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CONFLICT BETWEEN THE MEDICAL PATENTS AND THE RIGHT TO HEALTH

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Introduction

The clash between the human right to health and medical patents is an issue that has become a subject of great concern in the international law.¹ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)² regulates the patents for medicines which has been considered as a conflicting side to human rights, especially to right to health as enforced by the International Covenant on Economic, Social and Cultural Rights (ICESCR)³. There are tensions between the two regulations, thus it is important to find a balance between them and also solutions to the possible problems that the study might reveal.

The question is examined from the perspective of the issue of access to affordable medicines in developing countries focusing on the right to health as set out in the ICESCR and patent standards (and flexibilities) as required by the TRIPS Agreement. In the strict sense, there is no conflict between the right to health and patents. ICESCR and TRIPS do not contain mutually exclusive obligations. Yet, it is shown that tension between the two does exist. There are a number of ways in which such tension can be resolved. The United Nations (UN) Sub-Commission for the Promotion and Protection of Human Rights has contended that human rights should enjoy primacy over patents, yet there is no evidence to suggest that the right to health and/or access to essential medicines are considered prioritised norms under international law. The World Trade Organization (WTO) disagrees and views Intellectual Property Rights (IPRs) and human rights as complementary. In international law there is a strong presumption against conflict. In line with the principle of systemic integration a good faith interpretation of the relevant WTO and human rights provisions should lead to a reading of TRIPS' obligations which is coherent with human rights law. However, this balancing act must also take place at the domestic level and the success of such a coexistence approach, namely whether (developing) states are able to strike a balance between access to medicines and patent protection, will depend much on the actual implementation and interpretation by states. Consequently, some examples of state practice regarding the interpretation and implementation of TRIPS in light of the right to health are highlighted.

¹ P. Cullet. Patents and medicines: the relationship between TRIPS and the human right to health. – 79 International Affairs 2003(1), pp. 139-160.

² Trade-Related Aspects of Intellectual Property Rights. Marrakesh 15.04.1994, e.i.f. 01.01.1995.

³ International Covenant on Civil and Political Rights. New York 16.12.1966, e.i.f. 23.03.1976.

Ha-Joon Chang stated that:

“Patent monopoly creates a lot of problems. It allows the patentee to charge the maximum to consumers. This may not be a problem if the patented product is a luxury item, like parts that go into a smartphone, but can violate basic human rights if it involves things such as life-saving drugs.”⁴

The hypothesis of this study is that there is a conflict between the medical patents and the right to health, because medical patents are in some cases greatly restricting the right to health. However, there is also a solution to this conflict.

The research questions are as follows:

- Is there a balance between the medical patents and the right to health?
- If there is no balance between the medical patents and the right to health, then how to balance them?
- Why is it important that there is a balance between the medical patents and the right to health?
- Who is responsible for finding a balance between the medical patents and the right to health?
- What is the relevant legislation in connection with the subject?
- What is the common practice among States in connection with medical patents and the right to health?
- Where to strike the balance?

This study will benefit the society as a whole because if there is a balance between the medical patents and the right to health then the medicines will be made easily available for the public and also the interests of the pharmaceuticals companies are protected. It is self-evident why the availability of different medicines benefits the society. However, protecting the interests of pharmaceutical enterprises matters as well. If pharmaceuticals companies do not get rewarded for their efforts in producing and inventing medicines then they might lose interest in producing any more medicines which will impede the scientific progress of medicines.

⁴ R. Aggarwal and R. Kaur. Patent Law and Intellectual Property in the Medical Field. Hershey PA: IGI Global 2017, p. 21.

The research undertaken for this thesis is essentially a library-based qualitative research work and it is basically analytical, comparative and evaluative. The research work is significantly theoretical and academic, employing contextual analysis of issues and an evaluative appraisal of the existing international legal regime. It presents the patent law as it is today and examines its impact on the society and the human rights law and vice versa. It uses the so-called ‘human rights critique’ of the current patent legislation. This is because the human rights scholars and activists have, from its beginnings, taken an opposing approach towards the intellectual property (IP) protection of essential medicines, especially the extensive patent protection provided under the TRIPS, due to its negative impact on the right to health. The human rights approach and critique of the WTO rules and IP law has been said to be the most important when it comes to assessing the conflict between human rights law and trade rules.⁵ This is so because the human rights framework ‘shifts the focus’ of the analysis of the impact of IPRs over the human right to health, by reframing the ‘existing legal discourses that privilege legal rules protecting intellectual property over those protecting individual rights and social values’, by providing ‘a mechanism to hold governments accountable for providing at least minimal levels of health care’, and by emphasizing ‘the need to restructure incentives for medical research and innovation toward the treatment of neglected diseases and the health needs of the poor’.⁶ Through this method, therefore, it will be shown to the reader how these two areas of law are intertwined and interrelated, and how one affects the other.

The thesis has chosen available documents as the sources of data for a number of reasons. First, the research project is largely theoretical and most of the information required is already well documented in different sources such as the official texts of relevant legislations, judicial decisions, policy papers, and annual reports of the WTO TRIPS Council as well as secondary sources such as the works of leading academics in the field. The research project does not involve the use of interviews because it investigates issues with very significant political implications both at national and international levels. This may create significant challenges when it comes to getting approvals for interviews for instance.

The first chapter of this study will deal with the patents for medicines in the TRIPS Agreement. It will outline the protection given by the medical patents, but also the ways that the TRIPS Agreement provides the members with balancing this protection with other public interests. The

⁵ H. Hestermeyer. *Human Rights and the WTO: The Case of Patents and Access to Medicines*. Oxford: Oxford University Press 2007, pp. 12-15.

⁶ L. R. Helfer and G. W. Austin. *Human rights and intellectual property: mapping the global interface*. Cambridge: Cambridge University Press 2011, p. 90.

purpose of the TRIPS Agreement will also be touched upon. Some relevant TRIPS Agreement Articles will be analysed in connection with human rights. Also, the Doha Declaration on TRIPS and Public Health will be mentioned. Further, it will be discussed about the importance of patents. It will reason why the patent protection is necessary to get through the “valley of death” and to compensate for the research and development. Also, how to market the product through patent protection.

The second chapter will look at right to health and its relevant legislation. It will open the definition of right to health and find out who is obliged to promote right to health. European Union approach to the right to health will also be discussed. In the end of the chapter, it is shown, how the right to health is in conflict with the relevant patent law. Thus, the comparison of the object and purpose of the right to health and patent law treaties will be performed. What is more, the enforcement of these treaties will be analysed and how this affects the practice of member States.

The third and the final chapter will consider the means to resolve the conflict. Treaty interpretation and conflict resolution techniques are mentioned in this chapter. Also, superior norms. It is considered whether human rights, and the right to life more specifically, could be a peremptory norm and thus prevail over the intellectual property law. Then it will go in more detail into treaty interpretation as a way to find a balance between the medical patents and the right to life. It will look into the attitude of WTO towards the human rights in connection with the TRIPS Agreement and discuss the important amendment made to TRIPS Agreement. Additional keywords of this chapter are transition periods; the criteria of patentability; compulsory licences; parallel importation; limited exceptions to patent rights; and opposition and revocation procedures. Also some examples of the State practice are provided. In the end of the chapter, the new relevant provisions in regards of the TRIPS Agreement’s amendment will be analysed. Also, it is viewed, how the European Union incorporates this amendment in its legislation.

The most important sources used for this study are:

- I. Lasić. *Pharmaceutical Patents, Right to Health and Access to Essential Medicines: A Human Rights Critique*. Master’s Thesis. Lund University 2013.
- J. A. Sellin. *Does One Size Fit All? Patents, the Right to Health and Access to Medicines*. – 62 *Netherlands International Law Review* 2015(3), pp. 445–473.

- P. Cullet. Patents and medicines: the relationship between TRIPS and the human right to health. – 79 International Affairs 2003(1), pp. 139-160.
- H. Hestermeyer. Human Rights and the WTO: The Case of Patents and Access to Medicines. Oxford: Oxford University Press 2007.
- L. R. Helfer, G. W. Austin. Human rights and intellectual property: mapping the global interface. Cambridge: Cambridge University Press 2011.
- C. Raluca. Patents on pharmaceuticals and right to health. Master Thesis. 2016. Available at <http://arno.uvt.nl/show.cgi?fid=142086> (Accessed 17.03.18).

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Keywords: intellectual property, human rights, patents, pharmaceutical companies, State responsibility

1 Intellectual Property Covering Pharmaceuticals

Intellectual property is considered as a “creation of the mind”, under which it is possible to patent inventions stemming from the pharmaceutical sector.⁷ Article 27(2) of the Universal Declaration of Human Rights (UDHR) draws out the Intellectual Property Rights, and it says that “Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”⁸ What is more, Article 15(1)(c) of the ICESCR says that „The States Parties to the present Covenant recognize the right of everyone: To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”⁹

Nowadays, the most important treaty containing the intellectual property rights is the TRIPS Agreement, which became effective in 1995.¹⁰ It defines patent, as an exclusive private right or monopoly for an invention for a limited period of time (for twenty years),¹¹ that allows for the patent holder to forbid other parties from using their patented invention.¹² It is a requirement for the patent to be acquired, that the information concerning the invention is revealed to the public while submitting the patent.¹³ It should be noted that patents are only effective in the region that awards it. These rights allow patent holders to benefit for their efforts in creating the invention, by making a revenue as a result of selling the invention as a monopoly, thus enabling the inventor to avoid competition. Patents are believed to be a way to stimulate innovation and the progress of technology by allowing the patent owner to benefit from the prices of a monopoly stakeholder.¹⁴

⁷ World Intellectual Property Organisation (WIPO). What is Intellectual Property?. WIPO Publication No. 450(E). Available at http://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf (Accessed 17.03.2018).

⁸ UN General Assembly. Universal Declaration of Human Rights. 1948. Article 27 (2).

⁹ UN General Assembly. International Covenant on Economic, Social and Cultural Rights. 1966. Article 15(1)(c).

¹⁰ WTO. Overview: the TRIPS Agreement. Available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (Accessed 17.03.2018)

¹¹ *Supra* n 2. Article 33.

¹² *Ibid.* Article 28.

¹³ *Ibid.* Article 29(1).

¹⁴ L. R. Helfer. Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines. – T.C Halliday and G. Shaffer. Transnational Legal Orders. Cambridge: Cambridge University Press 2015, pp. 311-339.

Patent rights can be upheld in courts, but on the other hand, a court can also stop the patent protection when effectively challenged.¹⁵ Patents are usually granted by national patent offices, but can be also given by regional offices, for example the European Patent Office (EPO).¹⁶ These regional offices allow the person to file an application for patent protection in multiple countries, whereas countries then consider whether they allow the respective patent to be granted within its area.¹⁷ The World Intellectual Property Organization administered (WIPO) Patent Cooperation Treaty (PCT)¹⁸ has basically the same system in force.¹⁹ It is possible by using this system to request a patent protection in multiple signatory states to the treaty by using just a single application.²⁰

WIPO, being one of the agencies of the United Nations, has 191 members, and it is an international forum dealing with IP policy, data, services and collaboration. It strives to create a balanced and effective international IP system that makes innovation and creativity flourish for the benefit of everybody. WIPO was established in 1967 by the WIPO Convention, which sets out its mandate, governing bodies and procedures.²¹

Article 27 of the TRIPS Agreement states that there is a patent protection to all fields of technology. This means that members cannot exclude medicines from patent protection. Articles 28 and 33 of the TRIPS Agreement provide patent holders a set of exclusive rights for a minimum period of 20 years.

What is more, the TRIPS Agreement gives the members a chance to balance the patent protection with other public interests, such as access to medicines and public health. TRIPS Agreement's objective is not limited to the protection of intellectual property rights, but instead it recognises the need to find a balance between the promotion of technological advantages and the transferral and circulation of such know-how.²² This is seen in the phrasing of Article 7 TRIPS which was one of the key proposals made by developing countries during the negotiations and states as follows:

¹⁵ *Supra* n 7, p. 5.

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ WIPO. Patent Cooperation Treaty (PCT), (as modified on 3 October 2001). Available at http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=288637 (Accessed 17.03.18).

¹⁹ *Ibid.* Article 3.

²⁰ *Ibid.*

²¹ WIPO. Inside WIPO. Available at <http://www.wipo.int/about-wipo/en/> (Accessed 17.03.18).

²² *Supra* n 2, Preamble, Articles 7-8.

“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 conducive to social and economic welfare, and to a balance of rights and obligations.”²³

Article 8.1 TRIPS is conveyed more strongly and states that “members may adopt measures necessary to protect public health provided that such measures are consistent with the provision of this Agreement”.²⁴

Mentioned articles are relevant since they allow members to use measures to ensure access to reasonably priced medicines. However, they can be seen as limited in that they cannot be interpreted as general exception clauses analogous to Article XX GATT (or Article XIV GATS).²⁵ However, they are important since they lay out the Agreement’s purpose and principles and also provide a way to interpret and implement the TRIPS Agreement.

Furthermore, the Agreement lets the members decide which appropriate method of implementation to use in their national legal system with the requirement that minimum standards of the TRIPS Agreement are met.²⁶ Terms, such as ‘inventiveness’ and ‘novelty’²⁷, leave room for interpretative flexibility to take into account what is most favourable to social welfare and public health.

Additionally, the Agreement also provides a selection of options for developing countries to strike balance between patent protection and the right of access to medicines.²⁸ Consequently, a number of tools are available under the Agreement to developing members to make sure that the balance is in existence, for example, compulsory licenses, parallel importation and ‘Bolar’ exemption.

²³ *Ibid.* Article 7.

²⁴ *Ibid.* Article 8.1.

²⁵ H. Hestermeyer. *Human rights and the WTO: the case of patents and access to medicines*. Oxford University Press: Oxford 2007, p. 58.

²⁶ *Supra* n 2, Article 1.

²⁷ *Ibid.* Article 27.

²⁸ *Ibid.* Articles 30 and 31.

1.1 Importance of Patent Protection

By using the intellectual property protection in a correct way, it is possible for the relevant parties to reduce their risks in a significant manner, as the market success of a novel product is affected by many different factors. It allows for the patent holders, who have contributed to the invention of the process, to gain acceptable benefits.

Innovative technology can be brought to the market by a proper IP protection granting it an important role. IP also can be used by the technology-based enterprises to enhance competitiveness, while it does not matter if the companies are offering new or simply enhance merchandise or delivering services that are based on a new or simply upgraded technological know-how.

By creating a successful invention, technology-based companies enjoy more productive ways of running their business or even can put to market a completely new product. When the enhanced effectiveness of the business is the outcome of additional value that reinforces a greater flow of income or advanced efficiency.

It is imperative to handle a ground-breaking idea as a secret if it is the wish of the enterprise to gain some profits in commercialising the idea. It does not matter whether the business innovates in order to grow (general strategy of business) or it is just a counter-measure to the current market situation and its developments. If the secret comes out, then the others can use it to their own benefit and the monopoly advantage of holding this idea would be lost.

It has been proved by the empirical evidence that trade secrets are usually being used more by small and average-sized businesses, who tend to shy away from using patents in order to protect the work they have created so they could stay in competition.²⁹ These kinds of businesses explain this kind of behaviour with the reason that the patent system is a complex one with relatively high expenses. Australian-based study reveals that only 44 percent of the companies chose patent protection while an enormous 74 percent preferred to use trade secrets for keeping their ideas in secret. The size of the company was shown to play a big role in determining which

²⁹ M. Rogers. The Definition and Measurement of Innovation. Melbourne Institute Working Paper No. 10/98. 1998, p. 14. Available at <https://pdfs.semanticscholar.org/c71a/9e4a99732746d58da82f235799000901ff8e.pdf> (Accessed 17.03.18).

way to go, for example 75 percent of companies with 500 or more employees chose patent protection and only 35 percent of companies with 20 or less employees relied on patents.³⁰

Some (mostly, small and averaged sized companies, as explained above) see that innovation is being impeded by the complexity of the patent system and also its relatively high costs while for example, writing a patent claim or dealing with the “prior art” search, then the patents can be something that brings in more revenue, if used in a tactical manner, even for these small and average-sized businesses.³¹

For a thought that may result in a patentable innovation, the inevitable decision between the utilization of either the trade secret route or the patent route to defend it ought to be viewed as a key business decision that ought to be taken just at a propelled phase of its improvement when every one of the prerequisites of patentability are met, specifically, statutory subject matter, novelty, inventive step/non-obviousness, capable of industrial application, and suitable disclosure. While reaching that point, the decision would rely upon the idea of the creation, its business forthcoming, the nature of rivalry, the likelihood of its autonomous creation by rivals and the capacity of contenders to figure out it easily from the item created by utilizing it.³² It ought, nevertheless, be brought up that whatever the ultimate conclusion, originally it must be safe-guarded as a trade secret so that, later on a piece of it may be patented and whatever remains of it may in any case remain to be an associated trade secret and know-how, or implicit information that is possessed by entities related with the patent.

The facts contained in present patent files (patent facts) performs an important role inside the thought, screening and development of an idea. Such information can provide useful perception into whether or not an idea is new or no longer and whether to proceed similarly in growing an idea. Furthermore, proper evaluation of patent facts may additionally provide a perception into the method of capable competition and about developments in technology.³³

³⁰ *Ibid.*

³¹ C. M. Kalanje. Role of Intellectual Property in Innovation and New Product Development. Available at www.wipo.int/sme/en/documents/ip_innovation_development_fulltext.html#P64_14377 (Accessed 17.03.18).

³² *Ibid.*

³³ *Ibid.*

1.1.1 Stage of Research and Development

The efforts of a company, that it assumes in doing research to discover an original idea and then making it happen, can be measured in numerous indicators. Some of these are, total sales, data on innovation, expenses on product research and its development, innovation policies and the size of the company.³⁴ Intellectual property often influences the mentioned indicators in a direct or indirect manner. Thus, the tools of intellectual property continue their importance from the stage of creating an original idea to the stage at hand. So, if the company has not decided if they would like to go for the patent protection, then the trade secret is still a crucial measure of protection. Because no one would want that the contenders get their hands on sensitive data, then trade secrets are pertinent in also research and development phase. Rivals could seriously damage the competitive advantage, if information leaks about the final product.³⁵

It is at this stage, that the scientists of a product should take advantage of data sources which can make their venture flourish. Significant source of data in the face of patent documentation is often totally

During this period, researchers should at times consult several sources of data that would offer input for the success of their venture. Patent documents continue to be a significant source of data that is often not used enough.³⁶ This documentation has some valuable data that could be used by the company to keep away from needless use of their capital, be it time or cash, while in the process of research and development, which could lead to the decrease of normally great research and development expenses. Documents about patents can also be used to gain data, which offer the possibility to enhance the merchandise or to assemble the invention in an easier way, which can shorten the usually long time of commercialising the goods.³⁷

1.1.2 Most Crucial Phase of Innovation

To popularise the original concepts of technology in the marketplace, they need, quite often to be developed in a further technical manner. Small and average-sized companies often are not able to do these kinds of developments, for example, prototype testing and advantaging, since they do not own such facilities or assets. While these small companies might turn to the research

³⁴ R.G.M. Kemp and others. Innovation and firm performance differences between small and medium-sized firms. 2003, p.7. Available at <http://ondernemerschap.panteia.nl/pdf-ez/n200213.pdf> (Accessed 17.03.18).

³⁵ *Supra* n 55.

³⁶ *Ibid.*

³⁷ *Ibid.*

institutes, innovation centres, technology parks, other companies, universities, or to say shortly external facilities, then the intellectual property protection keeps the ideas safe and sound. What is more, when bringing a product to the market by a partnership and developing the invention in the future, then a strong negotiating position is offered by the ownership of intellectual property protection while trying to establish such a partnership. It is in the interest of both parties to initially clarify the issues of intellectual property ownership to evade potential conflicts that may rise.³⁸

Even the greatest goods need, in order to be properly commercialised, some fine marketing experience and the inventors of these products lack these kinds of skills.³⁹ The most crucial stage is commercialising the goods and it is difficult for these creators of inventions, especially the small and average-sized companies. A lot of potentially good inventions are lost in this stage because they do not get outside help or are just not fit for the market.⁴⁰

Patents can be relied on to attract investors to the idea, these could be financial organisations, venture capitalists, seed capital and other business angels who can offer some support to commercialise the product. Xerography is a good example to be considered. Xerograph was invented by Mr Carlson in 1937, but gained its patent protection in 1939. Mr Carlson struggled for almost eight long years to find a willing business angel to support his creation. The invention was finally made effectively suitable for market place by the firm named Haloid, which happened in year 1950.⁴¹ It can be reasoned that the choice by the Haloid Company to support the creation, was considerably affected by the fact that Mr Carlson had patent on his creation. Ideas that are potentially quite good and innovative are ended in this stage. By getting a patent protection on an idea, an inventor can safeguard the creation so it would not lose its value. It is an often occurrence that to keep the idea alive, it needs some support from third parties, whether this help is connected to marketing, finance, or technical awareness. Possessing intellectual property protection can be a great factor in determining the choices of these third parties whether they assist in commercialising the product or not.⁴²

³⁸ *Ibid.*

³⁹ P. A. Fisher. *Common Stocks and Uncommon Profits and Other Writings*. Wiley: Wiley Investment Classics 2003, p. 124.

⁴⁰ *Supra* n 55.

⁴¹ Xerox. *The Story of Xerography*. Available at <https://www.xerox.com/downloads/usa/en/s/Storyofxerography.pdf> (Accessed 17.03.18).

⁴² *Supra* n 55.

It may be easier for the players holding intellectual property rights to find business partners with fair terms and conditions. The partners can offer research and development facilities or even ways to commercialise the product.⁴³ If one holds a patent protection, then the business angels are more prone to invest in the product and this helps to commercialise the merchandise. These investors play a major role in.⁴⁴

1.2 European Union Practice and Approach

The European Patent Convention (EPC), also known as the Convention on the Grant of European Patents of 5 October 1973, is a multilateral treaty instituting the European Patent Organisation and providing an autonomous legal system according to which European patents are granted.⁴⁵

Under the Article 52 (1) of the EPC it states that “European patents shall be granted for any invention in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application”.⁴⁶

Article 53 then goes on to deal with the exceptions of patentability and states that European patents shall not be awarded for:

- “(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
- (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”⁴⁷

Article 54 (1) addresses the notion of novelty and states that: “An invention shall be considered to be new if it does not form part of the state of the art.”⁴⁸ Article 54 (2) adds that: “The state

⁴³ *Ibid.*

⁴⁴ *Ibid.*

⁴⁵ European Patent Office. Guide for applicants: How to get a European patent. Available at https://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_a_ii.html (Accessed 17.03.18).

⁴⁶ WIPO. Convention on the Grant of European Patents (European Patent Convention). 1973. Article 52 (1).

⁴⁷ *Ibid.* Article 53(a)-(c).

⁴⁸ *Ibid.* Article 54(1).

of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.”⁴⁹

According to the Article 56: “An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.”⁵⁰ This assessment is conducted according to the "could-would approach" and the following method of consideration is applied:

It is considered whether there is any teaching in the prior art as a whole that would (not simply could, but would) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves.⁵¹ Put differently, the main factor is that the person with relevant experience would do it because there was something in the earlier art that made him do it for the purpose of improving or solving some technical issue, and not because this person just modified or adapted the closest earlier art.

Lastly, Article 57 dealing with the patentability in the EPC states that: “An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”⁵² "Industry" should be understood in its broad sense as including any physical activity of "technical character", i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts; it does not necessarily imply the use of a machine or the manufacture of an article. Thus, Art. 57 excludes from patentability very few "inventions" which are not already excluded by the list in Art. 52(2).⁵³

Article 83 is about the revelation of information, and quite an important Article. By this Article, it is required that the applicant for the patent reveals the information about the product that he

⁴⁹ *Ibid.* Article 54(2).

⁵⁰ *Ibid.* Article 56.

⁵¹ European Patent Office. Guidelines for Examination. Available at http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5_3.htm (Accessed 17.03.2018).

⁵² *Supra* n 30, Article 57.

⁵³ European Patent Office. Guidelines for Examination. Available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iii_1.htm (Accessed 17.03.2018).

is or she is seeking intellectual property protection for, so that it could be replicated by an experienced individual.⁵⁴

In 1977, the international body called the European Patent Organisation (EPO) started its work, which derived from the European Patent Convention. It consists of two authorities: the Administrative Council and the European Patent Office. The latter one is the executive body of the EPO and it provides the inventors with a single application process, enabling these inventors to receive protection of the patent in more than 40 countries. The Administrative Council supervises the EPO. Organisation's member states' representatives compose the Administrative Council. Currently, EPO consists of 38 member states. However, there are additional 4 non-member states that the European Patent is recognised in, which of two of these are European states and two non-European. Board of appeal of the EPO deals with the appeals against the decisions of the EPO. It is a part of the organisation's structure, but the appeal board is considered to be independent from the Office when making their decisions. Board of appeal is bound only by the European Patent Convention.⁵⁵

1.2.1 European Union Biotech Directive

The European Biotechnology Directive creates the presumption that biological inventions are patentable subject matter. Recital 18 of the European Biotechnology Directive implies that the 1998 patent laws of member countries inadequately dealt with biotechnological inventions. It states that, because the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or "orphan" diseases, the Community and the Member States have a duty to respond adequately to this problem.⁵⁶

Article 3 of the Directive states that:

"1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

⁵⁴ *Supra* n 30, Article 83.

⁵⁵ European Patent Office. Governance. Available at <https://www.epo.org/about-us/governance.html> (Accessed 17.03.2018).

⁵⁶ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Recital 18.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.”⁵⁷ Thus, it is similar to the requirements brought out in the EPC and TRIPS Agreement, since novelty, inventive step and industrial application is referred to.

Finally, Article 4 of the Directive lists matters that are considered to be unpatentable. Article 6 underlines the inventions that cannot be patented because their commercial abuse would be conflicting to public order or morality, for example altering the germ line genetic identity of humans and the procedure of altering the genetic identity of animals if there is no significant benefit to humans or animals.⁵⁸

1.2.2 TRIPS Application within the EU

The Court of Justice of the European Union (CJEU) decided in its judgment of 18 July 2013⁵⁹, that following the enforcement of the Lisbon Treaty on 1 December 2009, TRIPS Agreement’s provisions wholly belong to the field of the common commercial policy, which means that the national courts of Member States do not have the jurisdiction to apply and/or interpret the TRIPS Agreement provisions on their own anymore. This was truly a controversial shift from the judgments of 14 December 2000⁶⁰ and 11 September 2007⁶¹, in which CJEU found that in the fields (e.g. patents) where the harmonisation of the Community has not yet been made, the Member States remained primarily competent.⁶²

In its Opinion 1/1994,⁶³ the CJEU clarified that the EC and its Member States were jointly competent to conclude the Final Act Embodying the Results of the Uruguay Round of

⁵⁷ *Ibid.* Article 3.

⁵⁸ *Ibid.* Article 6.

⁵⁹ Judgment of the Court (Grand Chamber), 18 July 2013. Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon.

⁶⁰ Judgment of the Court of 14 December 2000. Parfums Christian Dior SA v TUK Consultancy BV and Assco Gerüste GmbH and Rob van Dijk v Wilhelm Layher GmbH & Co. KG and Layher BV.

⁶¹ Case C-431/05. Merck v. Merck Generics. JUDGMENT OF THE COURT (Grand Chamber), 11 September 2007. Judgment of the Court (Grand Chamber) of 11 September 2007. Merck Genéricos - Produtos Farmacêuticos Ld^a v Merck & Co. Inc. and Merck Sharp & Dohme Ld^a.

⁶² M. M. Mora. The Practical Consequences of the CJEU Judgment of 18 July 2013 Changing Its Doctrine on the Respective Competences of the EU and its Member States to Apply the TRIPS Agreement: Have We Seen the Tip of the Daiichi Iceberg Yet?. – IIC – 48 International Review of Intellectual Property and Competition Law (7) 2017, pp. 784–812, p 784.

⁶³ Opinion of the Court of 15 November 1994. Competence of the Community to conclude international agreements concerning services and the protection of intellectual property - Article 228 (6) of the EC Treaty. Opinion 1/94.

Multilateral Trade Negotiations,⁶⁴ which includes the TRIPS Agreement. The prudent approach followed by the CJEU in this case was also plotted by the CJEU in its judgments of 14 December 2000 (*Christian Dior and AsscoLayher*) and 11 September 2007 (*Merck Genericos et al.*). In these cases, it found that in a field where the EC has not yet legislated and which falls within the competence of the Member States, the protection of intellectual property rights – and measures adopted for that purpose by the judicial authorities – do not fall within the scope of EC waters. Accordingly, the CJEU added that EC law neither requires nor forbids courts of Member States to apply and interpret provisions of the TRIPS Agreement governing matters such as patents, for which Member States continue to have the primary competence.

This state of affairs changed dramatically six years later. In its judgment of 18 July 2013, the CJEU, leaving aside the calm waters laid down by Opinion 1/1994 and its saga, the answer primarily proposed by the Advocate General, and the opinions of all the parties who filed observations, came to the conclusion that after the entry into force of the Lisbon Treaty on 1 December 2009, the provisions of the TRIPS Agreement fall within the scope of the EU's common commercial policy. This judgment was handed down in response to a referral for a preliminary ruling sent by a Greek court regarding the obligations of protection introduced by the TRIPS Agreement in relation to patents already granted when TRIPS came into force.

As a result of the judgment of 18 July 2013 the European Union is trying to introduce a “European patent with unitary effect⁶⁵” and a “Unified Patent Court” established by an international treaty alien to the EU.⁶⁶ This patent will be a classical European patent granted by the European Patent Office that will have “unitary effect” throughout the EU, if the applicant chooses so within one month after the granting of the patent. Although, during the early stages of the drafting of the Regulation seeking to introduce this patent, the plan was that it would be governed by EU law – in the end this idea was abandoned. The reason is that some stakeholders considered that the CJEU, due to its lack of specialization, is not well equipped to decide cases on patent matters. They thought that by removing substantive patent law from the text of the Regulation, the risk of having cases referred to the CJEU would be kept to a minimum. This explains why, at the last minute, Arts. 6–8 (substantive patent law) were removed from the text of the Regulation. Instead, substantive patent law was taken to Arts. 25–30 of the “Agreement

⁶⁴ WTO. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations. Available at https://www.wto.org/english/docs_e/legal_e/03-fa_e.htm (Accessed 17.03.18).

⁶⁵ Regulation (EU) 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection. O.J. 2012, L 361/1.

⁶⁶ Agreement on a Unified Patent Court. O.J. 2013, C 175/1.

on a Unified Patent Court”,⁶⁷ an international treaty that will introduce a new Patent Court competent to resolve disputes relating to the European patent with unitary effect and classical European patents.⁶⁸

⁶⁷ *Ibid.*

⁶⁸ *Supra* n 46, pp. 797-798.

2 Human Right to Health

The right to health is an important part of our human rights and of our understanding of a life in dignity. Worldwide, it was first expressed in the Constitution of the World Health Organization (WHO), which defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. What is more, it states that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”⁶⁹ UDHR⁷⁰ also stated health as part of the right to an adequate standard of living.⁷¹ Another distinction of right to health was made in International Covenant on Economic, Social and Cultural Rights⁷².

All States have signed at least one treat that promotes the right to health, thus this right is important globally. States strive to uphold this right by declaring it internationally, enforcing it in its legislature and policies, and also mentioning it at international forums. Human rights treaty monitoring bodies, WHO and Commission on Human Rights have recently turned their attention to the right to the highest attainable standard of health. In 2002 it was created by Commission on Human Rights the mandate of Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health.

2.1 The Basis: Universal Declaration of Human Rights

As the name suggests, Universal Declaration of Human Rights (UDHR) is not a treaty, but a declaration. Its purpose of adoption was to define the concepts of the terms “human rights” and “fundamental freedoms” that appear in the UN Charter – a document that is binding on all its signatory states. For this reason, the Universal Declaration of Human Rights is a fundamental constitutive document of the United Nations. In addition, many international lawyers believe that the Declaration forms part of customary international law and is a powerful tool in applying diplomatic and moral pressure to governments that violate any of its articles. The Declaration has served as the foundation for two binding UN human rights covenants: the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and

⁶⁹ Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

⁷⁰ *Supra* n 8.

⁷¹ *Ibid.* Article 25.

⁷² *Supra* n 9.

Cultural Rights. It serves as “the foundation for the international code of human rights”⁷³ and the concept of “humanitarian duty” of aid by countries more developed to help less developed countries is envisioned in it.⁷⁴ According to the Article 25(1) of the UDHR, everyone has the right to medical care.⁷⁵

2.1.1 Lawfully Binding Covenant

The International Covenant on Economic, Social and Cultural Rights (ICESCR) is a treaty, which multiple signatories, adopted by the United Nations General Assembly on 16 December 1966, and in force from 3 January 1976, which in its Article 12 ICESCR recognises and defines the right to health.⁷⁶ As ICESCR is a treaty then it is lawfully binding to its parties. Hence, the ICESCR delivers the foundation for the legal obligations under the right to health⁷⁷ that States parties need to conform with.

Article 12 of the Covenant recognises the right of everyone to “the enjoyment of the highest attainable standard of physical and mental health”.⁷⁸ "Health" is understood not just as a right to be healthy, but as a right to control one's own health and body, and be free from interference such as torture or medical experimentation.⁷⁹ Article 12.2 requires parties to take specific steps to improve the health of their citizens, including reducing infant mortality and improving child health, improving environmental and workplace health, preventing, controlling and treating epidemic diseases, and creating conditions to ensure equal and timely access to medical services for all. These are considered to be "illustrative, non-exhaustive examples", rather than a complete statement of parties' obligations.⁸⁰

Committee on Economic, Social and Cultural Rights, which is a body of human rights experts, deals with the monitoring of implementation of the ICESCR. It consists of 18 independent

⁷³ G. Backman and others. Health systems and the right to health: an assessment of 194 countries. – 372 *The Lancet* 2008, p. 2047. Available at http://www.who.int/medicines/areas/human_rights/Health_System_HR_194_countries.pdf (Accessed 17.03.18).

⁷⁴ M. Gumbel. Is Article 31 Bis Enough? The need to Promote Economies of scale in the International Compulsory Licensing System. 22 *Temple Int'l and Comp. L. J.* 2008, p 164. Available at <http://www.temple.edu/law/ticlj/ticlj22-1Gumbel.pdf> (Accessed 17.03.18).

⁷⁵ *Supra* n 8, Article 25(1).

⁷⁶ United Nations Committee on Economic, Social and Cultural Rights. CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12). 11 August 2000. Available at <http://www.ohchr.org/Documents/Issues/Women/WRGS/Health/GC14.pdf> (Accessed 17.03.18).

⁷⁷ H. V. Hogerzeil and others. Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?. – 368 *The Lancet* 2006, p. 305.

⁷⁸ *Supra* n 9, Article 12.1.

⁷⁹ *Supra* n 76, paragraph 9.

⁸⁰ *Supra* n 9 Article 12.2.

human rights experts, elected for four-year terms, with half the members elected every two years.⁸¹ All states parties are required to submit regular reports to the Committee outlining the legislative, judicial, policy and other measures they have taken to implement the rights affirmed in the Covenant. The first report is due within two years of ratifying the Covenant; thereafter reports are due every five years. The Committee then on the basis of the reports provided to them delivers its concluding observations to the states, which contains Committee's concerns and recommendations.⁸²

The United Nations Committee on Economic, Social and Cultural Rights delivered a document known as the General Comment 14, which contains a legally binding explanation about the right to health.⁸³ It is declared by this Comment⁸⁴ that the right to medicinal services comprises matters of access to essential medicines as defined by the World Health Organisation's Action Programme on Essential Drugs⁸⁵. What is more, the Comment says that the States have the duty to safeguard the right to health and also the Comment requires to abstain from interfering with this right, whether it is direct or indirect in its nature. It is also the task of the States to implement suitable administrative measures and legislation, and inhibit third parties from interfering with the assurances provided by the right.⁸⁶

It should be noted that ICESCR Member States have a pressing duty to follow the Article 12 to assure that the right to health is attained without any discrimination, however, it also takes into account the limits of available resources of its Member States and provides for a steady realisation of the right to health.⁸⁷

⁸¹ United Nations Human Rights Office of the High Commissioner. COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS. Available at <http://www.ohchr.org/en/hrbodies/cescr/pages/cescrindex.aspx> (Accessed 17.03.2018).

⁸² United Nations Human Rights Office of the High Commissioner. COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS. Available at <http://www.ohchr.org/EN/HRBodies/CESCR/Pages/WorkingMethods.aspx> (Accessed 17.03.2018).

⁸³ *Supra* n 76.

⁸⁴ *Ibid.*

⁸⁵ *Supra* n 77, p. 305.

⁸⁶ *Supra* n 1, p 148; *supra* n 76.

⁸⁷ *Supra* n 77, p. 306.

2.1.2 Essence of Right to Health

Everyone has the right to health. It relates to both the right of individuals to obtain a certain standard of health and health care, and the State obligation to ensure a certain standard of public health with the community generally.

The World Health Organization defines the right to health as a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity. States should ensure both freedoms and entitlements. The former include the right to control one's health and body, including sexual and reproductive freedom, and the freedom from interference such as torture, non-consensual medical treatment and experimentation. Entitlements include access to adequate health care facilities and services, as well as appropriate State measures in relation to the socio-economic determinants of health, such as food, water and sanitation, safe and health working conditions, housing, and poverty.⁸⁸

According to CESCR, the right to health also extends to underlying determinants of health in addition to timely and appropriate health care, thus making it a comprehensive right that comprises a wide range of elements that would lead to having a health life.⁸⁹ Right to health entails rights and freedoms, such as the freedom to control our own health, but also rights such as: the right to a scheme of health protection that provides for the equality of prospects in order for individuals to enjoy the highest attainable level of health; the right to prevention, treatment and control of diseases and access to vital medications.⁹⁰ Thus, the right to health is not to be understood as a right to be healthy.⁹¹

Therefore, medicines must be available, accessible, acceptable and of decent quality.⁹² Available means that functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party, however, this is connected to the capacity of a State to offer these facilities. Essential should, however, be provided, as in safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel

⁸⁸ World Health Organisation. Human rights and health. Available at <http://www.who.int/mediacentre/factsheets/fs323/en/> (Accessed 17.03.2018).

⁸⁹ *Supra* n 76, para 11.

⁹⁰ *Ibid.*

⁹¹ *Ibid.*, paras 7-8.

⁹² *Ibid.*, para 12.

receiving domestically competitive salaries, and essential drugs.⁹³ Accessible means that health facilities, goods and services have to be available to everybody indiscriminately, within the authority of the State party. Accessibility has four overlying dimensions:

1. Non-discrimination: health facilities, goods and services must be accessible to all, particularly the most defenceless or disregarded units of the populace, legally and factually, without discrimination on any of the forbidden grounds;
2. Physical accessibility: health facilities, goods and services must be within harmless physical scope for all units of the populace, particularly defenceless or disregarded groups, for example cultural minorities and aboriginal inhabitants, females, youngsters, teenagers, elderly, people with disabilities and people with HIV/AIDS. Accessibility similarly suggests that medical services and fundamental elements of health, for example non-toxic and drinkable water and suitable hygiene establishments, are within harmless physical grasp, as well as in rural regions. Accessibility further comprises suitable access to constructions for people with disabilities;
3. Economic accessibility (affordability): health facilities, goods and services must be inexpensive for everybody. Fee for health-care services, as well as services connected to the fundamental elements of health, has to be founded on the principle of fairness, guaranteeing that these services, whether privately or publicly offered, are of reasonable price for everybody, taking into account socially underprivileged people. Equity stresses that poorer households should not be excessively weighed down with health costs as related to wealthier households;
4. Information accessibility: accessibility comprises the right to seek, receive and impart information and concepts regarding health problems. Nevertheless, accessibility of information should not harm the right to have private health data treated with discretion.⁹⁴

Acceptability means that all health facilities, goods and services must be respectful of medical morals and ethnically suitable, for example respectful of the culture of individuals, minorities, persons and societies, thoughtful to sex and life-cycle requirements, as well as being intended to respect privacy and increase the health status of those concerned.⁹⁵ Quality indicates that as well as being ethnically adequate, health facilities, goods and services must also be scientifically and medically fitting and of decent quality. This necessitates, *inter alia*, capable

⁹³ *Ibid.*, para 12(a).

⁹⁴ *Ibid.*, para 12(b).

⁹⁵ *Ibid.*, para 12(c).

medical staff, scientifically accepted and unexpired drugs and hospital gear, non-toxic and drinkable water, and acceptable hygiene.⁹⁶

2.2 State Obligation to Uphold Public Health

Since the right to health is included in a number of international human rights treaties, then it is first and foremost the states' obligation to enforce the right to health and human rights standards in their respective territory.⁹⁷ ICESCR demands states to realise the right to health, but it also takes into account the assets of the relevant country.⁹⁸ It is obvious that different states have different capacities to fulfil the obligations arising from the ICESCR. This, however, does not mean that the states can sit still and do nothing, they must take reasonable steps in their respective capacity to strive in the direction of the full realisation of the right to health.⁹⁹

States have three different responsibilities, firstly, the responsibility to respect, which means that the state should refrain from taking steps that could have opposing effects on people's health (negative responsibility); secondly protect which means that the states have to set in motion laws or other measures that would ensure equal access to health care and also health-related services, which are usually provided by third parties; and lastly, fulfil, which means basically that the state must actually make sure that the full realisation of the right to health is implemented (latter ones being positive responsibilities).¹⁰⁰ Though fulfilling the right to health can be through progressive realisation, it is, however, required that each state takes considered steps toward the full realisation of the right and that they provide short-term solutions to respect the right to health.¹⁰¹

Medicine and public health, which are connected, but at the same time quite dissimilar terms, form the modern notion of health.¹⁰² Public health is concentrated on the health of the population as a whole, while medicine is usually focused on the health of a person.¹⁰³ It is unavoidable that when the concept of health is transported into the human rights field as the

⁹⁶ *Ibid.*, para 12(d).

⁹⁷ H. Hannum. The Status of the Universal Declaration of Human Rights in National and International Law. – 25 Georgia Journal of International and Comparative Law 1995/1996 pp. 287, 292.

⁹⁸ *Supra* n 9, Article 2.1.

⁹⁹ *Supra* n 76, paras 30-32.

¹⁰⁰ *Ibid.* paras 33-36.

¹⁰¹ UN Committee on Economic, Social and Cultural Rights. CESCR General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant). Para 10.

¹⁰² J. M. Mann and others. Health and Human Rights: A Reader. New York and London: Routledge 1999, pp 7-8.

¹⁰³ *Ibid.*

right to health, that the public health is merged into the right to health. Clarification between the notions is further contemplated by the fact that public health aims for the protection of population, while human rights are suggestively based on the guarantee of individual protection.¹⁰⁴

It is possible in the international human rights law that the public health restrains the other human rights. Therefore, it is possible that in case there is a widespread illness, the public health may derogate from individual liberties to protect civilisation. It has in fact become a trend in international health law, thus making obligatory health measures quite familiar in contemporary society.¹⁰⁵ It is justified on the grounds of public health and hence in sync with overall human rights values. In the case of epidemics, individual privileges of liberty of movement, identity, discretion, dignity, religion, expression and association may be limited.¹⁰⁶

The notion of public health is used a basis for the limitation of some human rights (particularly in the health context), however, it is not directly incited into the ICESCR and UDHR.¹⁰⁷ It can be justified on the basis that public health is in fact an obligatory measure in health law, and also because public health is closely connected to public order.¹⁰⁸

It is permitted for the state to take actions in case of grave risks to the whole population or to people in the population, according to the principle 25 from Siracusa Principles.¹⁰⁹ Furthermore, international rules propagated by the WHO validate restrictive measures on the basis of public health.¹¹⁰ The most relevant is still the Article 12 of ICESCR, which is used by the state for the inhibition of an epidemic illness.

¹⁰⁴ *Ibid.* p. 46.

¹⁰⁵ A. Eide and others. Economic, Social and Cultural Rights. Dordrecht, London: Martinus Nijhoff Publishers 1995, pp 125, 137-138.

¹⁰⁶ V. A. Leary. The Right to Health in International Human Rights Law. – 1 Health and Human Rights: An International Journal (1) 1994.

¹⁰⁷ *Supra* n 76.

¹⁰⁸ A. C. Kiss. Permissible Limitations on Rights. – L. Henkin. The International Bill of Rights – The Covenant on Civil and Political Rights. New York: Colombia University Press 1981, pp. 290, 302.

¹⁰⁹ UN Commission on Human Rights. The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights. 1984.

¹¹⁰ A. Kiss. Commentary by the Rapporteur on the Limitation Provisions. – 7 Human Rights Quarterly (1) 1985, pp. 15, 20.

2.3 European Union Approach

The Charter of Fundamental Rights of the European Union¹¹¹ (the Charter) brings together the fundamental rights of everyone living in the European Union (EU). It was introduced to bring consistency and clarity to the rights established at different times and in different ways in individual EU Member States. The Charter sets out the full range of civil, political, economic and social rights based. The Charter became legally binding on EU Member States when the Treaty of Lisbon entered into force in December 2009.

The Charter is sometimes confused with the European Convention on Human Rights. Although containing overlapping human rights provisions, the two operate within separate legal frameworks. The Charter of Fundamental Rights of the European Union was drafted by the EU and is interpreted by the Court of Justice of the European Union. The European Convention on Human Rights, on the other hand, was drafted by the Council of Europe in Strasbourg and is interpreted by the European Court of Human Rights. The Charter can be seen as the overarching framework for human rights in the EU, of which the European Convention on Human Rights forms only one part, albeit an important one.

According to Article 6 of the Treaty on EU¹¹² the Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union. The provisions of the Charter shall not extend in any way the competences of the Union as defined in the Treaties. The Union complies with the European Convention for the Protection of Human Rights and Fundamental Freedoms. Such accession shall not affect the Union's competences as defined in the Treaties. Fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and as they result from the constitutional traditions common to the Member States, shall constitute general principles of the Union's law.¹¹³

According to the Charter of Fundamental Rights of the EU “everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be

¹¹¹ European Union. Charter of Fundamental Rights of the European Union. – Official Journal of the European Union C83. Brussels: European Union 2010.

¹¹² European Union. Consolidated Version of the Treaty on European Union. Article 6. – Official Journal of the European Union C326. Brussels: European Union 2012.

¹¹³ *Ibid.* Article 6.

ensured in the definition and implementation of all Union policies and activities”¹¹⁴. Thus, Article 6 of the Treaty on the European Union and its access to vital medication and the right to health are equivalent in importance with the founding treaties of the EU.¹¹⁵

2.4 Conflict with Patent Law

Having established the concept and importance of the patents and the right to health, it is now time to consider how these two rights and their enforcement differ with each other.

The object and purpose of the ICESCR and the TRIPS Agreement are different.¹¹⁶ ICESCR is focused on human rights and promotes as a crucial element the right to health, while TRIPS is mainly focused on intellectual property rights. They have different starting points and main characteristics.¹¹⁷ The High Commissioner for Human Rights has said that there remain “fundamental differences of approach” between the two.¹¹⁸ The Special Rapporteur on the right to health has further said that TRIPS bears upon crucial elements of the right to health.¹¹⁹

International human rights law and TRIPS are also enforced in different ways. TRIPS is under the WTO dispute settlement mechanism and if a WTO member is found to be in violation of its obligations the Dispute Settlement Body may, as a last option, allow the complainant to withdraw trade or impose other sanctions against the violator.¹²⁰ The mere possibility of cross-retaliation is a powerful incentive, particularly for developing members, to comply with their TRIPS obligations.

The ICESCR, however, does not have an enforcement mechanism as effective as the WTO does and, even though human rights are supposed to be morally superior, the lack of enforcement

¹¹⁴ *Supra* n 88, Article 35.

¹¹⁵ *Supra* n 89, Article 6.

¹¹⁶ H. M. Haugen. Patent rights and human rights: exploring their relationships. 10 *Journal of World Intellectual Property* (2) 2007, p. 102.

¹¹⁷ F. Papadopoulou. TRIPS and human rights. – A. Kur and M. Levin. *Intellectual property rights in a fair world trade system. Proposals for reform of TRIPS*. Cheltenham: Edward Elgar 2011, p. 270.

¹¹⁸ UN Sub-Commission on the Promotion and Protection of Human Rights. Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. 2001, para. 22.

¹¹⁹ UN Commission on Human Rights. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, Submitted in Accordance with Commission Resolution 2002/31. 2003, para. 86.

¹²⁰ Understanding on Rules and Procedures Governing the Settlement of Disputes. Article 22. Available at https://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm (Accessed 17.03.18).

makes their position weaker compared to WTO procedures. Thus, it is understandable why members tend to comply more with the obligations of the TRIPS rather than the ICESCR.

Mostly in developing and least developed countries, it has been noted that high fees stemming from the strong patents on medicines, can, in a lot of cases, impair the access to essential drugs.¹²¹ There are two different schools of thought which concern the relationship between the intellectual property rights and the right to health.

On one side, it has been argued that the two rights are in fact in conflict, this because the protection granted by the IP rights undermines the right to health. As a solution to conflict, it has been suggested that when the responsibilities from different treaties conflict, then the human right to health should prevail.¹²²

On the other side, which is also supported by the WHO, it is believed that these two rights can actually live in harmony. WTO has underlined that the international trade treaties have built-in flexibilities when dealing with the right to health.¹²³ Nevertheless, it is often disagreed over where to draw an appropriate line between patent protection on one hand, and access to essential medicines on the other.¹²⁴

The transitional period for developing countries to apply the TRIPS Agreement provisions expired in year 2000, which made the United Nations Human Rights system shift its attention to responsibilities stemming from the TRIPS. Resolution 2000/7 on IP Rights and Human Rights was approved by the Sub-Commission on the Promotion and Protection of Human Rights.¹²⁵ It is noted in the Resolution 2000/7 that there are real or possible conflicts present between the application of the TRIPS Agreement and the realisation of economic, social and cultural rights.¹²⁶ This clash has a major influence on the right to health concerning access to patented medications.¹²⁷ Based on the notion that human rights must be given pre-eminence, Sub-Commission set out a plan to analyse IP related issues within the United Nations, in order

¹²¹ E. F. M. 't Hoen. TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha. – 3 *Chicago Journal of International Law* (1) 2002, p. 41.

¹²² L. R. Helfer. Human Rights and Intellectual Property: Conflict or Coexistence?. – 5 *Minnesota Intellectual Property Review* (1) 2003, p. 48.

¹²³ P. K. Yu. Ten Common Questions About Intellectual Property and Human Rights. – 23 *Georgia State University Law Review* (4) 2006, Article 7.

¹²⁴ *Supra* n 122, pp. 48-49.

¹²⁵ Office of the High Commissioner for Human Rights. Intellectual Property Rights and Human Rights. Sub-Commission on Human Rights resolution 2000/7.

¹²⁶ *Ibid.*

¹²⁷ *Supra* n 122, p. 55.

to address this conflict. As a result, the Commission on Human Rights adopted three resolutions: access to medication in the setting of epidemic;¹²⁸ an examination of TRIPS and public health by the High Commissioner for Human Rights¹²⁹; and an official Statement by the CESCR which says that IP linked treaties must be in harmony with the provisions of the Covenant.¹³⁰

Another concern is that some developed countries, such as the United States and also a number of European Union countries have signed two-sided treaties called TRIPS-Plus with some developing countries, after the adoption of the TRIPS Agreement.¹³¹ It is a concern, because TRIPS-Plus agreements are much stricter in the sense of IP protection than the original TRIPS Agreement requires. Thus, it is no surprise, that the UN High Commissioner for Human Rights and the World Health Organisation, based on human rights grounds, have articulated strong oppositions to TRIPS-Plus agreements.¹³²

As intellectual property policy has its effect on the direction of innovation in the field of health and it also affects the access to medicines, then it has essential impact on the realisation of the right to health.¹³³ Depending on the way the intellectual property policy is expressed and realised, it can have a positive or a negative role in the society.¹³⁴ The latter became evident in the setting of the world-wide Acquired Immunodeficiency Syndrome (AIDS)/ Human Immunodeficiency Virus (HIV) endemic, which depicted the negative aspect of the patent protection.

Prices for a three-drug combination of anti-retroviral (ARV) HIV therapy in 2000 from patent-holding companies exceeded USD \$10,000 per person per year, ensuring that treatment could not be extended to the vast majority of those living with HIV around the world. Generic

¹²⁸ Resolution 2001/33 U.N. Comm'n. on Human Rights U.N. Doc. E/CN.4/RES/2001/33 (2001); see also Access to Medication in the Context of Pandemics such as HIV/AIDS, Res. 2002/32, U.N. Comm'n. on Human Rights; Res 2003/29.

¹²⁹ High Commissioner Report. Available at <http://www2.ohchr.org/english/issues/globalization/trade/docs/5WTOMinisterialCancun.pdf> (Accessed 17.03.18).

¹³⁰ *Supra* n 122, p. 56.

¹³¹ *Ibid.* p. 59; Generic Resources Action International. TRIPs-plus. Through the Back Door: How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO. 2001.

¹³² *Supra* n 122, p. 59.

¹³³ M. El Said and A. Kapczynski. Access to medicines: The role of intellectual property law and policy. – Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law 2011, p. 1.

¹³⁴ *Ibid.*; World Health Organisation. Commission on Intellectual Property Rights, Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health (“CIPIH report”) 2006.

competition led to precipitous price reductions, so that today treatment can be provided for less than USD \$75 per person per year. This history has contributed to the growing recognition that strong medical patents in developing countries undermine access to medicines and sets the human right to health in danger.¹³⁵

Subsequently, it is obvious that the human right to health is weakened through the limitation of availability that the patent protection offers to the essential medications, especially in the developing countries. Also, it is worth noting that it is not plausible that stronger patent rights in developing countries will lead to any substantial offsetting gains in innovation for the affected countries. Developing countries represent a very small share of the world's pharmaceutical market, meaning that the marginal added value of stronger patent protection will be small, and is unlikely to outweigh the costs to access.¹³⁶

Many developing states had refused, for human rights concerns, from patenting medicinal products before the adoption of the TRIPS Agreement.¹³⁷ Without patent protection, it would have been possible to import generic copies, which would have decreased the prices of medicinal products because of the generic rivalry against the patented medicines.¹³⁸

Nevertheless, this option is not available anymore for TRIPS signatory developing countries and although transition period which lasts until 2033 for least developed countries while they do not have to apply patents on medicines, then it is only a short-term solution.¹³⁹ Initially, this transition period was until 1 January 2006, then it was extended for pharmaceutical patents until 1 January 2016, and then again until 1 January 2033.¹⁴⁰

TRIPS presents for all WTO signatories the obligation to award patents on medications, while establishing a high level of minimum IP protection principles. The flexibilities stemming from Articles 7 and 8 of TRIPS that among other things are used for the purpose of safeguarding public health, can only be used if they are constant with the provisions of the TRIPS.¹⁴¹ The flexibilities stemming from the aforementioned Articles are following: suitable criteria for the

¹³⁵ *Supra* n 133, p. 1.

¹³⁶ *Ibid.*

¹³⁷ *Ibid.* 2.

¹³⁸ M-H. Bonin and R. Elliott. Patents, International Trade Law and Access to Essential Medicines. – Canadian HIV/AIDS Legal Network 2002, pp. 2-3.

¹³⁹ WTO. Responding to least developed countries' special needs in intellectual property. Available at https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (Accessed 17.03.18).

¹⁴⁰ *Ibid.*

¹⁴¹ *Supra* n 2, Article 8.

patentability of medicinal products; effective measures to protect patent quality; and effective protections available after patents have been approved.¹⁴² The problem is that these flexibilities are not used enough and they should be used more, especially in the case of a HIV endemic. Even if TRIPS Agreement offers these flexibilities for the developing states to address the negative effects arising from the patent protection, then it backfires with the administrative burdens associated with these flexibilities.¹⁴³

Moreover, so-called secondary patents are being used by the medicinal industry, which makes it even less inventive.¹⁴⁴ These secondary patents can be used on new methods or practise of already known ingredients.¹⁴⁵ They are regularly effectively used by the medical companies in order to prolong or even gain patent protection for their medicines, which makes the secondary patents somewhat less creative than primary patents.¹⁴⁶

For example. Anti-HIV drug called Efarivenz (from China) had a number of different patents.¹⁴⁷ It is noteworthy that only one patent protected the actual active component. The drug continues to be protected by these so-called secondary patents (for example, one on crystallised forms of the medicine until 2018 and also certain solid dosage forms until 2019.), while the primary or the original patent expired in 2013.¹⁴⁸ Efarivenz is not the only one that enjoys these secondary patents, there is also the anti-HIV drug called Darunavir. Even more peculiar is that there is actually no patent on the active component of the Darunavir. It is solely protected by secondary patents, which offer protection to new recipes and mixtures of this medication, thus averting generic rivalry of this drug in China until 2023.¹⁴⁹

As it can be seen, then there are some points that clash between the medical patents under the intellectual property law on the one hand, and right to health under human rights instruments on the other one. The main problem is that the intellectual property rights can limit and do limit in some cases the availability of the essential medicines, which happens to occur most often in underprivileged countries, namely less developed and developing countries. Thus, it is relevant

¹⁴² *Supra* n 133, p. 3.

¹⁴³ *Ibid.*, p. 2.

¹⁴⁴ World Health Organization, Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Public health, innovation and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health 2006, p. 131; *Supra* n 133, p. 3.

¹⁴⁵ *Supra* n 2, Article 31(1); *Supra* n 133, p. 3.

¹⁴⁶ *Supra* n 2, Article 31(1); *Supra* n 133, p. 4.

¹⁴⁷ *Supra* n 133, p. 4.

¹⁴⁸ *Ibid.*

¹⁴⁹ *Ibid.*

to consider how to address the issue, if possible, so that the intellectual property law and human rights instruments could work in harmony, since the both of them are valuable to the society as a whole.

3 Means to Resolve the Conflict

There is a presumption against conflict in the international law. One way to avoid tension between responsibilities is through treaty interpretation.¹⁵⁰ According to this, norms are interpreted in light of another norm to avoid conflict. For example, where TRIPS gives members some leeway to determine the exact way how to follow their obligations or where it contains unclear terms that need explanation, the right to health may be used in order to notify policy choices and to strike a balance between both obligations.¹⁵¹

In case the treaty interpretation fails, then it is clear that a genuine conflict exists. If that happens, then a series of conflict resolution techniques are available, such as the *lex superior derogat legi inferior*, *lex posterior derogat legi priori*, and *lex specialis derogat legi generali*. The relevance of the latter two methods to actually resolve a conflict here is dubious. The *lex posterior* rule adopts that the contradictory norms originate from the same legislator, which at the moment is not the case, and as such this rule is difficult to apply.¹⁵² The *lex specialis* rule is only appropriate in a situation of conflict amid special and general international law. However, international human rights law and WTO law are subsystems of general international law. Therefore, on this matter, the *lex posterior* and *lex specialis* rules are unproductive conflict resolution techniques.

The best way to resolve the conflict between TRIPS and the right to health would be to form that one of the two norms has a superior position in the international law. That is precisely what some human rights bodies and analysts have reasoned for.

International law distinguishes that some norms are superior to others. *Jus cogens* or peremptory norms are norms “accepted and recognised by the international community of states as a whole as a norm from which no derogation is permitted”.¹⁵³ Generally acknowledged examples include the prohibition of genocide, slavery, torture, racial discrimination and crimes against humanity. Others have added to this list (the prohibition of gross violations of) the right

¹⁵⁰ J. Pauwelyn. *Conflict of Norms in Public International Law. How WTO Law Relates to Other Rules of International Law*. New York: Cambridge University Press 2003, p. 244.

¹⁵¹ X. Seuba. *Mainstreaming the TRIPS and human rights interactions*. – C.M. Correa. *Research handbook on the protection of intellectual property under WTO rules*. 1 *Intellectual property in the WTO*. Cheltenham: Edward Elgar 2010, p. 201.

¹⁵² International Law Commission (2006) *Fragmentation of international law: difficulties arising from the diversification and expansion of international law*. Report of the Study Group of the International Law Commission. Finalised by Martti Koskenniemi. UN Doc A/CN.4/L.682 para. 234

¹⁵³ United Nations. *Vienna Convention on the Law of Treaties*. 1969, Article 53.

to life, dignity and bodily integrity.¹⁵⁴ The Committee on Economic, Social and Cultural Rights finds that the provision of medicines is part of the minimum core content of the right to health and, thus, a non-derogable obligation.¹⁵⁵ International practice, though, proposes a narrow approach to the categorisation of *jus cogens* norms.¹⁵⁶ There is no international consent to extend *jus cogens* status past the prohibitions mentioned above. Furthermore, it is rather uncertain whether the resolve by the CESCR that the core content of a right is non-derogable would lead to the assumption that such core content is consequently a prioritised norm under international law. The ICESCR itself does not officially prioritise certain elements of a right above others, nor does it comprise a provision comparable to the ICCPR disallowing derogations from the rights preserved in the ICESCR. Instead, it provides for the option to enforce restrictions (Article 4 ICESCR). Additionally, the Committee's General Comment No. 14 is not legally binding. Accordingly, there is no proof to suggest that the present list of acknowledged peremptory norms includes the right to health or a right of access to essential or even life-saving medicines.¹⁵⁷

What is more, it has been argued that human rights as a production of United Nation's Charter obligations would enjoy pre-eminence on the basis of Article 103 of the UN Charter.¹⁵⁸ Article 103 states that "in the event of a conflict between the obligations of the members of the United Nations under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail". Obligations stemming from human rights treaties implemented within the UN framework, e.g. ICESCR, are then considered to be duties under the Charter, predominantly under Articles 55 and 56, and would thus prevail over WTO responsibilities. However, this interpretation of Article 103 is not plausible. Article 103 gives predominance to those obligations specifically stated in the UN Charter and originating from obligatory decisions by UN bodies, most especially Security Council resolutions adopted under Chapter VII, but not to human rights treaty duties or non-binding resolutions accepted by UN human rights bodies.¹⁵⁹

¹⁵⁴ F. Viljoen. *International human rights law in Africa*. New York: Oxford University Press 2007, p. 28.

¹⁵⁵ *Supra* n 76, para. 43.

¹⁵⁶ J. Vidmar. Rethinking *jus cogens* after *Germany v. Italy: back to Article 53?*. – 60 *Netherlands International Law Review* 2013, p. 22.

¹⁵⁷ J. Harrison. *The human rights impact of the World Trade Organisation*. Oxford: Hart Publishing 2007, p. 58.

¹⁵⁸ D. A. Yigzaw. Hierarchy of norms: the case for primacy of human rights over WTO law. – 38 *Suffolk Transnational Law Review* (1) 2015, pp. 62-63.

¹⁵⁹ Report of the Study Group of the International Law Commission. *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*. 2006, para 331.

As it is seen above, international law prioritises certain interests over others. Similar is accurate for the CESCR's approach that prioritises certain elements of rights as non-derogable obligations. Nevertheless, there is no proof that international law accepts human rights norms, except *jus cogens*, as higher norms than other international law norms.¹⁶⁰ There is no evidence that the whole international community recognizes the right to health as a peremptory norm. Therefore, *lex superior* rule cannot be used to resolve a conflict between the right to health and patents. Tension must be resolved through treaty interpretation in that case.

The main way, consequently, in which to evade a conflict between TRIPS and ICESCR is in interpreting the TRIPS Agreement in a way which is favourable to endorsing and protecting the right to health and access to medicines.¹⁶¹

International human rights law is not directly applicable within the WTO dispute settlement system. However, the WTO Appellate Body has confirmed that WTO law cannot be read in clinical separation from public international law and also that WTO law should be interpreted in accordance with the customary rules of treaty interpretation, meaning Article 31 and 32 VCLT.¹⁶² The WTO adjudicative bodies may consequently take account of human rights norms when interpreting TRIPS, yet some care is required when comparing an international treaty to which not all WTO members are a party to.¹⁶³ What is more, according to the WTO, the TRIPS Agreement promotes principles which are vital for the realisation of human rights and aims at striking a suitable balance between IP protection and human rights norms.¹⁶⁴ This is also in accordance with the Doha Declaration on TRIPS and Public Health, which is clear in the way in which members should settle any conflict between IPRs and public health. Paragraph 4 of Doha Declaration states that:

“The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner

¹⁶⁰ A. Hallo de Wolf. Human rights and the regulation of privatised essential services. – 60 *Netherlands International Law Review* 2013, pp. 199-200.

¹⁶¹ *Supra* n 117, pp. 293-294.

¹⁶² WTO Appellate Body Report, United States—Standard for Reformulated and Conventional Gasoline, adopted 20 May 1996, WT/DS2/AB/R, p. 17.

¹⁶³ WTO Appellate Body Report, European Communities and Certain Member States—Measures Affecting Trade in Large Civil Aircraft, adopted 1 June 2011, WT/DS316/AB/R, para. 844.

¹⁶⁴ CESCR. Protection of Intellectual Property under the TRIPS Agreement. Background Paper Submitted by the Secretariat of the WTO. UN Doc. E/C.12/2000/18, paras. 13 et seq.

supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

Although indirectly, it is referred here by the Doha Declaration to the promotion and protection of human rights.¹⁶⁵ For example, the Special Rapporteur on the right to health stated that “in this way, the Declaration reflects human rights perspectives, especially the right to health and the right to enjoy the benefits of scientific progress”.¹⁶⁶

Striking a balance between public and private interests is also a field familiar to IP laws. For example, the monopoly position granted to a patent holder is for a limited time and non-renewable, intended to provide creators with the possibility to recoup research and development expenses; in return creators must reveal their inventions, which has been an essential element of patent law since its beginning. Thus, patents aim to provide access to the information in the short term and access to the actual (patented) creation, and future creations, in the long term. Accordingly, the High Commissioner discovered a degree of compatibility between Article 15 and traditional intellectual property systems, yet suggested that the main problem is ‘where to strike the right balance’.¹⁶⁷

Special Rapporteur Anand Grover provided a report to the Human Rights Council in 2009 analysing the effect of the TRIPS Agreement on access to reasonably priced medicines.¹⁶⁸ He stated that “from a right to health perspective, developing countries and least developed countries should be enabled to use TRIPS flexibilities”.¹⁶⁹ He mentioned the following flexibility methods which members should include in their national laws: make full use of the transition periods; define the criteria of patentability; issue compulsory licences and provide for

¹⁶⁵ *Supra* n 151, p. 214.

¹⁶⁶ UN Commission on Human Rights. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, Submitted in Accordance with Commission Resolution 2002/31. UN Doc. E/CN.4/2003/58, para. 87.

¹⁶⁷ UN Sub-Commission on the Promotion and Protection of Human Rights. Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. UN Doc. E/CN.4/Sub.2/2001/13, para. 12.

¹⁶⁸ UN Human Rights Council. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover. UN Doc. A/HRC/11/12 (2009)

¹⁶⁹ *Ibid.* para. 27.

government use; adopt the international exhaustion principle to facilitate parallel importation; create limited exceptions to patent rights; and allow for opposition and revocation procedures.

India, for example, is a country that has taken full advantage of the transition period by allowing product patent protection only in 2005 upon the expiration of its TRIPS deadline.¹⁷⁰ Until that time, it did not permit product patents to be granted to medicines. Accordingly, it was able to develop a sturdy generic pharmaceutical industry.¹⁷¹

The TRIPS Agreement forces members to enforce its provisions, nevertheless it also states that “members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”.¹⁷² Therefore, developing members have a degree of freedom when executing the TRIPS provisions, provided that they stay within the limitations of TRIPS. Article 27.1 of the TRIPS Agreement lays down the conditions with regard to patentable subject matter and conditions for patentability. Although it is not possible to exclude medicines from patent protection anymore, Article 27.1 does not outline the notions of novelty or inventiveness and, consequently, leaves substantial flexibility for WTO members to resolve the way how to implement and interpret this responsibility.¹⁷³

For instance, India’s definition of “inventive step” is exceptional in that it is stricter than in many other countries as it necessitates an invention to include a “technical advance”, “economic significance” or both, in addition to the element that the invention is not obvious to a person skilled in the art.¹⁷⁴

What is more, India also introduced an exclusive section about patentable subject matter. Section 3(d) is one of the most debated amendments made to the Indian Patents Act. It was implemented due to the threat of so-called “evergreening”, which refers to the practice of the pharmaceutical industry to effectively extend the term of protection for patented pharmaceuticals by obtaining related patents for minor modifications made to the original product, new delivery systems for the pharmaceuticals, or new uses of the pharmaceutical. A problem also acknowledged by the Indian Technical Expert Group on Patent Law Issues that

¹⁷⁰ S. Chaudhuri. *The WTO and India’s pharmaceuticals industry. Patent protection, TRIPS and developing countries.* New Delhi: Oxford University Press 2005, pp. 67-68.

¹⁷¹ B. P. Mey. *Unfettered consumer access to affordable therapies in the post-TRIPS era: a dead-end journey for patients? Kenya and India case studies.* – 13 *Journal of World Intellectual Property* (3) 2010, p. 411.

¹⁷² *Supra* n 2, Article 1.1.

¹⁷³ *Supra* n 170, p. 71.

¹⁷⁴ Indian Patents Act 2005, sections 2(1) and 7(1).

stated that ‘every effort must be made to provide drugs at affordable prices to the people of India’.¹⁷⁵ Firstly, section 3(d) forbids patents for derivative, apart from if it can be shown that they provide a considerably enhanced efficiency. It is a provision that is exceptional and does not exist in any other patent regime.¹⁷⁶ The “evergreening” of pharmaceutical patents is made virtually impossible. In addition, section 3(d) encompasses a complete exception to patentability by declaring that the mere discovery of any new property of, or new use for, a known substance is not considered patentable.¹⁷⁷ India’s obstructive position on this subject differs with the tolerant approach in the United States and Europe in patenting subsequent medical usages of known pharmaceuticals.¹⁷⁸

India deliberately implemented TRIPS in a way which seeks to strike a balance between minimum standards of TRIPS and promoting right to health by providing access to medicines. However, this approach is not favoured by everyone and has received disapproval and criticism.¹⁷⁹ Novartis confronted the constitutionality and TRIPS compatibility of section 3(d) when the Indian Patent Office declined to grant a patent for its cancer medicine, Gleevec.¹⁸⁰ The case was contested up to the Indian Supreme Court, which supported the constitutionality of the provision.¹⁸¹ The Supreme Court’s judgment was interpreted as a victory for patients’ right of access to vital medicines by civil society.¹⁸²

3.1 Compulsory Licensing and Doha Declaration

A useful tool for balancing access to medicines and patent protection is found in the Article 31 TRIPS¹⁸³ dealing with the compulsory licensing. The use of this measure occurs when a relevant body gives its permission for a third party to manufacture the patented product or procedure without the permission of the actual patent owner. CL can be used to increase generic production, importation and/or domestic competition and therefore lower the medicine prices.

¹⁷⁵ D. Matthews. The right to health and patents. Legal studies research paper no. 156/2013. London: Queen Mary University of London, School of Law 2013, p. 7.

¹⁷⁶ J. M. Mueller. The tiger awakens: the tumultuous transformation of India’s patent system and the rise of the Indian pharmaceutical innovation. – 68 University of Pittsburgh Law Review 2007, p. 550.

¹⁷⁷ *Ibid.* p. 557.

¹⁷⁸ *Ibid.* p. 557.

¹⁷⁹ *Ibid.* p. 558.

¹⁸⁰ F. A. Khader. The law of patents. With a special focus on pharmaceuticals in India. LexisNexis Butterworths Wadhwa Nagpur, Guragon 2009, pp. 86 et seq.

¹⁸¹ Indian Supreme Court, Novartis AG v. Union of India & Others, Civil Appeal Nos. 2706–2716, 2013.

¹⁸² Médecins Sans Frontières. Indian Supreme Court Delivers Verdict in Novartis Case. Available at <http://www.msfaccess.org/about-us/media-room/press-releases/indian-supreme-court-delivers-verdict-novartis-case> (Accessed 17.03.18).

¹⁸³ *Supra* n 2, Article 31.

Of course, there is a possibility for patent holder to grant a third party a voluntary licence to produce or use its patented product or process. However, pharmaceutical corporations do not always favour this kind of approach which makes the granting of a CL, or merely the threat of it, a useful tool. It is up to the members to decide which grounds a CL is granted upon.

The agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between endorsing access to already obtainable medications and promoting research and development into new drugs. But the term "compulsory licensing" does not appear in the TRIPS Agreement. Instead, the phrase "other use without authorization of the right holder" appears in the title of Article 31.¹⁸⁴ Compulsory licensing is only part of this since "other use" includes use by governments for their own purposes.

Compulsory licensing and government use of a patent without the authorisation of its owner can only be done under a number of conditions in order to defend the reasonable interests of the current patent owner. For example: Normally, the person or company looking to obtain a compulsory licence must have first made an effort, although unsuccessfully, to obtain a voluntary licence from the right holder on reasonable commercial terms — Article 31b.¹⁸⁵ If a compulsory licence is issued, adequate remuneration must still be paid to the patent holder — Article 31h.¹⁸⁶ However, for "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try for a voluntary licence — Article 31b.¹⁸⁷ Compulsory licensing must meet certain additional requirements. In particular, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and usually it must be granted mainly to supply the domestic market.

It is not explicitly stated by the TRIPS Agreement which reasons provide excuse for using CL. In Article 31¹⁸⁸, it does mention national emergencies, other circumstances of extreme urgency and anti-competitive practices — but only as grounds when some of the normal requirements for compulsory licensing do not apply, such as the need to try for a voluntary licence first.

¹⁸⁴ *Ibid.*

¹⁸⁵ *Ibid.* Article 31b.

¹⁸⁶ *Ibid.* Article 31h.

¹⁸⁷ *Ibid.* Article 31b.

¹⁸⁸ *Ibid.* Article 31.

A compulsory license limits the rights of the patent holder, but does not take those rights away. TRIPS therefore specifies the conditions that need to be applied when countries want to grant a compulsory license. An important condition is that each case shall be considered individually. Also, in general, efforts should first be made to obtain a license from the patent holder (a so-called voluntary license), on reasonable terms. What is considered “reasonable” depends on national (case) law.¹⁸⁹

Patent owner is encouraged by the CL provisions to behave correctly. CL prevents the patent owners from misusing the monopoly rights granted to them by giving the patent owner a sign that when the patent rights are abused or the product is made non-available, then a third party could be given a permission to use the invention. CL is a necessary element in IPR law because it has a serious impact on the actual behaviour of the patent owner. Thus, to make sure that this system is used properly, the national legislation has to set the ground and conditions for it in a careful manner, which should include its use for reasons related to public health.¹⁹⁰

According to Doha Declaration the signatory states to TRIPS should be able to take the necessary steps to ensure the protection of public health and also be able to use the flexibilities provided by TRIPS in their full potential. The use of compulsory licenses should not be limited to only if there is a national emergency or any other case of great danger. The States should be able to decide the conditions that will permit the use of CL. It was Doha Declaration that extended the transition period in connection with the patents on drugs in least developed countries until 2016. Then the Council Decision prolonged the transition period until January 2033. Until that time the TRIPS Agreement will not apply to medicinal products in LDCs.¹⁹¹ The LDCs can still make a choice whether they want to implement patent protection for medicines before the deadline of 2033.¹⁹²

As CL is a mean to permit for the production and provident to the domestic market of the State that issues a compulsory license, then the Doha Declaration did not address the problem in connection with the LDCs with deficient or no engineering capability in the medicinal

¹⁸⁹ The TRIPs Agreement and Pharmaceuticals. Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals. Jakarta, 2-4 May 2000.

¹⁹⁰ *Ibid.*

¹⁹¹ WTO. WTO members agree to extend drug patent exemption for poorest members. Available at https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm (Accessed 17.03.18).

¹⁹² *Ibid.*

division.¹⁹³ This problem was addressed by the 2003 waiver Decision¹⁹⁴, which offered an answer for the unsettled matter and allowed for CL to be distributed by exporting countries to qualified countries that do not have the necessary manufacturing capabilities in the medicinal area.

3.1.1 Integrating 2003 Decision into TRIPS

As mentioned above, the 2003 Decision addressed the problem that was left unsettled by the Doha Declaration, specifically the problem of the developing or less developed countries with no capacity to produce the necessary medicine on their own. The answer provided by the 2003 Decision was that the Article 31(f) of the TRIPS was waived so that countries that have the capacity to produce medicines could export their inexpensive medicinal generic products similar to patented products under compulsory licenses also to the less developed and developing countries that have no engineering capability on their own.¹⁹⁵ This means that Article 31(f), which hinders the export of medicines, since it only permits to distribute medicines inside the country that issued a CL, was cast aside by the 2003 waiver Decision to offer an answer to the impoverished countries in order to receive inexpensive generic medications that are similar to patented products from capable countries.¹⁹⁶

Thus, the members of the WTO included on the 6th of December the “waiver” from the 2003 Decision in the TRIPS as a perpetual provision by accepting the alteration of the TRIPS Agreement.¹⁹⁷ Nonetheless, in order for the amendment to take effect and be officially incorporated into the TRIPS Agreement, the requirement was that at least two thirds of the members of the WTO had ratified the relevant provision. This was not achieved until 23rd of January 2017, when the needed quantity of States had finally ratified the innovative provisions.¹⁹⁸ It should be noted that the original deadline to do that was 1st of December 2007.¹⁹⁹ However, even if two thirds of the members of WTO have ratified the provision, then

¹⁹³ WTO Ministerial Conference. Doha Declaration on the TRIPS Agreement and Public Health. 2001, para 6; *Supra* n 2, Article 31(f).

¹⁹⁴ WTO. Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. Available at https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (Accessed 17.03.18).

¹⁹⁵ *Ibid.*

¹⁹⁶ *Ibid.*; *Supra* n 2, Article 31(f).

¹⁹⁷ WTO. Members OK amendment to make health flexibility permanent. Available at https://www.wto.org/english/news_e/pres05_e/pr426_e.htm (Accessed 17.03.18).

¹⁹⁸ WTO. WTO IP rules amended to ease poor countries’ access to affordable medicines. Available at https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm (Accessed 17.03.18).

¹⁹⁹ WTO. Amendment of the TRIPS Agreement. Para 3. Available at https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (Accessed 17.03.18).

the new provisions apply only in the countries that recognised the amendment, thereby replacing the 2003 Decision. Because of this, by the decision of 30 November 2017 of the General Council, the period for acceptances of the Amendment by the WTO Members was extended for the sixth time, until the 31st of December 2019 to enable for the rest of the Members to accept the amendment.²⁰⁰

It is required for the members of the WTO, who are planning to export using the “waiver” from the 2003 Decision, and indirectly the newly incorporated Article 31bis of the TRIPS, to alter their domestic legislation also, so they could actually make use of the amendment of the TRIPS Agreement and the new provisions in it. TRIPS Council has been officially informed, so far, by a rather small number of the members of the WTO, who have made the relevant changes in their domestic legislation, so that they could export medicinal products to countries who need them by using the new provisions applied to compulsory license, for example Canada, EU, India and Norway.²⁰¹ EU Member States have affirmed that they have officially recognised the alterations in TRIPS and affirmed that it will apply to the European Union as a whole.²⁰²

It is worth mentioning, that some States have proclaimed from the beginning, that the system is not planned to be used to import²⁰³, also a quantity of States have declared to plan to use this system in cases of crises or other tremendously crucial circumstances.²⁰⁴

By amending the TRIPS Agreement and adding the Article 31bis, the 2003 Decision, which contained the “waiver”, was finally integrated with the TRIPS. This was done to address the issue of the fact that the compulsory license did not provide any help to countries that have limited capacity to produce essential medicines on their own, usually these being less developed and developing countries of the WTO.

Article 31bis consists of five paragraphs, which of four are relevant to the study. First one allows for the developed countries which contain medical patents to hand out CL for the production and exportation of the needed drugs to the qualified countries which have no capacity to produce these drugs on their own. The second paragraph deals with compensation

²⁰⁰ WTO. Amendment of the TRIPS Agreement. Available at https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (Accessed 17.03.18).

²⁰¹ *Supra* n 197.

²⁰² *Supra* n 200.

²⁰³ *Supra* n 197.

²⁰⁴ *Ibid.*

to the current patent owner and it says that in a case when CL is handed out in the exporting State, then the compensation that considers the financial worth to the country the drug is exported, should be paid to the patent owner. This compensation does not have to be paid if the same product is already allowed under CL in the country that receives the drug from the exporting State. According to the third paragraph, the responsibility under Article 31(f) will not apply for the importing Member, if a developing or a less developed WTO Member State is at the same time a part of a local trade treaty. It only applies to the degree required to permit the medicinal goods manufactured or distributed to the relevant country under a CL to be transferred to other LDCs or developing states that are part of the local trade treaty and are troubled by the similar health issue. In paragraph four it is specified that no challenges should be taken by WTO Member States against any measures that will be afterwards taken in conformity with the TRIPS Agreement's Article 31bis and its Annex.²⁰⁵

3.1.2 About the Amendment

The Sixth WTO Ministerial Conference permitted the proposal to transform the Waiver Decision into a permanent alteration to the TRIPS Agreement²⁰⁶. The alteration could be formally adopted only after acceptance by two-thirds of the WTO members.

The two-thirds threshold for official adoption of the alteration was recently met and the amendment entered into force on 23 January 2017. The new Article 31bis allows developing and LDCs facing public health problems and lacking drug manufacturing capacity to import such drugs from third-country producers under compulsory licensing measures.

This flexibility, nevertheless, is not unconditional. Abundant conditions are imposed by Article 31bis (and the related Annex) and the derogation to Article 31(f) applies only "to the extent necessary to enable a medicinal product produced or imported under a compulsory licence in that member to be exported to the markets of those other developing or LDC parties to the local trade arrangement that share the health problem in question"²⁰⁷. Only eligible countries, either LDCs or developing countries with insufficient or no drug manufacturing capacity, are entitled to use the waiver²⁰⁸.

²⁰⁵ *Supra* n 199, para. 4.

²⁰⁶ WTO. AMENDMENT OF THE TRIPS AGREEMENT. Decision of 6 December 2005. WT/L/641.

²⁰⁷ *Supra* n 2, Article 31bis (3).

²⁰⁸ *Ibid.* Article 31bis (1).

Some of the noteworthy conditions attached to Article 31bis are as follows:

1. Before applying to the administration for a compulsory licence, the generic drug engineering business in the exporting country is required to negotiate a voluntary license with the patent holders.
2. The importing member states are required to provide a general announcement of intent. The qualified importing country must provide certain specified information to the Council, for example the specific name of the required medication and the expected amount of the medication. The announcement of intent is, nevertheless, not compulsory for LDCs.
3. The generic drug engineering firm, in the exporting country, is required to apply for two compulsory licenses: one in the exporting country, or home country, and one in the importing country, if the needed medication is also patented in the importing state.
4. The exporting country must also let the Council know about the grant of the compulsory license; the announcement must encompass the following mandatory information: the name and address of the licensee, the products, the quantity granted, the state to which the product is to be delivered, the period of the license, and the address of the website where the provider will post the data mentioned in paragraph 2(b)(iii) of the Annex.
5. There is an additional requirement for the exporting country to uphold a distinction (unique shape, colour, size or characteristic outer wrapping or even a dissimilar trade mark) between the generics factory-made for national use and the generics engineered for export. The justification for this distinction is to prevent abuse of Article 31bis.

The waiver in question is seen as a rare negotiation victory for third world countries. Unfortunately, the modification is not likely to make the desired real-world impact because of the overly burdensome bureaucracies that supplement it. The requirement of negotiating a voluntary license is a supplementary encumbrance that is likely to cause postponement to timely access to the immediately needed medication. Given this encumbrance, the generic engineering businesses may choose not to partake in the procedure.²⁰⁹

Additionally, the compulsory licenses required for using the waiver flexibility are required to be granted only for a prearranged time period. The grant of a compulsory license, within the overall system of the TRIPS Agreement, itself includes numerous time-consuming legal, administrative and procedural requirements. These may discourage the generic manufacturing

²⁰⁹ M. Z. Abbas and S. Riaz. Compulsory licensing and access to medicines: TRIPS amendment allows export to least-developed countries. – 12 *Journal of Intellectual Property Law & Practice* (6) 2017, pp. 451-452.

businesses from pursuing dual compulsory licenses. The limited length of the licenses may further aggravate this consequence. The disturbance to renew the compulsory license for restricted periods seems to be an administrative encumbrance, as the issue of admittance to the necessary medication is probable to remain sturdy as long as the medication patent is in effect.²¹⁰

Lastly, the limit on the amount of medications that can be mass-produced for export under Article 31bis appears to be irrational. Giving a clear estimation of the amount of the necessary medication, particularly in the case of epidemics and endemics, is almost unmanageable. If the requirement surpasses the predicted quantity, the burdensome endorsement procedure needs to be repeated for the acquisition of more medications. The supplementary encumbrance of compliance with the burdensome anti-diversion measures, which not only add to the price of manufacture but can also lead to lawsuit, may further dishearten generic drug producers from partaking in the regime.²¹¹

The waiver flexibility was envisioned to provide a speedy resolution to the problem of inexpensive admittance to indispensable medications, particularly in emergency circumstances. As argued above, the effectiveness of Article 31bis is expected to be hindered by the tiresome and needlessly burdensome endorsement procedures. Technical details and bureaucracies may dishearten the generic drug producers from using this provision.²¹²

The use of this flexibility also requires specific changes to domestic patent laws. LDCs seriously lack technical know-how in intellectual property and most of them have failed to incorporate this difficult provision in their domestic patent laws. As of February 2017, the waiver flexibility has been used only one time. This establishes that it did not offer a practical resolution to the problem emphasised in Paragraph 6 of the Doha Declaration. Making this flexibility a long-lasting resolution, without making changes to address the above-mentioned distresses, is doubtful to have any considerable real-world importance. Inexpensive admittance to indispensable medications may remain a dream for impoverished nations despite altering the TRIPS to explicitly address this problem.²¹³

²¹⁰ *Ibid.*

²¹¹ *Ibid.*

²¹² *Ibid.*

²¹³ *Ibid.*

3.2 Integration of TRIPS in the EU

It has been established above that because of the world-wide applicability of both human rights and intellectual property rights related provisions, the access to patented medications and the right to health is governed by the international law. Because of this, the Institutions of the European Union have integrated 2003 Decision by adopting two Regulations. In order to integrate the “waiver” from 2003 Decision into the laws of the European Union, EU set up an extensive basis to make sure that the poverty is decreased in connection with prices on different essential medicines.²¹⁴ The Regulations adopted belonged to the broader action strategy of the European Commission in 2001, which dealt with TB, malaria and HIV/AIDS.²¹⁵ First regulation is to avoid trade diversion into the EU of certain key medicines (Council Regulation (EC) 953/2003)²¹⁶ and the other one is on compulsory licensing of patent relating to the manufacture of pharmaceutical products for export to countries with public health problems (Regulation (EC) No. 816/2006).²¹⁷

3.2.1 EU Regulation to Avoid Trade Diversion of Key Medicines

A legislative act was suggested by the Commission to European Council and to the Parliament in 2001. The purpose of this act was to set up a global tiered pricing system for the most impoverished developing countries of the most important medications which prevent, diagnose and treat TB, malaria and HIV/AIDS and other similar diseases.²¹⁸ The idea was to set effective safeguards in place to prevent the spread of generic or cheaper medicines to other markets.²¹⁹ The idea of the Regulation 953/2003 was to make the producers of medications to increase the obtainability of drugs, which can be achieved by lowering the prices in developing states, and to also enhance the number of drugs being exported to the relevant countries, with that in mind that these medications would stay in the markets they were actually meant for.²²⁰

²¹⁴ European Commission. EXECUTIVE SUMMARY OF THE REFIT EVALUATION of the Council Regulation (EC) 953/2003 to avoid trade diversion into the European Union of certain key medicines. COMMISSION STAFF WORKING DOCUMENT 2016.

²¹⁵ *Ibid.*

²¹⁶ Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines.

²¹⁷ Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, para. 7.

²¹⁸ *Supra* n 216, preamble, para. 1.

²¹⁹ *Ibid.*

²²⁰ *Supra* n 214.

Therefore, the Regulation stressed that the necessary cheap drugs which were meant for underprivileged markets would not leave those markets, which could harm the price of these drugs in developed countries. It also recognised for enhanced action on TB, malaria and HIV/AIDS.²²¹ It should be noted that this Regulation in connection with pharmaceuticals did not extend to drugs carried by travellers meant for non-commercial individual use within the allowed limits set up by the customs duty.²²²

Both generic drugs and patented drugs were governed by the provisions of the Regulation, which means that both of them are valid for registration.²²³ Annex II to the Regulation provided a list of states of destination.²²⁴

It was prohibited by the Regulation, as a general responsibility, to import tiered priced medications into the European Union with the objective of releasing them into free circulation, repetitive export, putting them under suspensive processes or putting them in a free warehouse or free zone.²²⁵ Nevertheless, there were exceptions for some fixed circumstances, however, one has to keep in mind that safeguards were in place so that the medication would reach the destination that were provided in the Annex II.²²⁶

Commission encompassed the Regulation in its regulatory fitness and performance programme of 2013 (REFIT).²²⁷ Nonetheless, Regulation's mechanism has not been used much so far. For example, it was used by GlaxoSmithKline (GSK). After GSK had used this mechanism and registered its medicines under the relevant instrument, the outcome was a progressive, but considerable deterioration of the sale volumes.²²⁸ Because of this, it was found necessary to assess the functioning and influence of the incident in order to find out why the Regulation was not used as much.²²⁹

In July 2015, the assessment of the Regulation finally occurred. The assessment included five aspects (originally four, but one was added). These were effectiveness, efficiency, coherence, relevance, and the additional one: against the REFIT purposes, which takes into account

²²¹ *Supra* n 216, preamble, para. 2.

²²² *Ibid.* Article 10.

²²³ *Supra* n 214.

²²⁴ *Ibid.*

²²⁵ *Supra* n 216, Article 2.

²²⁶ *Ibid.* preamble, para. 9

²²⁷ *Supra* n 214, p. 2.

²²⁸ *Ibid.*

²²⁹ *Supra* n 214, p. 1.

whether it is suitable for objective, if the purpose can be served at lowest prices, and its prospective to be simplified.²³⁰

On the first criteria, effectiveness, there was no evidence to suggest that the registered products according to Regulation found their way back to European Union, this took into account the fact that supplementary measures were taken by GSK for the purpose to avert the product diversion. It was additionally found, among other things, that the price drop happened, which was not naturally because of the Regulation's effect; the stock of HIV/AIDS medications by the GSK was amplified to targeted States because of the Regulation, and because the corporation gave licenses to generic manufacturers, then more GSK's medications were supplied, which resulted in GSK's meaningful contribution to curing HIV.²³¹

On the second criteria, efficiency, the Commission was found, in operating the system, to only sustain administrative expenses. Extra costs were incurred solely by the pharmaceutical company GSK, which stemmed from addition of the logo and registration of its products through the Commission. The additional profits from the regulation were: the prices of drugs which were sold to developing states became more transparent; because of the decrease of need for GSK to implement other more costly processes to refrain from diversion of products to other markets, there was a counterweighing of expenses. It was established that European Union's expenses were in balance with the Regulation's profits.²³²

In regards, with the third criteria, coherence, it was established that the Regulation fitted with other European Union strategies and it is harmonious with European Union's responsibilities in the international level of public health and progress.

On relevance, which is the fourth criteria, it is suggested that the Regulation is not that relevant any more, since there is a low chance of the TB, malaria and HIV/AIDS medications to be diverted. Nevertheless, tiered pricing is still considered to present an important contribution. Nevertheless, it has been recognised that tiered pricing still presents an important influence to the over-all admittance to medications.²³³

All in all, it was determined by the evaluation, according to the four key aspects, that the Regulation is of restricted significance and has no noteworthy net profits. Nevertheless, the

²³⁰ *Ibid.* p. 3.

²³¹ *Ibid.*

²³² *Ibid.*

²³³ *Ibid.*

prices of upholding it are correspondingly limited and, most notably, reasonable. Additionally, evaluation against the REFIT purposes revealed that making the drugs accessible in the underprivileged developing states is pertinent, there is significance in the tiered pricing which is supported by the European Union through the Regulation. Thus, the elimination of the Regulation could send out a false signal that European Union does not support the notion of tiered pricing, because it was thanks to the Regulation that sent the businesses a message about this system. Consequently, it can be said that there is no harm in upholding the Regulation, since it is not that burdensome and costly.²³⁴

In 2016 the Regulation of 953/2003 was repealed and replaced by the Regulation 2016/793. This was done because the Regulation 953/2003 had been substantially amended several times, so in the interests of clarity and rationality, the Regulation was codified by Regulation 2016/793.²³⁵ Since 2016/793 is a codification of the 953/2003, then the essence of the initial Regulation remains in force.

3.2.2 EU Regulation on Compulsory Licensing

Members of the WTO were granted by the Doha Declaration the chance to hand out compulsory licenses as well as the liberty to decide on their own which grounds satisfy the approval of this license.²³⁶ For the purpose of helping out the members of the WTO who are not capable of producing their own medications, the WTO General Council approved after the Doha Declaration a Decision in 2003. In this Decision lies an opportunity to set aside some of the obligations that the TRIPS Agreement establishes in connection with the compulsory licenses.²³⁷

In 2006 European Union the legislation of EU was complemented with the purpose of complying and at the same time implementing the Decision of 2003.²³⁸ This was done by the European Parliament and Council by approving the Regulation 816/2006 which deals with enabling the lifesaving medication to be exported to states that cannot produce them on their own under compulsory licensing. It can be said that the regulation was one of the measures of the European action plan which was aimed to deal with less developed and developing countries

²³⁴ *Ibid.*

²³⁵ REGULATION (EU) 2016/793 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines (codification) (1).

²³⁶ *Supra* n 217, para. 1.

²³⁷ *Ibid.* para. 2

²³⁸ *Supra* n 197; *Supra* n 206.

that are struggling with public health issues.²³⁹ With the purpose of reaching identical conditions in the European Union market and to avoid competition's distortion, the regulation of compulsory licenses that enables medicines' production and export, was welcomed.²⁴⁰ This Regulation helps in a broader sense to deal with the issue of availability of inexpensive medications in the less developed and developing countries.

Similarly to Regulation 2016/793, the Regulation 816/2006 contains the same principle of disallowing the medicinal merchandise that was produced and exported under the compulsory license to the country of low capacity of production, to flow back to the European Union so that this product could be released for free circulation.²⁴¹ Regulation 816/2006 also pays in mind, in order to avoid facilitating overproduction and possible diversion of products, the parallel applications indicated by the applicant and already present compulsory licenses for the same goods and states.²⁴²

Regulation's key points are the following:

- The importing countries eligible to benefit from the scheme are:
 - the world's least developed countries;
 - those which have informed the World Trade Organization of their intention to do so;
 - those listed in the OECD development assistance committee list of low-income countries.
- The importing countries must confirm they will use the scheme for public-health purposes, not for industrial or commercial objectives.
- Any person who has failed to secure authorisation from the patent holder may submit a request for a compulsory licence to the relevant national authority.
- They must provide personal details, information on the product, the amount they intend to produce and the destination countries.
- This must be backed by a specific request from the country concerned, a non-governmental organisation or a United Nations body.
- The relevant national authority in the EU informs the rights-holder and verifies the validity of the request before taking a decision.

²³⁹ *Supra* n 217, para 5, Articles 10(4) and 13.

²⁴⁰ *Ibid.* para 4.

²⁴¹ *Ibid.* Article 13.

²⁴² *Ibid.* para 11.

- Conditions attached to the compulsory licence determine the quantities involved and duration of the concession. Products made under licence must be clearly identifiable by specific labelling or marking.
- Products manufactured under a compulsory licence may not be reimported and sold in the EU. Any suspected of breaking the law may, initially, be detained for 10 days and ultimately seized.
- A licensee failing to respect the conditions of a compulsory licence may find it reviewed and even terminated.²⁴³

The Regulation establishes a procedure for companies in the European Union wishing to manufacture generic medicines for use in the developing world to apply for a compulsory licence from a patent holder, which allows their manufacture.²⁴⁴ Thus, it is up for the domestic authority (Commission must be notified of the chosen relevant body by the State)²⁴⁵ to decide who to hand out compulsory licenses according to its domestic patent related legislation.

This system allows to import into the following countries: any least-developed country appearing as such in the United Nations list; any member of the WTO, other than the least-developed country members referred to in the previous point, that has made a notification to the Council for TRIPS of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way; any country that is not a member of the WTO, but is listed in the OECD Development Assistance Committee's list of low-income countries with a GNP per capita of less than 745 US dollars, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

However, any WTO member that has made a declaration to the WTO that it will not use the system as an importing WTO member is not an eligible importing country.²⁴⁶

Article 5 deals with the extension to least-developed and developing countries which are not members of the WTO. By this article the relevant country will notify the Commission and state that it has public health issues and will not use this measure for commercial purposes.²⁴⁷

²⁴³ *Ibid.*

²⁴⁴ *Ibid.* Article 1.

²⁴⁵ *Ibid.* Article 3.

²⁴⁶ *Ibid.* Article 4.

²⁴⁷ *Ibid.* Article 5.

According to Article 6 of the Regulation, anyone can file their request to receive a CL to a relevant body in the country or countries that allow patents or other protections. It is further required for the applicant that submits CL requests in multiple countries for the identical merchandise, to mention in every application of this intention with the detailed amounts of the product and the countries that the product is going to be imported to.²⁴⁸

Article 8 of the Regulation deals with the verification. This Article requires that the competent authority shall verify that each importing country cited in the application which is a WTO member has made a notification to the WTO pursuant to the Decision, or each importing country cited in the application which is not a WTO member has made a notification to the Commission pursuant to this Regulation in respect of each of the products covered by the application that:

- stipulates the names and probable amounts of the merchandise desired;
- except the importing state is a LDC, proves that the country is not capable the produce the necessary pharmaceutical on their own according to the Decision's Annex;
- proves that in case there is patent protection on the medication in the country of destination, then the relevant authority in that country has already issued a compulsory license or is planning to do it in the near future, so that the merchandise could be imported.²⁴⁹

Article 9 is about prior negotiation. By this article, it is required by the applicant to provide evidence to the authority about the fact that the applicant has negotiated with the current patent holder and these negotiations have failed. This cannot be done until a 30 day period has passed until the application for the CL. Nevertheless, this requirement can be ignored if a national emergency or something similar occurs, also if it is used non-commercially for the public purposes by following the Article 31(b) of TRIPS.²⁵⁰

Article 10 deals with compulsory license conditions. According to this Article, the license granted is generally non-assignable and non-exclusive. It is required not to produce more under the license that the importing country actually needs, while also keeping in mind the production of similar goods under the CL in other places. There has to be a set deadline for the license. The product can strictly be sold only in the market it is meant for and should not be sold in other

²⁴⁸ *Ibid.* Article 6.

²⁴⁹ *Ibid.* Article 8.

²⁵⁰ *Ibid.* Article 9.

markets, however an exception could allow to export from the imported country to a place that shares the same health problem, if necessary. There are a number of requirements for the packaging of the product manufactured under the CL, for example, it has to be clear that the product is subject to compulsory licensing. Before, distribution to the relevant country, the license holder will also have to post some information on the website (for example, quantity of the product), of which address has to be communicated to the relevant body. If it happens that the product is also patented in the country that it is distributed, then CL must be granted in that country before the import. It is possible for the relevant authority to check the documentation held by the CL holder to check whether the strict requirements stemming from the legislation is being followed. The license holder is the one responsible that the patent owner is being compensated.²⁵¹

The relevant body can choose to terminate the license under Article 16, if the license holder is not following the proper conditions. It is up to the competent authority to analyse and decide if the Regulation respected by the license holder, which can be done at the request of the patent holder or the licensee. When the license is terminated, then it can be that the licensee has to redirect on his own expenses the product to the places that need it or dispose of it, which is orchestrated by the competent authority. If it happens that the exported amount of medicine falls short of the needs of the country with the health problem, then the competent authority can modify the license to allow more of the product to be produced and exported. This application is then processed in a quicker and simpler manner.²⁵²

Additionally, Article 17 deals with the appeals against the competent authority.²⁵³ Article 18 is about safety and efficacy of medicinal products.²⁵⁴ And finally, Article 19 is about review, which requires for the Commission to file a report to the relevant bodies in regards of the functioning of the Regulation at hand with proposals (if any) for modifying the Regulation.²⁵⁵

It can be seen in the example of the Regulation in question, that the European Union has taken the incorporation of the 2003 Decision into its legislation quite seriously. This is because they have set in place a legal framework with strict provisions to address the issue of medicine

²⁵¹ *Ibid.* Article 10.

²⁵² *Ibid.* Article 16.

²⁵³ *Ibid.* Article 17.

²⁵⁴ *Ibid.* Article 18.

²⁵⁵ *Ibid.* Article 19.

availability. Thus, EU is providing its contribution in improving the health in developing or less developed countries that have no capacity to produce essential medications on their own.

Conclusion

The clash between the human right to health under the human rights instruments, such as the International Covenant on Economic, Social and Cultural Rights, and the intellectual property protection offered by the patents under the TRIPS Agreement, has been an issue for the less developed and developing countries for quite some time. This was most obvious in the case of HIV/AIDS epidemic in the underprivileged countries, where the essential medicines were not available because of the patent protection, which impeded the human right to health.

On the one hand, patent protection is necessary. This is because of the fact that patent protection is supposed to encourage innovation. If there would be no patent protection, then the companies would lose interest to put their efforts in research and development of different life-saving drugs. They do this research, because they know, that if they discover something new, then they can patent it and through this they gain a monopoly status to sell their original product on the market without market competition.

The first chapter of the thesis opens up the essence of the intellectual property. It brings out that the Article 27 of the TRIPS Agreement states that there is a patent protection to all fields of technology. This means that the inventors can protect their ideas even if it is in the field of pharmaceuticals.

The similar protection is provided under the Article 52 (1) of the EPC, which states that European patents shall be granted for any invention in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. The European Biotechnology Directive goes beyond and creates the presumption that biological inventions are patentable subject matter.

TRIPS application in the EU has been somewhat confusing, as it was decided in the CJEU's latest relevant judgment that after the entry into force of the Lisbon Treaty on 1 December 2009, the provisions of the TRIPS Agreement fall within the scope of the EU's common commercial policy, which left aside the calm waters laid down by Opinion 1/1994 and its saga.

The importance of patent protection, however, is essential, since as depicted in the first chapter, then the research and development costs of producing something new can be quite burdensome and the enterprises that deal with innovative ideas expect something in return, which is the

monopoly status that the patent protection offers. Without the patent protection, the companies would have no choice but to use trade secrets in their doings. However, this would impede innovation, since, as it is known, then when one applies for the patent, then one has to reveal the patentable product in a manner, that a skilled person could replicate the product if following the instructions provided by the applicant. Also, patent procedure is quite a complex and somewhat expensive procedure, which means that patents are not handed out randomly. Only products that satisfy the conditions of a patent system, for example novelty, can enjoy the protection that it offers.

It is considered in the second chapter, on the other hand, that human right to health is an important right as well with a moral purpose – so that the society could live its life in dignity. Worldwide, this right was first expressed in the Constitution of the World Health Organization, which defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. What is more, it states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

Universal Declaration of Human Rights also stated health as part of the right to an adequate standard of living. However, as the name suggests, it is a declaration and thus, not binding. But Universal Declaration of Human Rights did serve as a basis to produce a treaty that is binding on its member states, namely International Covenant on Economic, Social and Cultural Rights, which in its Article 12 ICESCR recognises and defines the right to health. Article 12 of the Covenant recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. "Health" is understood not just as a right to be healthy, but as a right to control one's own health and body, and be free from interference such as torture or medical experimentation. Article 12.2 requires parties to take specific steps to improve the health of their citizens, including reducing infant mortality and improving child health, improving environmental and workplace health, preventing, controlling and treating epidemic diseases, and creating conditions to ensure equal and timely access to medical services for all. These are considered to be "illustrative, non-exhaustive examples", rather than a complete statement of parties' obligations.

Also, the European Union recognises the right to health in the Charter of Fundamental Rights of the European Union. The Charter brings together the fundamental rights of everyone living in the European Union. According to the Charter of Fundamental Rights of the EU everyone

has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

It is required that medicines must be available, accessible, acceptable and of decent quality. Available means that functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party, however, this is connected to the capacity of a State to offer these facilities. Accessible means that health facilities, goods and services have to be available to everybody indiscriminately, within the authority of the State party. Acceptability means that all health facilities, goods and services must be respectful of medical morals and ethnically suitable. Quality indicates that as well as being ethnically adequate, health facilities, goods and services must also be scientifically and medically fitting and of decent quality.

Since the right to health is included in a number of international human rights treaties, then it is first and foremost the states' obligation to enforce the right to health and human rights standards in their respective territory. ICESCR demands states to realise the right to health, but it also takes into account the assets of the relevant country. This, however, does not mean that the states can sit still and do nothing, they must take reasonable steps in their respective capacity to strive in the direction of the full realisation of the right to health. States have three different responsibilities, firstly, the responsibility to respect, secondly protect, and lastly, fulfil.

In the third chapter, the means to resolve the conflict that the countries can use, are brought out. There is a presumption against conflict in the international law. One way to avoid tension between responsibilities is through treaty interpretation. According to this, norms are interpreted in light of another norm to avoid conflict. For example, where TRIPS gives members some leeway to determine the exact way how to follow their obligations or where it contains unclear terms that need explanation, the right to health may be used in order to notify policy choices and to strike a balance between both obligations.

International law prioritises certain interests over others. Nevertheless, there is no proof that international law accepts human rights norms, except *jus cogens*, as higher norms than other international law norms. There is no evidence that the whole international community

recognizes the right to health as a peremptory norm. Therefore, *lex superior* rule cannot be used to resolve a conflict between the right to health and patents.

The main way, consequently, in which to evade a conflict between patent law and human right to health is in interpreting the TRIPS Agreement in a way which is favourable to endorsing and protecting the right to health and access to medicines.

The excellent use of treaty interpretation has been made in India. India, for example, is a country that has taken full advantage of the transition period by allowing product patent protection only in 2005 upon the expiration of its TRIPS deadline. Until that time, it did not permit product patents to be granted to medicines. Accordingly, it was able to develop a sturdy generic pharmaceutical industry. Also, India's definition of "inventive step" is exceptional in that it is stricter than in many other countries as it necessitates an invention to include a "technical advance", "economic significance" or both, in addition to the element that the invention is not obvious to a person skilled in the art.

A useful tool for balancing access to medicines and patent protection is found in the Article 31 TRIPS dealing with the compulsory licensing. The use of this measure occurs when a relevant body gives its permission for a third party to manufacture the patented product or procedure without the permission of the actual patent owner. CL can be used to increase generic production, importation and/or domestic competition and therefore lower the medicine prices. Compulsory licenses, however, are not handed out easily, since they can limit patent holders rights. In cases of national emergencies, nevertheless, compulsory license can be justified.

According to Doha Declaration the signatory states to TRIPS should be able to take the necessary steps to ensure the protection of public health and also be able to use the flexibilities provided by TRIPS in their full potential. The use of compulsory licenses should not be limited to only if there is a national emergency or any other case of great danger. The States should be able to decide the conditions that will permit the use of CL.

As compulsory license is a mean to permit for the production and provident to the domestic market of the State that issues a compulsory license, then the Doha Declaration did not address the problem in connection with the less developed countries with deficient or no engineering capability in the medicinal division. This problem was addressed by the 2003 waiver Decision, which offered an answer for the unsettled matter and allowed for compulsory license to be

distributed by exporting countries to qualified countries that do not have the necessary manufacturing capabilities in the medicinal area.

The answer provided by the 2003 Decision was that the Article 31(f) of the TRIPS was waived so that countries that have the capacity to produce medicines could export their inexpensive medicinal generic products similar to patented products under compulsory licenses also to the less developed and developing countries that have no engineering capability on their own. This means that Article 31(f), which hinders the export of medicines, since it only permits to distribute medicines inside the country that issued a CL, was cast aside by the 2003 waiver Decision to offer an answer to the impoverished countries in order to receive inexpensive generic medications that are similar to patented products from capable countries.

The 2003 Decision was also incorporated into the TRIPS Agreement in 2017, when the two thirds of WTO members ratified the new provisions. By amending the TRIPS Agreement and adding the Article 31bis, the 2003 Decision, which contained the “waiver”, was finally integrated with the TRIPS. This was done to address the issue of the fact that the compulsory license did not provide any help to countries that have limited capacity to produce essential medicines on their own, usually these being less developed and developing countries of the WTO.

Article 31bis consists of five paragraphs, which of four are relevant to the study. First one allows for the developed countries which contain medical patents to hand out CL for the production and exportation of the needed drugs to the qualified countries which have no capacity to produce these drugs on their own. The second paragraph deals with compensation to the current patent owner and it says that in a case when CL is handed out in the exporting State, then the compensation that considers the financial worth to the country the drug is exported, should be paid to the patent owner. According to the third paragraph, the responsibility under Article 31(f) will not apply for the importing Member, if a developing or a less developed WTO Member State is at the same time a part of a local trade treaty. In paragraph four it is specified that no challenges should be taken by WTO Member States against any measures that will be afterwards taken in conformity with the TRIPS Agreement’s Article 31bis and its Annex.

In order to integrate the “waiver” from 2003 Decision into the laws of the European Union, European Union set up an extensive basis to make sure that the poverty is decreased in

connection with prices on different essential medicines. The Regulations adopted belonged to the broader action strategy of the European Commission in 2001, which dealt with TB, malaria and HIV/AIDS. First regulation is to avoid trade diversion into the EU of certain key medicines (Council Regulation (EC) 953/2003), which, in 2016 was repealed and replaced by the Regulation 2016/793. This was done because the Regulation 953/2003 had been substantially amended several times, so in the interests of clarity and rationality, the Regulation was codified by Regulation 2016/793. Since 2016/793 is a codification of the 953/2003, then the essence of the initial Regulation remains in force. The other Regulation is on compulsory licensing of patent relating to the manufacture of pharmaceutical products for export to countries with public health problems (Regulation (EC) No. 816/2006).

For conclusion, it can be said that even if there are tensions between the human right to health and the patent law, then the World Trade Organisation and European Union are dealing with reducing the conflict between them. This is seen in the various ways that the TRIPS can be interpreted and is encouraged to be interpreted by the WTO, as well as the recent amendment in the TRIPS Agreement that extend the limits of the compulsory license, so that the products could be exported to the countries in need. This is also welcomed in European Union, as the EU added two relevant Regulations to its legislation to accept the changes made in TRIPS Agreement in connection with the compulsory license. It is, however, still troubling that the various means to resolve the clash has not been used as much as desired. The reason could be that the system is still perhaps too complex and time-consuming or that the countries that have health issues are not competent enough to effectively take use of these measures.

Abbreviations

CESCR	Committee on Economic, Social and Cultural Rights
CJEU	Court of Justice of the European Union
CL	Compulsory License
EC	European Commission
EP	European Parliament
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GSK	GlaxoSmithKline
HIV/AIDS	Human immunodeficiency virus infection/acquired immunodeficiency syndrome
ICESCR	International Covenant on Economic, Social and Cultural Rights
IP	Intellectual Property
IPR	Intellectual Property Right
LDC	Least Developed Countries
OECD	Organization for Economic Co-operation and Development
R&D	Research and Development
SME	Small and Medium-sized Enterprises
TB	Tuberculosis
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration on Human Rights
UN	United Nations
VCLT	Vienna Convention on the Law of the Treaties
WTO	World Trade Organization
WTO	World Trade Organization

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