1 Public health over private intellectual property rights or vice versa?

Relating to the TRIPS Agreement and its many aspects, the Doha Declaration was adopted at the WTO Ministerial Conference in Doha, Qatar in 2001. The core idea behind it was to clarify misunderstandings relating to interpretations of the TRIPS Agreement together with the ways of which governments were applying public health principles.[58] The Declaration was an attempt to inter alia help with developing countries to access pharmaceutical products, such as medicines better than before. The Declaration entails provision about granting compulsory licenses which was aimed to be the solution for the attempt to find the successful method to increase access to pharmaceutical products in developing countries. Compulsory licensing had optimistic hopes for increasing the access but contrary to what was thought, it was not as successful as it was hoped to be.

Moreover, the Doha Declaration was seen as possible key player in resolving the ongoing imbalance relating to upholding efficient intellectual property scheme and simultaneously concentrate to guiding it towards both public and development interests.[59] Since the Doha Declaration hold public health having more value than private intellectual properties, it got support from public health perspective and was seen a significant achievement.[60] During negotiations one specific realization was made: public health could be viewed important, and something could be done to enhance it overall, not just in situations of health crisis. This realization arose when a draft written by Mr. Stuart Harbinson, who was the chair of the WTO General Council at the time, was discussed.[61] Moreover, there has been discussion that the Doha Declaration should be viewed as the guiding example when thinking about public health. Public health should always be supported and promoted, not only by developed countries but also developing countries. Although lacking on some levels, developing countries could promote public health through creating a procedure or systems for the protection of public health against anti-competitive practices and parallel importation for instance. Another way for developing countries to promote public health is to create better

[58] World Health Organization, Essential medicines and health products. The Doha Declaration on the TRIPS Agreement and Public Health. Accessible: https://www.who.int/medicines/areas/policy/doha_declaration/en/
[59] Birkbeck, C. D. *supra nota* 5, p 1.
[60] 't Hoen, E. (2003), *supra nota* 19, p 39.
[61] *Ibid*., p 51.

laws or modify already existing laws to more effectively use compulsory licensing and thus use it as effectively as it can be used.[62]

Despite viewed as a great achievement, the Declaration was not viewed necessary from the perspective of pharmaceutical companies. They argued that there was no need for such a Declaration because in their eyes, patents were not causing any problems and stating that if patent protection would be less strict, there would be consequences to the abilities to conclude research and development. The latter was especially a concern since pharmaceutical industry is based a lot on research and development.[63] Of course, here it should be kept in mind that pharmaceutical companies represent the private side; the private intellectual property rights and thus they want to ensure that there are enough incentives and monetary rewards for the right holders as well as ensuring that the development keeps going further and new products are being created in the process.

As already can be thought from the title of this subchapter, to gain a perfect balance between private intellectual property rights and public health. As will be discussed, governments are facing barriers because there must be enough incentives for the creators but there must also be enough contributions for developing the created inventions even further. Moreover, and self-evidently, there must be enough protection for those who create for their innovations because it will then turn to be one of the needed incentives to create. In addition, the aspect of public health should be considered and given high value as well. As seen, in this circle everything affects everything and every part of it is as important, so balancing the circle to be the 'perfect round' no part can be reduced more than other and that is where the problematic issues lie.

2.2.2 A possibility to increase access to pharmaceutical products through compulsory licensing

How then could access to pharmaceutical products to be establish in order to it be possible for all, even the least developed countries? Compulsory licensing exists in the Article 31 of the TRIPS Agreement and in brief, it is a way to use patented products without the consent of the right holder; governments can thus give permission to either do the patented product, use it or do the process that has been patented with a license. This type of license is a compulsory license.[64]

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[62] Sun, H. (2004). The road to Doha and beyond: Some reflections on the TRIPS agreement and public health. *European journal of international law, 15*(1), p 26.
[63] 't Hoen, E. (2003), *supra nota* 19, p 55.
[64] Abbas, M. Z. (2013). Pros and cons of compulsory licensing: An analysis of arguments. *International Journal of Social Science and Humanity, 3*(3). p 254.

Grounds for granting compulsory licenses are written in the Article 31 of the TRIPS Agreement, although TRIPS uses the phrase "*Other use without the authorization of the right holder*".[65] The grounds for granting compulsory licenses are decided in each member country. Because the grounds are not always clear nor simple with every case, countries have faced interpretation troubles concerning the Article and its wording. Moreover, the grounds for granting compulsory licensing are also subject to certain requirements and conditions that must be kept in mind when assessing cases. In addition, the Article 31c of TRIPS sets more grounds for compulsory licensing stating that the scope and duration of the use is limited to only for the purpose for what licensees were authorized.[66]

Grounds for governments grant compulsory licenses are the following: firstly, there must be an emergency or extreme urgency. An example of this could be quite similar to present situation with Covid-19 pandemic in the world. Although, some right holders are not likely to restrict the use of their patented products, since it is matter of public need, governments could still grant compulsory licenses due to the nature of health emergency or extreme urgency. Secondly, compulsory license can be granted if it is for the remedy anti-competitive practices. Those practices which restrict competition within markets are considered anti-competitive practices, for instance distribution agreements, where an agreement is concluded between the supplier and resellers and where the seller imposes the price that customers should pay.[67] In some situations that require competition law to intervene with right holders and their exercise of their rights that is against the competition in markets, compulsory licensing is used for remedy. Using compulsory licensing can be used to remedy in cases where it is used to correct the misuse of patents and is stated in the Article 31(k) of the TRIPS Agreement.[68] Worth mentioning is that in some cases, such as in those of anti-competitive practices, adequate compensation will be given to the patent holders although their consent is not necessary.[69] Thirdly, if the use is going to be public non-commercial use, a compulsory license can be granted as well. To explain briefly since there are a few debated on its interpretation, this means that for instance situations where the use is governmental as mentioned in the Article 31(b) of the TRIPS Agreement or to situations where the usage is not

[65] 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) Article 31
[66] *Ibid.,* Article 31
[67] Your Europe, Competition rules in the EU. 12 October 2020. Accessible: https://europa.eu/youreurope/business/selling-in-eu/competition-between-businesses/competition-rules-eu/index_en.htm
[68] Apostolopoulus, H. (2006). Anti-competitive abuse of IP rights and compulsory licensing through the international dimension of the TRIPS Agreement and the Stockholm proposal for its amendment. *Rich. J. Global L. & Bus., 6*. 265. p 276.
[69] Correa, C. M. (1999). *Intellectual property rights and the use of compulsory licenses: options for developing countries.* Geneva: South Centre. p 9.

commercial.[70] And lastly, if there are dependent patents at hand; when compulsory license must be granted in order to use an invention that would not be possible without another invention.[71] Cases like these, can be facilitated with granting a compulsory license but as with many other, also this has room for interpretation that do not always go hand in hand. Overall, the perspective of public interest is something that is the ground for issuing compulsory licensing.[72] What applies to this as well, is that the definition of what constitutes as 'public interest' can be quite different among member countries; for instance, in the United States the definition might cover different aspects than European countries within European Union. Of course, the US law and European law are overall quite different and where laws do not always follow the same path. One example is patent systems between these two, where in the United States one can get a patent being the "first to invent" whereas within European law, it is the "first to file"[73] so to speak.

The TRIPS Agreement solely leaves the Article 31 for countries to rely on when considering whether there exist the necessary grounds for compulsory licenses. What adds more to the troublesome starting point is that the grounds for granting compulsory licensees can be quite strict in so far that they are not given to every licensee, hence there might be even more uncertainty of whether it is appropriate to grant them or not.[74] Since a lot has been left to the member countries to decide and to interpret quite freely, the member countries are also able to determinate on what constitutes a national emergency.[75]

Compulsory licensing is one of the so-called flexibilities that is included in TRIPS relating to patent protection, but it is not added to the Agreement as a new and additional "flexibility": compulsory licensing has always been part in the Agreement, but the 2001 Doha Declaration assured and cleared up the use of it for countries and their governments. Prior that, as mentioned, it was not as clear to some countries of when to use them nor how to interpret the grounds in the Article. Such as interpreting the wording and some of the unclear articles of the TRIPS, there was, and still remains, uncertainty with the interpretation of compulsory licensing. Although interpretation was further clarified, the actual implementation of measures easing access to pharmaceutical products was left without a clarification.

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[70] DeRoo, P. (2011) Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs. *Michigan Journal of International Law, 32*(2). p 389.
[71] Correa, C. M. (1999), *supra nota* 69, p 18.
[72] Abbott, F. M., & Reichman, J. H. (2007), *supra nota* 51, p 929.
[73] Golchehreh, L. R. *United States Mission to the European Union Intellectual Property Toolkit*. p 8.
[74] World Trade Organization, TRIPS and Pharmaceutical Patents, Obligations and exceptions. Accessible: https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm
[75] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, 14 November 2001

Although viewed useful since countries can themselves decide the grounds for them, compulsory licensing also has brought up concerns relating to the usage of the Declaration to its fullest potential as well as pressure from developed countries. Also, one of the biggest concerns that arose was finding an affordable and trust-worthy source when for instance a country with poor production measurements issues a compulsory license for pharmaceutical products. This is seen to be one of the negative effects of the TRIPS Agreement's restrictions relating to pharmaceutical products such as medicines.[76] In addition, compulsory licensing can also affect markets in a negative way in a form of parallel exports. Exporting cheaper pharmaceutical products into markets that are more expensive will have a negative effect in markets.[77]

For developing countries, the Doha Declaration gave an extension for the transition period in order to implement the provisions of TRIPS, especially those relating to patents, among other areas. By doing so, developing countries received an important additional timeslot in the light of public health.[78] Moreover, Compulsory licensing was thought to enable developing countries to have better access to patented pharmaceutical products but in fact, compulsory licensing caused conflicting benefits between developing countries and companies that create these pharmaceuticals.[79] Pharmaceutical companies doubly focus on protecting the products and getting the profit while developing countries need these same products but for lower price which is not possible without lowering the patent protection and changing the motives behind innovation. Instead of enhancing access to pharmaceutical products, compulsory licensing negatively affected the access issue: compulsory licensing works only in higher income countries because in these countries citizens can afford purchasing these expensive patented products.[80] This is especially relevant here, because the access issue concerns heavily pharmaceutical products and pharmaceutical sector overall.

Although compulsory licensing negatively affected access to, contrary that what was hoped, it does have positive impacts also. Advantages for compulsory licensees entail inter alia scattering up monopolies which helps the residents of that country to have increased access for essential medicines with an affordable price. In addition, compulsory licensing can further

[76] 't Hoen, E. (2003), *supra nota* 19, p 56.
[77] Stevens, H., & Huys, I. (2017). Innovative approaches to increase access to medicines in developing countries. *Frontiers in medicine, 4,* 218.
[78] World Health Organization, Essential medicines and health products, The Doha Declaration on the TRIPS Agreement and Public Health
[79] Kumari, M. K., & Sharma, A. (2019). Doha Declaration: Compulsory Licensing and Access to Drugs. Global Journal of Medical Research. p 17.
[80] Abbas, M. Z. (2013), *supra nota* 64, p 256.

economic growth as well as research and development of products.[81] Enhancing research and development is important when discussing developing countries and their access to medicine, as well as overall issues relating to pharmaceutical products. Although, as with many controversial topics, also this could be viewed from another perspective: it can also negatively affect further development and research since the costs are lower on investments than the costs on research and development.[82] Especially, with developing countries, foreign investments can be quite important then they want to grow their local industries in so far that compulsory licensing affecting the investments negatively, could result losses in developing country in question. What is note-worthy, is that there are not completely proven cases that would show that there is a clear link between compulsory licensing and foreign investments that developing countries are receiving. In fact, one possible explanation is that since economic growth and institutional steadiness of the (developing) countries affects their received investments, it could be argued that compulsory licensees are not to blame.[83] Lastly, compulsory licensing has its advantage with helping developing countries to possibly direct patent holders to aim at using the patent and its potential to benefit fully their own country.[84]

Granting compulsory licenses could decrease innovation from the perspective of more developed countries because inventing new products and patenting them results with compensation and takes effort, but since from compulsory licensing only results to royalties, which are less than the money from exclusive rights, from the government it could be decreasing innovation to some extent.[85] Some argue, that compulsory licensing will not harm investments relating to research because multinational companies do not see developing countries being important when considering increasing or decreasing research investments.[86]

Referring back to the lack of access to pharmaceuticals, more specifically affordable medicines, which was aimed to be solved with the help of the Article 31 of TRIPS Agreement and Doha Declaration. In addition, and what relates to the issue, is the 2003 Decision on the Interpretation of Paragraph 6 that was aimed to also help with countries to better protect their public health. The Paragraph 6 was seen as powerful that the WTO stated that it would be the

[81] Kumari, M. K., & Sharma, A. (2019), *supra nota* 79, p 21.
[82] *Ibid.,* p 22.
[83] do Amaral, A. (2005). Compulsory licensing and access to medicine in Developing Countries. p 12.
[84] Abbas, M. Z. (2013), *supra nota* 64, p 255.
[85] *Ibid.,* p 254-255.
[86] do Amaral, A. (2005). *supra nota* 83, p 2.

last piece to the puzzle of removing barriers to less expensive imports of medicines.[87] Paragraph 6 of the Doha Declaration recognizes that:

> "*WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002*"[88]

This paragraph is more seen as 'cosmetic' rather than an actual solution for the issue because it did not provide anything concrete that would have solved the issue with lack of access to pharmaceutical products such as medicine. Still, developing countries struggle with using all the benefits that they could from the so-called flexibilities of the TRIPS Agreement. They face similar obstacles with compulsory licensing as well, hence they are not using them as much. The reasons for not using compulsory licensees could entail the lack of capabilities and the lack of stable and profitable national industry of pharmaceuticals.[89]

Even if the International Federation of Pharmaceutical Manufacturers has positively reacted to the Doha Declaration, certain pharmaceutical companies still argue against it, especially against compulsory licensing. Statements towards compulsory licenses and their way of blocking further research and development has been viewed as a threat to public health since new forms of pharmaceutical products result from research and development.[90] The concerns and resistance of pharmaceutical companies towards these relates to generic medicines which will be discussed later in this thesis.

The problem of accessing affordable pharmaceutical products in developing countries remains unsolved, hence this thesis will discuss alternative methods and approaches for solution in the next chapters. Moreover, since there are various interpretations of the TRIPS Agreement among the member countries, there are also differing views on the TRIPS Agreement overall, whether it being successful and great agreement or unsuccessful and failed agreement. Because there have not yet been any proper solutions for the access issues, it has been reasoned that the core problem of the whole debate on how to increase the access is the trying to solve *"a 'public good' problem with a 'private market' solution"*.[91] This is because there is the known obligation of promoting access to medicines to all but at the same time, there is

[87] Kerry, V. B., & Lee, K. (2007). TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?. *Globalization and health, 3*(1), 3. p 1-2
[88] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, 14 November 2001.
[89] Srinivas, K. R. (2006). TRIPS, access to medicines and developing nations: Towards an open source solution. *Access to Medicines and Developing Nations: Towards an Open Source Solution* (November 2006) p 3.
[90] 't Hoen, E. (2003), *supra nota* 19, p 56.
[91] Abbott, F. M., & Reichman, J. H. (2007), *supra nota* 51, p 987.

private market which cannot achieve that. Additionally, there are the measures set by governments that are aiming at balancing the purchasing powers for essential medicines. As long as these are in conflict, there continues to be unsolved solutions for the medicine-access problems in the world.[92]

2.3. Trying the impossible: supporting research and development while allowing access to pharmaceutical products through compulsory licensing

Since the beginning, the core question has evolved around the question of how to please everyone: how to promote research and development and still helping lacking countries to access pharmaceutical products but also protect intellectual property rights. One cannot be achieved without it affecting the others, or could it? As discussed, pharmaceutical products are protected with quite strict patent protection, and enhancing access to those products could result in decreasing the patent protection to some level which would affect the benefits of patent holders and possibly decrease the motivation to innovate and further develop pharmaceutical products. I note that upholding research and development is necessary for the future improvements of pharmaceutical products, but for promoting research and development, there are also need for incentives and motivation for concluding it. Furthermore, to keep research and development going, there is a need for suitable infrastructure and capacity for conducting research and development. Because all of this, developing countries cannot keep up with the wealthier countries although developing countries are in most need for the access to pharmaceutical products and the outcomes of the research done for instance relating to increasing the access.

Since patenting pharmaceutical products results in high prices on pharmaceutical products such as medicine, there has been suggestions by some WTO member countries that certain medicines on the WTO's list of essential medicines should be granted some exclusions from their protection and if not completely subject to exclusion, then protected in a loosely manner.[93]

While trying to achieve the balance, there have been suggestions to use compulsory licensing as a threat to patent holders so that access to pharmaceutical products in developing countries would increase. If developing countries would work in cooperation, forming an alliance and influence the prices of the products. For instance, even without manufacturing capacities for

[92] Abbott, F. M., & Reichman, J. H. (2007), *supra nota* 51, p 987.
[93] Abbott, F. M. (2000), *supra nota* 21, p 4.

pharmaceutical products, country could work in cooperation with another, and thus compulsory license could be issued.[94]

I note that if compulsory licenses would be used as a threat, it might in fact help increasing the access to pharmaceuticals in developing countries, but sometimes a threat will be answered with a threat. If wealthier countries would also form an alliance "against" developing countries it would most likely result in stricter patent protection than ever before which would only cause more difficulties for developing countries that are already dealing with many issues.

[94] Ooms, G., & Hanefeld, J. (2019). Threat of compulsory licenses could increase access to essential medicines. *Bmj, 365*, p 3.

3. VIEWS ON THE TRIPS AGREEMENT TO BROADEN PERSPECTIVES

As known by now, the TRIPS Agreement has been discussed widely in the world and there are disagreements towards some of the choices of wording in its articles. Those aside, the whole TRIPS Agreement could be viewed from different perspectives, such as form the perspective of public health. Furthermore, it could be viewed from the perspective of fundamental right of right to health or from the united framework point of view, where would not be room for fragmentation. As discussed, there is the pressing need for change in the current intellectual property protection rules in order to satisfy and balance the needs of both, the private and the public, interest groups.

To seek changes to the current global intellectual property system and to criticize it, does not mean that those who oppose stronger intellectual property protection are supporters of anti-intellectual property protection. Quite the contrary, because they support the idea of intellectual property protection to enhance competitiveness, development and balance[95] at the same time since everything they try to achieve by changing the current intellectual property protection system is trying to shift the system more towards better recognition of these values. The other end supports the idea of less strict intellectual property protection, and more specifically patent protection, because its positive effects would show when the level of protection is lower, since there exist more possibilities to access foreign technologies whether it would be in the form of adaption or 'copying'. This could be useful when considering access problems of developing countries.

Consequently, the main problem is that a large amount of the global knowledge is being privatized which causes developing countries to take the role of 'intellectual property consumers' rather than producers or exporters who they could be if the circumstances were different. Advocates who support the idea of having strong public interest leading the world's intellectual property scheme are few steps behind those who supports the opposite, because currently in the world, those who hold intellectual property rights have access to affect governments and consequently also can influence and shape intellectual property (protection) form of the world via negotiations for instance. [96] This is something that only a part of groups can do and something that gives a significant vantage which is again capable to break the

[95] Birkbeck, C. D. *supra nota* 5, p 3.
[96] *Ibid*., p 3.

balance between intellectual property protection and its guidance towards public and development interests.

3.1 Public health and the possibilities of generic medicine

"The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health".[97] (Doha Declaration)

Protecting public health is something that is hold in great value not only by the Doha Declaration's statement above and by developing countries, but also by more developed countries as well as by international treaties and international conventions. Moreover, protection public health is the link to healthy life which should be protected to the maximum. After all, it is right to health is a human right.[98] Access to pharmaceuticals improves to achieve better public health care in countries that public health standards are not met yet which then enables it to be a treated as human right that should be protected.

There are as many views how to examine the TRIPS Agreement as there are debates about it, in my point of view. The Agreement has been said not to pay enough attention to public health, rather the Agreement is, for instance, focusing on too high intellectual property standards that causes negative effects to accessing pharmaceutical products in developing countries as mentioned earlier. To view the TRIPS Agreement from the perspective of public health interest means that the motives behind the patent protection are different compared to the current. At the moment, the motives are quite economical since incentives for innovation relate to concrete rewards such as money. When the motives would concentrate more on creating balanced and equal patent system, where pharmaceutical products would be affordable and easily accessible, the incentives for innovation and motives behind it could shift from economical to more public health centered. Although, an economical incentive is quite needed as well because without it, the development and produce of pharmaceutical products would be rather difficult.

When examined from the perspective of public health, the lack of access to pharmaceutical products includes few issues, in which one is the actual capacity of a country to use flexibilities enabled by the Doha Declaration that were mentioned before, especially since there are such differing levels between developing countries and developed ones as well as levels of research and development within the countries. In contrary what was thought, the

[97] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).
[98] Abbas, M. Z. (2013), *supra nota* 64, p 256.

TRIPS Agreement added more to the unbalanced situation in the world relating to public health and trade. Because the Agreement allows Member countries to interpret the Articles quite broadly, intellectual property rights have moved around from one country to another, trade and economic growth in mind which has caused poor and developing countries to lack access to pharmaceutical products to which wealthier countries have been accessing all along. Before the TRIPS Agreement, countries could take part in trading pharmaceutical products in countries where patent rights were unrecognized and produced. For developing countries, this was useful since pharmaceutical products, such as medicines for certain serious diseases, were much cheaper than they are now when countries are following the TRIPS Agreement. [99] As discussed, after the Agreement, patent holders are entitled to exclusive rights to their products and such freely flowed trading system is not allowed anymore.

Giving more attention to the perspective of public health interest and then changing current ways towards more public health centered view can be quite difficult task to tackle, but even the discussed Doha Declaration supports that the TRIPS Agreement should be interpreted as well as implemented so that it braces public health and aims at enhancing access to pharmaceutical products.[100] The paragraph 4 of the Doha Declaration clearly states:

> *" ... 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."*[101]

What could be changed then, in order to bring more attention to public health? One debated question is the patent protection of pharmaceuticals that are closely related to public health and whether the patent protection should be as strict to these types of products. If a product enjoys lower patent production, the interest of investing to it might, and will, drop.[102] In addition, as already discussed, lower patent protection also results in loss of income and loss of incentives. At the same time, medicines that are closely related to public health are seen extremely necessary to be easily accessible everyone in need. One important question remains: how would those pharmaceutical products that are considered to be closely related to public health be decided without causing inequalities? When there is a problem of accessing

[99] Kerry, V. B., & Lee, K. (2007), *supra nota* 87, p 2.
[100] World Trade Organization, TRIPS: TRIPS and Public Health. The separate Doha Declaration explained. Accessible: https://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm
[101] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, 14 November 2001. Paragraph 4.
[102] Abbott, F. M. (2002). The Doha declaration on the TRIPS agreement and public health: lighting a dark corner at the WTO. *Journal of International Economic Law, 5*, 469. p 473.

pharmaceuticals within the countries of the world, there is no need to cause anymore imbalances or conflicting rights or Agreements.

When examined brand-name medicines that are sold in the pharmacies, strictly patent protected and compared to generic medicines, medicines that are the same when it comes to safety, quality and administrative aspects for instance, one can see that generic medicines are cheaper. This is due to the fact that with generic medicine, there are no expenses going into developing nor marketing the medicines, since the generic medicine is not the newest product.[103] When a medicine comes off patent, it could be again produced as an equivalent medicine which typically is less expensive than to do the original, 'in-patent' medicine. The prices between medicines sold by private sector parties compared to other companies producing the equivalent product could be substantially different.[104] There is no denying that generic medicines have changed the atmosphere within pharmaceutical products. Generic medicines have already had an impact on the access to medicines and promoting public health interests and thus have impacted greatly to the affordability and access because of the lower prices of the medicines.[105]

From the perspective of public health interest, the TRIPS Agreement has not succeeded. There yet remains the problem of the current patent system and how it does not take into consideration, nor help in anyway, the poorest. There are no investments going into areas where serious diseases are at their worst because the people who need those medicines cannot afford them.[106]

I find that although seems that the problems relating to public health and access to pharmaceutical products in developing countries are widely discussed and analyzed in relation to trying to find solutions for them, the steps taken to better the situation still are not concrete steps, only discussions and thoughts. And even if a new plan is made to better the access to pharmaceuticals, the plan stays as a plan or becomes a 'trial and error' situation, otherwise the problem would have been solved already.

How can access to pharmaceuticals become a global priority as discussed by Vanessa Brandford Kerry and Kelley Lee?[107] In their debate article, Kerry and Lee present the recommendation categories made by the Commission on Intellectual Property Rights,

[103] Cameron, A., Mantel-Teeuwisse, A. K., Leufkens, H. G., & Laing, R. O. (2012). Switching from originator brand medicines to generic equivalents in selected developing countries: how much could be saved?. *Value in health, 15*(5), p 664.
[104] *Ibid*., p 664.
[105] Abbott, F. M. (2002), *supra nota* 102, p 472.
[106] *Ibid.,* p 473.
[107] Kerry, V. B., & Lee, K. (2007), *supra nota* 87, p 6.

Innovation and Public Health in 2004 when the goal of that Commission was to find ways of improvement to access pharmaceutical products and further the development. Without going into much detail, briefly explained, those recommendations were divided into categories and those categories can be divided into more specific areas as follows; finding completely new products, further developing pharmaceutical products, supporting and promoting innovation even more in developing countries, giving products to developing countries and finally, supporting the WHO in its role.[108] For couple of these improvements, there are further studies conducted about them and there are some results to be seen whether positive or negative. For instance, supporting innovation has been something that the TRIPS Agreement has been aiming to do as for a long time. Moreover, the suggested improvements were gathered in 2004 which is over 17 years ago which means that a lot has happened in the years between.

Distinction needs to be made between aiming at protection of intellectual property rights and protection, and supporting, of public health. It could be argued that there is no possibility to achieve a perfect balance between these two but to decide which one to give a bit more efforts and support. This does not mean that while giving the other slightly more attention and thought (on how to enhance it or make improvements to it) that another would be left alone without any improvements or acts towards it. It would be a matter of choosing and then still keep working towards enhancing every aspect to reach as workable and stable balance as possible in every situation. This could possibly be done with the conflict with intellectual property rights and access to pharmaceuticals whilst still taking public health aspects into consideration. Either way, the TRIPS Agreement needs to be revised with strong emphasizes on public health and how to enhance access to pharmaceutical products in developing countries.

As the Doha Declaration states:

> "*The TRIPS Agreement should be interpreted and implemented in a manner that supports WTO members' right to protect public health and, in particular, to promote access to medicines for all*."[109]

3.2. Turning international fragmentation into new united international framework

As discussed, the TRIPS Agreement has received both supportive and critical feedback, and it has been revised from different perspectives. The TRIPS Agreement has also been reviewed

[108] Kerry, V. B., & Lee, K. (2007), *supra nota* 87, p 6.
[109] Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, 14 November 2001

in a way that has ended up being completely new ways of viewing it. One of these is a vision discussed by Graeme B. Dinwoodie together with Rochelle C. Dreyfuss. Both have also introduced an application of an international acquis in order to increase the unity and clarification of the aspects that TRIPS left behind. International acquis would be a same type of body that 'EU's acquis' is as stated in its definition: "…the body of common rights and obligations that are binding on all EU countries…"[110] Since it would be an international acquis, it would be the body at international level. Although being quite new term in this context, the term '*acquis*' has indeed been in use before; already by the WTO and in EU law where the term stands for the existing legal principles and commitments of the European Union and to which new members must comply. International acquis is specifically suggested because of the history of multinational system that was establish a long time ago.[111]

Dinwoodie and Dreyfuss discuss the overall success of TRIPS Agreement including its interpretation and impacts, but it also goes into more detail discussing the fragmentation within the international intellectual property system and how overall fragmented international law is and how there are several types of fragmentation.[112] International acquis would thus include a set of principles creating a common ground for a common and united intellectual property system decreasing the fragmentation and increasing balance internationally. Application of the international acquis could possibly solve the fragmentation that the Articles 7 and 8 of the TRIPS Agreement have caused with their wordings.

Moreover, altering the current international intellectual property into a united system where member countries to the WTO could more freely change the intellectual property law to their countries in a way to better suit for their needs and priorities. By doing so, the member countries would remain working internationally. What Dinwoodie and Dreyfuss suggest is that the international framework where the member countries would still remain within, would be focusing on protecting and promoting intellectual property system together with the lawmaking of it internationally. What changes is the power; the international framework would have a bit less power than before in order to member countries to alter their intellectual property laws to fit their priorities.[113]

When considering access to pharmaceutical products and how to increase the access, international acquis is essential in order to fix the current fragmentations and thus increasing

[110] EUR-Lex, Glossary of summaries, *Acquis*. Accessible: https://eur-lex.europa.eu/summary/glossary/acquis.html
[111] Dinwoodie, G. B., & Dreyfuss, R. C. (2012). *A Neofederalist vision of TRIPS: the resilience of the international intellectual property regime.* Oxford University Press. p 175-176.
[112] *Ibid.,* p 146-156.
[113] *Ibid.,* p 177.

access to pharmaceutical products. There is a need for it especially because of three issues, including regime shifting, new international intellectual property instruments and their balance as well as political leverage of powerful countries.[114] Among these issues, the thirdly mentioned is the most severe when discussing about developing countries. Supporters of a stronger intellectual property regime can easily block domestic legislation by applying the TRIPS Agreement rhetorically since there are no official guidance on interpretation set by authorities about unclear parts of the TRIPS. It has been stated that for instance compulsory licensing, and especially Article 31bis of the TRIPS Agreement, has been undermined through some of the provisions of the Free Trade Agreement.[115] Article 31bis of the TRIPS concerns the exporting of pharmaceutical products to countries such as some developing one, that is in need of it and cannot produce it on its own.[116]

The application of the suggested international acquis would be done by various means, such as in cooperation of already existing treaties, lawmaking templates and reorienting the whole intellectual property system. As mentioned, the acquis can, when applied, increase the integrity and clarity of uncertain aspects that for instance the TRIPS Agreement has caused. I find that when the acquis would be applied in connection with the TRIPS Agreement, it could possibly take more diverse understanding and further allow more in depth understanding of how the intellectual property regime should in fact work. The international acquis would gather laws more diverse than those from European Union and the United States, that is commonly known and applied. This could offer new perspectives for the access-process and to help formulate novel ways to increase the access to pharmaceuticals.

To better understand intellectual property laws of different countries allows deeper understanding of the intellectual property systems and how the suggested more united international intellectual property regime should work. Moreover, since fragmentation is partly caused by different interpretations, the suggested international acquis could also decrease the number of interpretations and form more united and coherent international intellectual property system for the future where different perspectives would be taken into account when making international intellectual property laws. Examination of diverse laws could be used as an example and guidance of where to further develop the international intellectual property lawmaking and as history, teach what not to do and what could be done better. This could be done also when trying to increase access to pharmaceutical products.

[114] Dinwoodie, G. B., & Dreyfuss, R. C. (2012). *supra nota* 111, p 180.
[115] *Ibid.,* p 180.
[116] 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) Article 31bis.

Sometimes, if one approach has been tested and altered, it does not mean that there should be multiple altering tries more, rather a completely new approach.

Reorienting the intellectual property system itself would happen through completely new perspective of maximum levels of protection instead of the known minimum standards of protection. Dinwoodie and Dreyfuss argue that the Article 1.1 of the TRIPS Agreement supports the claim that nonproprietary interests are protected in the same manner that those loaned or quoted from copyrighted works for instance.[117] The Article 1.1 of TRIPS states:

"... Members may, but shall not be obligated to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement."[118]

The obvious need and demand toward a completely new intellectual property rules have not only awakened private companies to demand stronger intellectual property protection than before but also the advocates of public interests together with civil society groups to desire loosen the already existing intellectual property protection rules, stating that current protection standards can cause decreasing of innovation as well as creativity of people.[119]

To conclude, the need for international acquis, including its exceptions and freedoms, is essential because it could possibly better encourage the development of further developed and completely new access instruments. It could also possibly increase the contributions of expertise to the world's policy development altogether.[120] This is all what could be useful when increasing the access to pharmaceutical products also in developing countries.

Clearly, there are enormous amounts of different studies concluded on the topic of access to pharmaceutical products in developing countries as well as of medical research and development, all of them focusing on the "traditional patent systems" and international agreements and their lack of certain proponents. It is also clear by know, that all these suggested approaches might fall and fail due to the same mistakes that have been done multiple times before.

As Dinwoodie and Dreyfuss, also Günter Frankenberg has done research on the topic and thus suggests an approach that is beyond traditional suggestions. His suggestion to enhance the access issues is a 'global constitution' and so-called 'IKEA-theory'. His vision entails that

[117] Dinwoodie, G. B., & Dreyfuss, R. C. (2012), *supra nota* 111, p 198.
[118] 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) Article 1.1
[119] Birkbeck, C. D. *supra nota* 5, p 1.
[120] Dinwoodie, G. B., & Dreyfuss, R. C. (2012), *supra nota* 111, p 189.

constitutions could be viewed as commodities. The suggested 'IKEA -theory' could help with easing developing countries to meet the wished levels of protection for their intellectual property.

The 'IKEA -theory' would work alike to the concept of the Swedish IKEA's furniture when putting them together; one purchases pieces of a whole furniture, takes them home and then builds it together but within the theory, constitutional ideas and items would be transferred to 'global constitution' as legal transplants and from the 'global constitution' to host environment, which are countries that are part of the global constitution. Frankenberg analyses the concept of 'global constitution' and explained its functions including the circulation of standardized constitutional items as marketable goods among the participants of the local, regional and transnational disciplinary discourse.[121]

Frankenberg notes that because the constitutional language is similar among constitutions, and there exists similar themes and values such as peace and human rights, there would be room for the establishment of a global constitutional regime. He defines global constitution being created by "*the process of transfer and functions as a reservoir or a supermarket where standardized constitutional items are stored and available…*"[122] Because constitutions already share similar ideologies and themes, Frankenberg suggests that it would be beneficial for constitutions to borrow and share elements. Although seemingly new and out of the box idea for easing the access issues relating to pharmaceuticals in developing countries, the actual implementation and governance of this type of an approach is rather complex. How could different legal rules or rights be borrowed and moved to a one legal regime to another without problems and how could a legal rule from other country fit into another county's legal system? Traditions vary between countries and each country has their own way of legal thinking that has been followed through centuries.[123] Whether this approach and theory could be used in increasing the access to pharmaceutical products is still quite unsure and many questions are still unanswered such as why a country with its own existing legal rules would want to implement another country's legal transplant into their own, especially if there are differences among their legal systems and visions. Furthermore, what will happen if the borrowed legal transplant does not fit into its new environment?

One of the reasons why these types of legal transplants could be suitable for increasing the access to pharmaceutical products is that because international intellectual property law

[121] Frankenberg, G. (2010). Constitutional transfer: The IKEA theory revisited. *International Journal of Constitutional Law, 8*(3), p 563.
[122] *Ibid.,* p 565.
[123] *Ibid.,* p 568.

interests are quite unbalanced and shattered, common and unified model of legal transplants would in fact help. Combining different legal rules and mechanisms will result in better results than solely testing one mechanism over and over again without succeeding.[124] Jean-Frédéric Morin and Edwards Richard Gold discuss that when adapting legal transplants, four causal mechanisms happen which all support each other; coercion, contractualization, socialization and regulatory competition. Without going into detail, when one of these disappears during the 'transplant' process, the rest remain, supporting the legal transplantation.[125]

Although Frankenberg suggest a new type of an approach where global constitution is similar to the idea of more united framework which possibly could be used in intellectual property rights system, it is more complex than the one Dinwoodie and Dreyfuss suggest. One of the biggest issues relating to the concept of global constitution is that there are yet concrete steps to be taken and quite a small number of studies concluded. The whole idea of a global constitution might seem quite theorical missing the practical application. From another perspective, global constitution and legal transplants could indeed work because during centuries, norms and principles together with different constitutional ideologies have been reaching over from country to country in the world, sometimes taking various forms depending on the constitution. Global constitution could be a collection of common doctrines, principles, norms and ideologies for every country and there could be common institutions as well.[126] With this, united intellectual property rights framework could be based on and to be established.

3.3. Access to pharmaceutical products as an element of right to health

Slightly returning to the analysis of public health view earlier, viewing the TRIPS Agreement from the perspective of human rights also focuses on giving right to health a high value. Lack of access to pharmaceutical products can be viewed as a problematic issue of human rights since the right to health is set in the Constitution of WHO, and one of the core components of it is accessibility. That accessibility entails access for everyone to facilities, goods and services. Moreover, accessibility has a few dimensions that include for instance non-

[124] Morin, J. F., & Gold, E. R. (2014). An integrated model of legal transplantation: the diffusion of intellectual property law in developing countries. *International studies quarterly, 58*(4), p 785-791.

[125] *Ibid*., p 781.

[126] Frankenberg, G. (2013). Constitutions as commodities: notes on a theory of transfer. In *Order from Transfer*. Edward Elgar Publishing.

discrimination. It has also been stated, that although there might exist barriers to achieve accessibility, there must be measures addressing the barriers.[127]

Pointing out that although well examined topic, lack of access to pharmaceutical products still remains as critical problem in developing countries and especially its impacts on human rights and health of the people in those countries. Moreover, even if examined, the issue does not get better at all since pharmaceuticals, when accessed, are still being sold at high prices which only the wealthier can afford. One could think why not sell pharmaceuticals for cheaper price and thus get them to more countries and individuals but as ideal that sounds the implementation of that is not easy, nor possibly at this time.

Pharmaceutical companies tend to protect their products with patents and tend to lean on the side of a strict protection rights but while doing so, pharmaceutical companies are facing challenges. There are numerous ways that access to pharmaceutical products is tried to be made easier for all, for instance generic medicine that was discussed briefly, counterfeited products and patent cliffs where a patent expires and thus competition increases. This is strongly related to generic medicine companies that can get their 'foot in the door' through this. What needs examination is the role of pharmaceutical companies within international intellectual property system and how access issues can be solved while promoting and protection innovation and rights of patent holders. Examples could be drawn from India, where the production of generic medicine is very high, but the people of India are fairly poor.[128]

If the focus would be on human rights, access to medicines should be increased with pharmaceutical products that are targeted to be more efficient. It is debated whether currently new pharmaceutical products that are produced are just more expensive improvements when there are also the generic medicines of those same ones that are cheaper and more accessible to people in developing countries. The focus should be on producing new pharmaceutical products that are somehow more efficient and different to those that already exists. But should those new and efficient products be strictly protected as well? Not necessarily. Sometimes, too strict patent protection can also harm innovation, meaning that when the motives include profit-making, there might not be motives to produce pharmaceuticals that developing countries are in the need of, since the profits are not going to be as high.[129] This is where

[127] World Health Organization, Human rights and health, Key facts. Accessible: https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health
[128] Abbott, R. (2013). Balancing Access and Innovation in India's Shifting IP Regime, Remarks. *Whittier L. Rev., 35*, 341. p 343.
[129] Abbott, R. (2013), *supra nota* 128, p 348.

balancing innovation and the tries to increase access to pharmaceutical products need to happen.

One could think that the conflict happens between these two perspectives, private and public, but there is also a third aspect to take into account which falls somewhere in the middle of both of these views.[130] This third perspective aims at finding balance and utilizing the already existing intellectual property rules in more effective way to achieve lasting long-term outcomes that serve everyone. This view of how the alternation of current intellectual property rules should be done seeks also to increase the access to knowledge which is linked to the access to pharmaceutical patents.

For increasing the access to pharmaceutical patents, and medicine, there cannot be a ready solution but there is a need for exploring various ways to achieve this goal. There exist various types of agencies in different developing countries that are already seeking ways to utilize current intellectual property protection rules and changed them to work better so that better the position of their own local innovators and researchers in order to uphold their economic situation as well as to get support from the investments that are coming from more developed countries. Because TRIPS failed in the eyes of developing countries, it is important to seek alternative methods to repair developing countries' unsuccessful tries to better their access to intellectual property, especially to access pharmaceutical patents.

Overall, the starting point when aiming at solving problematic issues related to patents and their protection, the main problem often lays in the ground of it all. This can be seen in all the approaches and different views where the efforts of trying to change the system are quite good and effective but still somehow fail at achieving better results. One of the examples of this is that if studied closes, there are actually billions that have been spent to medical research and development and it has not resulted in production of new medicines targeted to those countries that need them most, nor have those medicines been accessible or affordable. The common mistake is that even though the aims and approaches are on point and effective, all these approaches tend to still fail because of their targets are not fully thought through. The targeted groups or countries should be those who are affected serious diseases and tuberculosis for instance. Those are the countries that need access to pharmaceutical products and those countries are the ones that must be able to purchase them affordably. From the global point of view, these countries which typically are developing countries such as African

[130] Birkbeck, C. D. *supra nota* 5, p 1.

countries, are affected by these diseases the most in total of over 10% of the whole world's diseases. Some advocates who support changing our patent system promote access to medicine as a human right due to the nature of medicines being lifesaving in certain cases. To view it as such, there is the conflict remaining between allowing the markets and global trade to proceed which results in higher prices of medicine due to monopoly rights and promoting access to medicines as human rights that should be respected and treated like fundamental human rights normally.[131]

3.4. Opposing arguments on the TRIPS Agreement

Now that different perspectives of the TRIPS Agreement have been examined, there is one perspective that is a bit different but as important to discuss. The TRIPS Agreement can be viewed to focus on the wrong aims. First of all, the Agreement allows for actions that try to maximize profits from selling the pharmaceutical at higher price than necessary. This action has arguably three main issues that are negatively seen in the TRIPS. First to mention it that since pharmaceutical are sold at high price, there are significant amount of consumer that do not buy them depending on multiple reasons. Whether it is developing country that does not have the purchasing powers or a single consumer that does not want to buy pharmaceuticals at those prices and looks for cheaper alternatives. This leads to the second negative aspect which is counterfeits. Counterfeited pharmaceutical products are taking up a significant percentage of the global market. In addition to the pharmaceutical products being counterfeited, the consequences that can arise from consumer using counterfeited products can be serious. Also, if product is counterfeited, it does harm to the original product as well when considering the reputations of a certain patented pharmaceutical product. Thirdly and lastly, marketing of medical products consumes a lot of money and otherwise undue marketing which could be more wisely used in medical research and development.[132] Because of these aspects that the TRIPS Agreement allows to happen, it being the only international Agreement that finances research and development relating to health, opponents of the Agreement are arguing that the system is broken and cannot be used further.

Secondly, there are opposing arguments about the TRIPS Agreement and arguments that relate to country governments that either by misinterpreting the Agreement or confusingly acting, promote the wrong types of incentives to innovation. Currently, there are incentives of tax breaks and extension rights to patents that are being used but there is little proof that these

[131] Dentico, N., & Ford, N. (2005), *supra nota* 52, p 96.
[132] *Ibid.,* p 97.

incentives actually result into what is wanted. Also, these incentives are provided in areas that are neglected or given little attention. Either way, even if there is more consideration towards developing countries and neglected diseases, there still exists a lack of international policy that could make changes to pharmaceutical innovation regime.[133]

Changing something such as these is not easy and something that is done overnight, but when changed, it will drastically make a positive shift to accessing pharmaceutical products. The change can be done within countries, but much powerful instruments are needed which international agreements and treaties could provide. As Nicolette Dentico and Nathan Ford stated: *"health R&D must be treated as an international problem that requires an international solution"*.[134] If accessing to pharmaceuticals is wished to be something that can be done anywhere, in developing countries or not, the change must be international, it is not enough if out of all countries only two make drastic changes since there are various types of patent laws in countries. Also, currently the international rules and principles that are guiding international intellectual property rights are in the need of change.

Quite a good, and relevant example of the power of international cooperation and possible international Agreement or Treaty is the spreading of SARS -virus and how fast it got stopped. Within six days of it appearing it was already sequenced and soon after couple of months there was already test for diagnostic purposes ready to be used.[135] To transfer technology and knowledge, these types of goals are possible. Global cooperation can be much more successful than private sector approach when it comes to achieving such results but without the political input and right resources this will not be possible.

As seen, the TRIPS Agreement could be viewed from different perspectives and each perspective gives its own interpretation of the Agreement, whether it being worded unsuitable or it being selective towards only certain aspects such as making profit. To view the TRIPS Agreement from the perspective of public health there is a clear conflict between choosing either strict patent protection and protecting incentives to innovate and lower patent protection to allowing more access to certain pharmaceutical products that are needed for protecting the public health as well as promoting public health in countries. Viewing the TRIPS Agreement from the perspective of human rights it is clear that access to pharmaceutical products is a core element of right to health which is a fundamental human right that should always be protected and given high value.

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[133] Dentico, N., & Ford, N. (2005), *supra nota* 52, p 97.
[134] *Ibid.,* p 97.
[135] *Ibid.,* p 97.

To make changes to something that has been operating for a long time such as the TRIPS Agreement, it is not a simple task to do, and it is not enough to only examine the perspectives and point out flaws but also to look outside of the box and suggest radical or bigger changes than ever before.

The upcoming chapter introduces and discusses suggested methods and approaches towards more effective patent protection but also introduces an idea of reforming the current patent system that is now ruling regional and global market of pharmaceutical products, such as medicines, and both accessibility and affordability. Each of these approaches are suggestions and thus are analyzed with critical mindset and not yet meant to be concrete steps to solve all the problematic issues that the TRIPS Agreement and lack of access to pharmaceutical products have caused.

4. FINDING THE MOST SUITABLE APPROACH TO INCREASE ACCESS TO PHARMACEUTICAL PRODUCTS

After discussing the access issues relating to pharmaceutical products and examining both Doha Declaration and the TRIPS Agreement and their various flaws affecting developing countries' capabilities to access the products, it is necessary to look at the issue a bit further away. The prior discussion on the topic has showed that although studied broadly, there is still room for further research for finding the most efficient approach to increase the access to pharmaceutical patents in developing countries.

The WHO has published a report called "*Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*"[136] which includes an analysis of various proposals for supporting medical research and development in developing countries. The report discusses the importance of keeping long-term research and development going so that developing countries could have enough products to reach their health needs. Moreover, few of the proposals suggest a treaty framework for accessing pharmaceutical products that result from the research and development process as well as for knowledge-sharing.[137] For instance, this type of a framework would be a global one only relating to research and development (and mostly related to neglected diseases but could work as an example for others as well). The global framework would not replace the current intellectual property system but to be more such as an instrument alongside.

Whatever the approach or proposal, they should be aiming at increasing access to pharmaceutical products in developing countries by for instance easing on the rather strict intellectual property rights so that they would remove current intellectual property barriers that are now stopping innovation relating to pharmaceuticals. This way a lot more could be done to further support better access to pharmaceutical products in developing countries through capacity building for instance.[138]

Discussing the most suitable approach to increase the access to pharmaceutical products, it is important to acknowledge the public-private partnership that exist. Public-private partnership (hence forth 'PPP') are being explained by the WHO as follows:

[136] World Health Organization. (2012). Research and development to meet health needs in developing countries: strengthening global financing and coordination: report of the consultative expert working group on research and development: financing and coordination.
[137] *Ibid*., p 53.
[138] Stevens, H., & Huys, I. (2017), *supra nota* 77.

"*effective way to capitalize on the relative strengths of the public and private sectors to address problems that neither could tackle adequately on its own, in particular in respect of diseases that particularly affect developing countries where research by the private sector is deemed insufficient*".[139]

Public-private partnership is great way of helping developing countries to meet the same levels of health as developed countries, since both sides public and private, can contribute something to it. For instance, private sector has access to pharmaceutical products and their candidates and public sector that can provide the funding.[140] Although seemingly effective way to tackle the access issues, there are some aspects of the partnership to pay attention to. Public and private sectors have different markets, missions and strategies which will have an effect on the actual practical application and are something to take into account even when discussing the topic.

The methods suggested in this chapter are the Medicine Patent Pool, Push- and Pull -mechanisms and Open Source -model. All of these are explained and explored in relation of whether they would be fit for increasing the access to pharmaceutical products better than any other approach that has been tested. This chapter only discusses and examines these alternatives leaving them as suggestions, not aiming to point out which of these would be the most suitable one for solving access issues overall.

The core issue here, a need for a long-term solution, is to find an approach that both finds balance between protecting intellectual property rights so that incentives for innovations remain and also promotes public interest and access to those pharmaceutical products that result from innovations.[141] There is, and always has been, diversion when it comes to intellectual property protection; strong protection from the perspective of knowledge-based industries and less strict protection from the perspective of more developing businesses and countries. Approaches and methods suggested prior all lack the same components of reliability, sustainability for their mechanisms that could offer needed funding for research and development in order to better the access problem and further develop and improve the whole patent system.[142] Despite the lack of these aspects, it is not necessary to forget the already initiated suggestions, but a new agreement or treaty could be built on top of these with modifying them to work more effectively, as with the suggested treaty framework.

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[139] World Health Organization, Public-private partnerships (PPPs). Accessible: https://www.who.int/intellectualproperty/topics/ppp/en/
[140] *Ibid.*
[141] Birkbeck, C. D. *supra nota* 5, p 4.
[142] Moon, S., Bermudez, J., & Hoen, E. T. (2012), *supra nota* 55, p 2.

Let's examine some approaches that could increase the access to pharmaceutical products in developing countries or if not increase the access, then provide a functioning base for further building of access to pharmaceuticals.

4.1. The Medicines Patent Pool

As discussed, compulsory licensees can prove to be troublesome for increasing the access for pharmaceutical products, but there are other alternatives to achieving the goal and one of them is patent pools. World Intellectual Property Organization (hence forth 'WIPO') describes patent pools as:

> "*an agreement between two or more patent owners to license one or more of their patents to one another or to third parties*."[143]

Patent pools would thus be a key to accessing medicines better than before by allowing third parties to obtain non-exclusive licenses in order to develop the products.[144]

Patent pools have received support from NGOs such as Doctors Without Borders as well as Knowledge Ecology International. Because it was strongly suggested that a need for new type of entity relying on voluntary agreements between third parties and the patent holder to exists, ultimately also UNITAID, an international organization and hosted partnership of WHO, helped establishing Medicines Patent Pool (hence forth 'MPP') in 2010.[145] UNITAID gives funding for innovations aiming at effectively and affordably preventing serious diseases in developing countries. UNITAID was establish in 2006 and it pursues to increase access to medicines by promoting funding and innovation.[146]

The MPP works in cooperation with governments, civil societies, pharmaceutical industry and community and patient groups and it aims at decreasing the pricing on medicine as well as promoting further development of new pharmaceutical products and combinations. It works thought voluntary licenses allowing an entry of generic manufacturers. By doing so, it will also award innovators for their efforts.[147] The MPP operations are divided into three; it works

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[143] World Intellectual Property Organization. (2014). Patent Pools and Antitrust – A Comparative Analysis. Accessible: https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf (March 2014)

[144] Burrone, E., Gotham, D., Gray, A., de Joncheere, K., Magrini, N., Martei, Y.M., … & Kieny, M. P. (2019). Patent pooling to increase access to essential medicines. *Bulletin of the World Health Organization, 97*(8), p 575.

[145] Cox, K. L. (2012). The medicines patent pool: promoting access and innovation for life-saving medicines through voluntary licenses. *Hastings Sci. & Tech. LJ, 4*, p 291.

[146] Unitaid, *About Us*. Accessible: https://unitaid.org/about-us/#en

[147] Medicine Patent Pool (2011) *Stimulating Innovation, Improving Access*. Accessible: https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_lic_ge_12/wipo_gc_lic_ge_12_ref_factsheet.pdf January 2011.

in so called 'home' country where its administrator is based, in country or countries where medicines are being manufactured and thirdly, in countries that import the medicine as well as buy it.[148] Although the MPP concerns specially HIV medicines, its tools could be possibly used also with overall issues that developing countries are facing with pharmaceutical patents. For instance, when older medicines are not as effective anymore because of people's resistance, there is a need for more developed medicine but developing countries cannot access those since newer pharmaceutical products are more expensive because of their patents. Furthermore, in 2015, the MPP made the decision to include not only HIV medicines, but also medicines for tuberculosis and hepatitis C to its order.[149] The MPP could also be the answer to a problem such as adapting medicines for certain groups of population. Because there is difference between groups that need certain medicines among developing and developed countries, there can be lack of economic incentive for pharmaceutical industries in developed countries to produce medicine that answers the need in developing countries. One example of this are children with HIV in developing countries compared to the unlikeliness of children getting HIV in more developed and wealthier countries.[150]

By 2018, the MPP had concluded agreements with nine different patent holders and had various other licensing agreement negotiations going with private pharmaceutical companies. These agreements have resulted in thirteen different treatments and one completely new technology platform for fighting HIV.[151] The MPP is thought to have potential to increasing developing countries' access to medicines once its aspects and tools have been examined properly. One positive aspect of patent pools in general is that they can form themselves to achieve the desired goals. Furthermore, in the United States, patent pools have been recognized to have multiple advantages such as preventing patent blocking, better managing multiple owners of patents and most importantly, they are seen as easing technology transfers and access capacity building in developing countries.[152]

The main reasons why the MPP was initially established for medical technologies was to lower prices, spark up innovation as well as assuring that new medicines would be easily available in developing countries. The MPP works by acquiring licenses, given voluntarily by the patent holders, and then licensing them non-exclusively to third parties who can then further the development of a medicine for developing country's use. The patent holders will

[148] Gold, E. R., Piper, T., Morin, J. F., Durell, L. K., Carbone, J., & Henry, E. (2007). Preliminary legal review of proposed medicines patent pool. *The Innovation Partnership*. p 42.
[149] Medicine Patent Pool (2015) Five years of patent pooling for public health. *Annual Report 2015*
[150] Medicine Patent Pool (2011) *supra nota* 147.
[151] Medicine Patent Pool (2018) Expanding Access to Public Health. *2018 Annual Report*.
[152] Cox, K. L. (2012), *supra nota* 145, p 295.

get the royalties that stem from the generic versions.[153] Further, one of the advantages of the MPP is its ability of expediting the availability of less expensive and developed medicines in developing countries with the help of larger markets that promotes many producers in the market and compete which lowers prices.[154]

Although, the MPP suggests that the current parent system needs a reform, it does not fully need it to be changed. The patent holders would have their existing rights to collect monopoly prices, but only in developed countries where the income is higher.[155]

Those against the idea of patent pools overall in pharmaceutical industry state that if companies take part in a patent pools, it will impair and weaken their exclusivity. However, there are many different industries and to use patent pools in pharmaceutical industry could be different compared to other industries. For instance, pharmaceutical companies are 'valued' by their intellectual property, and it is unlikely that dominant entities would join the pool since they would not have a strong incentive.[156] Further, it is rather complicated to evaluate the MPP since it bases its functions on voluntariness; everyone taking part has freely decided to be in it. But, even with the voluntary nature, the MPP could be criticized not being able to achieve effective licensees with its current negotiation process where now it could be described being 'all or nothing'.[157]

Currently, because of the negotiations that must take place when the MPP sorts out the license agreement with the patent holder, the combination of voluntariness and the license agreement negotiations can cause various different licenses and outcomes. It has been suggested that there should be set a standard form of license. This is mostly because there can be no conflict with competition law which could be the case if the scope of the MPP expands in the future and if then there are various forms of license agreement with patent holders. Further, if the operation of the pool is not transparent, there might be it could fall in conflict with competition law also.[158] To avoid this, there should not be individual negotiations on licenses with patent holders, rather there should be a non-exclusive license which entails inter alia every country within the scope of the MPP, all of export, import and sales of the pharmaceutical products, standard royalties and manufacturing. Moreover, it has been suggested also that the MPP should set up a standard for patent holders to license every

[153] Cox, K. L. (2012), *supra nota* 145, p 297.
[154] Medicine Patent Pool (2011), *supra nota* 147.
[155] Quigley, F. (2015). Making Medicines Accessible: Alternatives to the Flawed Patent System. *Health and Human Rights Journal.* p 6.
[156] Srinivas, K. R. (2006), *supra nota* 89, p 6.
[157] Cox, K. L. (2012), *supra nota* 145, p 315.
[158] Gold, E. R., Piper, T., Morin, J. F., Durell, L. K., Carbone, J., & Henry, E. (2007), *supra nota* 148, p 52.

relevant patent not only part of them because it might cause unbalances between patents when some of them are seen more important than others.[159]

To conclude, the many good and effective features of the Medicine Patent Pool, such as focusing on decreasing the price on expensive medicine, its nature of being based on voluntariness, especially focusing on developing countries and providing benefits for all involved in the pool, might provide the needed tools to increase the access to medicine in developing countries. But if its disadvantages are seen too problematic or invincible, there are also other approaches to increase the access to pharmaceutical products in developing countries, that will be discussed in the upcoming chapter.

4.2. Orphan medicines

Within the European Union, there are estimated 30 million people that have a rare or uncommon disease[160] and that need special medicines for it. These medicines which purpose is to treat those diseases are called 'orphan medicines.' Although, what constitutes a rare or uncommon disease may vary depending on jurisdictions, within European Union for instance, the definition of rare or uncommon disease is that a disease that affects less than 5 persons in 10000 is a rare disease.[161]

The problematic aspect of medicines for rare diseases is that the development of necessary medicines does not have the same amounts of developers and producers compared to those that are dealing with for instance cancer medicine. One reason for this is that there are not enough incentives and motivation to develop medicines for rare diseases because the demand is quite low since there are less people in the World that have the rare disease. In some cases, due to the lack of interest of pharmaceutical companies, there does not exist a right medicine for the rare disease at all.[162]

From my perspective, since incentives play a significant role in further development and invention of pharmaceutical products, medicines, they should be paid more attention to. Further development of incentives could increase the amount of medicine produced and thus also increase the access to pharmaceutical products through various approaches. Here, member countries could have the possibility to motivate further development of the medicines

[159] Gold, E. R., Piper, T., Morin, J. F., Durell, L. K., Carbone, J., & Henry, E. (2007), *supra nota* 148, p 52.
[160] European Medicines Agency, Orphan designation: Overview. Accessible: https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation-overview
[161] European Commission, *Collaboration: A key to unlock the challenges of rare diseases research*. Factsheet. February 2020.
[162] Rinaldi, A. (2005). Adopting an orphan: Incentives to develop drugs for rare disorders raise hopes and controversy. *EMBO reports, 6*(6), p 507.

needed if they would provide incentives that are better than before. There could be funding from the governments to conduct more research and development and in fact, there are set of incentives that are provided for orphan medicine development. These incentives are provided by the EU in the Orphan Medicinal Products Regulation of 2000[163], and include inter alia protocol assistance, market exclusivity as well as administrative and procedural assistance for micro, small or medium sized companies.[164]It has been stated that without these incentives, it would be unlikely that there would be enough returns when compared to the investments.[165]

Examining all of this from the perspective of public health, it seems that the motives behind developing medicines for rare or uncommon diseases are not taking into account public health aspects. Because there are special incentives, it shows both that it is difficult to motivate researchers to get involved in orphan medicine and that the motives are not concentrating on public health aspects that much since the fact is that these rare or uncommon diseases that are lacking proper medicines, are not commonly happening and thus there is not as big of a need for the medicines as when compared to for instance HIV or AIDS in developing countries.

The reason why the topic of rare or uncommon diseases is relevant here in this thesis is that although not commonly met, these diseases affect a large amount of people in developing countries, where also some of the people from wealthier countries are living.[166] In addition, although now seen as rare and uncommon, these diseases might become common in the future and affect even more people in the world.

What thoughts arise for me is that if more and more medicines have been granted the EU orphan designation and more and more have also been accessing the market[167], is this partly be because of the incentives that are provided for the development of orphan medicines? If similar kind of incentives, or other way enhanced incentives, would be provided for also "regular" pharmaceutical products, could it increase the number of medicines reaching developing countries as well, so that access to those products would increase as well?

[163] Regulation (EC) No 141/2000 (The Orphan Regulation)
[164] European Medicines Agency, Human regulatory, Orphan incentives. Accessible: https://www.ema.europa.eu/en/human-regulatory/research-development/orphan-designation/orphan-incentives
[165] Llinares, J. (2011). Orphan designation key concepts and evaluation criteria. European Medicines Agency, p 12.
[166] Rinaldi, A. (2005), *supra nota* 162, p 507-510.
[167] *Ibid.,* p 507-510.

4.3. Open-Source model

As discussed earlier in the beginning of this fourth chapter, there is the report on Research and Development to Meet Health Needs in Developing Countries gathered by WHO. One of the discussed proposals in the report suggests open approaches to research and development, similar to an Open-Source model which could increase access to pharmaceutical products in developing countries.

Open-Source model for developing countries has been suggested as well due to its nature which could help these countries with innovation of pharmaceutical products and other medicine and cures for the most serious diseases these countries face. The Open-Source model would not have the same pitfalls that others have, and it would work as an opposite for a 'bunker mentality' which enables blocking of diffusion and further innovation. Because inventing new (and still producing older) medicines is vital for fighting the diseases in developing countries, it is important to share the knowledge. And it is for the best if sharing is also done wider. This is one of the reasons behind the Open-Source model which would not offer exclusive rights such as typical patent system does. In addition, one of the important aspects why this model has gotten support, is that availability reaches all. This 'Open-Source Pharma' has also received support of being completely new and competing model for the innovation of medicine.[168]

Under the Open-Source model, the commons are freely usable for all but should not be used with intellectual property rights to enclose it. This can be prevented with special licenses that could be formed in a way that enclosing of the commons can be prevented, including licenses that for instance that entail restrictions and limitations. Consequently, also the rights and obligations for entities would be included in these licenses. For instance, Srinivas suggests that licenses should mention that after changing something in the software, the changed version should be available for all as soon as possible, similar to a copy left principle. What Srinivas also pointed out in his article, was that there most likely exists a need for different kind of licenses, depending on the use of the commons. Moreover, there will most likely exist debate over the openness of the licenses of the Open-Source model because of the nature of the model where aims and reasons of developers vary.[169]

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[168] Balasegaram, M., Kolb. P., McKew, J., Menon, J., Olliaro, P., Sablinski, T., … & Wilbanks, J. (2017). An open source pharma roadmap. *PLoS medicine, 14*(4).
[169] Srinivas, K. R. (2006), *supra nota* 89, p 9.

The Open-Source method could be criticized for lacking enough motives and reasons why entities would want to participate in it, especially when there is not ownership right, but despite this, a 'gift economies' as suggested by professor Krishna Srinivas, are possible.[170] This shows how Open-Source models would be possible and that there is other incentives and motives for combining knowledge and skills to achieve further developed medicines and increase the access to pharmaceuticals as well. Furthermore, the suggested Open-Source model would provide more freedom for the developers than other models and it would also increase further development of products more effectively because of the shared knowledge. Especially, since there is lack of access to pharmaceutical products in developing countries, this model could provide the answer to it, since in pharmaceutical industry it is proven that cooperation and sharing knowledge can be and should be done in every stage of the process of developing or manufacturing a product.[171]

Other critique that the model could receive what I want to point out include the 'founding' fact that with pharmaceutical products patents are filed quite soon after the discovery. This is in contrary to the sole idea of the Open-Source model where patenting products at early stages is not preferred.

Whether, in concrete, developing countries could take advantage of the Open-Source model is unknown. To take the model into use, would need the support of the governments, schools as well as private sector in cooperation. There is still uncertainty about the capacities and capabilities of developing countries which, if not fully at its potential, could be the reason for this model to not succeed. Of course, developing countries could only use parts of the Open-Source, namely accessing the database or sharing their findings.

To add an extra option, among various pricing models, although not discussed in this thesis, is a tiered pricing model which is voluntary and specifically suggested to developing countries. This model is based on the concept of medicine sold with lower pricing compared to more developed countries, thus aiming at increasing access to medicines. This approach has received support from not only policymakers but also from pharmaceutical industries as well as from civil society. Selling medicines with lower price in developing countries increases not only the access to them but also supports the best possible profit plan because of the

[170] Srinivas, K. R. (2006), *supra nota* 89, p 8.
[171] *Ibid.,* p 10-14.

willingness of the consumer to buy the medicine of lower price. This is one of the reasons why tiered pricing model has been called a 'win-win' approach.[172]

Despite the positive 'win-win' situation of the tiered pricing model, it has also received critique. The model has been seen as deficient for its certain characteristics. Firstly, it is not as transparent when setting the prices nor can it fully take part in competition due to its nature. And secondly, there are differences between countries.[173] Thirdly, there is a lack of internationally set norm of price tiers that could be established. Further, nor is there any set norms for paying the costs of research and development in developing countries. And lastly, one of the main issues with this model, there is not enough decision-making power given to governments that are in charge with the guaranteeing of access to medicine.[174]

The most affordable and fair price for medicine is described to be a price that is able to both maintain research and development as well as can be funded by patients. It is also able to maintain production and allocating in a country.[175]

[172] Moon, S., Jambert, E., Childs, M., & von Schoen-Angerer, T. (2011). A win-win solution?: A critical analysis of the tiered pricing to improve access to medicines in developing countries. *Globalization and Health, 7*(1). p 1-2.
[173] Balasegaram, M. (2014). Is tiered pricing the way for vaccines? *The Lancet*, 384(9946), 852.
[174] Moon, S., Jambert, E., Childs, M., & von Schoen-Angerer, T. (2011), *supra nota* 172, p 9.
[175] World Health Organization. Essential medicines and health products. *Medicines Pricing and Financing*. Accessible: https://www.who.int/medicines/areas/access/en/

5. TRANSFORMING THE GLOBAL MEDICINE REGIME? A PROPOSAL FOR MEDICAL RESEARCH AND DEVELOPMENT TREATY

5.1. From uncertainty to reforming the global medicine regime

There is not enough access to pharmaceutical products in developing countries, as discussed earlier in this thesis but what is also lacking is research and development in the field of medicine, particularly newer medicine. The current research and development concluded does not cover enough of those countries who are affected the most by different diseases and those that do not have the necessary purchasing power to have access to patented medicines. Because pharmaceutical industry is a competitive one, the fact that those countries, namely developing countries, face specific diseases to which specific patented medicine are needed, cannot buy licensees to access patents, results to a small market for developed countries to produce these medicines. This results to situation in more developed countries where there are not enough incentives for innovation nor is there enough incentives to research and development of medicine.[176]

Furthermore, there are various alternatives to better enhance further development of medicine, such as in 2005 proposed Medical Research and Development Treaty (hence forth "the MRDT" or "the Treaty").[177] The MRDT aims at preserving balance between affordable medicines and medical treatments and promoting and offering incentives for innovation. It has been proposed that there would be a new set of obligations as well as flexibilities for those who need help on financially supporting research and development in their countries. What makes the proposed Treaty different from other prior suggested and tried methods, is the background of it. The proposal for the MRDT was put together by group of government experts together with other non-governmental ones. Later, in May 2005 the proposal was discussed during Consumers International briefing in Geneva. One of the founders of the Treaty, James Love, has described it to be "*... an attempt to look at this issue from the public health point of view instead of the commercial point of view*."[178] The commercial perspective stems from pharmaceutical industry which has a small market in more developed and wealthier countries than compared to the countries where the diseases are common but are developing and poorer countries. This way there is no commercial interest in producing or

[176] Moon, S., Bermudez, J., & Hoen, E. T. (2012), *supra nota* 55, p 1.
[177] Birkbeck, C. D. *supra nota* 5, p 4.
[178] New, W., (2005) *Medical R&D Treaty Debated At World Health Assembly*. Intellectual Property Watch. 30 May 2005.

patenting medicine for these diseases because developing countries cannot access them financially. From the public health perspective, this view is doing nothing good at better access to pharmaceutical products in developing countries. Furthermore, Ellen t'Hoen has also addressed the same issue, stating that even though there has been change for the better among medical research, there yet remains problems affecting developing countries that are not far as wealthy as developed countries.[179] The MRDT has also gotten support from Nicoletta Dentico and Nathan Ford, who discussed it stating that the Treaty could be successfully enforced and successful overall, because it could have the capability to conclude new political commitments and form new partnerships that would help with health innovations to become global public goods that are rewarded. Also, what they suggest is that not only should the reward for medical innovation be dependent on the social value but also it should be proportional to it. Furthermore, they support the idea of prices not increasing much, rather staying close to the costs of production.[180]

As mentioned, the proposal was proposed in 2005 and still remains as proposal, but few years back in 2012 it got support from WHO Consultative Expert Working Group that focuses on financing and coordinating. They strongly supported the idea that global medical research and development convention would be establish in order to countries better take part in the discussion and further terminate on the topic. International and binding Convention on this topic was firstly discussed already in 2004, couple years after the initial proposal for MRDT. The suggestion of international Convention on the matter was done because it could be done and executed under WHO which is an international body. This way, there would be more certainty and reliable norms than just a signed by countries that are in the Treaty.[181] One example of this is the Framework Convention on Tobacco Control from 2005 which is the first Treaty that is negotiated within WHO and relates to public health.

5.2. What makes the MRDT better than the rest?

In my opinion, creating and establishing a new Treaty seems something that first of all takes time and effort but also something that is needed to adjust many times before it is efficient enough for its purpose. In addition, new set of obligations as well as the planned "flexibilities" for those who need help on financially supporting research and development,

[179] New, W. (2005) *supra nota* 178.
[180] Dentico, N., & Ford, N. (2005), *supra nota* 52, p 96-97.
[181] Moon, S., Bermudez, J., & Hoen, E. T. (2012), *supra nota* 55, p 4.

seems a complex task which already partly failed with the TRIPS Agreement as discussed. Although, I believe that since there are governmental as well as non-governmental experts involved, its contents could be well-thought and thoroughly examined, taking various perspectives into account.

What makes the proposed MRDT special is that it promotes cooperation between developing countries to create their own and shared networks of technologies, not only supporting them to establish partnerships with wealthier countries. These partnerships can result in funding for research as well as different contributions that can better their global position. Consequently, when public partnerships have been established the know-how relating to medical development is not available only to private entities anymore. Currently, a significant portion of important know-how is hidden within the private sector.[182]

The MRDT has been compared partly to the Kyoto Protocol that was adopted in December 1997 and extended to 2020 by Doha Amendment (The Kyoto Climate Treaty), on its rewarding policy where across borders happening trading of rewarded credits could be possible.[183] The Treaty would be operating through the credit system where participant countries (which would be every country in this case, since the discussed topic is on global public good) are obligated to take part in medical research by giving a set percentage of the gross domestic product (GDP).[184]

5.3. The efficiency of the MRDT

For the goal of the Treaty being transforming the global medicine regime more affordable but not with the expense of innovation, and for the motive to propose such Treaty being for public health instead of commercial, are both showing that there is a will to change the current landscape of pharmaceutical patents and development for the better.

Considering this from my perspective, I wonder if pharmaceutical industry would be motivated by different factors than solely commercially, would the situation in developing countries be different. If research and development would be supported more via financing, the aim would change from gaining patents and strict protection, to more open and public health needs centered systems. If more support would come from governments globally, the

[182] Dentico, N., & Ford, N. (2005), *supra nota* 52, p 98.
[183] Consumer Project on Technology (now: Knowledge Ecology International) Proposal for Treaty on Medical Research and Development (February 2005) Accessible: http://www.cptech.org/workingdrafts/rndtreaty.html
[184] DiMasi, J. A., & Garbowski, H. G. (2007) Should the patent system for new medicines be abolished? *Clinical Pharmacology & Therapeutics, 82*(5). p 489.

focus would be more on public health aspects and thus help to ease the current issues with strict patent protection and developing countries.

Knowledge about medicines and everything medical related could a public good for its nature. It has been stated by Suerie Moon et al. that knowledge that is a public good is both 'non-rival' and 'non-excludable' because medical knowledge can benefit the whole world, despite it being product of one country and for other countries to use it, does not decrease the amount of knowledge in the other country.[185]

Critique could arise towards this type of proposals, especially concerning how to uphold competition and innovation, if patent protection would be loosened. To provide incentives to innovation, there would be rewarding system together with investments to certain research projects that are being viewed from the public health perspective to have social importance. Although seen a better option than, for instance, compulsory licensing or certain parts of the TRIPS Agreement, the MRDT has still received critique concerning mentioned credit system due to challenging implementation already from the beginning when it was proposed. If the described credit system would be taken into use, wealthier and more developed countries would still have leverage compared to smaller and less developed ones in so far that the MRDT would actually do nothing to help accessing problems nor to improve public health interest aspect. This is due to wealthier countries capabilities to trade more credits and less developed countries to, in the unsuccessful events, pay the failed or weak research and development costs. Consequently, this would only make developing countries to fall back even more on patents and their access to them.[186]

Other critiques that have arisen, have been arguing that no matter which approach the MRDT would lay its ground on, it would still be very costly when it comes to funding the medical research. Furthermore, the proposal has negative effects also when looked at from economical perspective. From that, the 'delay' of rewards will affect negatively research and development costs of the innovator because also the value of the product as well. For instance, novel and new products that have a high value in the beginning of the process when the risk is at its highest would be extremely affective by the reward system that is government funded. This is simply due to admirative side of governments which differs from the motives of researchers. Since the MRDT aims at affordable and accessible medicines to be a global public good, it takes a lot of consideration when it comes to decision-making. What governments need to decide is inter alia group of diseases that are categorized as the most important ones as well as

[185] Moon, S., Bermudez, J., & Hoen, E. T. (2012), *supra nota* 55, p 2.
[186] DiMasi, J. A., & Garbowski, H. G. (2007), *supra nota* 184, p 489.

the designated enforcement bodies or organizations who take the lead. Self-evidently, organizing and selecting takes time and effort which consequently lowers the value of innovations.[187]

The need for the proposed Treaty, or such a similar one, has been reasoned with some of the lacking aspects of the current existing rules. Suerie Moon et al. have discussed, and supported, the need for a global governance in order to establish medical research and development as a public good for all, emphasizing the need for both political and financial aspects to taken into account. What they discuss are the main four components that are lacking currently: affordability of medicines, finance that is sustainable, efficient innovation process and the focus towards public interest perspective.[188]

The proposal being a Treaty means that it would be binding to every signatory and if the Treaty concerns medical research and development, it is likely that no country would want to not become a signatory to it. If most of the countries would sign on it, there would exist a risk that the ones that did not agreed on it would fall behind on new medical products and their development. But, on the contrary, the proposal of the MRDT has also gotten critique that it is unlikely that countries would be willing to become parties to the Treaty, especially when it obligates them to give out certain amount of their GDP every year to medical research and development purposes.[189]

Also, what causes challenges with the possibility of establishing the MRDT is that TRIPS Agreement still exist. The relation that these two would have might cause conflicting issues. What happens to countries whose governments that are signatories to TRIPS Agreement when they might take part in the MRDT and give their contributions as obligated to? Would it be possible to comply with TRIPS Agreement but also take part and possibly act in contrary to TRIPS when obligations from the MRDT would come upon the countries? Already, countries contribute to research and development of pharmaceuticals so what would happen to their resources when portion of it would go into funding and rewarding innovations that have a high value to public health? Also, problematic issues could arise relating to the administrative parties and enforcement of the Treaty and Agreement simultaneously. Furthermore, it is important to take into consideration the possibility of free riding, which must be somehow managed so that it would not happen. In addition, consideration should also be put to the

[187] DiMasi, J. A., & Garbowski, H. G. (2007), *supra nota* 184, p 489.
[188] Moon, S., Bermudez, J., & Hoen, E. T. (2012), *supra nota* 55, p 2.
[189] DiMasi, J. A., & Garbowski, H. G. (2007) *supra nota* 184, p 489.

management of countries compliance to the Treaty. One suggestion to this concern is that there should be transparency requirement as well as reporting obligation.[190]

Questions arise when thinking about sharing of the knowledge relating to medicines and medical research and development. For me, one question is, if one country benefits from the results of other country, how should the payment go? This is important because investments that go into the research and development process can be quite big and that is why if not regulated properly can cause conflicts and imbalance between those countries part of the circulation of medical knowledge.

Moreover, I empathize that the discussed need of change towards more balanced, thoughtful and effective global patent system together with the MRDT, cannot be achieved with governance alike today's, rather there is crucial need for a global governance to push medical research and development together with medical knowledge to be a public good that is accessible and affordable to all. Furthermore, the benefits of that public good should reach everyone and every country as well. What is worth mentioning as well is that, despite there is a need for 'Treaty level' legislation, it does not mean that there should not be other alternative approaches when trying to find solutions for increasing the access to pharmaceutical products in developing countries and pushing current patent system towards more coherent one globally. There should be ongoing examination of different methods also to seek the right approach to balance the access to pharmaceutical products and provide enough incentives to innovation.

[190] Moon, S., Bermudez, J., & Hoen, E. T. (2012), *supra nota* 55, p 3.

CONCLUDING REMARKS

Already from the beginning of the discussion of intellectual property rights protection, developing countries have brought up their concerns about pharmaceutical patents being too expensive and inaccessible for them. Patented pharmaceutical products are far beyond the reach of developing countries because of the high prices and low buying power of developing countries. The TRIPS Agreement was thought to be the solution for the access issues, but it resulted to even more complex issues than before, such as unclear wording of its Articles and various interpretations among member countries. Due to these reasons, international intellectual property system has been fragmented and unbalanced. There is a need to solve how to balance research and development and access to pharmaceutical products in a way that neither of these will be impaired. Without research and development, there cannot be new, nor improved pharmaceutical products and without access to pharmaceuticals, developing countries will be in trouble and large number of the world's population will be without medicines. What is also important is that pharmaceutical products are being protected and patent holders have their rights to them, but also to the extent that does not impair the improvements of increasing the access to those products.

One of the most known and possibly so far effective approaches is compulsory licensing. Compulsory licensing exists in the Article 31 of the TRIPS Agreement and in brief, it is a way to use patented products without the consent of the right holder; governments can thus give permission to either do the patented product, use it or do the process that has been patented with a license. This type of license is a compulsory license.[191] Compulsory licensing can be issued on certain grounds. These grounds are set in Article 31c of the TRIPS Agreement. In order to governments to issue compulsory licenses, there must be an emergency or extreme urgency, the use is for the remedy anti-competitive practices or for public non-commercial use and when the case concerns dependent patents.

Compulsory licenses, that were thought to be the answer for the lack of access to pharmaceutical products, have more disadvantages than advantages when considered from the perspective of less developed countries. Compulsory licensing is viewed to negatively affect accessing pharmaceutical products in developing countries because of the fact that those licenses work in higher income countries because of the purchasing power of its citizens. The usage of compulsory licenses was thought to enable developing countries to have better access to patented pharmaceutical products but in fact, they caused more conflicting benefits

[191] Abbas, M. Z. (2013), *supra nota* 64, p 254.

between developing countries and companies that create these pharmaceuticals than before. Pharmaceutical companies protect their products with strong patent rights and aim at getting the profit out from them while developing countries need these same products but for lower price which is not possible without lowering the patent protection. It can be viewed that compulsory licensing only works in wealthier countries because in these countries citizens can afford purchasing pharmaceutical products that are more expensive because of the strong patent rights.

To gain a broader perspective of the issues relating to pharmaceuticals patents and access issues especially in developing countries, it is needed to view the TRIPS Agreement. Viewing the TRIPS Agreement gives deeper understanding of the fragmentation and other issues that concern developing countries and their access issues. Furthermore, the TRIPS Agreement can be examined better when there are a few different perspectives. This thesis has analyzed three possible visions of the TRIPS Agreement. Firstly discussed was the perspective of public health together with generic medicines. As a base, Doha Declaration states that no one should prevent any of the member countries from protecting public health which is backed up by its another statement concerning the interpretation of the TRIPS Agreement that should be done in accordance with a manner supportive of protection of public health and promoting access to pharmaceutical products. The discussion evolves around how to take public health aspects into account better than before and the patent protection of pharmaceutical patents that are considered closely related to public health. As known, generic medicines have transformed the atmosphere among pharmaceuticals while being more affordable and accessible, thus promoting public health. The TRIPS Agreement is seen to undermine public health interests if examined from the perspective of public health and it is needed to revise the Agreement emphasizing public health aspects as well as focusing more on accessibility of pharmaceuticals in developing countries.

Secondly, one of the discussed views on the TRIPS Agreement is quite different, suggesting a bit of a change to the international intellectual property regime. Dinwoodie and Dreyfuss suggest there to be an application of international acquis to unify and clarify aspects of the TRIPS and its consequences. This vision is discussed since there exists fragmentation among countries which needs to be taken care of before trying to solve access issues to pharmaceutical products. With this suggestion, there would exist a common ground for the intellectual property system where would not be any unclear articles causing fragmentation nor would there be various interpretations. By doing so, the international framework would lose some of its power, but member country governments would get a bit more thus be able to

modify their own intellectual property laws more into their likings. Considering from the accessibility perspective, international acquis could be helpful; fragmentation and various interpretations are one of the core problems which needs fixing. One suggestion relating to the same topic, is legal transplants and global constitution introduced by Frankenberg in the same chapter. His suggests that since there are common themes and principles already among countries, no matter the jurisdiction, a global constitution should be established where mechanisms and legal rules would be changed across nations.

Thirdly, access to pharmaceuticals, especially in developing countries, should be treated as a human right, as it is an element of right to health. The TRIPS Agreement does not promote this. The incentives for innovation are not based on respecting human rights but on monetary rewards and rights for the patent holder. The motives behind research and development, and thus innovation should be based on protecting public health and promoting right to health. Mainly here, the problematic issue is to find a balance between these.

Despite the TRIPS Agreement being overall a great and successful Agreement, it has failed when considering the point of view of developing countries. Lack of access to pharmaceuticals still remain, as do the fragmentation among countries. Furthermore, it is not enough to view the Agreement from different perspectives but also consider the concrete approaches to take in order to increase the access to pharmaceuticals because although methods such as compulsory licenses and many more, developing countries still face difficulties obtaining pharmaceutical patents nor have their access to them increased.

This thesis discussed three main methods and approaches to increase access to pharmaceuticals in developing countries: The Medicine Patent Pool, Orphan medicines and Open-Source model. All of these three had its own “theme”. While the Medicine Patent Pool promotes shared knowledge, the Orphan medicines focus on incentives. Open-Source emphasizes that vital knowledge belongs to all.

Firstly, with Medicine Patent Pool, the idea behind it was to allow third parties to obtain non-exclusive licenses in order to develop medical products by acquiring licenses, given voluntarily by the patent holders, and then licensing them non-exclusively to third parties who can then further the development of a medicine for developing country’s use. Also, the main reasons why this type of patent pool was initially established for medical technologies was to lower prices, spark up innovation as well as assuring that new medicines would be easily available in developing countries. Part of the critique the Medicine Patent Pool has received include the concern of pharmaceutical industry that companies taking part in a patent pools,

might impair and weaken their exclusivity. In addition, the operation of these patent pools needs to be transparent, otherwise there will be conflicts with competition law. Opposing side does not support the idea of the pools having individual negotiations on licenses with the patent holders.

Secondly, with orphan medicines, the theme evolves around incentives. Since there are over 30 million people with a rare or uncommon disease in the world without proper medicines for its cure, there is a need for developing new medicines for these diseases. Especially, if these diseases will spread. As known, incentives play a significant role in developing new pharmaceutical products, and because of that there are set of incentives that are provided by the EU Orphan Medical Products Regulation. If specific kind of incentives would be taken into use when dealing with access problem of pharmaceutical products in developing countries, it could provide a new way of increasing the access or develop new but affordable medicines for developing countries' use. Downside of orphan medicines and the incentives relating to them is that with the problem of not accessing pharmaceuticals in developing countries, it is not mainly about the development of new medicines as with orphan medicines but with developing ways to simultaneously protect patent rights and lowering prices of pharmaceuticals.

Thirdly, as discussed, the model of Open-Source, where commons are freely usable for all and are prohibited to be used with intellectual property rights to enclose them. The Open-Source model would not offer exclusive rights such as typical patent system does which is seen to be one of its positive aspects. In addition, one of the important aspects of why the Open-Source model has gotten support, is that availability reaches all and the ideology that vital knowledge belongs to all. Open-Source model would provide more freedom for the developers than other models and it would also increase further development of products more effectively because of the shared knowledge. Despite all the positive aspects, this model has gotten critique due to its lack of incentives to innovation. If the model is open and accessible for all, what could motivate innovators to develop new medicine and researchers to research further if they will not have any protection or rewards as they are enjoying currently. Although, here as well, the core problem lays with taking into account global public health interests but simultaneously promoting innovation and competitive markets.

As asked in the beginning of this thesis, whether compulsory licensing is helping developing countries to have better access to pharmaceutical products or not, opinions vary. In my opinion, the initial reaction was that compulsory licensing will rescue the situation with developing countries but as time went on and the practical application started, negative effects

about them arose. Even so, I believe, that compulsory licensing should not be forgotten, just altered a bit. Would then one of the discussed methods be a more suitable solution? Probably. I believe that either just Medicine Patent Pool could have a significant role on increasing the access to pharmaceuticals in developing countries, or if not just Medicine Patent Pool, then a mixture of pools and the ideology about the incentives of Orphan medicine. The fact that Medicine Patent Pool would allowing third parties to obtain non-exclusive licenses in order to develop the products is a significant aspect. Combining shared knowledge and licensing, in my opinion is a great direction towards accessible pharmaceuticals.

But before transforming the whole medicine regime, I believe it is more important to revise how the TRIPS Agreement is viewed and once again examine the visions that might arise when analyzing the Agreement again. So, to answer the last question of this thesis of whether the TRIPS Agreement should be interpreted differently to better understand the issues relating to it and the consequences of it, my answer is yes. Being a strong supporter of public health aspects and right to health, I believe it is needed to interpret and view the TRIPS Agreement again with more focus on public health aspects as well as to pay attention to the wide fragmentation within the intellectual property rights regime.

Many different approaches have been established to better the position and access of developing countries to the pharmaceutical markets but because it is necessary to uphold innovation and patent protection, lowering or loosening of patents cannot be achieved easily. The last part of this thesis discusses whether a transforming the global medicine regime is needed in order to finally solve the access issues. One of the analyzed suggestions is the Medical Research and Development Treaty proposal from 2002 that offers a new perspective of public health, instead of considering the problems from commercial perspective, to solve access problems as well as to try to make medicines more affordable globally in order to less developed countries to participate in the market. The proposed treaty aims at achieving these through focusing more on research and development and funding it differently. The main aspects that the Medical Research and Development Treaty proposal includes consist of six different set of concepts. To the Treaty to work as wished it focuses on creating a global, health-need driven research and development agenda that prioritizes mainly neglected diseases since those are the ones that affect developing countries the most and are taking up to 10% of the global diseases in total. Moreover, the Treaty proposal would order a new type of funding mechanism that will more focus on health research and development through help from each and every country that is part of it. The countries and their government would have to comply enabling also the developing and poor countries to have access to affordable

medicine and other medical innovations as well as for the tools and results that stem from the concluded research. That is who also the developing and poor countries can have a change to do follow-on research and innovation. Lastly, the Treaty would assure that the openness and transfer of technologies and knowledge would be strengthened globally in order to help the developing countries even more.[192]

It has been stated that, although already HIV and AIDS medicines and their development has been successfully reaching also developing countries, the need for further research is still present. Aiming at globally more affordable medicines, the Treaty takes also into account that incentives to innovation will not suffer, meaning that while aiming at more affordable medicines, it will not be done in the expense of innovation such as other alternatives might have done.

After analyzing all the above, few thoughts remain unsolved for me. One could wonder why the common goal should not be easing developing countries together to achieve the wished, at least a minimum, access to pharmaceutical patents, at least to certain and most valuable ones. Because there once was the common decision of granting compulsory licenses and additional time and Doha Declaration enabled flexibilities to least developing countries, why could not there be a time frame of a similar kind, to help developing countries as much as would be possible to get them obtaining patents better. If these less developed countries could climb up the latter towards the more developed countries, it could, in a long run, be beneficial for every country. Since competition is good for the markets and societies, would not it to be even more beneficial and better for the market if there would be more entities taking part to the competition? With competition, there could not only be even further developed pharmaceutical patents but there could also be better medicine and treatments for the diseases of the world. Even the TRIPS Agreement supports the idea of the best possible mutual supportive relationship between different organizations in order to achieve more balanced state that can further public health aspects in the world. Although the Agreement itself did not result to the wished outcome from the perspective of developing countries, it does help to achieve overall better cooperation and stable atmosphere among countries though supporting the cooperation among various intergovernmental organizations.

Despite the need for reform of patent protection and medicines, and all suggested approaches that would increase access in countries were purchasing powers are very limited, there are hope in the future. Already, with both HIV and AIDS medicines there are changes that have

[192] Dentico, N., & Ford, N. (2005), *supra nota* 52, p 98.

been happened for the better. Access to these important, yet patented medicines, has increased in developing countries where the biggest need for them is present. If the pressing access problem would be seen more broadly from the perspective of the whole world, it could be easier to also see the problem from the perspective of global health. When perspectives are changed, new approaches and solutions arise which helps with finding novel ideas and solution for problems. To me, increasing the access to pharmaceutical products in developing countries comes down to couple of aspects to consider: first, choosing the right view on the TRIPS Agreement as a base for the change, and secondly, choosing the right approach for application that best supports the chosen vision.