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A COMPARATIVE ANALYSIS OF THE LEGALITY CONCERNING COMPULSORY LICENSING IN DEVELOPED AND DEVELOPING COUNTRIES

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ABSTRACT

The purpose of this research is to understand the legality concerning compulsory licensing provisions and its legality in terms of international regulations, conventions and agreements between the developed and the developing nations in the world. The goal of this research paper is to reach a conclusion whether the actual usage of compulsory licensing by governmental institutions would constitute a breach of several patent protection law agreements recognized by multiple countries worldwide. In order to understand the fundamental legality matter behind compulsory licensing, this research is going to focus on three fundamental research questions which underlines the whole concept of compulsory licensing from the viewpoint of the patent rights holder as well as from the governmental perspective.

To ensure that the aims and goals of this research paper has been fulfilled in its entirety, the practical research has been conducted through a qualitative empirical research method. Main focal point within international compulsory licensing legislations is The World Trade Organization, Trade Related Aspects of Intellectual Property Rights agreement (TRIPS), due to its distinctive nature and major recognition of countries around the world.

This research contains an introduction which introduces the reader to the topic including the research questions, followed by an historical analysis of intellectual property rights development of conventions and treaties from the earliest compulsory licensing provisions, leading to specific compulsory licensing provisions of the infamous TRIPS-agreement, thus extending the issues of compulsory licensing between developed countries and developing countries amongst patented pharmaceutical products and competition law.

Keywords: Intellectual Property, TRIPS-agreement, Compulsory Licensing

INTRODUCTION

We begin the introduction by briefly explaining the nature of patent exclusivity and the rights and obligation behind such a unique right, through the viewpoints of classical economic theorists; Adam Smith and Thomas Jefferson. Smith argued against the exclusiveness rights of patents in his *"Lecture on Jurisprudence"* he found the greatest parts of exclusive rights *"greatly prejudicial to society"* yet, also recognizing the importance of rewarding the inventor monetarily.[1] Jefferson supported this viewpoint, recognizing the preferable approach in limiting the states involvement in the enjoyment of rights.[2] Various others theorists such as; John Stuart Mills, Jeremy Bentham and John Smith reasoned for the exclusive rights of patents being the best and most effective way in promoting innovation solely dependable on private domains.

Throughout centuries intellectual property has been a widely discussed topic mainly due to its intangible nature. The balancing of the exclusive rights embodied in the patents causing conflicts, litigations and settlements throughout the world whereas, various conventions, treaties and agreements have tried to find a balance in the enjoyment of a legal "monopolistic" right whom the most recognizable protection for intellectual property is the infamous Paris Convention for the Protection of Industrial Property (1883) and World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (1994). Two of the distinguishable legislation was a result of an inadequate uniform protection of intellectual property across the developed and more importantly the developing countries around the world.

This research focuses on the development of patent rights across Europe and the rest of the world, as well as how the issuing and usage of compulsory licensing has evolved in the scope of pharmaceutical patented products. The debates caused by the rights conferred in these patents deemed to be originating from the fundamental principles of human rights as well as rights recognized by international agreements. Arguments by the rights holder have generally concluded

[1] Hovenkamp, H. J. (2016*). The Emergence of Classical American Patent Law*: *Faculty Scholarship 1799*. 58 Ariz. L. Rev. 263, 273.
[2] *Ibid*., 273-274.

by time and effort on research and development of the novel innovations, one could reason the remuneration system allowed the economic growth in Europe. Same applying for creations of art, music, designs or trademarks in distinguishing a unique, novel invention from the rest. In the counterargument for the exclusiveness of intellectual property right appears in; the right to health, competition law and the remarkable profit-rich industry of pharmaceutical products. The unavoidable conflict by nature does not get more convenient, due to the highly controversial provision of the TRIPS Agreement's compulsory licensing provisions by permitting members to balance exclusivity of rights via the access to patented pharmaceutical drugs affordably to the general public by issuing a license by third parties.

This extensive research's focal point is to understand the legality of compulsory licensing by examining the rights holders perspectives of rights and obligations as well as from a governmental point of view by narrowing the comparison with the developed countries with the developing countries in the usage of compulsory licensing provisions, which is imperative to this research in order to be completely able to answer the questions underlying the legality issues behind compulsory licensing between different national intellectual property rights legislations. Additionally, the history of the patent regimes development will be essential to understand how the legal functions of the TRIPS Agreement, Doha Declaration and several other agreements and conventions impacts the legality issues of compulsory licensing provisions the research focuses on enforcement issues on an international level as well as on a European Union (EU) level. The relevance of this research paper will question intellectual property rights protection on patented pharmaceutical products including compulsory licensing provisions during the pandemic times of Covid-19 outbreak of 2019, notably, the vaccine for the Covid-19. Furthermore, three research questions are fundamental in order to fully comprehend the legal aspects of compulsory licensing within international agreements with the focal point in the TRIPS Agreement, listed below:

- How does compulsory licensing restrict the effective use of patented pharmaceutical products under TRIPS article 31?
- In which way does compulsory licensing force exclusive patent holders beyond legal capacity according to TRIPS article 30-31?
- Should compulsory licensing be enforced only on a national level or also adopted on a multinational level, such as the EU?

1. GATT- AND TRIPS- AGREEMENT AND THE DOHA DECLARATION

Over centuries the intellectual property protection has accounted for vast development of rights dating back to the continental Europe, in Venice 1474 notably the first known patent statue. The Venetian patent statue of 1474 is arguably the backbone of the development of intellectual property rights protection in Europe.[3] The statue reminded very much alike the modern day of patent rights. Novelty of devices, works or instruments were essential for sufficient patent protection granted by law, recognizing the importance in protection of inventions in the development of economic status by permitting the inventor an enjoyment of rights for 10 years in preventing third parties from the use of his invention without consent. The patentee could challenge anybody for the infringements of his invention, thus seek remunerations of damages created by the third party. Thus, allowing non-transferable licensing of the invention in the usage by third parties along with limitations to the rights holder if the enjoyment of this right collided with the state's activities. As a result of such enjoyment conflict, the rights holder could be compelled by the government alone in the usage of such invention in the form of compulsory license.[4]

Prior to the Paris Convention (1883), lack of harmonization on inadequate patent protection prevailed among countries. National laws focused their enforcements of intellectual property rights on protecting nationals excluding foreigners and proof for genuine need of an international alignment of rights existed.[5] The Congress of International Patents in Vienna 1873 recognized the issues of inadequate patent protection among the civilized nations and understood the importance of timely and monetary efforts put into novel inventions by the patentee and therefore, adopted important resolutions in the protection of inventions granted by the legislature of all civilized nations that the inventions should be patentable by everyone, even foreign nationals for a minimum protection of 15 years. Furthermore, acknowledging that patent rights could be limited by reasons

[3] Nard, C. A. (2019). *The Law of Patents*: *Aspen Casebook Series* (5th ed.) New York, USA: Wolters Kluwer, 10-11.
[4] Mandich, G. (1948). *Venetian Patents (1450-1550)*, Journal of The Patent Office Society, 30(3), 157-247, 177-180.
[5] Seville, C. (2013). *The principles of international intellectual property protection: from Paris to Marrakesh*, W.I.P.O.J. 2013, 5(1), 95-104, 2-3.

of non-enjoyment of this protection in a specific country where the invention has not been utilized for its specific purpose by allowing countries to draft regulations on patent protections on obliging patent holders to permit usage by others where public interest demands it, against a suitable remuneration.[6] The Venetian Statue and the Vienna Congress are evidence towards limitations of an exclusive monopolistic rights in an international patent regime for public interests across the civilized nations, contributing to conflict between the developed countries and developing countries in the light of the intellectual property protection.

The Paris Convention for the Protection Industrial Property in 1883 (ParC) was founded upon the international protection of industrial property and one of the great achievements of the convention was claiming priority for applications made in a foreign country by a patentee. A right holders patent protection granted in one country may seek protection in other countries within twelve months after the date of the first application by fulfilling certain conditions the later applications of the protection will be entitled to the priority of the first date of the application.[7] The Paris Convention is seen as the cornerstone of the international industrial property law system and which is still in force to this day and effective, providing basis for the TRIPS Agreement for the protection of intellectual property.[8] Above all, the ParC described compulsory licensing provisions in detail as; only to be used in the prevention of abuse by the rights holder, failure to work or insufficient working before the expiration date of four years from the date of filing the patent application, considering that no justification of legitimate reasons is presented by the rights holder.[9] The license shall be non-exclusive and non-transferable: *"even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license."*[10]

In 1893 the administrative offices of the Paris Convention and the Berne Convention (protection of literary and artistic works) formed an international organization; the United International Bureaux for the Protection of Intellectual Property (BIRPI). The BIRPI was abolished by the creation of the World Intellectual Property Organization (WIPO) in Stockholm (1967).[11] The

[6] Hildebrandt, A. (1875). *The International Patent Congress in Vienna, 1873*: *Translation of DR. Herman Grothe´s report*. London, UK: Simpkin Marshall, & Co. Retrieved 10 December 2020, from https://books.google.ee/books?id=tiAPHQAACAAJ&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=snippet&q=license&f=false, 49-50.
[7] Paris Convention for the Protection of Industrial Property (ParC), World Intellectual Property Organization, 1883, art. 4 A-I.
[8] Seville, C. (2013), *supra nota* 5, 4.
[9] ParC (1883), *supra nota* 7, art. 5A (2-4).
[10] *Ibid*., art. 5A (4).
[11] Yu, P. K. (2016). *Five decades of intellectual property and global development*, W.I.P.O.J. 2016, 8(1), 1-10, 2-3.

organization's resolution meant a direction towards more internationally recognized intellectual property protection by ensuring cooperation among the nations, creating minimum standards for patent protection and leaving room for the national legislation to implement them freely. As why the Paris Convention was vital in the development of the patent protection is the result of uniformity of protection. As discussed, the protection of inventions in the early 15th century already recognized the issues and importance of property protection attributed to patent holders. The Paris- and Berne Convention played a vital role in the development of GATT Agreement, TRIPS Agreement and Doha Declaration, remains an essential role to this date in the protection of intellectual property law and limiting abuses of competitive practices by the right's holders.[12] The General Agreement on Tariffs and Trade (GATT) entered into force in 1948 later being modified and amended in 1986-1994 of the trade negotiations on the Uruguay Round.[13]

The European Patent Convention (EPC), an intergovernmental agreement resulted in the desire of creating a uniform protection and patent applicability in Europe, the convention was signed in 1973 and later amended in 2000. The so-called *"European Patents"* co-exist with national patents which meant the patent application granted through European Patent Organization (EPO) was only valid within the states for which it was granted for.[14] All of the European Union members must join EPC, based on single application of patents in any of the contracting states examined by the EPO in Munich. The Convention was made in conformity with the Paris Convention Article 19; Members of the Union may conclude special agreements between themselves for the protection of industrial property.[15]

The European Patent Convention recognized contractual licensing of a patent application in parts and/or whole territory of the contracting states, since there are no particular provisions of compulsory licensing, thus leaving the members solely to apply the provisions within conformity of the ParC (1883). A continuation of the agreement is the Convention for the European Patent for the Common Market of 1976 (Community Patent Convention, 76/76/EEC), the preference to create a unitary and autonomous patent protection throughout the European Economic Community, governed by the jurisdiction of the European Court of Justice.

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[12] Grubb, P. W. (1999). *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy*. (3rd ed.) New York, USA: Oxford University Press Inc., 37-40.
[13] *Ibid*., 30.
[14] Peers, S. (2011). *The constitutional implications of the EU patent*, E.C.L. Review 2011, 7(2), 229-266, 1-3.
[15] ParC (1883), *supra nota* 7, art. 19.

The Community Patent Convention (CPC) recognized compulsory licensing applying to all community patents, concerning only the territory of the state in question, adding that the rights of the patent are not exhausted when applying the provision, thus admitting compensation to the proprietor on the issuance of a compulsory license, providing for a final appeal to a court of law. Giving more flexibility in the licensing of rights compared to the other treaties, in the extent of patent holder's rights, appealing to the rights holder by giving a statement for the usage of the inventions in terms of monetary compensation and minimizing the renewal fees, thus applying only to businesses with lower financial assets since the patent applications and renewal fees are high.[16]

It can be concluded that development of patent protection regimes has been a series of unsuccessful attempts in creating internationally recognized patent protection within compulsory licensing provisions, despite the Paris Convention; playing a substantial role in the development of internationally recognised intellectual property law. It can therefore be concluded, that the development of these conventions and multilateral agreements insufficiency to conclude a uniformly recognized patent protection and more specifically concluding a general rule for compulsory licensing. The creation of the World Trade Organization and the infamous Trade-Related Aspects of Intellectual Property Rights Agreement in the light of compulsory licensing will be the next topic of this research.

1.1. Trade-related aspects of intellectual property rights and pharmaceutical patents

In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19 of the Paris Convention (1967)[17]

Despite the protection enforced by The Paris Convention, EPC and CPC, a demand for more widespread protection of the rights around the world still existed. The developed countries expressed concerns of the lacking intellectual property rights protection in the developing countries in the world demanding a widely acknowledge agreement to be enforceable throughout the member states. The GATT recognized these issues and the negotiations started in 1986 aimed

[16] Community Patent Convention (76/76/EEC) for the European patent for the common market, OJ L 017, 26.01.1796, 1-28, art. 44.
[17] The Agreement on Trade-Related Aspects of Intellectual Property Rights, World Trade Organization (WTO), 1994, art. 2(1).

to fulfil an added protection on an international level. The GATT established in 1947 led to the establishment of the World Trade Organization in 1994. Which all of the members would ratify the new text of the Final Act of the Uruguay Round of GATT in becoming WTO members would accept the TRIPS provisions as part of the final negations of 1991.[18]

The developed countries expressed concerns of the lacking intellectual property rights protection in the developing countries in the world demanding a widely acknowledge agreement to be enforceable throughout the member states of the United Nations.[19]

TRIPS Agreement Article 7 concludes as follows:
"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer of technology, to the mutual advantage of producers and users of technological knowledge and in manner conducive to social and economic welfare and to a balance of rights and obligations".

Articles 1 through 8 express the fundamental principles of the agreement considering methods of balancing the exclusive rights and obligations of a patent holder in order to promote innovation and allowing access to relevant technology in the protection of public health, whereby pharmaceutical patents is a widely discussed matter in relation to this agreement[20]; allowing members freely to determine the approach in implementing the provisions within their own legal systems and practice and most importantly giving equal rights to foreigners in relation to nationals.[21] Arising debates between the developed and developing nations since the establishment of TRIPS on the balancing of the rights and obligations of the patent holders in the light of human rights arguably has been impacted by the compulsory licensing provisions of the agreement,[22] therefore, this chapter will focus on fundamental principles and objective of this agreement and the underlying issues behind it. Ensuring the balancing of rights are accordingly to the principles of this agreement, rights may be transferred through a non-exclusive license without the

[18] Huala, A. (2001). *Trade-related aspects of intellectual property rights and developing countries*: *The Developing Economies*, 39(1), 49-84, 53-60.
[19] Owoeye, O. (2015). *International patents law and public health: revisiting the TRIPS compulsory licensing regime and the Doha Paragraph 6 System*, E.I.P.R. 2015, 37(12), 782-795, 2-3.
[20] Pusceddu, P. (2014). *Access to medicines and TRIPS compliance in India and Brazil*, E.I.P.R. 2014, 36(12), 790-80, 1.
[21] WTO (1994), *supra nota* 17, art. 2-3.
[22] Tuosto, C. (2004). *The TRIPs Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licences*, E.I.P.R. 2004, 26(12), 542-547, 1-2.

permission from the rightsholder, namely; compulsory licensing.[23] Do these limitations of an exclusive rights restrict the effective use of patented pharmaceutical products under TRIPS Agreement article 31?

The compulsory licensing through the agreement regarding pharmaceutical patents from the industrialized part of the world have not been widely used by the less- and least developing countries[24]; despite the fact that WTO members may adopt measures necessary to protect public health, according to article 8 of the TRIPS Agreement. As to why compulsory licensing provisions have not been effectively implemented by the less- and least developing countries is a matter of understanding the differences between the legislations in the developed countries and developing countries, as history has shown the birth of patent rights has its roots in the development of an intellectual property rights in the developed countries. Compulsory licensing provisions will cover the essential licensing rights of the TRIPS Agreement and its effective use in the developing countries as well as the controversial questions raised among patent holders in the developed countries.

1.2. Compulsory licensing provisions

It is evident that the distinctive nature of exclusivity enrooted in the patent rights and the character of the TRIPS Agreement elicits controversy, uncertainty and conflicts among patent holders and third-party licensees. Compulsory licensing as a method of limiting the rights of the patent holder will be the topic of this chapter.

TRIPS Agreement article 31 concludes that the where the law of a Member allows, the patent may be used by the government or third parties authorized by the government without the authorization of the rights holder. Before utilizing compulsory licensing provisions, the following conditions are to be met: the licensee must seek a voluntary agreement on reasonable terms excluding acts that constitute a national emergency; to ensure adequate protection of the rights imbedded in that patent and the license shall be non-exclusive and predominately for the domestic market for non-commercial public use in case of extreme urgency.[25] The list is extensive before a compulsory

[23] WTO (1994), *supra nota* 17, art. 31(1).
[24] Paas, K. (2009). *Compulsory licensing under the TRIPs Agreement - a cruel taunt for developing countries?* E.I.P.R. 2009, 31(12), 609-613, 6.
[25] WTO (1994), *supra nota* 17, art. 31.

licensing may be issued, hence, creating several limitations for the licensee before being able to apply the provisions of compulsory licensing for addressing public health concerns.

One of the fundamental limitations on compulsory licensing are found in TRIPS article 31(f) stating that the license should be authorized predominately for the supply of the domestic market of the member state authorizing such use and the non-predominately part to be exported. This evidently leads to challenges with nations lacking manufacturing capacity.[26] What constitutes *"a predominately part"*? One argument suggests that at least 50% of the products supplied for the domestic market shall be *"predominant"*,[27] inevitably raising controversy in balancing of the patent rights, thus creating disputes between the patentee and licensor, as it was seen on the issuance of compulsory licensing in 1997 by the South African Government addressing the significant public health concerns against human immunodeficiency virus (HIV) at that time. A counteraction by The United States resulted in placement of South Africa into the trade sanction list 301 and instituting a patent infringement suit by the Pharmaceutical Manufacturers Association including 39 pharmaceutical companies.[28] The suit was eventually dropped and settled.[29] Yet, many other countries have been found on the U.S watch list after utilizing the compulsory licensing provisions by the TRIPS Agreement in order to ensure sufficiency of intellectual property rights protection[30], which explains the controversial topic between the right for protection and the right to license of these protective rights can encounter.

Despite the fact that patent holders are entitled to royalties on the issuance of compulsory license based on economic value of the authorization, the pharmaceutical companies are not eagerly dedicated in voluntary nor compulsory licensing proceedings. A determine of the economic value of a patent might be extremely complicated when calculating the right amount of royalties paid to the rights holder[31], further creating uncertainty in licensing of a pharmaceutical patent by the rights holder. Despite the TRIPS Agreement allowing member states in applying compulsory licenses, why does it fail its effective function by the developing countries in terms of patented pharmaceutical products?

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[26] Paas, K. (2009), *supra nota* 24, 3.
[27] Collins-Chase, C. T. (2008). *The Case against TRIPS-Plus Protection in Developing Countries Facing Aids Epidemics: A comment*, 29 U. Pa. J. Int´l L., 763, 772.
[28] Owoeye, O. (2015), *supra nota* 19, 3.
[29] Wakely, J. (2011). *Compulsory licensing under TRIPs: an effective tool to increase access to medicines in developing and least developed countries?* E.I.P.R. 2011, 33(5), 299-309, 3.
[30] Wakely, J. (2011). *The impact of external factors on the effectiveness of compulsory licensing as a means of increasing access to medicines in developing countries*, E.I.P.R. 2011, 33(12), 756-770, 9.
[31] Choi, A. J. P. (2010). *Compulsory licensing as an antitrust remedy*, W.I.P.O.J. 2010, 2(1), 74-81, 6-7.

Perhaps one reasoning to the discussion is the uncertainty and compensation issues it raises with rights holders. An exemplary case of how complex the process of applying a license can be showing the pharmaceutical company's willingness to license is the case of Bayer AG v. Natco Pharma Ltd. regarding compulsory licensing for public health interest in India, 2012. Natco acquired a voluntary licensing of a kidney and liver treating drug and waited the obligatory three-year limit to apply again but this time for a compulsory license. The reasons for applying a compulsory license was due to the Bayer's pricing on the drugs unreasonably high for the Indian market to be affordable for the public including to efficiently exploit the patent rights in that country. Resulting in a lawsuit by Bayer AG, the Indian High Court ruled in Natco Pharma Ltd.'s favour.[32] This ruling by the Indian High Court provides evidence on how complex a compulsory licensing process can become when not considering the lawsuits opened by the pharmaceutical companies which complicates and delays the process of effective usage of compulsory licensing applied by the developing countries.

Since the TRIPS Agreement provided such immense limitations on issuance on compulsory licensing during the Doha Ministerial Conference in 2001, the Declaration explicitly recognized the precured public health concerns in the developing countries and the need for patented pharmaceutical products, within those countries lacking manufacturing capacity. The Doha Declaration instructed the Council for TRIPS to find a *"expeditious solution"* to the problem.[33]

Resulting in the Implementation Decision by the WTO-members in 2003. The waiver allowed; exporting countries of a generic drugs made under compulsory license to meet the needs of importing countries, with certain limitations; the payment of remuneration to patent holders on the exporting side in order to avoid double payment of a generic drug under compulsory licensing.[34] Canada being the first one in adopting the implementation into national legislation, resulting in the first and only successful importing of a generic drug Apo TriAvir by Rwanda in 2007. The successful importing did not come without complications, causing immense delays and expenses for the corporation.[35]

[32] Bonadio, E. (2012). *Compulsory licensing of patents: the Bayer-Natco case*, E.I.P.R. 2012, 34(10), 719-728, 3-4.
[33] Declaration on the TRIPS agreement and public health, World Trade Organization (WTO), 2001, para. 6.
[34] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, World Trade Organization (WTO), 2003, para. 2-3.
[35] Wakely, J. (2011), *supra nota* 29, 6.

The Doha Declaration was a sum of negotiations and intentions of clarifying the flexibilities that member states are entitled to, acknowledging the severity of health crises and its importance facing the developing countries. Abolishing the need for a voluntary licensing before the issuance of compulsory licensing for a non-commercial use by granting freedom for the WTO-members freedom to determine the grounds which compulsory licensing may be granted for and to determine what may constitute a national emergency and cases of extreme urgency, for implementing the compulsory licensing provisions.[36]

The new Amendment on the TRIPS Agreement in 2005 still posed some limitations of the compulsory licensing provisions by the importing country; a member wishing to import pharmaceutical patented products has to notify the council for TRIPS of its intentions to issue a compulsory license and about the quantity needs. And that the exporting country has to ensure the rights of the patent holder are respected, preserved via active monitoring of the system; such as providing a fair compensation to the patent holder considering the economic value of the licensee in the market destination in authorizing only the manufacturing of the exact amount needed in identifying these drugs specially intended for its intentions.[37]

Even after the amendment of TRIPS Agreement in 2005, the Doha Declaration reached an acceptance by two thirds of the members, declaring the protocol enforceable on 23rd of January 2017 yet failing to be ratified by all the member states extending the deadline for the seventh time until 31st of December 2021.[38]

Regardless the efforts addressing public health concerns through amendments and flexibilities provided by the Doha Declaration, compulsory licensing has not been effectively used as a method in the crises by the developing countries.[39] Despite the fact that an agreement recognized by the member states allowing the provisions in TRIPS for compulsory licensing specific usage in order to overcome health crisis in the developing countries evidently points out that the fear of retaliation by the patent holders and created tensions between the developed countries and developing

[36] WTO (2001), *supra nota* 33, para. 5(c-d).
[37] Alì, G. S. (2016). *The sound of silence: international treaties and data exclusivity as a limit to compulsory licensing*, E.I.P.R. 2016, 38(12), 746-756, 3.
[38] Amendment of The TRIPS Agreement-Seventh extension of the period for the acceptance by members of the protocol amending the trips agreement, General Council Decision, World Trade Organization, 2019.
[39] Owoeye, O. (2015), *supra nota* 19, 7-8 and 14.

countries by other means necessary minimizes the effectivity in applying compulsory licensing provisions in spite of the Doha Declaration.

The previous proposal of Community Patent regulation of 2000, on compulsory licensing;
"The Commission may grant a compulsory license for lack or insufficiency of exploitation of a Community patent or in the case of dependent patents. It can also authorize the use of a Community patent in some specific situations: in times of crisis, in other situations of extreme urgency, or in a situation where it is necessary to remedy a practice deemed after a judicial or administrative process to be anti-competitive."[40]

In Europe, the European Union adopted a new regulation on December 2012 of the Regulation 1257/2012 implementing the enhancement of cooperation in the area of creation of unitary patent protection including a new unified patent court which operates within the exclusive jurisdictions only on those participating members within the European patents with unitary effect.[41] Despite the, Article 8 of the Regulation, recognition of a unitary patent licensing within the EPO allowing the third party for the usage of an invention the licensing of right does not focus on specific compulsory licensing provisions, on compelling the proprietor in licensing. Not excluding the international agreements on enforcing of intellectual property rights, the aim of a unitary patent regime is a uniform protection of intellectual property right throughout the Union.[42]

According to a majority of the industry study a need for a unitary patent to improve the limitations of the current patent system in Europe. In this topic we are going to put our main focus on the unitary patent regulation and its effect on compulsory licensing in the regional manner and if compulsory licensing should be enforced only on a national level or also adopted on a multinational level, such as the EU? Despite that the proposal of 2000 would have supported the provisions of compulsory licensing in the TRIPS Agreement and the Doha Declaration, the Unitary patent regime did not implement this in the Regulation of 1257/2012, stating in the 10th recital;

[40] Proposal for a Council Regulation on the Community patent (COM/2000/0412 final) of The Council of the European Union of 1 August 200, OJ C 337 E 278, 28.11.2000, 278-290, art. 21.
[41] Regulation (EU) No 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, OJ L 361/1, 31.12.2012, 1-8, art. 18.
[42] Kaisi, A. (2014). *Finally a single European right for the EU? An analysis of the substantive provisions of the European patent with unitary effect*, E.I.P.R. 2014, 36(3), 170-180, 1-2.

"European patents shall be governed by the laws of the members and their respective territories regarding compulsory licensing."[43]

There are many aspects on why the compulsory licensing provisions was not and should not be implemented on an EU-level. Implementing a compulsory licensing regime on an EU-level may have an adverse effect on the functioning of the internal market considering international exhaustion of patentee rights after a product is put on the market, thus allowing the product to be sold to other countries without violating the patentee's rights which is evidently confirmed by the Regulation 1257/2012 article 6.[44]

Therefore, a harmonized implementation of compulsory licensing on an EU-level, might affect the patentee's normal exploitation of the rights recognized by the Paris Convention and TRIPS Agreement. The creation of a unified patent protection within the internal market is for now focused on the enforcement of harmonization and the creation of European Patents, leaving the member states in enforcing the disputes created by the compulsory licensing issues between the developing countries.

1.3. Intellectual property rights and competition law

In which way does compulsory licensing force exclusive patent holders beyond legal capacity according to TRIPS article 30-31?

Intellectual property law and competition law has developed, from being seen as two separate aspects of law into being interdependent of each other. Patent law expressly granting the inventor exclusive rights for an invention, entitled to remuneration for time and effort of research and development costs and on the contrary, competition law controlling this exclusive right to prohibit abuses of dominant position. In theory the patent law tries to promote innovation through beneficial approaches and competition law adjusting the rights to be as favourable to the consumer as possible.[45] The nature in both of these legal systems can be compared to a double-sided coin, their different nature in achieving specific goals within legal systems, which furthermore affirms

[43] Regulation (EU) No 1257/2012, *supra nota* 41, recital 10.
[44] Kaisi, A. (2014), *supra nota* 42, 8.
[45] Beier, F-K. (1999). *Exclusive rights, statutory licences and compulsory licences in patent and utility model law*, IIC 1999, 30(3), 251-274, 3-4.

the tensions and disputes arising from the right holder's perspective and the intellectual property rights effective legal use within conformity of several international legislations, conventions and agreements in the scope of compulsory licensing.

The TRIPS Agreement recognizes competition law through articles 8, 31 and 40.[46]
One of the basic principles of TRIPS is to prevent potentially abusive practices of intellectual property rights holder[47], furthermore article 40(1-2) acknowledges; that some intellectual property licensing and measures and practices restricting competition may have a negative effect on the transfer of relevant technology; therefore, allowing members to take appropriate measures in the prevention in abuses of intellectual property rights within relevant law and regulation of that member.[48]

The exception recognized by TRIPS article 30 bears in mind, that the members may only limit exclusive rights conferred by a patent if it does not unreasonably interfere with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interest by the patent owner taking into account third-party legitimate interests.[49]

The highly debatable provision of the TRIPS article 31(k) in this agreement underlies conditions for the use of compulsory licensing in the light of anti-competitive acts determined by judicial and administrative processes. The previous set forth conditions of article 31(k) subparagraphs are abolished if abusive practices are found of the rights holder, possibly affecting the remuneration paid to the rights holder.[50] Thus coming to question can a refusal in granting a voluntary license constitute an abuse of a dominant position by the rights holder?

A refusal in granting a licensing in the light of TRIPS article 28(1) states as follows: *"prevent third parties not having the owner´s consent in processes or acts…"* cannot in theory itself constitute an abuse of a dominant position by the patentee, yet TRIPS article 30 recognizes that members may impose limitations for the exclusivity on the patent with certain conditions, it still leaves the members to implement this provision in the national law. Henceforth, in order to

[46] Mandrescu, D. (2015). *Compulsory licensing - between health and competition: using competition law policy to promote access to medicine*, G.C.L.R. 2015, 8(4), 167-183, 5.
[47] WTO (1994), *supra nota* 17, art. 8.
[48] *Ibid*., art. 40(1-2).
[49] *Ibid*., art. 30.
[50] *Ibid*., art. 31(k).

understand why a refusal of a voluntary licensing may constitute an anti-competitive behaviour, we have to look a case outside the EU's jurisdiction. The case concerning Hartford-Empire Co. v. United States 323 U.S. 386, where the court decided that the patent holder is not entitled in granting access of the patent to the general public, yet such practices violated competition law principles of abuse of dominant position, thus compelled a license of the patent for specific remunerations to the rights holder.[51] Despite not recognizing compulsory licensing in the U.S law itself and yet, applied the provisions of compulsory licensing in order to cease abuses of patent rights holder, demonstrates how a refusal to license might still constitute as anti-competitive behaviour, making the conflicting law vivid.[52] Does the refusal of licensing consider as anti-competitive in the light of EU law based on within the light of this case?

The competition law in the EU is regulated by TFEU articles 101 and 102. The European Union recognizes the importance in regulating anti-competitiveness acts. Article 101(1)(b) explicitly states that all practices that are anti-competitive regarding limiting or controlling technical development shall be prohibited between member states.
The infamous case in the refusal to grant a voluntary licensing of IMS Health under article 102 TFEU, the European Court of Justice concluded three conditions to be met in order for an undertaker to be issued a compulsory licensing[53]:

I. *"the undertaking that requested the license must intend to offer new services for which there was consumer demand that were not offered by the dominant firm"*
II. *"there must be no objective justification for the refusal to grant the license"*
III. *"the result of the refusal to supply the license is to eliminate all competition on the relevant market"*[54]

A refusal may only be considered anti-competitive if the refusal is not objectively justified, excluding effective competition and by prohibiting the appearance of new products in the relevant

[51] Supreme Court of the United States decision, 08.01.1945, Hartford-Empire Co. v. United States, 323 U.S 386.
[52] Satsangi, U. (2016). *Juxtaposition of refusal to license pharmaceutical patent: appropriate remedies for generic manufacturers under patent law and competition law*, E.C.L.R. 2016, 37(4), 157-164, 5.
[53] Court decision, 29.04.2004, IMS Health GmbH & Co. v NDC Health GmbH & Co. KG, C-418/01, EU:C:2004:257.
[54] Paul Craig, P., Búrca, G. D. (2015). *EU Law: Text, Cases and Materials*. (6th ed.) New York, USA: Oxford University Press, 1077.

market, thus the Doha Declaration states that the promoting in transfer of technology is relevant in order to overcome the public health problems recognized by the members.[55]

The case with Magill TV Guide concerning copyright is nevertheless important concerning the refusal of license, the ECJ applied the same conditions in the ruling as IMS health yet also applied the essential facility doctrine for the first time on intellectual property law cases[56]; the dominant company controlling the essential facility has the obligation to make that facility available to its competitors who cannot pursue their own activity without the access to that facility for a specific fee.[57] The Court made it clear that there shall be no right in order to duplicate the patented products, hence forth excluding compulsory licensing as a method of producing a generic version of an existing patented drug.[58]

Whether an exclusive patent holder is obliged to grant a license to its competitor based on the violation of TFEU article 102 or not, is determined if the additional circumstances prevail or therefore considered abusive by the proprietor. The EU itself is a party to the TRIPS Agreement and member states have obligations to protect intellectual property, protection that meets the international conventions obligations may not necessary mean that it´s justified under EU law.

Since the Doha Declaration declares that members may implement compulsory licensing without the grant of a patent holder because of public health concerns, national health crises or due to extreme urgency determined by the nations themselves. Member states may take appropriate measures to prevent or control such practices having an adverse effect on competition according to the TRIPS Agreement, concluding that protection taken according to the TFEU articles of 101 and 102 may be considered *"appropriate measures"* in the light of the European Union.

Depending on the case and measures taken, refusal of licensing by a patent holder may be disclosed as abusive behaviour of dominant position of exceptional circumstances. Although the Doha Declaration allows compulsory licensing excluding specific requirements in the TRIPS Agreement, it may affect intellectual property rights holder towards voluntary licensing in the fear

[55] WTO (2003), *supra nota* 34, para. 6-7.
[56] Commission decision (89/205/EEC) of 21 December 1988 relating to a proceeding under Article 86 of the EEC Treaty (IV/31.851 - Magill TV Guide/ITP, BBC and RTE), OJ L 78, 43-51, 43.
[57] Hatzopoulos, V. (2006). The EU essential facilities doctrine. *Research Papers in Law*, European Legal Studies. Belgium: College of Europe. Retrieved 9 December 2020, from https://www.coleurope.eu/research-paper/eu-essential-facilities-doctrine, 7.
[58] Mandrescu, D. (2015), *supra nota* 46, 8.

of compulsory licensing or threat of anti-competitive behaviour. Suggesting that the anti-competitive measures governed by the European Union may force the patent holder beyond legal capacity in the light of TFEU article 101 and 102. However, one study suggests that the European Union is unable to interfere in the patent practices in the pharmaceutical patent industry due to lack competence in the field of value granted patents. Decreasing the ability to question the fact of anti-competitive acts of patent approval applications.[59]

[59] Minn, M. (2018). *Patent settlement agreements and the refusal to license in the light of competition law*, E.I.P.R. 2018, 40(2), 109-112, 2.

2. EFFECTS OF PRINCIPLE OF EXHAUSTION AND PARALLEL IMPORTATION ON COMPULSORY LICENSING

TRIPS Article 6 concludes that nothing in the Agreement is utilized to address exhaustion of intellectual property rights[60], therefore leaving each Member to choose their own exhaustion policy. The Doha Declaration para 5.d leaves each Member free in implementing its own exhaustion policy without a challenge.[61]

The TRIPS Agreement article 28(1), only allows imposed limitation on the patent holders abuse of dominant position or in cases of compulsory licensing with the conditions set forth under TRIPS article 31 including the Doha Declaration.

Exhaustion of rights implicates rights holder's loss of control over resold patented products in circulation. The reasoning behind this principle is that the compensation after the first sale of the protected product should be enough that it would be considered unjustified to profit from a resale of the in second-hand market.[62] Meaning that the rights are exhausted after the first sale of the protected goods.

Since the TRIPS Agreement leaves each member state to choose their own exhaustion policy by three different principles of exhaustions. Firstly, national exhaustion meaning simply a sale of intellectual property sold to a foreign country does not exhaust the rights from the country of origin granting the proprietor the right to prevent importation from that foreign country. Secondly, the principle of international exhaustion, leaving protected intellectual property rights sold to a foreign country from the origin country exhausted from the country of origin which allows resale the product by third parties once put in circulation. Thirdly, regional exhaustion which concerns a certain area exhaustion of rights once put into the market.[63]

[60] WTO (1994), *supra nota* 17, art. 6.
[61] WTO (2001), *supra nota* 33, para. 5 (d).
[62] Feros, A. (2010). *Free movement of pharmaceuticals within the EU-should rights be exhausted regionally?* E.I.P.R. 2010, 32(10), 486-497, 3.
[63] Bonadio, E. (2011). *Parallel imports in a global market: should a generalised international exhaustion be the next step?* E.I.P.R. 2011, 33(3), 153-161, 2

The national exhaustion principle provides the most favourable form of protection for an intellectual property rights holder, since the rights basically never exhaust, thus the proprietor is allowed to oppose parallel importation which is discussed more specifically in the next chapter. The international exhaustion principle is favoured evidently by the developing countries since it allows to distribute low priced pharmaceutical products in a high-priced country via the second-hand market by buying the products from low priced countries and then reselling them.[64]

Why exhaustion policies affect compulsory licensing? Simply because if international exhaustion policy is applied then it can be argued that voluntary licensing may be an option instead of compulsory licensing or by allowing second-hand trading by the international exhaustion principle.

The European Court of Justice has confirmed a community-wide exhaustion since the 1960´s.[65] According to TFEU articles 34-37, the EU recognizes a regional exhaustion which prohibits the protection of intellectual property in the second-hand market, as evident to be a restriction of the fundamental principles of the EU´s free movement of goods. The first sales doctrine is applied around the European Union as the rights are exhausted after the first resale of the product reflected by a caselaw presented before the ruling of exhaustion of patent rights in 1974 between Centrafarm v. Sterling drugs;

"The exercise, by the patentee, of the right which he enjoys under the legislation of a member state to prohibit the sale, in that state, of a product protected by the patent which has been marketed in another member state by the patentee or with his consent is incompatible with the rules of the EEC treaty concerning the free movement of goods within the common market."[66]

Since it is clear that the compulsory licensing is mostly issued by the developing countries as the compulsory licensing provisions in TRIPS Agreement and the Doha Declaration clearly states that it is to be used for national emergencies and that international exhaustion is favoured by the

[64] *Ibid*., 2-3.
[65] Avgoustis, I. (2012). *Parallel imports and exhaustion of trade mark rights: should steps be taken towards an international exhaustion regime?* E.I.P.R. 2012, 34(2), 108-121, 6.
[66] Court decision, 31.10.1974, Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc., C-15/74, EU:C:1974:114, judgement 1.

developing countries, the discussion of exhaustion policies involves parallel importation which will be our next topic of this research.

2.1. Parallel importation

According to TFEU articles: 34-35: *"quantitative restrictions on imports and exports and all having equivalent effect shall be prohibited between Member States."*

The exhaustion of intellectual property rights is the foundation to understand why parallel importation may be harmful for patent protection and be useful for exploiting the patent holder's rights through compulsory licensing, as parallel importation has an important role in the distribution of patented products in the developing countries, essentially lowering priced patented pharmaceutical drugs.[67]

Can a parallel importation of a compulsory licensed drug be misused by the importing country? As it is evident from a European Union's perspective, the community wide exhaustion allows parallel importation, therefore the patent protection for second-hand markets cannot be legally justified. The previously mentioned case concerning Canada and Rwanda is considered to be the first successful compulsory license within importation to third parties in the scope of Doha Declaration paragraph (para) 6. Rwanda successfully applied a compulsory license for Apo-TriAvir drug and through the Doha Declaration para 6, exported the drug to a third-party with insufficient or lacking manufacturing capacity.[68] Since the exporting country of this drug is also entitled financial remuneration it can be said that the effects of parallel importation via compulsory licensing methods are of low risk of patent protection breaches. The underlying goal for the developing country is accessing affordable generic drugs for the general public, thus the parallel importation along with compulsory licensing can be an effective method in lowering the price of patented pharmaceutical products.[69] Notably, the developing countries prefer international exhaustion method since it allows the importation of lower priced patented products from around the world.

[67] Ariyarathna, L., Kariyawasam, K. (2020). *Pharmaceutical patents and access to generic medicines in developing countries*, E.I.P.R. 2020, 42(2), 108-118, 7.
[68] *Ibid*., *9.*
[69] Bonadio, E. (2011), *supra nota* 63, 2-3.

As was the active role of parallel importation by the Indian generic manufactures to Brazil and Thailand in the 1990´s. Section 107 A (b) of The Indian Patent Act of 1970, explicitly allows parallel importation by persons authorized to produce, sell or distribute the product, which is in other terms does not impose an infringement of patent rights.[70] Consequently meaning that since the Doha Declaration permits importations of patented pharmaceutical products countries lacking manufacturing capacity. Parallel importation could be used as method of lowering the average prices of the patented drugs, by acquiring the products through importation from abroad rather than directly from the manufacturer. The result of international exhaustion of rights withholds the reselling rights of the patent holder after first utilization or put in circularization thereto, allowing parallel importation.[71]

Since parallel importation is allowed in the scope of compulsory licensing by the developing countries, would the patent protection be altered in the scope of parallel importation and can the compulsory licensing be exploited by governments in order to fulfil economic enjoyment in that country? Parallel importation by nature does not constitute to any patent protection breaches by the Doha Declaration or the TRIPS Agreement nor under European Union law, thus creating immense difficulties in the acquirement of these drugs through political and administrative processes of acquiring compulsory licenses, conceivably restricting the effective use of these pharmaceutical products in the developing countries. The next chapter will cover the essentials for public policy issues in concerning health emergencies due to inadequate access for pharmaceutical products in developing countries.

2.2. Intellectual property and public policy and health

The emergence of the TRIPS Agreement was undoubtedly initiated due to lack of uniform protection of intellectual property rights between the developed and developing countries, the aim to create an adequate, minimum protection on intellectual property rights. From the beginning of the 1980's pharmaceutical corporations initiated aggressive lobbying campaigns in to securing a greater patent protection abroad leading to the GATT Agreement and evidently to

[70] Ghosh, S. (2013). The Implementation of Exhaustion Policies: Lessons from National Experiences. *Legal Studies Research Paper*, No. 1248. Wisconsin: University of Wisconsin, 40. Retrieved 10 December 2020, from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2390232, 40.
[71] *Ibid*., 40-41.

the TRIPS Agreement. The developing countries including Brazil, India and South Africa, among others, naturally opposed in moving to a global intellectual property rights protection.[72]

The need for protection of pharmaceutical patents in the developing countries create tensions between the western countries when undoubtedly the TRIPS Agreement was a result initiated by the developed countries due to inadequate protection of intellectual rights in foreign markets, yet 99% of the patents are owned by the industrialized nations.[73]

The most common argument by the patent holders is the significant research and development (R&D) expenses of the invention of a novel drug consisting of increasing safety, efficacy and regulatory requirements. This industry has one of the highest ratios of R&D expenditures in sales, amounting to 15% of the net sales of pharmaceutical products in 2015 compared to software and computer services of 10,5%. Reasoning that the expenditures for R&D are directly related to the prices of drugs in the open market, let alone in Europe, €33,500 million were spent on R&D according to a study conducted in 2015 by the European Federation of Pharmaceutical Industries and Associations.[74] In spite of that, the pharmaceutical industry is a multibillion-dollar global market, generated by high profits, without considering the "monopolistic" right imbedded in patents, giving the clause for higher drug prices. As shown evidence, R&D expenses are associated with the prices on drugs, but to which extent is the price "surge" justificatory in the light of public health policy considering the developing countries?

The European Patent Convention article 53 clearly states that patents shall not be exploited in a way that is contrary to public order or morality, namely acts overriding public interest.[75] The TRIPS Agreement recognizes the prohibition on granting patents that are against *"ordre public"* or morality.[76] One research suggest that the protection of *"human health is considered a*

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[72] Sundaram, J. (2015). *Analysis of TRIPS Agreement and the justification of international IP rights protection in the WTO's multilateral trading system, with particular reference to pharmaceutical patents: Information & Communications Technology Law*, 24(2), 121-163, 124-126.
[73] *Ibid*., 127.
[74] Athanasiadou, A. (2018). *Patent Settlements in the Pharmaceutical Industry under US Antitrust and EU Competition Law*: *International Competition Law Series,* The Netherlands, Kluwer Law International B.V, Retrieved 17 December 2020, from http://bit.ly/3gY4Ivt.
[75] Malbon, J., Lawson, C., Davison, M. (2014). *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary*, *Elgar Commentaries*. Cheltenham, UK and Northampton, USA: Edward Elgar, 434.
[76] TRIPS (1994), *supra nota* 17, art. 27 (2).

subspecies of public order"[77], thus questioning the justification in the protection of pharmaceutical patents within public order and morality. The exclusivity conferred by a patent may be limited by members of this agreement if it does not interfere with the normal exploitation of that right and not resulting in prejudice considering interests of third parties[78], yet The European Convention of Human Rights also recognizes limitations submitted to the protection of property in the light of public interest.[79] Despite these limitations, the developed countries have an advantage of intellectual property rights know-how whereas, developing countries lack the sufficient knowledge in intellectual property, thus minimizing the possible use of the compulsory licensing provisions delivered by the TRIPS Agreement.[80]

Section 84 of The Indian Patent Act provides several conditions in order for a compulsory licensing provisions to be issued; a failure; to satisfy the reasonable requirements of the public with respect to the patented invention; or failure to make the patented invention available to the public at a reasonable affordable price; or failure to work the patented invention in the territory of India[81], which are specifically mentioned by the TRIPS Agreement article 31 including the Doha Declaration. Thus, leaving the compulsory licensing provisions to be implemented in the countries own national legislation within the conformity of the TRIPS Agreement further constitutes to the controversial nature of the agreement.

The Bayer v. Natco case provides convincing evidence how the responsibility to respect the right to health is imbedded in the national law in India by prioritizing public health concerns, if not respected by the pharmaceutical industry's access to these patented inventions. Thus, promoting voluntary licensing by the pharmaceutical companies over compulsory licensing making it essential in the distribution of patented drugs in the country, which is an exemplary illustration on how balancing of exclusive rights could be addressed.

Since the primary responsibility of ensuring compliance with public health regulations lies within the state, whereas, the right to prevent third party usage of the patent right lies within the patent

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[77] Correa, C. M. (2007). *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, *Oxford Commentaries on the GATT/WTO Agreements*. (1st ed.) New York, USA: Oxford University Press Inc., 289.
[78] WTO (1994), *supra nota* 17, art. 30.
[79] European Convention on Human Rights, Council of Europe, 1953, art. 1.
[80] Ihguba, B. U., Onysei, I. S. (2016). *International intellectual property agreements as agents of sustainable development of developing countries,* African Journal of Legal Studies 2016, 9 (1), 1-9, 13.
[81] Patents Act, Intellectual Property India of 19 September 1970, sec. 84 (1).

holder's obligation. The underlying matter is that compulsory licensing may be used as a last resort in safeguarding public health concerns by the state in implementing limit the intellectual property protection for a limited time.[82]

The Doha Declaration clarified the limitations provided by the TRIPS Agreement on created restrictions by usage of third parties in light of public health concerns.[83] The Doha Declaration allowed a more comprehensive use of compulsory licensing in terms of public health crises or concerns, thus allowing the members themselves predetermine an emergency situation within national legislation in order to be compelled to use the provisions provided by TRIPS article 31. Thereby, abolishing the need for a voluntary licensing before the issuance of compulsory licensing for the public and non-commercial use, granting freedom for the WTO members to exploit this right in addressing public health concerns.

A noteworthy company called Gilead Science issued a voluntary license for Hepatitis C drug by permitting distribution to over 90 countries concerning over 100 million people, leading to payments of royalties, product registrations, medical educations, training and safety monitoring and other related business activity is a substantial evidence of successfulness of a voluntary licensing compared to compulsory licensing.[84]

Crucial case in the scope of compulsory licensing is the case between the Swiss Multinational company Roche and several governments in the light of patented H5N1 antiviral medicine, Tamiflu. The dispute arose when governments around the world tried to take a hold of the drug after being dormant for years.[85] Roche successfully was able to avoid the issuance of compulsory licensing in many countries by increasing the global production and distribution of Tamiflu and granting generic voluntary licenses to generics pharma manufactures. As earlier mentioned in this research the increase of voluntary licensing is arguably an effective way to insure in meeting the needs for protection of human health, especially in the less and least developing countries in the

[82] Li, P. H. (2013). *Rights and responsibilities in patents: a precautionary patent framework in WTO law*, E.I.P.R. 2013, 35(9), 516-526, 7.
[83] WTO (2001), *supra nota* 33, para. 4.
[84] Oke, E. K. (2019). *Defining the right to health responsibilities of patent-owning pharmaceutical companies*, I.P.Q. 2019, 1, 43-60, 8-10.
[85] Vaaver, D., Basheer, S. (2006). *Popping patented pills: Europe and a decade's dose of TRIPs*, E.I.P.R. 2006, 28(5), 282-291, 5.

world. But sometimes the voluntary licensing's fails, as so was the case with the government of Taiwan in applying for a compulsory licensing for the Tamiflu drug.[86]

A good illustration about an aggressive policy of compulsory licensing imbedded as a governmental strategy provided freedom of the Doha Declaration in achieving universal access of medicines to the population of Thailand, which did not constitute a contingent health crisis or nature of extreme urgency, thus an outcome of this type of aggressive approach resulted in a generic version of a Plavix-drug being distributed 5 per cents lower than it´s branded version.[87]

Another example of potential abusing method of compulsory licensing; between 2001 and 2005, the Brazilian government threatened the pharmaceutical companies with compulsory licensing in order to negotiate lower prices of drugs and successfully in many cases, lowering 50% of the actual market price for drugs, saving a total $1.2 billion in anti-retroviral drugs during this period.[88] Since it is evident that compulsory licensing has not been widely accepted by the patent holders, it can be concluded that these facts of the balancing of the exclusive patent rights and the usage of these rights within compulsory licensing provisions create disputes between the developed and developing countries in terms of patent protection laws. Whether, a patent holder's rights can be exploited by the means and usage of compulsory licensing is entirely up to the government's policy of intellectual property rights as a whole within the conformity of the TRIPS Agreement and the flexibilities provided by the Doha Declaration.

The overlapping disputes emerging out of the idea of compulsory licensing, is a result imbedded in the private and public domains, between the state institutions and pharmaceutical industry as a result of different approaches and goals towards the general market and the general public within the patented products. The right and respect for public health are mainly governed by the state´s legislation and public policy, whereas the pharmaceutical industry develops pharmaceutical products in order to meet the market demand, thus giving the right for compensation for the R&D costs for developing and patenting drugs. Therefore, not only leaving obligations to respect public health by the governments but as well as creating obligations for the private domains for the respect of human rights.

[86] Bonadio, E. (2012), *supra nota* 32, 8
[87] Ariyarathna, L., Kariyawasam, K. (2020), *supra nota* 67, 6.
[88] Alì, G. S. (2016), *supra nota* 37, 5.

One suggestion implies in meeting the obligations to respect the fundamental human rights, is voluntary licensing of the products at a reasonable, affordable price, making it possible to sell the products at a lower price to meet the consumer market in the developing nations without having the need to license at all. The above-mentioned case in India is a good example of effective public policy of compulsory licensing by accessing affordable drugs for the general public.[89] Can voluntary licensing be an effective way to meet the guarantees of rights protection for the patent holder as well as addressing the needs for human rights protection within the developing countries in the light of patented pharmaceutical products?

Undoubtedly, an underlying need for pharmaceutical products exist in the developing countries and the protection recognized by the western society overlaps with the idea of protection of human health in the developing countries creating a conflict despite the fact that the TRIPS Agreement and the flexibilities provided by the Doha Declaration. Suggestively implying in meeting the obligations to respect the fundamental human rights is voluntary licensing of the products at a reasonable and affordable price or alternatively selling the products at a lower price to meet the consumer market in the developing nations without having the need to license at all.

[89] Oke, E. K. (2019), *supra nota* 84, 8-10.

CONCLUSION

The inevitable difference between legislations in the developed- and developing countries contributes to the majority of differences in implementing the TRIPS Agreement in national legislation and in practical implications. Thus, giving rise to conflicts between pharmaceutical companies and the developing countries in need of patented pharmaceutical products for the emerging health emergencies.

Despite the efforts in harmonizing patent regimes between the developed and developing countries through various amendments of the TRIPS Agreement and supplementary multilateral treaties, the compulsory licensing is considered to be a highly controversial topic between the patent holders and issuing countries of compulsory licensing provisions, in terms of remuneration and patent protection issues both in and outside of the European Union.

Considering the recognition of compulsory licensing and enforcement through the TRIPS Agreement and several supplementary treaties, conventions and agreements for the purpose of enforcing minimum patent protection obligations and rights for member states. The aim of the compulsory licensing has not been previously achieved due to various issues relating to protection concerns around the patent right holders, thus creating legal disputes in various jurisdictions around the world.

As to answering the first research question on; “How does compulsory licensing restrict the effective use of patented pharmaceutical products under TRIPS article 31?”, goes without saying that the major need of pharmaceutical products in the developing countries is the monopolistic right imbedded in the patent rights are exclusive which is enforceable within the world-widely recognized TRIPS Agreement. The nature of the compulsory licensing agreement compels patent holders to license their inventions for a specific territory for a specific amount of time against specific remunerations. Thereby, the compulsory licensing provision under article 31 in the TRIPS Agreement did impose limitations, explicitly under paragraph (f) of the article, by constraining the usage of this provisions in countries lacking of manufacturing capacity. Thus,

The Doha declaration abolished the need for manufacturing capabilities in exploiting the set forth compulsory licensing provisions in countries lacking manufacturing capacity, arguing that the nature of compulsory licensing restricts the effective use of patented products in an indirect manner. Since complexity of the agreement itself recognizes the exclusive rights imbedded in patents, thus making sure the availability of such rights for those in need. Notwithstanding the restrictions, the answer for the question is complicated and can be seen as a comparison to a double-sided coin in the perspective of the rights holder and the licensor. Following the second research question the answer to;

"In which way does compulsory licensing force exclusive patent holders beyond legal capacity according to TRIPS article 30-31?".

The main focus which could force the patent holder beyond legal capacity within the exclusive patent rights is through anti-competitive acts and acts that are against public order and morality, which in some scope is hard to define since the patent holders have specific rights and obligations within the exclusivity imbedded in that right. The compulsory licensing itself forces patent holders into an agreement which compels them to accept remuneration and in certain instances, even below the market price compared to voluntary licensing. In some cases, the provisions of compulsory licensing has been used as a threat in negotiating lower prices of drugs in the developing countries, thereby forcing the patent holder beyond legal capacity within their right to protection of invention within the scope of the agreement. Thus, it can be said that acts that go beyond the right holders normal exploitation of the patent, may be considered as anti-competitive or outside of the scope within public order or morality. Concluding that the compulsory licensing forces the patent holder beyond legal capacity to some extent considering the normal exploitations by the patent holder.

Since the TRIPS Agreement is an international agreement and lack the European Union's similar extensive uniform enforcement on intellectual property protection and explicitly within the framework of compulsory licensing it is fair to ask;

"Should compulsory licensing be enforced only on a national level or also adopted on a multinational level, such as the EU?".

Lack of full harmonization in the European Union and proper knowledge in intellectual property rights protection within the scopes of compulsory licensing, creates difficulties in enforcing such provisions outside of the TRIPS Agreement, because of the TRIPS Agreement and the Doha Declaration leaves each member state by their own in implementing the provisions of compulsory licensing along with the European Union's legislation. The present circumstances of intellectual property rights protection are still highly enforceable by multilateral treaties, thus recognized by the European Union. The current legislative measures in compulsory licensing is left to a national level of implementing compulsory licensing provisions and it can be fair to say that in order to achieve a highly efficient protection and granting procedural by the European Union would be needed to create a uniform protection of intellectual property rights between the developed and developing countries in addition to the obligation of securing public health concerns. In the light of competition law, the compulsory licensing would be a more sensible thing to be enforced on an EU-level; but as far as the Patent Conventions and the future patent agreements, there is no sign of an EU-level enforcement of compulsory licensing in site as confirmed by the Regulation 1257/2012 on harmonizing patent protection in the EU.

Considering all facts and disclosers of this research, the underlying issue with compulsory licensing and the usage of such provisions in the TRIPS Agreement and relevant supporting provisions of compulsory licensing is the balance between the rights of the patent holder and the issuing country of such rights creates controversies upon this date. Bearing in mind the effects of compulsory licensing throughout centuries, it is fair to ask how the future of legislations and regulations on compulsory licensing effect the nations capability to meet the need for protection of human health and on the other hand the necessary to protect the rights of a patent holder.

Specially the times of the prominent pandemic of the Covid-19 outbreak of 2019 and the possible questions of patentability and compulsory licensing of the vaccine, particularly from the developing countries lacking manufacturing capacity and proper know-how on intellectual property disputes. It can be finalized by this research that the issuance of compulsory licensing is a complex process despite the amendments provided by the Doha Declaration. The future of the compulsory licensing provisions of imminent pandemics might have a special effect on the development on which grounds compulsory licensing may be issued and on what terms to promote flexibilities in applying life-saving drugs for those in need.

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