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PATENT RIGHTS OR PATIENT RIGHTS?

An assessment of intellectual property and right to health within the Covid-19 pandemic

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ABSTRACT

The outburst of Covid-19 and the global unequal distribution of vaccines among the world countries turned on again the existing tensions between the global rich, developed north and the global south on the role played by intellectual property (IP) in relation to access to vaccines. Their opposing positions on the issue brought to a deadlock at the WTO, where since months a proposal on a temporary suspension of IP is being discussed with no solution in sight. In fact, if rich developed countries consider it as the reason why vaccines got developed so fast, developing countries sees in it the main burden towards an equitable production and roll-out of Covid-19 vaccines.

Considering the pandemic situation and the heated debate at the WTO, this thesis will explore the role that IP plays in relation to the right to health to check whether it enables or limit the fulfilment of the state's duties towards that right. My work will start from a theoretical analysis of the international legal framework around IP, will proceed through an assessment of the consequences deriving from its practical implementation and will end with a closer look at the role played by IP in the actual pandemic situation, with the hope to give the reader an encompassing perspective on the issue.

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INTRODUCTION

Rationale

Covid-19 has dramatically changed life on the planet, severely pressuring national health systems and many healthcare facilities worldwide. Instantly, the great demand made medical treatments and personal protection equipment very hard to find everywhere. Therefore, governments had to find quick ways to satisfy the increasingly demand of medical supply. Their level of economic development determined greatly their success or failure, widening the already existing disparities between the developed "global north" and the least developed "global south". Many have described Covid-19 as an "inequality virus" (GIWPS, 2021 16 April, 27:30-28:00).

Vaccine research, development and roll-out also suffer from inequality. In fact, after a first initial phase of global solidarity, open science and exchange of data regarding the virus dna, the attitude became one of competition, secrecy and "business as usual" among the stakeholders in the race for the vaccine. It was therefore unsurprising that the first vaccines developed came from the big pharmaceutical companies settled in the developed countries and supported with massive governmental funds. On the contrary, of the many compounds studied in the developing countries, only a few turned out to be successful.

Intellectual property on pharmaceutical products has always played a problematic role regarding the enjoyment of the right to health. To avoid the unpleasant situation of entire global areas without adequate vaccine supply because of intellectual property on the western produced vaccines, the governments of South Africa and India proposed in October 2020 a temporary waiver on TRIPS – the international legal framework of trade-related intellectual property protection - that would last until "global herd immunity" is reached.

The issue has fuelled a heated debate at the WTO on the role played by intellectual property protection within the pandemic that polarized into two incompatible positions that I will analyse in this work. In particular, the strong opponents, represented by pharmaceutical companies and developed countries, consider strong protection of intellectual property as the reason why vaccines got developed so fast. The contrary least developed and developing countries, backed by NGOs and international institutions, see in it the main reason why vaccines are not adequately available at the moment.

This polarization of ideas mirrors the tension between the "global developed north" and the "less developed south" that has always existed on the issue. In fact, whereas the first group considers intellectual property protection as a necessary incentive for innovation, the second group sees in it a major threat against the enjoyment of human rights, especially the right to health. For this reason, the frail balance between the state and pharmaceutical companies' obligations towards the enjoyment of the right to health and their intellectual property protection rights has historically often been under pressure.

The outbreak of Covid-19 and the ongoing debate at the WTO are then the perfect historical framework not only to analyse the position of the different stakeholders and the justifiability of their claims, but also to look at the issue from a new perspective and eye-witness whether the complex TRIPS "system", as it is designed, promotes or hinders the enjoyment of the highest standard of health at a global level. Moreover, Covid-19 is the first case – in our contemporary world – of a problem that encompasses national boundaries, hitting both rich and poor countries with such rapidity at the same time.

Research questions

The aim of my work is to explore the complex relationship between intellectual property rights and the human right to health. To assess the topic in the most extensive way I will look at the functioning of the intellectual property protection system both in "normal" and "pandemic times". My research question consists of three related questions:

On balance, does the existing intellectual property system adequately enable or serve as a barrier for states to fulfil their duties towards the right to health?

In particular, has the intellectual property system been a barrier for a more equitable roll-out of Covid-19 vaccines?

In light of the Covid-19 pandemic, are reforms of the intellectual property system needed to advance the right to health?

The answers to these questions should provide the reader with a full and encompassing understanding of the intellectual property protection system, its consequences, shortcomings and possible solutions in relation to the human right to health.

Structure

My thesis is divided into three chapters. The first and the second chapter will provide an answer to the first question, while the third chapter will specifically deal with the second question on intellectual property and Covid-19. The last question will be assessed in the conclusion.

The first chapter: "Intellectual property and TRIPS Agreements" explores the TRIPS Agreement, why it was created, how does it function, what are its objectives and what is its relationship with the human rights system. Since my focus is on access to medical treatments and right to health, the spotlight is on the patent system, which is the most important concrete expression of intellectual property protection within the pharmaceutical and biotechnology industry.

The second chapter "Intellectual property and Right to Health", starts with an analysis of the normative content of the right to health and the states and business obligations towards it. Then it conducts an exploration of how the TRIPS Agreement is put into practice at the national level and the challenges it encounters in relation to the promotion of the right to health, both within the least developed and developing countries and the developed ones.

The third chapter "Intellectual property, the Right to Health and the Covid-19 pandemic" analyses the role that intellectual property is playing within the Covid-19 crisis. After an exploration of the failed countermeasures taken by the international community to defeat the pandemic and the need of a new, bolder solution, the focus will be on the temporary TRIPS Waiver proposal put forward by the governments of South Africa and India back in October 2020 which is still under debate. In particular, I will analyse the positions of the different stakeholders, the progress and the solutions proposed from October 2nd 2020 – the day in which the Waiver proposal was issued at the WTO – till June 10th -11th –the days in which the last (until July) formal WTO meeting to discuss the waiver took place. The end of the chapter will be dedicated to an analysis and final discussion of states' and pharmaceutical industry's behaviour during the pandemic in relation to the right to the highest attainable standard of health, taking three Statements by the UN Committee on Economic, Social and Cultural Rights on the Covid-19 pandemic issued in April 2020, November 2020 and April 2021 respectively as my point of departure.

For reasons of availability of resources and reliability (the vaccines I analyse have received the "emergency approval" from the international pharmaceutical agencies FDA and EMA and

therefore can be considered as safe), I will deal with all the western based vaccines, especially with AstraZeneca, Moderna and Pfizer/BioNtech.

The conclusion will present a summary of the main issues analysed and the relative findings and will propose possible alternatives to the actual intellectual property protection system.

Materials

The materials I have consulted in the field of intellectual property are the TRIPS Agreements with their complementary Doha Declaration, which together provide the legal basis of the system. Books and articles, especially from authors Sellin, Ho, Helfer and Austin have been a great support in understanding the functioning of this complex system.

Concerning the human right to health I analysed ICESCR, CESCR documents with particular attention to the General Comment n.14, and, among others, the work of the Special Rapporteurs on Health Paul Hunt and Anand Grover, the "Ruggie Principles" on Business obligations and the 2016 High Level Panel on Access to Medicines.

In regard to the Covid-19 situation, I consulted the WTO documents produced during the debating sessions on the TRIPS Waiver proposal, NGOs reports, pharmaceutical companies' declarations, US government, EC (European Commission) and EP (European Parliament) documents. For the assessment of the "right to health" situation of Covid -19 of great help have been WHO Declarations and CESCR Statements, especially the ones issued in April 2020 and November 2020 and in April 2021. Lastly, on-line conferences and newspaper articles have revealed to be particularly useful to track and chronicle the constantly changing pandemic framework with the latest updated information.

Definitions

The main subjects of this thesis are intellectual property and the human right to health. However, if the concept of human rights is universally known, this is not the case with the definition of intellectual property. Therefore, it deserves some clarification up fronts.

As defined by the WIPO, the World Intellectual Property Organization:

> "Intellectual property (IP) refers to creations of the mind – everything from works of art to inventions, computer programs to trademarks and other commercial signs". (WIPO, 2020, p.1)

The objects of intellectual property are the "creations of the mind" - recipes, formulas, data, ideas… - that, because of their "non-tangibility" can be in many places at the same time, are not subjected to consumption, are not exclusive (in the sense that A's possession of e.g. the apple pie's recipe does not preclude B's possession of the same recipe) and whose marginal cost of providing them to an external user amounts to zero (Hettinger, 1989, 34-35).

Because intellectual property is *per se* an abstract concept, its enforcement is done through a variety of "tangible" tools: patents, trademarks, copyrights and trade secrets. It is relevant to briefly define what these entail.

When granted, patents allow inventors to exclude other people from creating and distributing the product or copies of it without his own explicit consent for about 20 years during which the inventor is able to sell his own product on the market at the price he deems appropriate. Every other individual/industry wishing to reproduce a "generic version" of it has to wait until the patent has expired. Patents are the most common form of intellectual property protection within the pharmaceutical world. I will deal with them extensively since they are highly relevant for the focus of my thesis. (Poticha and Duncan, 2019, 291-293; WIPO, 2020, 8-11).

When registered, trademarks provide an industry the exclusive right to use certain signs/symbols/names for around 10 years that can be extended under the payment of an amount of money. Their main aim is – also with the help of advertisement campaigns – to influence the costumer to buy the branded, advertised and "original" product rather than its cheaper, non-branded version. (Helfer and Austin, 2011, p. 18).

Copyrights are normally used to protect artworks (e.g. books, songs) and are granted as soon as they are available. As for patents, copyrights allow the inventor to have full control on his creation and to prevent that third parties may exploit his work without consent. They include both the "moral right" of the author to be recognised as such when his work is publicly available and the more economic "authors right" which is a financial remuneration for the agreed exploitation of his creation. Copyrights are by far the most extensive rights: they stretch until 50 or 70 years after the author's death. Even if I will not deal with them in my work, copyrights will make a further appearance in the conclusion. (Helfer and Austin, 2011, p.17; Brougher, 2014, 2-4; Poticha and Duncan, 2019, 290).

Lastly, trade secrets are intellectual property rights on confidential and valuable information fundamental for the reproduction of a product (e.g. manufacturing processes, pharmaceutical test data, formulas…) and known only by a limited amount of people. Differently from patents, trade secrets do not offer the manufacturer a temporary monopoly, thus leaving anyone who is able to reproduce the product through independent research and development (R&D) or reverse engineering to put it on the market without any form of legal sanction. However, the advantage of trade secrets over patents is that, leaving undisclosed very important information, as long as no one is able to reproduce the very same product, the "monopoly" on the market can go well beyond the 20 years granted for the patent. The concept of "trade secrets" will be briefly addressed in section 2.2.2 of this work and will appear again in chapter 3 because "trade secrets" are playing a fundamental role in the context of the Covid-19 pandemic. (Brougher, 2014, 5-6; Poticha and Duncan, 2019, 289).

Theoretical background

Intellectual property can be inserted in a wider debate about its justifiability with different positions that I will briefly explain below. A "theoretical" digression is important not only to better frame and contextualize intellectual property, but also to critically assess (something that I will do in chapter 2.3) its very existence and draw useful conclusions for our inquiry.

In addition, a justifiability theory of intellectual property is needed in virtue of the particular status of "legal right" that it has. Considering the formulation of article 27.2 of the Universal Declaration of Human Rights (UDHR) and later article 15.1.c of the International Covenant of Economic, Cultural and Social Rights (ICESCR) that I will cite below, someone may even consider it a "human right" (e.g. Vawda, Baker, 2013, 67-68).

> 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.

Rights on property are normally granted on tools that could be ideally exploited by others than the owner who, in this way, would not be able to enjoy them. (e.g. a car, a house…) However, being intellectual property rights on "creations of the mind" that could be simultaneously used by many people without precluding access to anyone, third party exclusion must be adequately justified in order for the right to be in place.

Three main theories justify intellectual property: The Lockean, the Hegelian-personality theory and the utilitarian one.

The Lockean theory relies on John Locke's idea that people are entitled to own intellectual property on the products of their work because they crafted them with their own body, to which they have absolute property and because the core value of products is given through human labour.

However, since we live in a world where a free flow of ideas is allowed, we can imagine all our contemporary creations as "social creations" which owe their existence (partially) to previous other creations. Therefore, it is impossible to entirely attribute the value of a work to any particular labourer. If a possible inventor is detected, he/she may be rewarded for the effort put into the creation but nothing in Locke's thinking establishes that the reward should come in the form of IP protection rather than through prizes or financial aids. In addition, John Locke's original theory contained the proviso that private property could be granted only if there was "enough and as good left for others". It is safe to say that this is absolutely not what happens in the case of patents because, as long as the patent is granted, everyone else is excluded from reproducing the creation (Hettinger, 1989, 36-44).

The personality theory stems from Hegel's work on "Philosophy of Right" and in his notion of "the will as the core of an individual's existence". Because he believes that the external expression of the will is a tool for self-actualization, the rights on intellectual property have to be seen as "moral rights" given to the author because his/her creation is an expression and extension of his/her own personality.

However, if this can be true for piece of arts or music, the argument seems to not work properly with patents on chemical compounds or industrial tools (Khair, Hashim, 2020, 117-118, 120-121).

Arguably, the strongest theory used to justify intellectual property rights (at least in the form of patents) is utilitarianism which justifies the temporary monopoly on the market (and a restricted access to the product due to the high costs) with the greater aim of long-term social and economic welfare. In fact, according to this utilitarian view, if IP did not exist, there would be ephemeral incentives for creators to devote their own time, knowledge and resources for a project that could be easily "stolen" by other manufacturers. Since human creativity is one of the most important engines we have to drive progress, it is relevant for economic and social development to incentivize, recognize and reward it (Hettinger, 1989, 44-49).

The utilitarian theory, in virtue of its (apparent) superiority over the others is the interpretative framework I am going to use for my work.

1. INTELLECTUAL PROPERTY AND TRIPS AGREEMENT

Introduced in 1995 to harmonize the different domestic intellectual property (IP) standards, the "Trade Related Aspect of Intellectual Property Rights" Agreement – better known as TRIPS - is considered as the "international constitution" with regard to IP law. Its aim is not the introduction of a "one size fits all" IP regime across all nations, but to set an international minimum IP protection standard that has to be respected and implemented by the different domestic IP laws around the world. In fact, only in this way the IP of inventors is adequately respected globally.

The objective of this chapter is to explore the text of the TRIPS Agreement to understand its functioning. After a small background history on why the Agreement was realized (1.1), the chapter will move to the "interpretation key" of the Agreement: its article 7 and 8 that respectively set its objectives and principles (1.2). Subsequently, the chapter focuses on patents why they are important within the pharmaceutical sector and how they can be granted (1.3). Knowing that intellectual property protection in the form of patent system may clash with the enjoyment of human rights, the chapter analyses how the text of the TRIPS avoids possible tensions thanks to a large autonomy given to the national governments (1.3.1) and through the "TRIPS" Flexibilities and the Doha Declaration (1.3.2).

1.1. A look back to history: from Paris to TRIPS

The IP protection system dates back to the medieval times, when *"litterae patentes"* were given as a privilege to foreign inventors to produce and sell their creation inside the monarchy without any external competition for a limited period of time. In exchange, the inhabitants would get to know a new invention that they could reproduce as soon as the monopoly period was over.

The industrial revolution in England changed the trends because it started giving patents to all the creations which accomplished some procedural requirements. England was then followed by the US, which in 1790 enforced its own "US Patent Act", and by a post-revolutionary France in 1791. By the 19th century, almost every monarchy in Europe had its own domestic patent legislation.

However, with the increase in international trade, inventors started seeking an international recognition of their creations, something impossible to obtain at that moment because patents were allowed only within the national jurisdiction and patens law varied greatly among different countries. Therefore, the 1883 Paris Convention on the protection of Industrial Property and the 1886 Berne Convention on the Protection of Literary and Artistic Work became the first and foundational elements of a common European patent law. (Dreyfuss and Pila, 2018,4). With the Paris Convention the contracting parties established also a Union with regulation and supervision powers, a task overtaken in the 1970s by the UN administered agency WIPO (World Intellectual Property Organization).

Patents soon established themselves as the key to success and survival for many industries and manufacturers across the developed world. However, despite the existence of various international treaties, patent protections became again an issue in the 1980s when, with the globalization process, many developed world industries wanted to have their patents equally recognized also overseas. The Paris and Berne Convention, being stipulated only among developed countries, were powerless in front of developing countries which refused to grant the same level of patent protection. Moreover, the Conventions were unable to concretely sanction all the countries whose national IP laws did not enforce the international standards set. The rise of piracy, counterfeit goods and generic pharmaceuticals inside the developing world at prices that were much more affordable than those requested by the developed world industries, caused financial losses in the latter industries which started to push for a global harmonization of intellectual property laws in order to have their rights – and also financial gains - granted. (Sellin, 2014).

In the democratic system of the WIPO the coalition of dissenting voices from the developing countries blocked any request brought by developed countries to modify their IP system. Therefore, the United States, joined by Canada, Japan and EU, moved their requests for a stronger intellectual property protection inside the GATT (General Agreement on Tariffs and Trade) where, in virtue of their great economic power, they also had more influence on the decisions taken. Moreover, being the GATT dispute settlement system much more efficient than the former based on WIPO, countries whose patent system did not respect the standards would face a real threat of heavy sanctions.

Therefore, in the eight Uruguay Rounds that led to the shift from GATT to the WTO (World Trade Organization) regime, a necessary condition for becoming a member was to sign the

TRIPS Agreements (Trade Related Aspects of Intellectual Property) which legally obliges every member country to harmonize its own domestic, intellectual property regime with the minimum international standard set by the Agreement. If a country dares to transgress, the sanctions will be heavy because the WTO Dispute Settlement System is highly effective. (Helfer and Austin, 2011). Despite their opposition, the large democracies in developing countries such as India, Brazil and South Africa were forced to accept the new regime. (Sundaram, 2015).

The introduction of the TRIPS Agreements brought to the creation of the TRIPS Council, which had to check on the national implementation of TRIPS and assist developing countries while changing their own patent regime. In virtue of their financial and economic situation, developing countries were given time until the 1 January 2000, while least developed countries had time until the 1 January 2006. (Helfer and Austin, 2011, pp.24-29; 35- 38) The transition period for the latter was extended three times: until July 2013 (WTO IP/C/40), then until July 2021 (WTO IP/C/64) and lastly, due to the Covid-19 consequences, in October 2020 another extension period was granted following their request (WTO/ IP/C/64).

1.2 TRIPS Objectives and Principles

Even if perceived as an "obligation" by the least developed and developing countries, the correct interpretation of TRIPS lies on its articles 7 and 8 which respectively describe objectives and principles of the Agreement and are its "guiding lights". (Rochel, 2020). In fact, those two articles are the guarantee that, inside an Agreement that they consider unfair, the needs and interests of the developing countries will always be taken care of (Geiger and Desaunettes, 2017, pp. 68-ff cited in Rochel, 2020, p.26).

In fact, Art. 7 states that:

> 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.

The aim of the IP protection is the "promotion of technological innovation" with the end goal of "social and economic welfare" that counterbalances the possible short-term conflicts

between human rights and intellectual property rights that may arise during the monopoly period, finally leading to a "balance of rights and obligations".

As Spina Alì (2020) considers, the "rights" cited can be intended as "human rights" and not as some form of "legal rights", a perspective that is strengthened by the fact that "social and economic welfare" can be achieved through the correct implementation of economic and social rights. Mentioning the respect for human rights as an important element of the TRIPS Agreement implements the credibility of the whole IP system that, on the contrary, would not be justifiable anymore (Rochel, 2020, pp.28-30). Lastly, this "human rights" interpretation is recalled also in article 8.1:

> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Article 8.1 is interesting also because it highlights the national autonomy in regards to IP law, "provided that such measures are consistent with the provision of this Agreements" as the way to "balance the rights and obligations". In fact, it is only at the national level that the goals of TRIPS can be really achieved. (Slade, 2016, 959-974).

Article 8.2 further explores why "such measures" are needed:

> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

To sum up, if interpreted reasonably according to Article 7 and 8, TRIPS provides states with the possibility of striking a balance between IP and other human rights obligations.

1.3 TRIPS Patents

Since my work aims to address the impact of TRIPS on the human right to health and patents are granted for pharmaceutical products, in this section I will focus on patents, why are they important, how they are granted and how it is possible for states to – while ensuring IP protection – still be able to satisfy their human rights duties towards their citizens.

Developing a drug is a long process, with many obstacles and financial burdens. This is especially the case when the entity tested is a new chemical or molecular compound. The overall financial investments- even if they are not entirely shouldered by pharmaceutical companies- are estimated to be typically from $800 million to almost $ 2 billion (Light, Warburton, 2012). The steps from drug discovery to the market approval are many and only a few of the drugs produced turn out to be successful, thus leaving time and money invested for the R&D of other failed products without any form of financial gain.

The first moments of a drug discovery happen inside the laboratory, where only a few of the many compounds tested turn out to be promising. In a later stage those successful compounds go on a three - phases clinical test in order to detect their effectiveness. In the Phase I the compound is tested on animals to check its toxicity on "living beings". If there are problematic reactions the compound and the research will be stopped. If shown to be promising the compound will be brought to Phase II trials where it will be tested on a small number of healthy volunteers. In this phase the focus of the research is to understand whether and how the human body absorbs the drug and how the organs react. If there are no strange effects and the compound is considered to be safe the research will be moved to Phase III – the most important one - where the drug is given to wider groups of people to test efficacy and possible side effects. This last phase of testing is conducted in many centres all over the world so more clinical data are available, therefore leading to a more reliable assessment.

If the data collected are promising, they have to be submitted to a regulatory agency (FDA in the US; EMA in the EU) that has to certify the safety and the efficacy of the drug before it is put on the market. Only at this point, after around 6 to 10 years of research and trials, the pharmaceutical company is able to put its medicine on the market and to make financial gains.

The path for the research and development of a generic variation of the "original" drug is not so steep as the one described above: in this case we should not analyse a new compound but we simply want to create a copy of a drug that is already existing and efficient. In order to get market approval from a regulatory agency the generic manufacturer should only prove that the drug he aims to commercialize is as safe and efficient (bioequivalent) as the original drug already existing on the market. The time spent and the finance involved are for sure less burdensome in this second case than in the first one. (Ho, 2011, 9-15).

In light of the burdensome and risky process of pharmaceutical production, if patents did not exist, the pharmaceutical industry would have no incentive for R&D of new products because,

after many years of works, time and money, whoever generic producer could easily copy the product, sell it at a lower price and still obtain financial gains (because he did not have to start the research from scratch).

Therefore, the IP recognition through the patent system not only empowers pharmaceutical manufacturers recognizing them as the legitimate "inventors" of a product, but, giving them a 20 years' monopoly on the market, it is also fundamental to recoup their R&D costs – not only of the successful compounds, but also those on failed products that have never reached the market.

First of all, *conditio sine qua non* for receiving a patent is to be found in TRIPS Article 27.1:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

TRIPS article 28.1 specifies that both products and processes can apply for a patent request and enlists the deriving rights:

> A patent shall confer on its owner the following exclusive rights:
>
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
>
> (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

However, in order to receive a patent on its product the inventor shall also respect TRIPS article 29.1:

> Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

Access to "sufficiently clear and complete" information regarding the patented product is, in fact, the price that the inventor has to "pay" to the community in order to have its 20 years of market monopoly. In return, once the monopoly is expired, through these information manufacturers "skilled in the art" are able to produce a generic duplicate of the drug that, for sure, is cheaper and more accessible than the original one. In fact, the market monopoly and the

high prices of treatments with possible consequences on the health of some people are the "necessary evil" that the society has to bear in order to guarantee innovation and greater social welfare in the long run.

1.3.1 A compatibility reading of TRIPS and human rights (1): Freedom of interpretation, international exhaustion, national IP challenges and transitional period

However, how much of this short term "necessary evil" is actually necessary and how much of it can, in reality be avoidable? As articles 7 and 8 of the TRIPS Agreement state, in order to avoid massive conflicts between IP rights and the enjoyment of other human rights, national governments have some autonomy regarding the interpretation and the national enforcement of these laws.

Freedom of interpretation

The (arbitrary) vagueness of the definitions contained in the Agreement leaves a free space of manoeuvre to the national governments that, in this way, can do their "balance of rights and obligations". Below I present some examples.

Even if TRIPS article 27.1 requires granting patents without discrimination "in all fields of technology" and to "both products and processes" the Agreement does not specify what we should intend as "invention", "new", "inventive step" and "industrial application". "New", for example, can be understood in two ways: in its strictest interpretation it means that the invention should not have been previously known anywhere in the world; in its most relaxed interpretation it embraces new uses of a known and already patented product. The US as a developed country applies the latter definition of "new" but developing and least developed countries can adopt the strictest one without fear of being sanctioned. "Inventive step" means that the invention should create a significant advantage over what is already present on the market but no further explanation is given. Lastly, "capable of industrial application" is a very vague definition that may entail a very broad category of products, irrespective of their commerciality. (Ho, 2011, 62- 65; Sellin 185- 188).

India is a good example of a developing country with an individual and original interpretation of what can be patentable. India, more than any other developing country, was strongly hit by

the TRIPS Agreement because in the previous system it recognized patents only on processes and not on products. In this way, finding new methods to duplicate the expensive original product, the Indian pharmaceutical manufactory became the largest in the world. Regarding the definition of "new", the country adopts the strictest definition and allows patents on new "forms" of known substances only when they prove to have an improved efficacy over the precedent version. However, since it is difficult to prove the efficacy of an invention at the moment in which the request of a patent is filed (normally very early in the process) because an efficacy determination is assessed through years of collecting clinical data, Indian patent law rarely concedes patents on new "forms". Also, in regard to "inventive step", the country has its own, individual interpretation: to have this last requirement granted, the inventor who files a patent should show that his invention has a "technical advantage" and/or "economic significance" (Ho, 2011, 92-97).

Another example is TRIPS art. 62.2 which explains that the patent examination's process should be "within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection" but without giving any specification of the term "reasonable". Normally the patent term is counted for 20 years from the day in which the application is filed, therefore granting exclusionary rights to the inventor even before the patent has been granted. However, this is in no way an obligation: in fact, nations can decide to start counting from the moment in which the patent is actually granted, therefore reducing the "technical patent term" to the result of the subtraction between the 20 years of patent and the duration of the patent analysis. In this latter way, the longer or more delayed the analysis of a patent application is, the less will be the patent duration.

Moreover, if we consider that patented drugs cannot be commercialized without a regulatory market approval from agencies such as FDA or EMA, which is normally done at the very end of the trials when data about safety and efficacy have been collected, the "effective patent term" is even shorter, with an average of around 10 years. As a consequence, some (developed) countries provide market exclusivity beyond the "effective patent term" or provide an extension of the patent period but this is in no way a legal obligation. (Ho, 2011, 21-24; 68-69).

International exhaustion

A third possibility is given through the use of what is called "international exhaustion". Even if the inventor has the right to exclude third parties from reproducing, selling and importing its creation without his consent, it is up to the single nation to decide when the intellectual property rights related to the patent have been domestically and internationally "exhausted". The concept is highlighted in TRIPS art.6 that states:

> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

If a country adheres with the principle of "international exhaustion", it considers the IP rights of the patent owner to be exhausted after the first global sale of his product because it believes the inventor has already received his adequate reward. Therefore, this country can import the patented product from a nation to which the patent owner initially sold his invention without incurring any legal sanction.

Even if patent owning companies are against it, this principle enables countries which support it to buy drugs at the lowest market price, therefore ensuring a fairer and greater access to medicines also during the monopoly years without eliminating the IP profit deriving from the selling in countries which do not stick to it. Unsurprisingly, this principle is recognized by countries such as India and South Africa and it is strongly rejected by developed countries such as US and EU (though regional exhaustion is accepted in the latter case). (Ho, 2011, 40-50; 67; Sellin, 2014, 190).

National IP challenges procedures

A fourth possibility is the allowance, through TRIPS article 62.4, of national procedures to enable third parties to challenge both patents applications and already patented products. Indian law, for example, provides both the possibility to pre-grant (to be made after a patent request is filed and before it is granted) and post-grant (after a patent is granted) oppositions. In the first case, everyone who considers that the invention does not satisfy at least one of the necessary requirements for a patent to be issued, can present his objections. The success rate of pre-grant opposition is very high: 80%, while in post-grant the opposition can be presented only by "interested parties" (people with commercial interests in the field – workers or researchers) and only during the first year in which the patent is granted. (Ho, 2011, 101-102).

Transitional period

A fifth option is the full use of the "transitional period", which is the period granted to developing and least developed countries to harmonize their own weak or inexistent national intellectual property protection system with the minimum standard requirements requested by the TRIPS Agreements. As stated in Chapter 1.2.1, those countries obtained a 5 (if developing) to 10 years (if least developed) transition period, which was further extended in October 2020 due to the outburst of the Covid-19 pandemic.

However, as compromise, those nations had to find ways to secure and recognize IP protection of patented products once their transitional period was over. This was made possible through the creation of a mailbox provision and exclusive market rights (EMRs). With the mailbox provision the national patent offices, as soon as the transitional period expires, will have to analyse the patent requests that have been sent and stapled during the transition years and will have to judge their "newness", "inventive steps" and "industrial application" not in relation to the current year but in relation to the year in which the patent request was filed. The exclusive market right is given to drugs which have a pending mailbox application and allows inventors to still retain some commercial rights on his own product even if it has not been patented yet. (Ho, 2011, 84-86; Sellin, 2014, 170-172).

The last possibility is given through the accordance of flexibilities, which, due to their relevance, will be the subject of the next subparagraph.

1.3.2 A compatibility reading of TRIPS and Human Rights (2): TRIPS Flexibilities and the Doha Declaration

TRIPS article 30 and 31 provide exceptions to the current patent system allowing manufacturers to produce the generic version of a patented product without the authorization of the inventor.

Although TRIPS article 30 does not furnish any example of concrete situations in which a non-authorized use may be put in place, it however describes the criteria under which it can be issued: the measure must be limited (e.g. in the purpose, in its duration…), it must "not unreasonably conflict with a normal exploitation of the patent" and it must not "unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties". In her book Sellin makes a list of examples of possible exceptions compatible with article 30:

> Use of the invention for teaching and research; commercial experimentation on the invention to test or improve on it; experiments carried out for the purpose of seeking regulatory approval for the marketing of a product after the expiration of a patent (the so-called Bolar, early working or regulatory review exception). (Sellin, 2014, 195).

The Bolar-exception, obtained thanks to Canada's Patent law, allows generic manufacturers to work with the patented drug to study, develop and stockpile a generic version of the drug that will be commercialized as soon as the patent expires. Without the Bolar exception the monopoly duration of the original drug would actually exceed the 20 years granted by the patent because no generic version would be available. (Sellin, 2014, 196).

Article 31 allows the manufacturing and selling of a generic version of the original product while the patent is still active. Also known as "compulsory licensing" because the patent on the product is temporarily waived irrespectively of the (lack of) authorization from the patent holder, this article is the most important of all in order to ensure the "balance of rights and obligations" set by article 7. In fact, compulsory licensing is mostly used in circumstances of national emergency or extreme urgency (as described in article 31.b) and/or public health or interest (e.g. the impossibility of access to medicines due to their prohibitive cost). Because TRIPS do not explain under which conditions a country can be declared in "emergency" or "urgency" it is up to the single nation to define these terms.

TRIPS art.31 enlists a number of procedural conditions that have to be satisfied to grant compulsory licensing. First, it is not possible to advocate compulsory licensing for a whole category of products because it is only given to a singular product on a "case by case" basis. (31.a) Second, before issuing a compulsory licensing, the government has to seek a compromise with the patent owner through an authorized, "voluntary licensing" of its product. If, after "a reasonable period of time" no solution is found, then compulsory licensing can be put in place. (31.b) However, article 31.b later specifies that this requirement does not apply in situations like the ones of "national emergency or extreme urgency", or in cases of "public non-commercial uses" where nations are required to fast and concrete responses and can inform the patent holder in a second moment. Third, the patent holder in virtue of his status as "inventor" "shall be paid adequate remuneration" (31.h) in the form of royalties decided by the country which issued compulsory licensing. Lastly, independent judges should review both the legal validity of the compulsory licensing issued and the financial remuneration expected for the patent holder. (31.i, 31.j).

When granted, the rights obtained through compulsory licensing are "limited to the purpose for which it was authorized" (31.c) and end "once the circumstances which led it cease to exist are unlikely to recur" (31.g). Moreover, the compulsory licensing is "authorized predominantly for the supply of the domestic market" (31.f) Formulated like this, the sentence creates a great problem of access to medicines to all the (mostly poor) countries which do not have any pharmaceutical manufacture and that, because of domestic supply, are unable to ask for help from another country. This serious hurdle was assessed in the Doha Declaration, that I will explain below. (Sellin, 2014, 193- 211).

The Doha Declaration and the article 31bis

Adopted by the 4th ministerial conference in Doha in 2001 and strongly supported by a coalition of NGOs and developing countries, the Doha Declaration paved the way for a more equitable access to medicines and the use of compulsory licensing also within poor, non-manufacturing countries. The problem, universally acknowledged by all the WTO Members, was addressed in the famously known "paragraph 6" of the Declaration where the TRIPS Council was invited to find an expeditious solution" and to "report to the general Council before the end of 2002". (WT/MIN (01) /DEC/W/2).

The answer came in 2003 as the Council issued a formal waiver of TRIPS article 31.f, allowing non-manufacturing countries which face serious health threats to import the needed medicines from third, manufacturing countries. Even if mostly useful for least developed nations, the waiver can be used also by richer, manufacturing countries if they may need higher quantities of a drug than those they can manufacture. However, since many developed countries have pledged to never use the waiver as importing members (Australia, Canada, EU, Iceland, Japan, New Zealand, Norway, Switzerland, US) and many others stated they would import medicines only in case of extreme urgency (Hong Kong, China, Israel, Korea, Kuwait, Mexico, Qatar, Singapore, Taiwan, Turkey and UAE), the main and only beneficiaries of it will only be least developed countries.

As stated in paragraph (2.a) of the waiver, in order to use it the importing member should make a notification to the TRIPS Council where it:

> (i) specifies the names and expected quantities of the product(s) needed;
>
> (ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing

capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision.

The exporting countries, after having adapted their national laws to allow export of compulsory licensing, according to (2.b) have to (i) manufacture only the exact amount of product needed by the importing country, (ii) specifically label these products e.g. with special packaging colours/shaping, (iii) and publicly posting the information in (i) and (ii). Lastly, (2.c) they should notify the TRIPS Council "of the grant of the licence, including the conditions attached to it". (WT/L/540)

The products eligible for the waiver are all "pharmaceutical products": not only drugs but also the active ingredients needed to produce them and diagnostic kits. (Ho, 2011, 197- 210; Correa, 2004, 1-37). "As for compulsory licensing, also importing member who are using the waiver have to pay some royalties to the inventor".

The aim of the 2003 proposed waiver was to transform it in a permanent amendment (article *31bis*) of the TRIPS Agreement, as it is possible to read from the 6 December 2005 Decision and its Protocol. (WT/L/ 641, 2). However, because some countries criticized the Waiver, article *31bis* became a formal amendment of TRIPS only on 23 January 2017, (WLI/100). The countries which have not yet approved it have time until 31st of December 2021 (WTO Analytical Index, 2020, 5). Despite the controversies, the amendment is today formally recognized as an integral part of the TRIPS Agreement, which has to be enforced by all the members that subscribed to it until now.

The Doha Declaration is fundamental not only because it was the trigger for the creation of TRIPS Article 31bis, but also because, contrary to the international community behaviour at that time, it highlighted the importance of compulsory licensing as an essential element for the promotion of public health and as a necessary tool for the balance of "rights and obligations" stated in article 7.

In fact, the historical background of the Doha Declaration is characterized by a few controversial events. The first one occurred in 1997 in South Africa where, in response to Mandela's government introduction of parallel importation of medicines within the national law, 39 Big Pharma companies sued it with the accusation of a TRIPS Violation. The case was

later stopped because many NGOs (Oxfam International, Medicines Sans Frontieres, Health International) and national organizations opposed fiercely the lawsuit and later worked to assure that governments which used TRIPS Flexibilities would not be challenged in trials anymore.

They also sponsored various international meetings on global equitable access to medicines but unluckily no progress was made because developed countries kept pursuing their interests effectively hindering an equitable access to medicines in poorer countries. An example is the dispute settlement proceeding issued in 2001 by the US against Brazil's provision on compulsory licensing for access to HIV/AIDS medicaments.

However, US (and developed countries) strong opposition to it was challenged when, after some US Congress members received letters soaked in anthrax, the US government used the threat of compulsory licensing with the pharmaceutical industry Bayer, which produced *Ciprofloxacin*, the only drug against it. The inconsistency of US argument against compulsory licensing and the serious threat posed by the HIV/AIDS pandemic was the right framework to get things moving in the Fourth Ministerial Conference held at Doha in 2001. (Abbas and Riaz, 2018, 34-35).

The Doha Declaration coming from the Conference, in fact, besides recognizing the importance of intellectual property protection "for the development of new medicines" (paragraph 3), argues that it "should not prevent Members from taking measures to protect public health" (paragraph 4). In particular, it states once and for all that:

> […]
>
> (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
>
> (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

2. INTELLECTUAL PROPERTY AND THE RIGHT TO HEALTH

After having showed the functioning of the TRIPS Agreement and how it guarantees "on paper" the enjoyment of the human rights, the following chapter zooms on the practical relationship between the right to health and the intellectual property protection system.

The first paragraph (2.1) gives information regarding the content of the right to health and the states (2.1.1) and business obligations towards it (2.1.2), while the second paragraph (2.2) focuses on the consequences of the implementation of the TRIPS Agreement both within the developing (2.2.1) and the developed countries (2.2.2). After having analysed the UN position (2.2.3) regarding the actual intellectual property system, the chapter ends with a preliminary conclusion on its justifiability (2.3).

2.1 The Right to Health

The 1946 WHO (World Health Organization) Constitution defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" and considers that the "highest attainable standard of health" should be given to everyone "without distinction of race, religion, political belief, economic or social condition" (WHO, 1946, 1).

The WHO Constitution paved the way for the subsequent formulations of the right to health to be found in article 25 UDHR and in article 12 ICESCR. Together, these documents give a full perspective of the definition of health (WHO), the citizens' entitlements towards it (UDHR- "adequate standard of living and well-being including food, clothing, housing and medical care and necessary social services") and the states duties in respect to it (ICESCR). In particular, ICESCR article 12 is relevant because, since it was signed in 1966, it made the right to health legally enforceable.

Therefore, my inquiry will mainly focus on the content of article 12 ICESCR, which considers that:

> 1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
> 2. The steps to be taken by the States Parties to the present Covenant to achieve

> the full realization of this right shall include those necessary for:
> (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
> (b) The improvement of all aspects of environmental and industrial hygiene;
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
> (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

A fundamental interpretational key of ICESCR article 12 is the General Comment (GC) n.14, that, published in 2000 during the outburst of the HIV pandemic, gives some further details on the right to health. In particular, the relevance of the GC n.14 in regard to this work lies in a few key aspects: a better explanation of the real content of the right to health with its essential elements (the so called AAAQ Framework) and an outline of the State national and international obligations.

Regarding the first point, paragraphs 8 and 9 of the GC n. 14 do not consider the right to health as the right to be healthy but rather as a right to certain entitlements and freedoms considered to be necessary to reach a condition of physical and mental well-being. (Ooms, Keygnaert, Hammonds, 2019, 100; Tobin and Barret, 2020, 68). In fact, health depends on too many aspects and the State may be unable to "provide protection against every possible cause of ill health". Among the entitlements, paragraph 8 reminds that everyone shall have "equality of opportunity […] to enjoy the highest attainable level of health".

The steps that states have to take in order to grant the enjoyment of the highest standard of health are – as GC n. 14 paragraph 2 outlines – not limited to those described by article 12.2 ICESCR. However, worth mentioning –also in light of the current pandemic – is article 12.2 (c) which considers the "prevention, treatment and control of epidemic, occupational and other diseases". This means that states have to create a system of emergency medical care, make available technologies and implement immunization programmes for controlling the spread of infectious diseases. (CESCR, 5-6).

Paragraph 12 of the GC then highlights the essential elements of which the right to the highest attainable standard of health is composed, which are: availability, accessibility, acceptability and quality (the so called "AAAQ Framework"). *Availability* (12a) means that there must be within a state a sufficient quantity of health and health-care facilities, goods, services and programmes. They will vary depending on the state resources but they will have to include the underlying determinants of health, hospitals, trained medical and professional personnel and

essential drugs as defined by the WHO Action Programme on essential drugs. *Accessibility* (12b) means that health facilities, goods and services have to be accessible (i) without discrimination on the ground of race, colour, sex, language, religion, political or other opinion, nationality, birth or other status (as described by art. 2.2 ICESCR); (ii) in a physical sense- which means everyone, but especially vulnerable people, should be able to reach them; (iii) in an economic sense – "health facilities, goods and services must be affordable to all"; (iv) giving everyone the " right to seek, receive and impart information and ideas concerning health issues". *Acceptability* (12c) means that "health facilities, goods and services must be respectful of medical ethics and culturally appropriate". Lastly, *Quality* (12d) relates to the importance that medical facilities, goods and services are "scientifically and medically appropriate and of good quality". (CESCR, 2001, 4-5).

Looking at the two above paragraph we may conclude that access to medicines is a fundamental element for the enjoyment of the right to health, in particular they have to be physically and economically accessible, available in sufficient quantities, acceptable and of good quality. (Vawda, Baker, 2013, 65-66; Sellin, 2014, 84)

Nowadays, the right to health is recognized in many other international legal documents such as CEDAW, CRC, ICERD and in regional treaties.

In addition to article 12 ICESCR, the right to health is indirectly contained also in article 15.b ICESCR which considers the right of everyone to "enjoy the benefits of scientific progress and its applications", whereas among the benefits General Comment n.25 (CESCR, 2020b) considers also vaccinations "and the like" (par. 8). Article 15.b has an instrumental value towards article 12 ICESCR; in particular, "the promotion of scientific progress should facilitate better and more accessible means for the prevention, control and treatment of epidemic, endemic, occupational and other diseases (art. 12.2 (c))". (CESCR, 2020b, par.64).

2.1.1 States obligations towards the Right to Health

2.1.1.1 Progressive realization and the "minimum core" obligations

An important characteristic of the right to health and also an explanation of why this right is not a substantive right to be healthy is that, as every other economic, social and cultural right, it is subject to "progressive realization" which means that a state is required to do significant actions and financial investments in order to grant everyone the enjoyment of the right. The

economic and financial situation of every nation being different, it would be impossible to require the exact same objective standard of ESCRs. Therefore, what is being asked is that (art.2.1 ICESCR):

> Each State party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, *to the maximum of its available resources,* with a view to achieving progressively the full realization of the rights in the present Covenant by all appropriate means, including particularly the adoption of legislative measures (*italics* is mine).

The principle of "progressive realization", however, does not imply that States are allowed to proceed at a slow pace towards the enjoyment of these rights. On the contrary, as paragraph 3 of GC n. 3 (1990) explains, it is necessary that deliberate, concrete and targeted steps to reach the Covenant's goals are taken in the shortest possible time.

Every state is free to decide its own most "appropriate means" in order to grant the broadest human rights protection to its own citizens, but, in order to assure that governments consider human rights as their first priority, they have to explain to the CESCR the rationale of their decisions and actions. (CESCR, 1990, 2). This means that also States with very few resources have to be able to satisfy "a minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights incumbent upon every state party" (CESCR, 1990, 3). If a minimum core obligation did not exist, then the existence of a Covenant would be senseless.

According to General Comment n.14, among the "minimum core obligations" we find the following:

> (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;
>
> […]
>
> (d) To provide essential drugs, as from time to time defined under the WHO Action programme on Essential Drugs;
>
> (e) To ensure equitable distribution of all health facilities, goods and services;
>
> […]
>
> (b) To provide immunization against the major infectious diseases occurring in the community;
>
> (c) To take measures to prevent, treat and control epidemic and endemic diseases;
>
> […] (CESCR, 2000, 13).

Looking at the detailed GC n.14, we can conclude that access to essential medicines is a minimum core obligation that every state must fulfil regardless of its economic situation.

The concept of "minimum core obligations" is important also in the case of limitations of the right to health in cases of necessity. ICESCR article 4, however, reminds that these limitations must be "determined by law only in so far as this may be compatible with the nature of the right and solely for the purpose of promoting the general welfare in a democratic society". Being limitations and not derogations of rights, states have always to ensure that the "minimum core obligations" are always satisfied.

In general, the right to health being subject to "progressive realization", retrogressive measures should not happen. If this is the case, then they must be introduced only after a very careful consideration of alternatives and always after having used the maximum of the Sates' available resources at that moment.

2.1.1.2 States national obligations

Like for the other rights, states have an obligation to respect, protect and fulfil the human right to health.

Considering the right to health in its aspects related to access to medicines, the obligation to respect means that states do not have to impede or limit an equal access for everyone to health services, have to refrain from discriminatory practices, from marketing unsafe drugs and from applying coercive medical treatments. (CESCR, 2000, par.34).

According to the obligation to protect, States have to take measures in order to ensure that medicines and other health related products are: physically accessible to everyone, of good quality, economically affordable, and available inside their own territory in sufficient quantity. In relation to this last point, the 2006 Report of the Special Rapporteur on the right to health, clearly says that States:

> […] might have to make use of the Agreement on Trade-Related-Aspects of Intellectual Property Rights (TRIPS) flexibilities by passing and using compulsory licence legislation, thereby ensuring that medicines reach their jurisdiction in adequate quantities. (UNGA, 2006, par.47).

It is then the duty of a State to incentivize through adequate funding the pharmaceutical sector so that needed but non available treatments and vaccines for common or new diseases are

developed. Even if main principles of international human rights law are non-discrimination and equality, sometimes when dealing with vulnerable groups, States have to take measures in order to prioritize vulnerable individuals over others. (UNGA, 2006, par. 47-49-53). Moreover, within their duty to protect, States have to adopt legislations or other measures necessary to prevent that third parties could limit the enjoyment of the right to health through, for example, the assurance that vulnerable groups are protected, the control of the marketing of medical equipment and medicines by third parties and the control that the privatization of the health sector does not limit availability, quality, accessibility and affordability of health services and medicines. (CESCR, 2000, par.35)

Lastly, the obligation to fulfil is the obligation to "take positive measures that enable and assist individuals and communities to enjoy the right to health" through, for example, the adoption of a national health policy, the creation of a training system for doctors, the establishment of a health system insurance that is affordable to everyone. (CESCR, 2000, par. 36). An example of the violation of the duty to fulfil is the failure to take measure that grant the equitable distribution of health facilities, goods and services. (CESCR, 2000, par.52).

2.1.1.3 The state's international obligations

Besides their national obligations, States have also some international commitments that they pledged to observe in order to guarantee higher standards of living and social and economic progress (UN Charter, art 55-56; ICESCR art.2.1). As for the national level, the state's international obligations amount to the respect, the protection and the fulfilment of the right to health.

A concrete example of states' international obligations to respect is to refrain from entering into trade treaties that may conflict with the national obligation to promote the right to health. Before signing such treaties, a human rights impact assessment should always be done. (CESCR, 2017, par.13) In its 2011 "Guiding Principles of Business and Human Rights", Special Rapporteur Ruggie stated that, if signed, these treaties should always contain a space of manoeuvre for foreign governments in order to enable them to always meet their domestic human rights obligations. (HRC, 2011, par. 9). As stated in the 2006 Report on the Right to Health,

> In the context of medicines, this responsibility means that no rich State should encourage a developing country to accept intellectual property standards that do not take

> into account the safeguards and flexibilities included under the TRIPS Agreement. In other words, developed States should not encourage a developing country to accept "TRIPS-Plus" standards in any bilateral or multilateral trade agreement. They should help developing countries establish effective, integrated, inclusive health systems that include reliable medicine supply systems delivering quality affordable medicines for all, and support research and development into the priority health needs of developing countries. (UNGA, 2006, par.64).

Moreover, when dealing with situations of emergency, "given that some diseases are easily transmissible beyond the frontiers of a State, the international community has a collective responsibility to address this problem". (CESCR, 2000, par.40).

Lastly, in coherence with art. 28 UDHR, States are required to create an international environment that promotes and enables everyone the fulfilment of human rights. (CESCR, 2017, par.37).

2.1.1.4 The state's obligations in relation to businesses enterprises

Since the business obligations and the relationship between States and businesses enterprise was unclear and really never addressed, in 2005 the "Special Rapporteur on the issue of human rights and transnational corporations and other business enterprises" John Ruggie was given the task to analyse and reframe in an ultimate report this contentious subject. Its work, published in 2011 in the already mentioned "Guiding Principles of Business and Human Rights" and the 2017 published General Comment n.24 will be the main source of this paragraph.

As already stated in the 1990 GC n.14, a fundamental element of States obligation to respect is the prevention and protection from human rights violations pursued by third parties (among them also business enterprises). This means that, unless they furnish an adequate justification, States are never allowed "to prioritize the interests of business enterprises over Covenant rights" (CESCR, 2017, par.12).

In ensuring their duties to protect, states have the positive duty to establish laws that require businesses to respect human rights, periodically check on them and on other policies related to enterprises in order to assure that they grant the business respect of human rights, educate them on how to act in compliance with their human rights obligation and enhance them to explain their methods of addressing the impact they have on human rights. (HRC, 2011, par.3). States have also the duty to check that, as paragraph 22 of the 2017 report outlines, the privatization

of some services is not conditional on the ability to pay. Instead, when businesses have direct links with the State (e.g. controlled by it, it receives a substantial support from it, it is used by it for the delivery of services essential for the enjoyment of human rights), it is expected that it engages in further activities to prevent human rights violations. (HRC, 2011, par.4-5-6). A failure in one of these activities from the State amounts to a violation of its duty to protect. (CESCR, 2017, par.18).

Regarding their duty to fulfil, States have to direct the "efforts of business entities towards the fulfilment of Covenant rights". In particular, paragraph 8 of the 2017 report, elaborates that:

> in designing a framework on intellectual property rights, for instance, that is consistent with the Universal Declaration of Human Rights and with the right to enjoy the benefits of scientific progress stipulated in article 15 of the Covenant, States parties should ensure that intellectual property rights do not lead to denial or restriction of everyone's access to essential medicines necessary for the enjoyment of the right to health […].

Moreover, even if States are not legally bound by any international law to control and regulate the extraterritorial activities of the businesses present inside their own territory, it is desirable and recommended by human rights treaty bodies that they take steps to prevent that they commit international violations of human rights. (HRC, 2011, par.2). In fact, even if States are not directly responsible of the actions that third party enterprises are doing, they are nevertheless considered internationally accountable in the situation in which they failed to "take appropriate steps to prevent, investigate, punish and redress private actors' abuse". (HRC, 2011, par.1; CESCR, 2017, par.32).

2.1.2 Business obligations towards the Right to Health

In 2000 the Millenium Development Goal 8 recognized that pharmaceutical companies share with the state the responsibility to ensure the highest attainable standard of health; in 2008 the Special Rapporteur on the Right to Health Paul Hunt published a report on his on-field research on pharmaceutical duties towards the right to health and access to medicines (UNGA, 2008, par.2), an issue that received poor attention until that moment. This section will briefly analyse its main elements remembering that, even if it is debated whether businesses are legally bound under international human rights law, they have at least a moral responsibility to respect, protect and fulfil the human right to health.

First of all, “pharmaceutical companies should adopt a human rights policy statement which expressly recognises the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company” (paragraph 1). Secondly, the needs of vulnerable and disadvantaged people should always be a priority for them. Specifically, particular attention should be given “to the very poorest in all market, as well as gender related issues” (paragraph 5). Third, with the exception of limited ground, key information related to access to medicines has to be disclosed in a way that is publicly available (paragraph 6 and 7). Always related to the issue of transparency, pharmaceutical companies have to “disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels, that impact or may impact upon access to medicines.” (paragraph 17)

To ensure the high quality of medicines, these have to comply with the Good Manufacturing Practice Guidelines set by the WHO and with other international regulatory requirement for quality, safety and efficacy (paragraph 20). In relation to neglected diseases, pharmaceutical industries should publicly commit “to contribute to research and development” (par.23), engage with WHO and other relevant organizations with the aim of increasing its effort towards research and development for neglected diseases (par.24) and finally contribute with international initiatives which are looking for “new, sustainable and effective approaches to accelerate and enhance research and development for neglected diseases” (par.25). When selling their products, pharmaceutical companies have to ensure that their medicines are affordable to (almost) everyone, analysing the economic situation of the states in which they aim to sell and adopting policies such as differential pricing, public-private partnership, donations or voluntary licensing. Moreover, the company should publicly disclose the discounted price for developing countries, “the quantity and quality of its drug donations, the number of beneficiary patients treated each year and the amount of any tax benefit arising from its donations”. (par.33-38).

In regards to patents and licensing the report remembers pharmaceutical companies their duties to respect the spirit of the Doha Declaration, leave needy countries free to adopt the TRIPS flexibilities with the purpose of promoting access to medicines and recognize that least developed countries are not yet members of the TRIPS Agreements. (par.26-27-29). On the contrary, in these countries pharmaceutical companies should actively engage in voluntary licensing of products with the aim of increasing their availability and affordability (par.30) and

should abstain from filing patents for trivial modifications on already existing medicines. (par.31).

Lastly, when pharmaceutical companies reunite in associations, these guidelines apply in the same manner (par.46).

2.2 Intellectual Property and the Right to Health: conflict or coexistence?

After having seen how access to essential medicines is among the "core" duties that States have in relation to the highest attainable standard of health – a concept that was also highlighted in UN Commission of Human Rights Resolution 2001/33 regarding the HIV pandemic – this section analyses how the TRIPS system works in practice to check whether its outcomes are compatible with the state and business duties towards the right to health.

Reminding that intellectual property protection is always a bargain between the fulfilment of the monopoly interests of the producers and the enjoyment of human rights of the population, the previous chapter showed how, thanks to the vague wording of the TRIPS Agreement, the parallel licensing, international exhaustion, transition periods and most importantly the use of flexibilities, every nation is – at least on paper – able to successfully provide by itself to the "balance of rights and obligations", being compatible with the Ruggie Principle explained in paragraph 9.

This "complementarity" view can also be spotted in a 2001 report by the UN Secretary General on TRIPS, where WTO highlights how individual human rights and public interest are the traditional foundations of intellectual property protection. (ECOSOC, 2001, 7). However, "paper" and "real world" implementation can be very different, therefore the rationale to assess the "practical" consequences of the system, both within the developing (2.2.1) and the developed world (2.2.2).

2.2.1 Intellectual property protection and right to health in the developing world

When it was introduced in 1995, the least developed and developing countries were by far the most struck by the new TRIPS pharmaceutical regime because it forced them to introduce

patents also on health products which before, due to their importance, were not patented. Their forced membership caused an abrupt rise of costs on pharmaceutical products and the short term impossibility to create cheaper, generic versions available and affordable to everyone. Even though the TRIPS Agreement allows for flexibilities, in reality they are considered as controversial and problems revolve around them (Khachigian, 2020,1138), both in political and structural terms.

High costs of medicines

First of all, because patented products do not allow for the generic competitions, the high prices hinder access to medicines to a large part of the population. Problematic are the costs of medicines for non-communicable diseases like cancer, that despite their "differential pricing" for developing countries are still unaffordable to the most (Gopakumar, 2015, 374-375). Being the income distribution of the population living in developing countries uneven, rich people in these countries are able to pay whichever sum of money, guaranteeing a safe financial gain to the pharmaceutical companies which prefer to keep high prices (Guennif, 2017, p.560).

Compulsory licensing: structural limitations and political pressure

A possible way for States to trigger market competition is the "threat" of compulsory licensing in the hope that pharmaceutical manufacturers will lower their prices. However, to use the TRIPS flexibilities, a whole body of institutional and administrative mechanisms is needed that, due to the lack of resources, many developing and least developed countries cannot afford. WTO, WIPO and developed countries have the duty to furnish technical assistance to countries in need but, as an external review of WIPO noted, little advice was given on how to use TRIPS flexibilities. (WIPO, 2011). In fact, developed world patent offices, rather than teaching developing countries the patent standards adopted by the latter, educate them on the one, stricter, adopted by them. (Gopakumar, 2015, 388).

Moreover, when a government wants to use compulsory license it incurs the duty to provide information in relation to the prevalence of a disease condition, the number of people affected, the sales monitoring of the patented medicines and so on. A state with no finances to assess these public health indicators will never have the chance to use compulsory licensing. (Gopakumar, 2015, 383).

In addition, developed countries and pharmaceutical corporations have always pressured developing countries not to adopt TRIPS flexibilities threatening them with economic retaliation. Beside the already mentioned South Africa case, Thailand in 2006 and 2007 was pressured by pharmaceutical companies Merck and Abbot to withdraw from the market the compulsory licensing on its product *Plavix, Ritonavir* and *Clopidogrel*. On its side, the EU Trade Commissioner informed the Thai Government that its actions would result in its isolation from the global market (UNSG, 2016, 24), while the US Trade Representative added Thailand to its "Priority Watch list" in the "Special 301 Report" imposing high taxes on the importation of three Thai products. (UNSG, 2016, 25). Being these non-HIV products, developed countries feared that the compulsory licensing (initially allowed for HIV related products) would enlarge the pool of medicines for which compulsory licensing could be asked. However, limiting compulsory licensing only on HIV related products would mean depriving a large amount of the global population the right to health. (Son, Lee, 2018b, 1436).

Even if illegal under the WTO Law, the US Government has always used the USTR "Special 301" registry to enlist the countries which do not offer an adequate intellectual property protection standard for US products and among them we also find the countries which issued a compulsory licensing. (Vadi, 2004, 202; Gopakamur, 2015, 385-386). Even if developing countries are free to use the mechanism of compulsory licensing according to their interpretation of "national emergency", the fact that, contrary to the UN System, the WTO dispute settlement system has "teeth", the choice between the grant of the right to health of the citizens and economic sanctions is sadly very easy to make. For this reason, the "US Special 301" keeps frightening foreign governments ever since. For example, a report released by the USTR in 2018 shows how the US is still committed to reinforce IP protection measures in a number of countries, among which we can find the developing Mexico, Argentina, India and Indonesia.

Due to its strategic importance in a world where patents on pharmaceuticals are constantly growing, it is necessary for every developing country to be able to use it without being politically pressured or burdened by its lack of resources as a reason not to have it granted. (T'Hoen, Veraldi, Toebes, Horgezeil, 2018, 189). Even if it is the easiest way for having available medicines, compulsory licensing has always been viewed as only a temporary solution that, in the long run, will not be able to solve the health related problems of developing countries. (Guennif, 2017, 563; Gubby, 2020,51).

The structural limitations of the Doha Declaration

Given that domestic compulsory licensing is a long and hard process to obtain, the article *31 bis* introduced after the Doha Declaration to allow the exportation of drugs to countries without a domestic manufacturing is even harder because it contemplates the issuance of two types of compulsory licensing; one for the exporting and one for the importing member. Leaving aside the many, cumbersome and time consuming passages needed to activate the waiver (and fully described in chapter 1.2.3.2), the absurdity is that, because article *31bis* has a validity limited in time, if international compulsory licensing is further needed or if the quantities of the product are not enough, the whole process has to be restarted again. Being able to determine the exact amount of drugs needed at the outburst of a pandemic is almost impossible, therefore the decision to put a temporary limit to the article *31bis* is senseless.

In addition, in order to use the article *31 bis*, the domestic legislation both of the importing and the exporting country should be changed. However, due to its incredibly long and cumbersome application process, article *31bis* has been used only once in 2007 in Rwanda (importing) and Canada (exporting country). When in 2009 the Canadian pharmaceutical company *Apotex* finished delivering the drugs to Rwanda, it said it would never use the waiver anymore. Given the fact that only a small amount of developed countries decided to modify their domestic legislations in order to be compatible with the waiver requirements, the system will be hardly used in the future. As Abbaz and Riaz conclude, this is a clear example of regulatory ritualism where the imposition of so many rules is at the expenses of the real goal. (Abbas, Riaz, 2017, 37- 45; Ooms, Hanefeld, 2018, 4-5). However, with the rise of always more patented drugs, the need of a functioning system is more urgent than ever. (Adekola, 2020, 5).

TRIPS-Plus Treaties

Not satisfied with the freedom given from TRIPS to the developing countries, developed ones started adopting bilateral trade agreements with stronger IP clauses. Commonly known as "TRIPS Plus", these agreements ripped poor countries off some of the autonomy they had. Very common IP provision in these agreements are, for example, the requirement that with "new" member States understand at least one of the following: new uses, new methods or new processes of using a known product; another one is that delays in granting a patent are adjusted with an extension of the actual patent terms. Patent linkage, a controversial tool that requires that health authorities, when granting market approval of a drug, coordinate with patent offices,

(therefore "linkage") has also been definitely recognized within these agreements. These rules prolong the monopoly period of pharmaceutical products and delay market entrance of generics. Furthermore, some agreements pose some limitations to the interpretation of "national emergency" and to the use of compulsory licensing. Unluckily, due to their strong accountability system, if IP rules are violated, penalties will be stricter than ever. (Gleeson et al, 2019, 6; Shadlen, Sampat, Kapczynksi, 2020, 80-84; Gleeson, Lexchin, Lopert, 2018, 11-19).

Why, then, poor countries accept such agreements? Because they are built on a "constructive ambiguity" that apparently still gives leeway to national governments and that is fundamental for negotiators to get them signed (Son, Lee, 2018a, 1174-1175). Moreover, the bargaining power of developing countries is generally weaker than those of rich countries, therefore they are unable to influence the standard setting- process within the international WTO framework. (Gleeson, Lexchin, Lopert, 2018, 21).

Amy Kapczynski (2015) titles a paper asking whether the TRIPS-Plus Agreement TPP is bad for our health. Actually, TRIPS-Plus are also in complete dissonance with the state international duty to create a global enabling environment that favours the enjoyment of the right to health and with the obligation, reported in the 2006 Report on the Right to Health, not to encourage developing countries in entering into "such agreements.

Structural problems related to R&D of neglected diseases

Lastly, the patent system has an incommensurable structural problem: the way in which it is designed does not give adequate incentives to the pharmaceutical companies to invest in R&D of the so called "neglected" or "very neglected diseases" that mainly occur within least developed and developing countries. In fact, in a system that is mainly focused on the financial gains that derive from the monopoly period, even if a drug against leishmaniasis or dengue were to be found, almost none inside the developing countries would be able to pay the high monopoly prices that the pharmaceutical company would set (Cullet, 2003, 142; Gopakumar, 2015, 376).

This lack of interest is very well shown by the very little number of drugs expressly targeted for the "third world" that have been manufactured in the last years. Between the 1975 and the 1999 only 15 among the 1393 new drugs produced were suitable for the neglected tropical

diseases. (Chirac, Torreele, 2006, 1560- 1561; Sunyoto, 2020, 531). In the first decade of the 21st century, among the 336 new chemical entities approved, those related to the neglected diseases were only 4. (Gopakumar, 2015, 375-376). Lastly, from 2012 to 2018, of the 256 new therapeutic products only 8 were aimed at neglected diseases. (Sunyoto, 2020, 531). This trend is also called in the literature as the "90/10 syndrome" because 90% of global research spending is used for diseases that affect only the 10% of the global population that lives in the rich, developed world" (Guennif, 2017, 559).

The problem arising from it is that sick people in the developing countries are treated with drugs that are aimed at curing other diseases, therefore receiving medicines which are not of the best quality to treat them. If we consider that studying and finding new treatments against neglected diseases is both an international community (UNGA, 2006, par.64) and a pharmaceutical duty (Hunt, Khosla, 2008, paragraph 23-24-25), the fact that so few new medicine compounds against them have been discovered in the last years should make us think whether enough infectious diseases research programmes have been developed and whether they are adequately funded.

2.2.2. Intellectual property protection and right to health in the developed world

The aim of this section is to assess the consequences of the actual IP system among the developed world to check whether, at least here, IP brings some forms of economic and social welfare.

Strategic uses of patents

In a 2020 published article, author Helen Gubby explains how IP system is used by big pharmaceutical companies with the financial asset necessary for paying the patenting costs to exclude other manufacturers from the R&D of generic versions through the adoption of the so called "wrap around" strategy. The strategy consists in "wrapping" around the main patent for a medicine also other "secondary" patents (for e.g. the dosage, the delivery system, for the combinations...) hindering competitors from creating the generic version of the patented drug. In fact, if the drug is covered by many layers of patents, it will be very difficult for the generic manufacturer to find different ways to reach the same result because the risk of infringing some

of the many patents and being sanctioned is very high. (David, Halbert, 2017, 153). Moreover, as secondary patents are probably applied for in a later stage than the main patent, the generic manufacturing of a medicine will be delayed in time. As a consequence, the pharmaceutical company ensures for itself the whole control over the market for a time that is longer than the actual patent.

These "blocking strategies" can be both for defensive (in order to give the pharmaceutical company the assurance to work without any form of disturbance) and offensive purposes. In the latter case the pharmaceutical industry files for a patent for different processes or products that they do not intend to work on but that could be alternative solutions for possible competitors. In 2016 Torrisi (Torrisi et.al., 2016, 1374-1375) discovered that the number of patents filed as an "offensive strategy" was substantial: between 36%-38% of patents are never used.

Another "strategic" way of patenting is to prolong the actual monopoly term with the request of secondary patents just before their expiry on "new forms", "new uses" or on slight alterations of the original chemical compound. This practice is called "evergreening" (Beall et.al, 2016) and, although it is allowed inside the developed countries, its justification is very controversial because, differently from the R&D on new compounds where the success rate is low and the clinical trials are many, the R&D on variations/ameliorations on an already successful and marketed product are much easier, faster, and less expensive. Therefore, the additional monopoly years on the market are hardly justifiable in terms of R&D recoup costs and even less in terms of innovation because the longer the patent, the more difficult it is to generate a healthy competition. This very controversial trend is dangerous not only in terms of financial expenses but also in terms of innovation. In fact, if many years of market monopoly protection are assured even for little changes to the original product, why should the pharmaceutical company invest many years of work, competences and money to develop a new medicine that has a high percentage of possible failure?

A third strategy approach is the "pay for delay" agreement, where the generic manufacturer is paid by the patent owner company in order to delay the market entrance of the generic version. (Barazza, 2014, 80). Sometimes these agreements contain also clauses where the generic manufacturer is asked by the patent owner not to challenge the validity of its secondary patents in cases in which this may be dubious. These clauses are problematic because, as the patent system may reduce access to medicines for a limited period of time, the possibility for experts

to question the validity of a newly granted patent is an important tool that, in this way, is quickly wiped away. These agreements have been judged very damaging for the public health budgets by the European Commission, which, in 2009, decided to fine some of the pharmaceutical companies (among them Novartis and Johnson and Johnson) which were known to have entered such agreements. (Gubby, 2020, 50).

Strategic uses on patents have a direct negative consequence on innovation and the right to enjoyment of the benefit of science, which, in turn, has consequences on the right to health in terms of access to medicines. Limiting both competition and innovation, strategic patenting goes at the expenses of the welfare of the society.

Fake diseases

Another great problem of the intellectual property protection system is that the desire of controlling the market through monopolies leads pharmaceutical companies to develop medicines faster than they should, boosting their safety and efficacy and rushing them to the market before the long-term health effects can really be assessed. This move is risky in relation to the good quality criteria of the medicines and goes against both the national duty to assess the quality framework of a medicine (CESCR, 2000, 21) and the duties of pharmaceutical industries.

Moreover, Vawda and Baker argue that to increase their market sales, some pharmaceutical companies spend a lot of money in "marketing studies" and invent new, fake diseases to make their own product (which, of course, is able to defeat them) more attractive. (Vawda, Baker, 2013, 72). This tendency to invent "fake" diseases is called "disease mongering" and is closely analysed by *Plos Medicine* (2018). However, despite many Big Pharma such as Abbot, AstraZeneca, Johnson &Johnson, Pfizer, Novartis were fined from $95 million to $3 billion for "disease mongering" and faking scientific results between 2007 and 2012, this did not stop them from carrying on with it. (Yaqub, 2014).

Structural vagueness

Structural vagueness is not always positive: TRIPS article 29.1 is the example of a structural vagueness that extensively favours only pharmaceutical industries. To obtain a patent, the article requires the inventor to disclose its invention in a manner that is *sufficiently clear and*

complete for a generic manufacturer skilled in the art to reproduce it. However, it is not explained what *sufficiently clear and complete* means (Garrison, 2020b). Therefore, WTO Member states are free to require that the applicant explains *a way* (even poor, as long is sufficient) or the *best way* to realize the product. Normally the patent filing is made quite early in the R&D process, so, if afterwards new valuable information on the best manufacturing way are acquired, there is no legal obligation for the inventor to publicly disclose them**.** These additional information, normally referred to as "know-how" (broadly) or trade-secrets (narrowly) pose an additional threat to innovation and reproduction of some generics where they are necessary (e.g. the vaccines).

However, the presence of such undisclosed information seems to violate the silent agreement on which the whole intellectual property protection is based upon: a period of market monopoly and great revenues in exchange of the disclosure of the invention for the greater global good. As Garrison explains, it is as if the pharmaceutical industry had its cake and eat it too!

From the evidence above, it seems that the actual IP system is a burden not only for the developing world countries but also for citizens in the developed world. In fact, even if originally designed for greater economic and social welfare, the evidence shows that IP system ended up being a tool for pharmaceutical companies to obtain safe financial gains at the expenses of all of us.

2.2.3. The UN Position

In the debate among human rights and intellectual property protection, the UN clearly stated its position in 2000 where, with the Resolution 2000/7, it recognized the existence of "apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law on the other" (ECOSOC, 2000, par.2) and therefore reminded all governments of the "primacy of human rights over economic policies and agreements" (ECOSOC, 2000, par. 3).

In the following years other various statements, reports and relations were produced by UN members, with the aim of regulating the interaction between IP and human rights, criticizing the introduction of TRIPS Plus treaties and assisting developing countries in the transfer to the

TRIPS regime. Even if they are non-legally binding, they are nevertheless considered important soft law instruments that have to be followed by the international community.

Among these, the 2001 Report of the High Commissioner on Human Rights highlights why TRIPS are incompatible with the Human Rights discourse: "the promotion of public health, nutrition, environment and development are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves"; "the Agreement sets out in considerable detail the content of intellectual property *rights* […] only alludes to the *responsibilities* of IP holders that should balance those rights in accordance with its own objectives"; TRIPS has " an impact on States' ability to decide on development strategies" and lastly, it "focuses on forms of protection that have developed industrialized countries". (HCHR, 2001, par. 22-25). In their documents, UN Members often outlines the human rights supremacy over intellectual property: the former are natural (in the sense that they are intrinsic in the human nature), inalienable and irrevocable while the latter are instrumental, artificial and temporary. (ECOSOC, 2001, par.6).

In his 2003 Report, the Special Rapporteur Paul Hunt remembered that a joint study by the WTO and the WHO showed that already existing problems of access to health services in developing countries have been worsened by the introduction of TRIPS and highlighted the international obligations of the UN member States. (HRC, 2003, par. 88-89) In his 2004 Report he expressed concerns for the neglected diseases and the fact that the actual TRIPS design incentivizes only the study of "profitable diseases" (HRC,2004, par.42). In 2008, Hunt published the already mentioned "Guidelines for Pharmaceutical Companies in relation to access to medicines".

In 2009 the Special Rapporteur Anand Grover made a detailed analysis of both TRIPS and TRIPS-Plus Agreements, noting the problems arising for developing countries when they want to implement TRIPS flexibilities, citing the examples of South Africa, Thailand and India. He also criticized the article *31bis*, advocating for a substantial revision and expressed his concern in relation to the adoption of TRIPS-Plus Agreements. He concluded the report recommending poorer countries to review their own laws in order to take full advantage of the TRIPS flexibilities. (HRC, 2009). A number of later reports both by the Special Rapporteur on the Right to Health and the Right to Culture highlighted the state's international obligations not to support nefarious agreements such as TRIPS-Plus, which are extremely damaging for the enjoyment of human rights in poorer country.

In 2016 the Secretary General Organized a High Level panel on Access to Medicines in which he further highlighted that WTO Members should respect the spirit of the Doha Declaration (UNSG, 2016, 9). Because TRIPS flexibilities should not be seen as an exception but as a fundamental part of the TRIPS machinery, concern is expressed in relation to the fact that TRIPS members have "not pursued implementation of the flexibilities that protect the health of their populations with the same vigour as they have enforced intellectual property protection" (UNSG, 2016, 20). The Report then remembers the supremacy of human rights over intellectual property rights, but is well aware of the fact that WTO accountability system is much stronger than the human rights one. It then outlines how between public health objectives and TRIPS there is a misalignment and how this may result in tensions, especially with regards to the use of flexibilities and the trend of "patent thickets" (pag.21-23). In light of the above, WTO Member states and their pharmaceutical industries must refrain from limiting in any way (threats, retaliation, entering dangerous TRIPS-Plus bilateral agreements) the international enjoyment of the right to health. (pag.27-28).

The last document about IP and right to health is the 2020 issued General Comment n.24 on the right to enjoy from the benefits of science (CESCR, 2020b) which, recalling the Doha Declaration, highlights the fact that IP should be supportive to the right to health and advocates for the use of TRIPS flexibilities when needed. (par.69). IP should not bring to negative consequences; when it is the case then states should resort "other incentives, such as so-called market entry rewards, which delink remuneration of successful research from future sales, thus fostering research by private actors in these otherwise neglected fields".

2.3 Is the patent system really justifiable?

In light of the above mentioned findings, is it possible to justify the actual patent system as it is structured right now? My answer is no because the two main rationales for their existence - the incentive for innovations in order to boost the economic and social welfare and the need to recoup high R&D costs- seem to be at odds.

In regard to the first one, the actual trend shows that pharmaceutical companies prefer investing in "me too" drugs (Hollis, 2004) or in "secondary patents" of already existing medicines because of safe financial returns. Despite their duties, no significant discoveries have been done

in the field of neglected and very neglected diseases, while treatments for critical illnesses have been mainly realized and financed by public institutions. The pharmaceutical sector came only in a later stage, when clinical trials had to be conducted and the public sector did not have the adequate tools and expertise to assess multicentre trials. This pattern was visible also for AZT drugs against HIV (Sharife, 2016) and was repeated in light of the current Covid-19 pandemic (Rutschman, 2021a). On the contrary, paragraph 2.2.2 showed how pharmaceutical industries "gamed" the system for their financial interest and at the expenses of the global enjoyment of the right to health. At the end, being the situation as the one described above, it is possible to say that the "greater welfare" that TRIPS wants to achieve seems to be only that of pharmaceutical companies.

In addition, the idea that IP protection is necessary to boost innovation has been challenged by a study held by Neves, Afonso, Silva and Sochirca (2021) that shows how the impact of IP on innovation does not always follow a straight line but it is rather mixed. To those claiming that the financial gains deriving from the market monopoly are immediately used for R&D of new medical products, Caso (2020) mentioned how Stiglitz managed to show that the pharmaceutical industry, in real, invests the great majority of it in activities that are very far from the medical innovation (e.g. pharmaceutical lobbying).

Also the second justification about recouping R&D costs seems untenable. In fact, it is important to remember that Big Pharma thanks to its strong lobbies (at least in the US) managed to get heavy tax discounts on its revenues. In addition, with the creation of public-private-partnerships an amount of funding for the biomedical research actually comes from public taxes.

The exact assessment of R&D costs of new drugs has always been hard because of opaqueness and lack of collaboration from the pharmaceutical industry. More than 15 years ago a study from the Tufts Center analysed 68 products coming from 10 different pharmaceutical industries and concluded that on average the R&D costs of a new medicine was around $800 million and $1.8 billion. However, since the names of the drugs and the companies partaking in it were not revealed, it is difficult to assess the transparency of the work. The data on which the study relies were directly given by pharmaceutical companies, which have all the interest in boosting them. If looked closely, the analysis reveals what Sharife (2016, 93) considers a "fuzzy math": absent were the tax deductions but included in the R&D costs there was also the "cost of capital" which, said differently, is the financial gain the pharmaceutical industry would have had if,

instead of using its money to venture in drugs R&D, it had invested it in the stock market. Curiously, the addition of these costs, whose justifiability is questionable, doubled the R&D expenses. (Sharife, 2016; Light and Warburton, 2012).

Moreover, even if the WTO states that human rights are among the foundational element of TRIPS and therefore compatible with the ICESCR (ECOSOC, 2001, 7), it is surprising that, while creating

> "[…] new rights for producers of IP and obligations for the users and consumers, it barely speaks about the rights of the users of IP, which is uncharacteristic of an international agreement created and administered by a world governing body" (Sundaram, 2015, 122-123).

Patents are subjected also to another, ontological criticism on their "human rights status" on the basis of art. 27 UDHR and art.15.1.c ICESCR. Two comments have to be made. The first one is that – even if the vague wording of the document may lead to an interpretation of intellectual property rights as human rights – in real intellectual property rights do not *necessarily* overlap with the human rights conception.

The point was highlighted also by the Special Rapporteur in the field of cultural rights Farida Shaheed that emphasised how patent laws cannot be justified in terms of "right to protection of moral and material interests of authors", especially when they "inadequately respect […] the right to health". (Baker, 2021, 260). In addition, General Comment n. 17 (CESCR, 2005) clearly stated that "the scope of protection of the moral and material interest of the author provided for by article 15, paragraph 1(c) does not *necessarily* coincide with what is referred to as intellectual property rights under national legislation or international agreements" because, in contrast to human rights, intellectual property rights are of a temporary nature and "primarily protect business and corporate interests and investments" (par.2). The concept was taken by previous UN Documents (e.g. ECOSOC, 2001, par.6) which did considered IP as "real rights" because of their temporary (and not timeless) and artificial (rather than intrinsic – they are granted by the State and can be revoked) nature and widely used also in the literature (e.g. Cullet, 2003; Ygzaw, 2015; Spina Alì; 2020).

The second point is that, even if they were considered as human rights, UDHR and ICESCR do not mention that "the protection of the moral and material interests resulting from any […] production of which he is author", should be necessarily shaped in the form of patents.

To sum up, despite the WTO claims, in light of the above the actual patent system seems to be hard to justify. Access to medicines is not only a personal right but also an international duty that does not have to be limited by international political strategies or private interests. The way in which TRIPS is actually framed and the history of pressure and oppression by developed countries and pharmaceutical lobbies are concrete obstacles to the creation of an international environment that enables everyone – at a global level- the enjoyment of the highest attainable standard of health.

3. INTELLECTUAL PROPERTY, THE RIGHT TO HEALTH AND COVID-19 PANDEMIC

The rationale of this chapter is to analyse, through the concrete example of Covid-19 pandemic, the role of intellectual property protection in the form of patents within the bigger framework of the need of an equitable global vaccine roll-out. After having described the various but insufficient countermeasures to fight the pandemic (3.1), the chapter focuses on the TRIPS Waiver Proposal (3.2) put forward by South Africa and India back in October 2020, highlighting the different positions inside the debate and showing the problematics both of the patent system per se and the inadequacy of the TRIPS flexibilities in a global pandemic. Lastly, paragraph (3.3), following two CESCR Statements on the right to health issued in response to the pandemic, analyses the behaviour of states and pharmaceutical companies in relation to the intellectual property.

Covid-19 is the perfect case study not only because we are living in the midst of a pandemic, but also because it has been a great stress test for the justifiability of the TRIPS system and its respect for health rights in a global emergency.

3.1 International countermeasures to the Covid-19 pandemic

The aim of this chapter is to describe two international countermeasures that have been taken to tackle the Covid-19 pandemic: the ACT-Accelerator with its vaccine pillar "COVAX" (3.1.1) and the C-TAP and Open Covid Pledge program (3.1.2) to analyse whether they are sufficient or whether new solutions to fight the pandemic are needed.

3.1.1 The ACT- Accelerator and its "vaccine pillar": CEPI and GAVI "COVAX"

In April 2020 various governments, scientists, civil society organizations, philanthropists and global health organizations such as the Bill & Melinda Gates Foundations, CEPI, FIND, Gavi, the Global Fund, UNITAID, Wellcome, the WHO and the World Bank established together the Access to Covid-19 Tools (ACT) Accelerator. Its aim is to bring about the best global response to the pandemic through an integrated system of diagnostics, therapeutics and vaccines.

Its “vaccine pillar”, presents a three level structure provided by CEPI, which deals with the “vaccine development and manufacturing”, the World Health Organization, which oversees “policy and allocation issues” and Gavi which is responsible for “procurement and delivery at scale” of the vaccines. (Rutschman, 2021b). With a 1.4 $ billion raised by July 2020 for the vaccines programmes of Moderna and Inovio, CEPI was the major funder of the Covi-19 vaccine R&D (Lancet, 2020, 1405), followed by the US government with its “Operation Warp Speed”, the European Union and the Gates Foundation. (Wouters et al., 2021, 1026).

Why was so much public money used to co-financing vaccines R&D when, through the patent system vaccines can enjoy the advantages of the monopoly once put into the market? Because, as Rutschman (2021a) states, vaccines are among the most unprofitable pharmaceutical goods with a high financial investment risk and few financial revenues condensed in a short time frame. In fact, after a peak on requests due to epidemics or the rise of some infectious diseases, they become useless. The market is so unprofitable that neither the possibility of issuing a patent is appealing.

That is the reason why at the beginning of the pandemic, despite the high numbers of people infected, the private sector was reluctant to engage in the R&D of vaccines and why massive funding and advanced market commitments by the “vaccine pillar” were made. In this way, what should have been a risky investment for the pharmaceutical industries, probably became their safest one because the highest risk was carried by rich governments and international organizations. (Eccleston-Turner, Upton, 2021, 7).

Regarding vaccines procurement and delivery, in May 2020 GAVI designed the Covid-19 Access Facility, also known as COVAX to offer participating countries the fastest and most equitable vaccine supply, irrespectively of their ability to pay. Currently joined by 190 countries, COVAX has two different systems for self-funding countries and least developed countries. The high income, self- funding countries join the “COVAX Facility” and by committing to purchase a defined amount of vaccines, they are enabled to receive a cost discount, while all the countries who are not able to (fully) pay for their vaccines join the “COVAX AMC”, where, thanks to external donations they have access to vaccines. Self-funding countries can but are not required to donate money to the COVAX AMC. (Cook, Farrar, 2021, pp. 436-437). The COVAX plan is, in a first time, to distribute vaccines enough to immunise around 3% of the partaking populations – ideally healthcare workers, nurses and doctors - while in a second time, according to vaccines availability, joining countries receive a

quantity of doses that allow them to vaccinate around 20% of their population. Jabs distribution in the second phase prioritizes the countries with more vulnerable health systems and where the virus spreads with more facility. (Gosh, 2021).

However, despite the efforts, COVAX is not giving the hoped results for various reasons.

First of all, COVAX is underfunded. The project started because states such as Italy, Norway, the UK, Canada and the Bill&Melinda Gates Foundation were asked to shift their annual donations of US $ 177.5 million from the pneumococcal program to this new, at this time more relevant program. (Nhamo et al., 2021, 334) However, this means that the attention to COVAX brought away money for the R&D of other, still relevant treatments. In February 2021 an international commitment pledged to donate around 4$ billion, (Wouters et al., 2021, 1028) while in May President Joe Biden pledged to donate to COVAX around 80 million of surplus vaccine doses. (White House, 2021) and in the G7 conference held at the middle of June participating countries committed to donate one other billion. (Brown, 2021 14 June). These are surely important news to reach the very modest COVAX aim to vaccinate 20% of the world population. However, if we stick to this plan, many poor people may have to wait until 2023 or 2024 for their vaccination (The Independent Panel for Pandemic Preparedness and Response, 2021a ,6), too late if we consider that meanwhile Covid-19 variants are raging and that not all of our currently approved vaccines give the best response.

Another important problem is the lack of vaccine supplies available to COVAX. In fact, differently from the COVAX AMC where partaking states are not allowed to enter into bilateral agreements with pharmaceutical companies, member states of the COVAX Facility can order jabs also outside the GAVI programmes. Therefore, many self-funding states entered bilateral agreements with pharmaceutical companies where, despite a higher cost of the jabs, they were able to receive vaccine doses faster than within the COVAX Facility. In return, also pharmaceutical companies privileged the more financially appealing agreements with a resulting highly disproportional distribution of vaccines that favoured the developed countries. Moreover, in many cases the quantity of vaccines delivered to the rich, developed countries was way bigger than their actual needs. For example, Canada purchased vaccines in a quantity that is 10 times higher its actual population, while the US purchased vaccines to cover about 4 times its actual population.

The situation worsened when, in an egoistic fear of “not having enough doses” many countries imposed a ban on exportations, making the vaccines supply more difficult than ever. To

complicate things, in April 2021 the Serum Institute of India, with whom vaccine company AstraZeneca issued a voluntary licensing of vaccine production aimed to the COVAX AMC supply to the least developed countries, blocked the exports in order to boost the vaccinations within its own country that, at that moment was suffering from a serious upsurge in cases. (Gettleman, Schall, Mashal, 2021). This led to a shortfall of 190 million doses by the end of June 2021. (WHO, 2021).

The last and most important problem lies in the intrinsic structure of COVAX. First of all its goal is really conservative: even if the 20% of population in least developed countries will manage to receive the vaccine, what about the remaining 80% of the population? (Lancet, 2021, 941). Donations and fundings from rich economies are seriously needed because a "herd immunity", which is the only way out of the pandemic, cannot be obtained with so few vaccines. (Lancet Commission on Covid-19 Vaccines and Therapeutics, 2021, 563). Beside this, COVAX lacks an intrinsically sustainable structure. As Rutschman (2021b) considers, the same ratio in which COVAX was divided among self-funding and poor countries, enabling the first to purchase vaccines also outside the program, works against the main goal of an equitable access to vaccines because it leaves economies with greater purchasing power to use it at their own advantage.

To sum up, COVAX has been revealed as unable to stop what it was created to avoid: nationalism and unequitable distribution of vaccines. The seriousness of the situation was explained also in the WHO Press conference of the 10th of May where WHO Director Ghebreyesus (04.01 min) stated how high income and upper middle income countries, which together represent the 53% of the world population got access to the 83% of the available vaccines, while the rest of the world population was receiving only the 17% of the global vaccines. Of course, if confronted with the few doses that reached the least developed countries in January this is a significant goal, but in terms of the global fight against the pandemic there is a serious need to rebalance the situation, especially if we consider that the least developed countries are the most vulnerable to the Covid-19 consequences. Although the US pledge to donate 80 million vaccine doses to COVAX is a great help, the situation shows also the inadequacy of the reliance on goodwill external donations as the only global way out from the pandemic. In fact, ourworldindata.org shows how, almost at the middle of June, the African continent administers less than 2% of the available vaccines. With a population of 1.3 billion people and only 41 million of doses received, Africa will probably reach in 2024 the level of vaccinations that western countries currently have. Great expectations were set for the G7

meeting held at the middle of June: in a pre-summit English prime minister Boris Johnson pledged to vaccinate the entire world. However, the promise was not maintained. To guarantee all countries the same levels of vaccine coverage, at least 11 billion of doses are needed, while the G7 countries committed to donate only 1 billion. (Brown, 2021 14 June).

Beside the "vaccine pillar", also the whole ACT Accelerator has showed not to be the best response to the pandemic. In fact, it "has suffered from insufficient funding and a structure in which each component (diagnostics, therapeutics and vaccines) competes for funding with the others" (Lurie, Keusch, Dzau, 2021, 1234). Instead of incentivizing a common solidarity, the whole system reinforces existing inequities. (The Lancet, 2021b, 1419).

3.1.2 The Open-Covid Pledge and C-TAP

Differently from COVAX, the Open-Covid Pledge and C-TAP (Technology Access Pool) are forms of "voluntary licensing" initiatives promoted by the international community to enable all possible manufacturers to (re)produce freely Covid-19 technologies or treatments without incurring in legal sanctions and granting at the same time the greatest possible supply and help for everyone.

The Open Covid Pledge was created in April 2020 to incentivize IP holders of creations relevant to the Covid-19 pandemic to license them freely without asking for the royalties. However, among its partners (https://opencovidpledge.org/partners/) it is impossible to spot any of the BigPharma which currently retain the IP of the most effective vaccines against Covid-19, therefore making it impossible for generic manufacturer to reproduce them.

C-TAP was realized in May 2020 under the recommendation of the government of Costa Rica with the purpose of providing a "single platform for the developers of Covid-19 vaccines, tests, devices and medicines to temporarily share their data, know-how and technologies with quality-assured manufacturers" (WHO, 2021 16 January). The importance of C-TAP is crucial because beside patents, other forms of intellectual property such as "trade secrets" and know-how are extremely needed in order to develop a successful copy of a vaccine. In fact, differently from the normal pharmaceutical products where the generics can be obtained through a reverse-engineering of the original product, vaccines are harder to develop and therefore manufacturing know-how is needed. Differently from COVAX which provides a short-term solution, the C-TAP facility, allowing for the creation of new manufacturing capacity of vaccines is thought

for a long-term solution. However, similarly to the Open Covid Pledge, C-TAP as well struggles to secure the support of drug companies (Perehudoff, Jager, 2021).

3.2 The TRIPS Waiver Proposal

It is in a global framework of failed access to treatments and unwillingness to cooperate (as it is possible to see from the "big absents" of C-TAP and Open Covid Pledge) that we have to understand the temporary TRIPS Waiver Proposal made by India (the worldwide supplier of vaccines generics) and South Africa and first presented to the WTO Assembly on the 2nd October 2020 as an additional countermeasure against Covid-19. The issuance of a waiver is allowed by WTO Article IX.3 which establish that:

> In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided for in this paragraph. (Marrakesh Agreement establishing the World Trade Organization).

The aim of the waiver proposal is to scale-up medical treatments, technologies and vaccine manufacturing related to Covid-19 enabling every manufacturer in the world to reproduce and distribute them faster. In this way, considers Sangeeta Shashikant (The People's Health Movement, 5:38 min) it is possible to reach an equitable access to vaccines, where "equitable access" means availability through the scale up of manufacturers and affordability through a global diversification of suppliers.

The proposal of South Africa and India is:

> a waiver from the implementation, application and enforcement of Section 1 [copyrights],4[industrial designs], 5 [patents] and 7 [protection of undisclosed information] of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19. The waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity hence we propose an initial duration of [x] years from the date of the adoption of the waiver. (IP/C/W/669).

The content of the waiver is s similar to the C- TAP and the Open Covid Pledge because it tackles both the patents (section 4) and "trade secrets" (section 7 on protection of undisclosed information) but, differently from the previous programmes that are based on a voluntary commitment, if the waiver is passed at the WTO it becomes legally binding for the Members.

Supporters of the waiver are, of course, the majority of the least developed and developing countries while its fierce opponents, unsurprisingly, are the rich developed countries: EU, UK, US, Switzerland, Norway, Australia, Canada and Japan. Unluckily, in order to pass the waiver a consensus was needed and this was not the case. As a consequence, because no real solution could be found in October, the TRIPS Waiver was further discussed in the successive meetings, without any definitive conclusion.

Only in the formal meeting of the 10th and 11th of March, under the supervision of the new WTO director Ngozi Okonjo-Iweala, a "third way" was promoted (Josephs, 2021 16 February) in which pharmaceutical companies were invited to issue more voluntary licenses and partnership with developed and developing world manufacturers in order to scale-up vaccine production. However, this "solution" was not really felt as such.

Despite the negativity, on the 5th of May the US Trade Representative Katherine Thay released a statement in which she announced "the Biden-Harris administration support for waiving intellectual property protections for COVID-19 vaccines" (USTR, 2021). Even though this is a surprising move coming from a state with a very powerful pharmaceutical lobby, it is still unknown whether the statement from the US will change the overall situation. The hope is that, seeing this bold move, other developed countries might take the TRIPS Waiver into more consideration.

However, the answer from Europe did not seem very encouraging. In fact, while the President of the European Commission Ursula Von der Leyen declared its readiness to discuss the waiver proposal and encountered the favour of countries such as Italy and France, on the contrary Germany maintained its strong opposition. Germany has a key position in the debate because, "Germany is the EU's biggest economic power and home to a major pharmaceutical sector, including BioNTech which developed one of the most widely used coronavirus vaccines [Pfizer]". (BBC, 2021 6 May).

Meanwhile, the Covid-19 situation has changed and new mutation strains have emerged. Therefore, on May 25th the sponsors and co-sponsors of the TRIPS Waiver Proposal issued a new, revised text in light of the:

> continuous mutations and the emergence of new variants and consequently the many unknowns with respect to SARS-COV-2 and its variants and the global need for access as well as the importance of diversifying production and supply. (IP/C/W/669/Rev.1, par. 3).

The new text differs from the previous one which was considered too broad and vague specifying that the TRIPS Waiver is only on "health products and technologies" needed to prevent and contain the Covid-19 outbreak (par.4) and proposing a first duration of 3 years. If the "exceptional circumstances" remain, the TRIPS General Council will be in charge of determining the date of termination of the waiver. (par.5)

The new revised text was discussed by the WTO in its formal meeting on the 8th and 9th of June but, again, no final agreement was reached. (Associated Press, 2021, June 9). The topic will be discussed at the next meeting in September.

The following section is dedicated to the presentation of the debate: the first part outlines the critics from the opponents, while the second one presents the answers given from the supporters.

3.2.1 Against the TRIPS waiver

The main opponents of the waiver are developed countries and the pharmaceutical companies. Their arguments are very similar because they often share common interests, in fact the majority of the vaccines that have received emergency market approval are coming from these countries, respectively US for Moderna, Pfizer, and Johnson&Johnson, Germany for Pfizer (BioNTech), Switzerland for Moderna (the swiss based manufactory Lonza has a manufacturing agreement) and UK and Sweden for the AstraZeneca vaccine.

Below I will present the main arguments against a TRIPS Waiver proposal.

IP is not a barrier to equitable access to vaccines – on the contrary, it is the engine of innovation

When the TRIPS Waiver proposal was issued in late 2020 by South Africa and India, no Covid-19 vaccine had been developed yet. Therefore, how could intellectual property already be a burden? There is no evidence of that, therefore further clarity is required by the supporters on this (Ezell,2021).

On the contrary, intellectual property is the real engine of innovation and also what has delivered Covid-19 vaccines so fast. In fact, it is no coincidence that the best vaccines come from Germany and the US because those two countries have a strong IP tradition. Normally it

can take up to $1 billion and 20-50 years to develop and distribute a vaccine but thanks to IP the average is now 14 years. Therefore, "IP is a key enabler, not a barrier, to access to these medicines" (Ezell, 2021). The technologies which have been used to develop the vaccines are the results of years and decades of research, made possible thanks to the existing intellectual property. (Caso, 2021, 10). Therefore, it is possible to say that IP is the "bedrock upon which today's Covid-19 vaccines have been built". (Steven and Schultz, 2021, 4).

Waiving intellectual property would mean taking away from the pharmaceutical companies their "life blood" and poses a serious threat on innovation (Nack et. al, 2021 May 31, 2:34:00 min), a serious mistake that should not be made. The mRna technology has been studied for a long time and it is so powerful that it can be used to treat other illnesses. Albert Bourla, CEO of Pfizer, wrote in an Open Letter to his colleagues his fear that, without IP protection, many biotech companies would have no incentive for taking a big investment risk in the future. (Bourla, 2021).

The importance of intellectual property in the form of patents was further highlighted in a letter that the coalition of the pharmaceutical research and manufacturers of America (PhRMA) sent to president Joe Biden in March 2021, where, after having stated how Covid-19 vaccines are complex biological products and how their manufacturing requires experience, expertise and equipment, they say that:

> Intellectual property protections have been essential not only to speed the research and development of new treatments and vaccines, but to facilitate sharing of technology and information to scale up vaccine manufacturing to meet global needs. Eliminating those protections would undermine the global response to the pandemic, including ongoing effort to tackle new variants, create confusion that could potentially undermine public confidence in vaccine safety, and create a barrier to information sharing, Most importantly, eliminating protections would not speed up production. […] Intellectual property is the foundation for both the development and sharing of new technologies. Perhaps more than any other time in history, society is seeing and benefiting from the innovation supported by intellectual property. (PhRMA, 2021 5 March, 2).

Even if Joe Biden later expressed support to the waiver in early May, not everyone shares his view. For example, Susan Danger, CEO of the American Chamber of Commerce in the EU, stated that an IP Waiver will not improve the distribution of vaccines around the world. (AmCham EU, 2021, 7 May).

Lastly, even if IP was a problem, some pharmaceutical industries such as Moderna and AstraZeneca have already pledged not to enforce their intellectual property rights. In particular, Moderna issued a statement on Covid-19 in which it stated that:

> We feel a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. (Moderna, 2020 October 8).

Voluntary and compulsory licensing are good solutions

If intellectual property was really a problem the actual TRIPS Agreement system already provides some forms of flexibilities that can be used in emergency situations, as it is the case of Covid-19. In particular, these are compulsory and voluntary licensing, therefore the adoption of a TRIPS Waiver seems unnecessary.

As already stated above, compulsory licensing enables governments to reproduce a pharmaceutical product that is currently under IP regardless of the willingness of the original manufacturer which will obtain some royalties in return. Compulsory licensing has already been adopted by some countries to face the current pandemic and it is important as a bargaining tool because. Historically, countries which have threatened to use it obtained what they wanted.

However, the best solution to get out of this situation are voluntary licenses which have already been issued by some pharmaceutical companies, which are doing all their best to end as quickly as possible the pandemic. For example, previous to the development of vaccines, as Gilead Sciences drug *Remedesivir* was believed to be a possible Covid-19 treatment, the company signed non-exclusive voluntary licensing agreements on a royalty free basis with many generic pharmaceutical manufacturers in the developing world. (Ezell, 2021).

When AstraZeneca developed its vaccine, it issued also a voluntary license with the Serum Institute of India for the manufacture of 1 billion doses for the COVAX AMC, with Daiichi Sankyo to supply Japan (IFPMA, 2021), with China BioKangtai, Brazil's FioCruz, Russia R-Pharm and South Korea's SK Bioscience. (Stevens and Schultz, 2021, 9). Voluntary licenses were also made by Johnson and Johnson with the Aspen Institute in South Africa and Sanofi in France. Both the two pharmaceutical industries pledged to sell their vaccines at a not-for-profit basis (AstraZeneca, 2020, 23 November; Johson&Johnson, 2020, 23 September). Moreover, Novartis, Bayer ad GSK started a collaboration for the development of the CureVac vaccine. All these pharmaceutical companies pledged to donate part of their vaccines to the least developed countries. In particular, Pfizer pledged to supply COVAX with 40 million of its vaccines, J&J with 500 million, CureVac with up to 100 million in 2021. (IFPMA, 2021).

Voluntary licensing seems to be the best solution because, instead of being forced to issue compulsory licenses and free their IP, pharmaceutical companies are enabled to evaluate the various generic manufacturers to ensure that they have the right competences to develop a safe and reliable vaccine. (Ezell, 2021; Steven and Schultz, 2021). This view is shared also by Roettingen, chair of the WHO solidarity trial, who considers that know-how and technologies are much easier shared by the pharmaceutical companies under a voluntary licensing condition rather than a compulsory licensing or a TRIPS Waiver. (Usher, 2020, 1790). Voluntary licensing is also the best viable option considered by the European Commission (EC, 2021, May 21) and also the "third way" proposed by WTO Director Ngozi Okonjo Iweala at the WTO Meetings held on the 10th and 11th March. However, if voluntary licensing agreements do not come, countries are free to use compulsory licensing which is more than enough to end the pandemic.

The real problems for an equitable roll-out of vaccines are lack of raw materials, competences and capacity

Endorsing the TRIPS Waiver would bring to the wrong conclusion that IP constitute a barrier toward access to medicines when the situation is exactly the opposite. The real bottleneck, says Thomas Cueni, president of the International Federation of Pharmaceutical Manufacturer Associations (IFPMA), are "the capacity, the scarcity of raw materials, scarcity of ingredients, and it is about the know-how." (Miller, Nebehay, 2021). Also the European Commission shares the very same idea:

> Intellectual property is not and should not be an obstacle to equitable access to COVID-19 vaccines and therapeutics during the pandemic. Limited manufacturing capacity, access to raw materials and other inputs are the main bottlenecks as regards the production of COVID-19 vaccines. In addition, know-how is key due to the complexity of the production process. (EC, 2021. 4).

The point on raw materials is made also by Pfizer CEO Albert Bourla, who states:

> The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine. These 280 different materials or components are produced by many suppliers in 19 different countries. Many of them needed our substantial support (technical and financial) to ramp up their production. Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world (91 countries to date.) The proposed waiver for COVID-19 vaccines, threatens to disrupt the flow of raw materials. It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine. Entities with little or no experience

> in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk. (Bourla, 2021).

The very same view is shared by the American Chamber of Commerce in EU, which states:

> In addition to risking undermining quality standards, such a move may also give rise to numerous counterfeit products on the market, all of which would impact both patient safety and overall trust in the efficacy of vaccinations. Ultimately, it will also disincentive companies to contribute resources and technology to research and vaccine production. (AmCham EU, 2021, 7 May).

In conclusion, as stated by intellectual property lawyer Ralph Nack in an online-conference held at the end of May 2021, (Nack et.al, 2021, 31 May 1: 55: 48 h – 1:57:20 h) if intellectual property was really a problem, it was the last one, after the two very burdensome problems which are technology transfer and raw materials availability.

Geopolitical factors

Waiving IP would not come to the advantage of least developed and developing countries which lack capacities, but it would only advantage "giants" such as China and India which have manufacturing capacity but do not have our western technologies. In such a way, the US could lose its last primacy on biotechnology, therefore, it is better not to share patents and knowledge. (Caso, 2021, 13).

A TRIPS Waiver is unlikely to end the Covid-19 pandemic

Not only IP is not the problem to a global equitable roll-out of vaccines, but a TRIPS Waiver is also not a viable solution to end the Covid-19 pandemic because, even if the waiver passed, vaccine manufacture and supply would not be boosted immediately: in fact, in order to set and approve a new vaccine manufactory several months are needed. The proponents of the waiver have been unable to document the existence of other manufacturing capacity and the existing capacity could not be easily converted to produce the advanced Covid-19 vaccines currently in use. (Sauer, 2021). Brougher and Kingsbury (2021) consider the lack of public information about the new mRNa vaccines and their complicatedness as a hurdle that will not be defeated by a TRIPS Waiver. The simple suspension of IP rights will not boost access to vaccines.

3.2.2 In favour of the TRIPS waiver

The following section explores the answer provided by the supporters of the waiver at the critics of the opponents with the aim to show the reader the problems and the limitations posed by the TRIPS Agreements. Differently from the opponents, the supporters of the waiver are not only developing countries, but also NGOs, many more academics, Nobel prize winners… therefore I will use a wider range of materials than in the previous section.

Intellectual Property is a problem for a global equitable access to vaccines and Covid-19 treatments

To answer the claim that there is no indication that IP has been a barrier for Covid-19 medicines and technologies, the South Africa delegate prepared in November 2020 a detailed analysis of the at the time possible treatments against the pandemic and their patent coverage (vaccines technologies considered) with examples of past difficulties with vaccines and previous political pressures aimed at limiting the use of compulsory licensing (IP/C/W/670).

Also the NGO Medecins Sans Frontieres (MSF) issued a Report in 2020 with a detailed analysis of the IP problematics in relation to Covid-19 treatments. In the early days of the pandemic, as testing kits reagents, ventilator valves and N95 respirators were short of supply, IP stood in the way of a more equitable access to treatments and technologies. For example, in northern Italy two engineers who managed to reverse-engineering a ventilator valve, were threatened by the manufacturers for patent infringement. (MSF, 2020 November, 8). In relation to the (at that time) not yet developed vaccines, researches have reported how the mRNa technologies that have been used to develop Pfizer/BioNtech and Moderna vaccine were already covered by at least 100 background patents (MSF, 2020, November 7; Gaviria and Kilic, 2020a, 2020b). If the move of South Africa and India had to be understood as a precaution against possible IP impediments on vaccines, the reality has showed that they were right because, except few (useless) cases, intellectual property has been maintained.

As stated before, patents are not the only forms of intellectual property protection: trade secrets on important data or information relating to the medical product are also another possible way. Considering the failure of programmes like C-TAP or Open Covid Pledge, the TRIPS Waiver proposes to temporary disclose the trade secrets as long as the pandemic is raging. Although

not appreciated by pharmaceutical companies which consider that their incentives for innovations are threatened, the actual Covid-19 pandemic can be seen as a situation where, for the greater global good, such information have to be disclosed. (Levine, 2020a; 2020b). The disclosure of information to advance public interests is not only a universal moral duty, but it is also entailed in the laws both in the EU and in the US (IP/C/W/672, 20-21). A TRIPS Waiver would also embrace the disclosure of trade secrets, enhancing a cooperation between generic manufacturers and pharmaceutical companies.

However, as long as the waiver does not pass, there is no general duty from the pharmaceutical companies to share such information and this is the exact reason why Moderna statement not to enforce its IP rights during the pandemic is nonsensical. Not having disclosed the manufacturing know-how on the vaccines, its commitment is nice but useless (Labonte, Johri, 2020, 5 November; Santos, Fletcher, 2020) because no one is able to reproduce the vaccine. The answer from the opponents of the waiver is that, since Moderna has spent the past decade working on the mRNa technology, it should not be compelled to give these technologies away. (Ezell, 2021).

The case of AstraZeneca vaccine is a different one. Although the University of Oxford, which discovered and developed the vaccine initially pledged not to enforce IP rights, it then later entered in a partnership with the private AstraZeneca company which was in charge of manufacturing it. (Garrison, 2020a). Due to the high funding received by the US and the EU the company pledged to sell it at cost during the pandemic without advancing its IP rights.

However, from the dubious contracts it made with the EU it seems that these special conditions are valid only as long as the company declares the pandemic to be over. (Weintraub, 2020 8 October). Moreover, AstraZeneca adopts a differential pricing strategy where those who pay more are the most vulnerable countries such as Uganda, Bangladesh and South Africa. (Mazzucato, Ghosh, Torreele, 2021, April 20). Because they have not funded the development of the vaccine as rich countries did, Africa UNAIDS director Winnie Byanyima says that a shot of AstraZeneca in Uganda costs around 7$ and in other least developed countries the price is up to 9$. (GIWPS, 2021 April 16). Also in this case the commitment from AstraZeneca seems doubtful and, having the company never disclosed its own IP information and manufacturing "know-how", it is equally impossible for generic manufacturer to reproduce the vaccine. (IP/C/W/672, 30).

In response to Ralph Nack, the IP lawyer who considered that technology transfer and availability of raw materials were the real problems, global health activist Achal Prabhala (Nack et.al, 2021, May 31, 1:59:00 h) not only mentioned the fact that, beside technology transfer and raw material intellectual property was definitely a problem citing the German president of CureVac words that patents are an obstacle, but he also explained how patents stay at the very beginning of a generic vaccine development process. (2:00:11 h). In fact, without the legal permission to get rid of intellectual property, it is impossible for generic manufacturers to embark in the vaccine production. A TRIPS Waiver would enable everyone to, at least, start the process, solving one third of the problems. (2:02:50 h).

The fact that IP is a burden for an equitable access to vaccines is shared not only by least developed countries and some academics (e.g. Tanveer et.al. 2020; Mazzucato, Ghosh, Torreele, 2021, 20 April; Nature Editorial, 2021; Kapczynski and Ravinthiran, 2021) but also by NGOs, WHO Executive Director Ghebreyesus (2021, 22 April) institutions, Nobel prize holders (Yunus, Donaldson, Perron, 2020) and CSOs (CSO, 2021a; CSO, 2021b; GNU, 2021). Among these, interesting is the position of the European Parliament which, although the European Council is against the waiver, on 10th June 2021 voted a resolution in which it:

> calls for support for proactive, constructive and text-based negotiations for a temporary waiver of the WTO TRIPS Agreement, aiming to enhance global access to affordable COVID19-related medical products and to address global production constraints and supply shortages (EP, 2021, 1).

C*ompulsory and voluntary licensing are not viable solutions*

In regard to the actual possibility of compulsory licensing as a way to get rid of intellectual property protection, South Africa and India remember its many bureaucratic burdens and shortcomings as obstacle to the full enjoyment of the TRIPS flexibilities. As I have already mentioned, in order to grant compulsory licensing a country should have a national legal system that enables this procedure and, as we know, many least developed and developing countries do not have it.

Some countries such as Germany, Australia, Brazil, Canada, Chile, Colombia, Ecuador, Hungary, Indonesia and Russia have recently tailored their national laws in order to grant it (MSF, 2021 May, 3-5; Wong, 2020, 3), therefore, since, as a compulsory licensing (for those who can) brings to the temporary suspension of intellectual property as well as the waiver

proposal, the opposition of some of these countries (Germany in particular) seems difficult to understand.

It must not be forgotten that, even if article *31bis* on international emergency export for non-manufacturing countries was approved in 2017, it revealed to be so cumbersome that many developed countries decided to immediately opt-out as possible exporting countries. Therefore, this cannot be considered a viable solution for non-manufacturing countries. (Labonte, Baker, 2021, January 9; IP/C/W/673,7-9). In reality, compulsory licensing would be problematic also for manufacturing countries whose industries are unable to produce the national vaccine supply because the majority of them, when the TRIPS Agreement were amended, decided to never use article *31bis* as importing countries.

Another obstacle is the fact that due to TRIPS-Plus treaties, some least developed and developing countries do not have this flexibility at disposal anymore (McMahon, 2020, 144-146).

In addition, the delegate from South Africa reminded how, even within the pandemic framework, the EU and the US pressured least developed and developing countries to limit their use of compulsory licensing. In particular, in the USTR 2020 Special 301 Report were criticised countries which improved their laws to make use of compulsory licensing and countries which made use of compulsory licensing. Among them worth mentioning are Chile, Indonesia, Colombia, Egypt, India, Malaysia, Russia, Turkey, Ukraine and El Salvador. (MSF, 2021 May, 6). Also the EU's annual IP report criticised and pressured least developed countries for their compulsory licensing laws. (MSF, 2020, 5)

It is then important to state that compulsory licensing can be used only on a "case-by-case" and "country-by-country" basis (Independent Panel on Pandemic Preparedness and Response, 2021a, 3) and this would immensely slow down the whole (already burdensome) process because the waiver to IP in relation to Covid-19 is not only one product but on all the Covid-19 related medicaments or technologies. In a situation where speed is of the essence, the burdensome compulsory licensing system would bring no positive consequences. However, if some countries share the view that they can solve their Covid-19 problems only with the issuance of a compulsory licensing they are free not to implement the waiver within their domestic legislation. But they should equally give the possibility to other countries to use the waiver supporting – and not opposing – it. (IP/C/W/672, 1- 5).

Lastly, compulsory licensing can be used only on already patented products. In the actual IP landscape, where new patents are filed but not yet published, compulsory licensing cannot be assessed. In order to remove legal risk, a solution that is quicker and more efficient than compulsory licensing seems much needed. (MSF, 2021 May, 6-8). Moreover, differently from compulsory licensing of medicines where through reverse-engineering it is easier to reconstruct the whole development process of the product without asking information related to the "know-how" to the original manufacturer, in the case of Covid-19 vaccines, especially those developed with the new mRNa technology, it is extremely needed that medicine manufacturer share their "know-how" with generic manufacturers to scale up the vaccine production. Compulsory licensing does not bind the vaccine manufacturers to the sharing of information while the TRIPS Waiver, encompassing also the "trade-secrets" could partially solve these problems. (MSF, 2021 May, 9).

As a consequence of what was stated above, one may conclude that, differently from compulsory licensing, being an agreement between the pharmaceutical industry and the manufacturer, voluntary licensing could be the real solution. This is exactly what happened between the pharmaceutical company Johnson &Johnson and the Aspen Institute in South Africa and pharmaceutical company AstraZeneca and the Serum Institute of India, where the latter obtained a license for the manufacture of the vaccine doses that would have supplied the COVAX AMC. The TRIPS waiver supports any voluntary licensing agreements but, declares the South Africa WTO delegate Mustaqueem de Gama, these arrangements often lack transparency and most of the time contain geographical and volume distribution clauses that limit the actual distribution of the vaccine doses. (IP/C/W/672)

This is dangerous because the scarcity of vaccines tends to keep their prices high and because, once again, the arbitrary limitation on production is not what is actually needed for the global fight to the pandemic. (MSF, 2020 October, 4-7). Citing the Gilead example of voluntary licensing *Remedesivir*, MSF notes how the company excluded Brazil, China, Russia and most South American countries from it. (MSF, 2020 October, 8). Moreover, the majority of the vaccines produced through voluntary licensing are not destined to the local market: similar to the doses produced by the Serum Institute, also the majority of those produced by South Africa were destined to the foreign markets (Dorfman, Kirstein, 2021 January 20). Putting limits on the quantity of vaccines produced is not only nonsensical in the bigger framework of fighting the pandemic but also dangerous.

In fact, as it happened with the Serum Institute of India, the vaccine doses to COVAX were stopped and delivered to the national market in a moment of drastic upsurge of the cases, causing a loss of 150 million doses to COVAX AMC. Moreover, pharmaceutical companies seem not to sympathize with the voluntary licensing system because, as stated in the previous paragraph, the initiative of C-TAP and the Open Covid Pledge were not successful among them. Their lack of willingness in engaging in voluntary licensing is expressed by the fact that only in March 2021 and only because internationally pushed by the TRIPS Waiver proposal and the new WTO president, they committed to increase their vaccine voluntary licensing also to other developing countries manufacturers.

About raw materials, competences and capacity

Among the main arguments that developed countries and pharmaceutical companies bring against the TRIPS Waiver, there is the fact that the real problem for them is a lack of raw materials, know-how and competences. Although this is a fair point, if looked more closely it is possible to find that behind all these elements there is always a silent problem of intellectual property.

Regarding the lack of raw materials, Barclay and Stoller (2021) point that, while pharmaceutical industry defenders consider it to be a major bottleneck in vaccine roll-out and supply, they "don't attempt to explain why these shortages are so pervasive". Their answer is easy: beside the high demand caused by the pandemic, the commerce of these materials is monopolized and full of intellectual property barriers that do not enable generic manufacturers to step in. In fact, the tools needed for biopharmaceutical manufacturing are monopolized by four main industries: Merck, Danaher, Sartorius and Thermo Fisher which possess the vast majority of the patent thickets for the production of biopharmaceutical tools and set the price as high as they want. With 2.800 patents granted over the last decades (Braclay and Stoller, 2021; Cision, 2021) it is impossible for generic manufacturers to enter the market. A temporary waiver of patents on all the health technologies and products as the one proposed by India and South Africa would eliminate this burden.

Moving to the lack of competences as a reason why vaccine roll-out is not possible, this is not real. MSF (2020, 6) explains how existing R&D manufacturing in developing countries is critical to the supply of Covid-19 medical tools. India, for example, not only has always been the "pharmacy of the world" and has produced the vast majority of vaccines we normally know,

but its Pune based Gennova pharmaceutical industry is developing a mRNa based vaccine. (Nair, 2021 Mai 27). Moreover, for all the vaccine manufacturers which are not able to deal with the mRNa technology, this is said to be actually easier to reproduce than the normal one with the viral-vector. (Muglia, 2021 March 1). Hemanth Nandgala, managing director of one manufacture in Hyderabad, said that if J&J or Moderna vaccine recipes were available, he would not think twice and start reproduce them. (Clinton, Prabhala, 2021 May 5). Competences are present and those which may be missing could be transferred through a disclosure of intellectual property protected "trade secrets". That is exactly what the TRIPS Waiver asks for.

Moreover, in cases in which competences are lacking, we shall remember that, as stated in TRIPS Article 66.2:

> Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Many pharmaceutical companies claim that technology transfer is difficult, however, as Baker (Raoul Wallenberg Instutute, 2021 July 14, 40 min) highlights, this is not true because they always engage in technology transfer within their cartel.

Lastly, concerning the lack of manufacturing capacity, the situation is only partially true. It is true because, as WTO Director Ngozi Okonjo Igweala states (WHO Press Conference, 2021 June 1). the needed vaccines are around 14-15 billion doses a year and the actual vaccine manufacturer have a capacity of 5 billion doses. It is false because, as stated by a study from the Tony Blair Institute, there are 16.7 million litres of manufacturing capacity in the world and only 25% is currently used to tackle the Covid-19 pandemic. (Dace et al, 2021, 25). Chelsea Clinton from the Clinton Foundation and Indian access to medicine expert Achal Prabhala (2021, 5 May) mentioned how there is still available manufacturing capacity both in the western developed countries (e.g. Canadian Biolyse pharmaceutical company has spare capacity to produce batches of the J&J vaccine but as long as J&J impedes it, it will not be able to produce it) and in the developing world as well: Brazil, Cuba, UAE and Iran have all manufacturing facilities. The same point is also argued by Human Rights Watch (HRW, 2021) which explains that also Bangladesh, Denmark and Israel possess unused manufacturing capacity hindered by the existence of intellectual property.

These claims can be justified also by the fact that, from the beginning of the pandemic, many developed, developing and least developed countries started R&D of possible Covid-19

vaccines. This means that there is a great quantity of manufacturing capacity for the production of our western and safe vaccines. Because of the unused manufacturing capacity, MSF concludes that the:

> "limited action and the overall unwillingness to share Covid-19 health technologies by multinational corporations […] demonstrate how maintaining structural barriers is prioritised over the achievement of global equitable access to all needed medical tools to combat Covid-19". (2020, 6)

To sum up, as Burku Kilic says, the issues of intellectual property protection and lack of capacity is "the chicken and egg problem" where, if intellectual property were lifted, a greater amount of manufacturing capacity would be accessible. (The People's Health Movement, 2021, 28:50).

Responding to the critics regarding the possibility of creating counterfeit or low-quality vaccines, the supporters of the waiver remember that the grant of intellectual property has nothing to do with quality and that even multinational pharmaceutical companies have been recalled in the past for failing quality standards. Intellectual property should never be confused with issues of product quality or reliability (IP/C/W/672, 22) because these are two different things.

Intellectual Property rights were not the reason why vaccines were developed so fast

Against the claim that intellectual property was the main reason why Covid-19 vaccines developed so fast, developing countries, NGOs and civil society organizations are together in highlighting that it was the massive governmental and philanthropic funding together with the common desire to end a deadly pandemic (MSF, 2020, 3; IP/C/W/672, 3) that was the main engine to bring as fast as possible a Covid-19 vaccines.

In fact, all the western- produced vaccine benefitted from EU, US or CEPI funding. In particular, considering only the US investments for the vaccines (US$ 1 billion for Astra Zeneca, US$ 600 million for Johnson& Johnson, US$ 1.6 billion for Novavax and US$1.427 billion for Moderna) (Nhamo et al., 2021, 327) and considering that, if similar to those of drugs development, the costs for vaccines R&D may vary between $800 million and $2 billion (Light and Warburton, 2012) we may say that the funding were substantial. Pfizer, the only company which decided not to accept any federal moneys, was as well indirectly helped because its

partner (and mRNa technology developer) BioNtech received a 445$ million grant from the German government (Reuters, 2020 15 September).

Moreover, we know that one of the reasons why the vaccines were developed so fast was that, e.g. in the case of Moderna, the mRNa technology has been studied for many years in a partnership with the national institute of health (NIH) (Rutschman, 2021). All the actual vaccines rely on a genetic blueprint that has been discovered within the NIH framework in 2016 against the MERS coronavirus and that can be used for any type of coronavirus. When the Covid-19 arrived, Dr. Graham, one among the researchers behind the genetic blueprint, emailed it to the manufacturer Moderna and within a month the company produced enough vaccine to run the clinical trials. So, the private sector came only in a second, supporting time: "We [NIH/public sector] did the front end. They [Moderna/ private sector] did the middle. And we did the back end". (Gebrekidan, Apuzzo, 2021).

Because the research for a Covid-19 vaccine was done through a Public-Private Partnership and because many governments poured billions in vaccine R&D, taking all the risks of an unsuccessful outcome, intellectual property on vaccines seems hard to rectify.

Geopolitical reasons

The argument proposed by the opponents of the waiver is short-sighted. In fact, even if this was the case, the western countries would rather prolong the pandemic with its disastrous consequences in terms of global health, lives and economic losses than share their technology. (Caso, 2021, 13).

TRIPS Waiver will not boost access to vaccines immediately, but …

No, as the opponents say, TRIPS waiver will not boost access to vaccine immediately but it will free every manufacturer from the legal and bureaucratic burdens that they have to face when they ask for the licensing of a product, therefore enabling them to produce generic versions. The waiver is a long term solution that has to be complemented with the short term, necessary but not sufficient solution of COVAX.

3.3 Intellectual property, Right to health and Covid-19: the CESCR perspective

This section presents the UN perspective on the State and pharmaceutical companies duties towards the enjoyment of the highest attainable standard of health within Covid-19 and IP, taking as a point of departure three Statements issued by the UN Committee on Economic, Social and Cultural Rights (CESCR) respectively in April and November 2020 and in April 2021. Paragraph 3.3.1 will critically assess States and pharmaceutical companies' behaviour towards the pandemic while paragraph 3.3.2 will provide some concluding reflections based on the actual status quo.

The first Statement on pandemic issued in April 2020 (CESCR 2020) is quite general and reminds the international duty "to protect and mitigate the impact of the pandemic on vulnerable groups […] as well as communities and groups subject to structural discrimination and disadvantage" (par.15) also through the sharing of research, medical equipment and best practices in combating the virus (par.19). Decisions that may obstruct the access to vital equipment for the world poorest victims of the pandemic should not be taken (par.20).

The Statement issued in November 2020 (CESCR, 2020a) is more vaccines and IP oriented and emphasizes already in its first lines that "every person has a right to access a vaccine for Covid-19 which is safe, effective and based on the application of the best scientific developments" (par.2). Priority must be given to health care staffs, social workers and vulnerable people, both at the national and at the international level (par.5).

IP is considered as a mere social product that should not undermine access to vaccines. TRIPS flexibilities, even if "insufficient to adequately face the pandemic", should be used "to ensure access to a Covid-19 vaccine for all". CESCR expresses then its support to the TRIPS waiver proposal issued by India and South Africa (par.6) and reminds pharmaceutical companies to "refrain from invoking intellectual property rights in a manner that is inconsistent with the right of every person to access a safe and effective vaccine for Covid-19 and with the obligation for States to guarantee […] universal equitable access to vaccines for Covid-19". (par.7) On their side, States should ensure that business do not invoke IP in a manner that is inconsistent with the universal right to access a safe and effective vaccine for Covid-19 (par.8) and do not have to compete with each other regarding the vaccine supply (par.10).

In April 2021, due to “the discrepancy between the enormous potential of vaccines to improve global health and their limited and unequal positive impact to date” (par.2) the CESCR issued a further statement (CESCR, 2021) recalling the states and business duties in relation to intellectual property (par. 7-10). It also invited states to use their voting rights to honour their international duty to guarantee a global access to Covid-19 vaccines. (par. 3) and highlighted that a failure in approving the waiver will stand in the way of global economic recovery (par.14).

3.3.1 An assessment of developed States and pharmaceutical companies’ behaviour towards the right to health

One year and a half inside the pandemic, it is sad to see that, despite the international pledge to respect, protect and fulfil human rights and international collaboration, States and pharmaceutical companies have completely failed to honour their commitments, showing a selfish behaviour in a situation that can be solved only through international cooperation. Lawyer Brook Baker commented that the human rights response has failed miserably, leaving too many (poor) people “stand in line to die”. (Raoul Wallenberg Institute, 2021 July 14, 35 min).

In fact, rich developed countries have preordered so many vaccines that they have exhausted the entire pharmaceutical manufacturing capacity for the year 2021 (Mullard, 2020). Moreover, in April the EU has already started negotiations with Pfizer to purchase 1.8 billion doses for 2022. (Reuters, 2021 April 9). To fulfil their duties towards the right to health, instead of purchasing massive amounts of vaccines, rich developed States should have given priority to the globally most vulnerable peoples in poor countries and to the healthcare workers (see CESCR, 2020 par.15; CESCR, 2020a par. 5). Sadly, while the rich countries were well underway with the vaccines, healthcare workers in Africa received their first shots (Tam, 2021 April 11).

Focusing on the IP, the CESCR (2020a) recommends pharmaceutical companies not to invoke it in a manner that is inconsistent with the right to access to vaccines (par. 7). The debate at the WTO on the TRIPS waiver showed that IP is indeed a problem for an equitable development and vaccines roll-out and that the rationales for the establishment of an IP regime on vaccines – recoup of R&D costs and innovations - are at odds in the context of the pandemic.

In fact, the development of the Covid-19 vaccines was massively financed by the public sector which took all the risk on its shoulders. Actually, the Covid-19 vaccines have shown to be one of the most lucrative investments of the pharmaceutical sector because of the almost total lack of risks and the high financial revenues. "Pfizer expects revenues from the coronavirus vaccine […] to reach $ 26 billion this year, a staggering sum that would make the shot the most lucrative medicine in pharmaceutical industry history measured by sale in a single year", writes Pagliarulo (2021, May 4). If we think that vaccines R&D may have cost no more than $2 million, the financial gains are huge. Regarding the innovation, doubts may arise on the role of IP among pharmaceutical industries because the actual blueprint of the mRNa technology – which is the most efficient one in regards to Covid-19 vaccines – was discovered by researchers at the US federal NIH.

Moreover, even if this was not the case, TRIPS flexibilities and temporary waivers are instrument exactly designed for situations of emergency that have to be used. As WHO Executive Director Dr. Ghebreyesus states: "If not now, when?" (The Guardian, 2021 March 5). If we are not allowed to use them during a pandemic, when can we use them?

Also states should ensure that IP is not invoked in a manner inconsistent with the right of *every person* to access to vaccines (CESCR, 2020a, par.8). Considering the massive amounts of vaccine doses ordered by developed countries, IP is surely not a problem for them but developing countries have clearly demonstrated how it is a burden for them, therefore developed countries should use their voting rights (CESCR, 2021, par. 3) and let the waiver pass. In opposing to it, rich countries not only failed to ensure that IP is not invoked in an inconsistent way (CESCR, 2020a, par.8), but they actively burdened the enjoyment of the right to health in many world countries (CESCR, 2020, par. 20).

Access to available, affordable and quality medicines and the prevention and containment of pandemics are considered among the "core obligations" that states have to fulfil and that the international community has pledged to provide in case of state' impossibility. The active obstructionism that both developed countries and pharmaceutical companies are doing goes not only against their duties in relation to the right to health, but, since access to vaccines is also among the benefits of the scientific progress (CESCR, 2020b), their behaviour is also against their duties towards article 15.1.b ICESCR on the right to science.

Quick vaccination is the only mean we have against a pandemic that has costed us many lives and economic losses: because our western manufactures are unable to produce vaccines for the

entire world, the need to expand our manufacturing capacity- also through a temporary waiver on TRIPS - is compelling. Unvaccinated areas are the perfect spot for new Covid-19 variants to thrive and spread, seriously threatening the efficacy of our most promising vaccines (Wadhera, 2021 July 7). Moreover, the possibility of a third injection will boost the request within an already overloaded market.

The world has already the manufacturing capacity needed to produce more doses of vaccines, therefore, the fact that no concrete actions have been done leaves us think that probably States are not doing efforts to the *maximum of their available resources* to make vaccines globally available (CESCR, 2021, par.4). This doubt may find its confirmation in the words of the WHO Executive Director Dr. Ghebreyesus which, in a World Bank Spring Meeting stated that IP was the "elephant in the room" that everyone sees but nobody wants to talk about (WB, 2021 April 9, 25:35 min). To fake their unwillingness to talk about IP, rich developed countries pledged to donate to COVAX but, bearing in mind the deluding G7 meeting their actions seem to be merely symbolic.

The lack of political willingness can be seen also within pharmaceutical companies which have never adhered to the C-TAP and the "Open Covid Pledge" programmes and have behaved inconsistently in relation to their "Good Covid-19 Company Practices", as a report from the pharmaceutical accountability foundation shows (2021).

Besides what seems a lack of willingness to engage and find real solutions to the Covid-19 pandemic, both the CESCR Statements issued in November 2020 and April 2021 highlight the fact that TRIPS flexibilities are insufficient to cope with the current pandemic, perfectly framing the words of the Waiver- supporters who showed the structural limitations of the compulsory licensing. This strengthen the idea that the ultimate solution to the pandemic has to be searched outside of the TRIPS Agreement.

3.3.1 A way forward or a step back?

To sum up, in order to comply with the CESCR Statements and be coherent with their duties towards the right to health (but also the right to benefit from the scientific progress in the form of vaccines), states should both donate consistently to COVAX and expand their vaccine manufacturing capacity through committing to the TRIPS Waiver proposal, therefore ensuring everyone global access to vaccines. This perspective also shared by the Independent Panel for

Pandemic Preparedness and Response (2021b) which in April issued a very detailed Report on the pandemic stating that WTO and WHO had to:

> Convene major vaccine producing countries and manufacturers to get agreement in voluntary licensing and technology transfer arrangements for Covid-19 vaccines […]. If actions do not occur within 3 months, a waiver of TRIPS Intellectual Property Rights should come into force immediately. (2021b, 63).

However, once more, the reality is very different: not only no concrete advancement in relation to the TRIPS Waiver has been made, but a dubious alternative solution made by the European Commission on the 4th of June summarizes the lack of (willingness of) understanding of the structural shortcomings of the TRIPS.

In fact, after having stated that voluntary licensing is the best solution to aim for (against which the TRIPS Waiver supporters have nothing against if the voluntary licensing agreements are transparent and not geographically and quantitatively limited), if these are not met the compulsory licensing flexibility can be used. In particular, in order to overcome the recent problematics in relation to its use by least developed countries:

> EU considers that all WTO members should be ready to agree on the following:
> a) The pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived;
> b) To support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory licence, the remuneration for patent holder should reflect such affordable prices;
> c) The compulsory licence could cover any exports destined to countries that lack manufacturing capacity, including via the COVAX facility. (EC, 2021a, 4 June, paragraph 9).

Sadly, the elements considered by the European Commission are all already contained in the TRIPS Agreement and in its Doha Declaration, therefore there is a lack of understanding of the real aim of this proposal. As Sangeeta Shashikant from Third World Network (People's Health Movement, 20:43) states, the proposal is nothing else than "an old wine in a new bottle".

In conclusion, if Covid-19, after the debated response to the HIV crisis back in 2001, was the perfect opportunity for WTO states to show how the TRIPS regime is directed towards global common good (De Campos - Rudinsky, 2021, p.536), the reality of the facts presents a system that is unable to take care of what matters most – global health – not only because of a lack of political willingness but also because of structural problems. It is clear that the actual system should be changed as fast as possible.

CONCLUSION

This concluding section will present a brief summary of the main arguments and findings (concluding summary) and some thoughts on the possibility of alternatives to the actual system (concluding perspectives).

Concluding summary

The aim of this thesis was to analyse the complex relationship between the right to health and international intellectual property protection in order to answer to my research questions.

The first chapter dealt with a close in-text analysis of the TRIPS Agreement, providing a "compatibility" reading between patents (as the concrete expression of intellectual property within the pharmaceutical sector) and the enjoyment of human rights. This is possible thanks to TRIPS article 7 and 8 which, providing the interpretative key of the whole agreement, consider the national governments as the most entitled to preserve the "balance between rights and obligations" through a subjective implementation of the vague wording of the agreement. In addition, the so called "TRIPS flexibilities" enable governments, in case of emergency, to temporarily lift intellectual property to guarantee the enjoyment of human rights.

The second chapter conducted an analysis of content of the right to health, the states and business duties towards it and the "practical" implications of the TRIPS Agreement, both on developing and developed countries.

Political pressures by foreign governments and structural shortcomings like the lack of R&D in the field of the neglected diseases not only shrink the above mentioned state autonomy, but generate great limitations regarding the developing States' ability to live up to the duty of protection of the right to health of their citizens. In doing so, both the international community and businesses neglect their international duties of cooperation and assistance.

The case of the developed countries is a bit different: a generous governmental interpretation of the TRIPS Agreement allows pharmaceutical companies to patent also new forms/uses of an already patented product, therefore extending its monopoly period on the market. However, this practice also defined as "secondary patenting" has started to be used as a marketing strategy in order to keep potential competition away. This behavior, in addition to being unfair because it

maintains the prices of the medicines higher than they should be, is a limitation to the free flow of information and innovations which in turn has consequences for the right to health.

The chapter ended with a discussion of the justifiability of the normative utilitarian basis of the actual patent system, providing a negative answer. Not only the innovation that it should bring is not so easy to detect, but also the calculation of the huge R&D costs of medicines seems to be biased.

The third chapter conducted an analysis of the role that IP played regarding global access to vaccines focusing on the different stakeholders' view on the TRIPS Waiver proposal brought at the WTO by India and South Africa and through an exploration of the CESCR statements on pandemic and the consequent states and pharmaceutical companies behaviour. Two important conclusions were reached: (i) the lack of willingness to cooperate among the biggest to render the Covid-19 vaccines a "global common good"- something that not only goes against the right to health but also the right to benefit from the scientific progress - (ii) and many structural shortcomings that make TRIPS unable to cope with situations of global emergency.

On the basis of these findings, does the existing intellectual property system adequately enable or serve as a barrier for states to fulfil their duties towards the right to health? Now we can conclude that the patent system within the pharmaceutical field is a hindrance towards the state duties regarding the right to health. In fact, despite the in-text "compatibility" reading between the two systems (chapter 1), the reality shows that neither developing nor developed countries adequately benefit from the actual IP protection (chapter 2). On the contrary, it seems that the "greater social welfare" that IP achieves is the one of the pharmaceutical companies which manage to exploit the system and generate great revenues at the cost of the health of the global population.

In particular, has the intellectual property system been a barrier for a more equitable roll-out of Covid-19 vaccines? As chapter 3 explains, the debate at the WTO on the role of intellectual property during the pandemic and the many voices from academics, NGOs, government representatives and international institutions have confirmed the problematic role played by it.

In light of the Covid-19 pandemic, are reforms of the actual intellectual property system needed to advance the right to health? The answer is yes. However, Covid-19 has only exacerbated and made more compelling our need for a change, that should have been pursued irrespectively of the pandemic, as chapter 2 shows. Possible alternatives are discussed in the next section.

Concluding perspectives

A change of the actual IP system is needed not only because patents have revealed to be inadequate to guarantee the right to health and cope with severe emergencies like the Covid-19 pandemic, but also because their existence has become hard to justify. In fact, the utilitarian explanation is both hard to rely on (has chapter 2.2.4 showed) and problematic also from the same utilitarian perspective. As Amy Kapczynski (2012) – citing economists such as Yoram Barzel and Glenn Loury – says, the patent system is designed in such a way that it resembles a race with many competitors fighting for only one, big prize which is the monopolistic control of the market. The problem with such an approach is that "too many players will chase the same reward and dissipate resources in the process" (Kapczynski, 2012, 984).

Considering that the toxic human behaviour regarding the planetary wellbeing is likely to cause other pandemics (Constable, Kushner, 2021), the need to completely rethink the actual patent system is compelling. In particular, a revised system of IP protection should be prepared to both challenge itself on the R&D of fundamental but financially risky pharmaceutical products (e.g. vaccines, neglected diseases) and at the same willing to get rid of its patents in situations of severe emergencies.

The disastrous consequences of Covid-19 are then the perfect opportunity for considering a change of a system that has been revealed to be unjust. In fact, the momentum generated by the pandemic led to the creation of a "WHO Council on the Economics of Health for All" (WHO, 2020 November 13) chaired by Prof. Mariana Mazzucato, (WHO Press Conference, 2021 7 May, 9:00 – 14:20). The Council's aim is to identify new ways to shape the global economies and to build societies that are healthy, inclusive, sustainable and equitable. The rationale is to reverse the usual logic focused only on economic gains with one where economy should be at the service of global health. Among the challenges of this new Council, there is also the need to reshape the ways in which incentives for pharmaceutical innovation are created. This is exactly the framework where a substantial revision of our patent system has to be put.

Therefore, the next important question is: how can we shape an intellectual property system where both pharmaceutical innovation and right to health are finally really taken care of in a balanced way?

In the long-term, a possible alternative could be to adopt something similar to the copyright system also within the pharmaceutical world, where as long as "author rights" in form of "royalties" are paid, everyone is free to reproduce the invention without any form of legal

sanctions. In this way both an increased access to medicines and treatments and a rewards on innovation are granted. In fact, even if they will not have a short time monopoly on the market and their products will be sold at lower costs than the patented one, pharmaceutical companies will have financial revenues in form of "royalties" for many more years from all the manufacturers willing to produce a generic version.

Another valid alternative is the "Health Impact Fund", (Hollis and Pogge, 2008) a rewarding system that aims at incentivizing pharmaceutical R&D in all those fields which, due to their riskiness or the lack of purchase power from potential clients, are mostly neglected. Thanks to philanthropic donations or governmental funds (which would be proportionate to their annual GDP) the Health Impact Fund would be enabled to establish a 10 years' reward system for all the medicines registered within the fund. The reward will be distributed among the registered medicines in a way that is directly proportional to the – qualitative and quantitative - health impact they have on their patients. In exchange, the manufacturers pledge to sell the medicines worldwide at cost also once their membership to the fund expires.

This new perspective of reward should incentivize manufacturers to invest money in the R&D of both neglected diseases and vaccines that with the actual patent system are the least analysed by pharmaceutical companies. In fact, if a treatment against some neglected diseases is to be found, the reward of the pharmaceutical manufacturer will be very high because it will not only greatly enhance the life conditions of the people affected, but, since those diseases severely burden a great number of people within the poor countries, the prize will take into account also the "quantity".

Regarding vaccines, they are never studied because their utility is only during a short-time emergency situation, too short for the pharmaceutical companies to recoup their R&D costs. If registered within the Fund, those vaccines would receive rewards for the whole 10 years' period, even if used only for a few. In fact, the final aim of medical treatments should be the eradication of illnesses and the lack of further need of vaccines is a good sign the illness is no dangerous anymore.

If the Health Impact Fund was in place during the Covid-19 pandemic and the major vaccines were registered with the fund, not only they would receive a great amount of prizes for having literally saved the world, but the need of a long debate on a TRIPS waiver proposal would not be there. In fact, the vaccines registered with the fund would be sold at cost everywhere and would not be covered by any form of IP, leaving every world manufacturer free to reproduce

them. Actually, it would be the very same vaccine producers that incentivize the transfer of the technology know-how to assure that generic manufacturers would reproduce a generic vaccine that is as efficient as the originals. In this way, not being able to supply the huge world requests, vaccine producers would still gain the Fund financial rewards from the health benefits generated by their generic versions.

Even if at the moment it is considered as a complementary tool to the actual patent system, if supported internationally by many governments around the world, the Fund could aim in a not so distant future to be the main incentive for innovations and scientific discovery. Considering that the actual pandemic has showed the importance of massive public funding in the health system and the fact that with a possible introduction of a taxation system also for multinational companies more money will be at the disposal of national governments, I believe that this could be a smart, and human-rights friendly way to invest money for the global common good.

Of course, shifting from a patent to a system which globally enables the full enjoyment the right to health will require some time. Therefore, in the short-term a substantial revision of the actual one is needed. A shortening of the long bureaucracy for compulsory licensing and article *31bis* would guarantee a quick access to treatments; a decrease to a less extra-monopoly years of patents on new forms/uses of the same products with the establishment of a maximum price cap would avoid the use of "evergreening" methods as a marketing strategy anymore. Last but not least, the "know how" for fundamental medicines should not be kept secret but should be exhaustively explained when filing for a patent request.

Health is literally the most precious thing we own without which we are unable to fulfil any of our duties. Therefore, not only we should care for it at a global level, but we need to prioritize it among everything else building and nurturing a system that recognizes its fundamental value within our lives.

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