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MASTER THESIS

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„The Question to What Extent Patents Hinder the Bigger Roll Out of Vaccines in the COVID-19 Pandemic – An International Overview “

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INTRODUCTION

As we live in a constantly developing world, where new innovations are created every day, there is an ongoing need for them to be protected. Patents are an efficient way to provide immaterial property protection to new inventions and also preserve their exclusivity to their holders. Nowadays the markets are tough and there is competition between the rivals and therefore patents allow their holders to have the rights to prevent others from making, using, or selling their invention and that way allowing them to succeed and have a rewarding position in the markets.

There has been a rising number of discussions concerning the status of the patent protection and the monopoly position it can offer to the bigger manufacturers during this ongoing crisis around the COVID-19 virus and the vaccines to fight against it. It has brought up questions and different opinions in favor and against whether new rulings should be done in order to overcome a worldwide pandemic more efficiently in the future. Some believe that the patents for the vaccine doses and their manufacturing limit other pharmacy companies entrance to the COVID-19 vaccine development as only a couple of the largest companies hold the rights to manufacture the doses. Others argue that the main issue is the lack of the base materials and equipment needed for the process and the considerably long process and the amount of investments that is needed in order to build enough capacity for the supplies compared to the current status. These diminish the production a lot as only a few factories are able to produce the vaccines and therefore the distribution to all over the world is not as fast as it could be without the restrictions. This situation has caused a lot of debate whether the patent rights should be eased during this worldwide pandemic for the common good, helping the less fortunate parts of the world as well.

The topic of this thesis is very current and has gained a lot of space in the news headlines. The questions about it has arose and also various opinions in favor and against have been published. There is also an ongoing debate and discussion for example in the European Union and in the United States about whether the legislation should be altered or should there be some changes made for the crisis situations like the pandemic in case for the future. There is also personal interest for the topic and it is intriguing to go more in-depth

to the reasoning behind everything and get to receive more knowledge through the research process.

The structure of this thesis handles the topics and various issues in chronological order including four main chapters. The first chapter consist a short overview on intellectual property rights and patents and their legislation. After that the chapter focuses more about the basics of the blocking patents and what is the meaning behind that concept and what do they do and how they affect the patent processes. The second chapter presents the world's situation with the COVID-19 pandemic and offers some insight to the manufacturing of the vaccinations and whether the patent protection plays a large role in the pandemic and elaborates the issues and problems there might be. The next chapter concentrates on the legislative waiver that has been suggested to take into force and how this waiver would affect to the patent rights and what changes could happen because of that. The waiver has a split group of people in favor and against so the subject would be analyzed on both sides. The last chapter looks more closely into the ways the vaccines can be distributed to the countries in need without the waiver. It introduces some of the main organizations that play a big role in regards to the fight of the pandemic. The chapter will also provide different scenarios about the future of the waiver and the acceptance of it as well as the point of view of the efficiency of the patent protection.

The research and the majority of the information retrieval about the COVID-19 is done using a social-legal methodology, including different published news articles and various published notices from international organizations and legislative bodies. However, the information about immaterial property and patents is mostly from official published journals and books and therefore it has a more doctrinal methodology aspect included. This thesis refers to the literature and other sources that are already widely recognized and that is why it follows a deductive approach through the pages.

The aim for this master's thesis is to provide a more in-depth overview about how the patents are being used and the concrete effects of them in the current case of COVID-19 vaccinations. It will also provide a thorough research out from all perspectives that are concerned of this worldwide situation. To be able to reach the aim, there are a few research questions that will help to provide a correct and precise knowledge relating to the topic. The first research question is why companies that have patents to the vaccines

do not want to give rights to other manufacturers and third parties. Following the first question, there is another stating what are the pro and contra effects of the vaccine companies' actions regarding the patent issue. The main research question is whether the proposed waiver is necessary or not? And another research question states whether patents are even suitable in regards of a global pandemic. In addition, there is also many subsidiary questions that will target issues in global economy and the equality of the countries and the people during COVID-19.

By analyzing and taking a more critical approach to the arguments mentioned in the resources, this thesis will critically evaluate the real need for the patents in the pandemic crisis and what are the real underlying problems it might face in the future. All the solutions found for the research questions will be found in the conclusion.

There are not many correctly applicable sources in the form of academic literature for this topic because the current ongoing nature of the COVID-19 is relatively new and therefore, books about this topic have not yet been published. However, a lot of academic journals can be found and in addition several trusted sources from the internet that can be referenced as well. This thesis is directed towards all people, who are eager to learn more about the current problems between the patents and the COVID-19 vaccines and their pharmacy companies and what kind of issues might arise if the regulations might change.

I. BLOCKING PATENTS IN THE SCHEME OF INTELLECTUAL PROPERTY

The first main chapter introduces the base for the topic of this thesis. The other chapters will then continue to deepen the topic introduced here and connect it to the ongoing situation we are facing today all around the world. This chapter is structured in a way that the knowledge on the previous chapter is linked and useful when moving onto the next chapter. In the beginning there is a short summary about intellectual property rights and the protection they provide to different inventions. This thesis focuses mainly to patent issues and therefore, the next thing introduced are the main aspects of the patent protection and legislation and the main operators and legal texts. The European Patent Office is one of the largest working organs in the patent system and it plays a key role in granting patents. There is also an interesting form of patents called blocking patents that cause variations to the mass of ordinary patents. Those have a character of a calculated, well executed and planned patent that would give the patent holder an advantage compared to others in some cases in cases where the requirements for the invention and prior art are met. This topic is discussed more in chapter three where it is linked to the current pandemic situation.

1.1. The Basis of Intellectual Property Rights

Intellectual Property Rights covers a large variety of different creations from art and brand logos to inventions which have an important role in today's businesses and cultures. There are different laws that have been designed to protect these creations using intellectual property rights. Altogether the intellectual property law is quite multifaceted including national and international legislation in all of the main fields of the IP. As our world evolves and people develop new ideas and technology constantly, intellectual property rights become important to designers, inventors and scientists as they want to secure their innovation in order to be able to attract investors to develop their innovation, if lucky

make a profit and stop it from being misused by imitators at least for a fixed amount of time.[1]

The Universal Declaration of Human rights provides the largest outlines for more specific ones by stating that there should be moral and material interest that comes from the production of the intellectual property.[2] There are also the Paris Convention of the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886) that notice the importance to protect intellectual properties of the art. The protection of patents dates as far back as to the fifteenth century in Venice, where the intellectual property rights were recognized for certain groups of professions.[3] Nowadays, there are over twenty different international treaties that help to protect the intellectual property. Those are all administered by the World Intellectual Property Organization (WIPO).

The WIPO is a specialized agency of the United Nations that focuses to ensure that the intellectual property rights concerning creators are protected worldwide and that they are rewarded accordingly for their works. As the world faces more and more changes every day because of the technological innovations and increasing trading and globalization, WIPO has an important part by making sure national legislation for intellectual property evolves and ensures that all the main features are recognized.[4]

Intellectual property in usually divided into two categories.[5] First part is Industrial property that includes patents, industrial designs, trademarks and geographical indications under its name. The other category contains copyright and its related rights to artistic and scientific works.

[1] WIPO, 'What is intellectual property?' <https://www.wipo.int/edocs/pub-docs/en/wipo_pub_450_2020.pdf> accessed 15 June 2021
[2] Universal Declaration on Human Rights (adopted 10 December 1948) 217 A(III) (the United Nations General Assembly) Art 27
[3] WIPO, 'What is intellectual property?' <https://www.wipo.int/edocs/pub-docs/en/wipo_pub_450_2020.pdf> accessed 15 June 2021
[4] Ibidem.
[5] Ibidem.

As the world becomes more modern and developed every single day, it is important to realize the importance to protect the intellectual property. By protecting those, it automatically gives more security and courage to creators to keep going and bring more ideas and inventions to the table and investors continue to support the process financially, which plays a big role in the process. By doing that, our well-being and development as a humanity continues to grow and it widens the possibilities in the technological and cultural areas of our society.[6] Therefore, when the growth can be noticed in those areas, it automatically reflects also to resources available and that can boost the economic status by creating new industries and simply enhancing the quality of life by bringing new things for people to enjoy.[7] This highlights the fact that the public interest has a huge effect on the intellectual property system as a whole.

1.2. Patent as an Intellectual Property Right

Patents are considered to be one of the first forms of intellectual property that was known in modern legal systems. Patenting a new invention means that the patent owner receives the exclusive rights to the innovation and no one else can use, sell, make or import the invention without the owner's permission.[8] However, there is an exception to private use or academic research for example where the exclusivity regulations does not apply. The time for patent protection is limited to 20 years and after that the invention is free for everyone's usage. The patent period may be able to maximize the profit to the patent owners and can cause a positive and competitive incentive to create more as the invention is published. After the twenty-year time period, the public can also get their hands on the invention and further their basic knowledge.

An invention that is considered to be patentable, must bring something new to the table that is not a known information in the field of the patented invention. In addition to the novelty of the invention, it must have a high enough utility rate and an inventive step,

[6] WIPO, 'What is intellectual property?' <https://www.wipo.int/edocs/pub-docs/en/wipo_pub_450_2020.pdf> accessed 15 June 2021
[7] Ibidem.
[8] Finnish Patent and Registration Office PRH, 'Patents' <https://www.prh.fi/en/patentit.html> accessed 15 June 2021

which means the invention has to include something completely new in a precise and more technical level.[9]

Patent protection is usually territorial as countries have variations in their national laws and the protection is applied under those laws. However, there is also regional and international patent systems that help reduce the costs and gain protection more easily in a number of different countries. If the patent is applied through the national system in the EU, the procedure is different in each country and one has to fulfill the procedure in every country, one wishes to gain protection. In the EU there is something called the European Patent Convention which allows you applying for patent protection to forty-two countries with just one application. The applicant can choose the states where the protection is needed and then after the application period and the grant of the application the applicant, now patent proprietor, receives a bundle of national patents. If there is a need for a patent internationally, the Patent Cooperation Treaty allows for a convenient ad easier way to do that. Only one application is needed for over 150 countries. The applicant can decide in which countries the patent should be proceeded after usually 30 months from first filing of the invention and includes the receiving of the search report and opinion about the patentability of the invention.

1.3. The European Patent Office

The European Patent Office (EPO) was established in 1973 and it is the largest regional patent office in the world. It examines the patent applications and enables protection to inventions in up to forty European countries.[10] In addition to the variations of the patent applications at the previous chapter, the EPO administers a further option called the Unitary Patent that offers patent protection in one single application to twenty-five different EU countries.[11] However, this patent process is not yet in force as of right now.

[9] WIPO, 'What is intellectual property?' <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf> accessed 15 June 2021
[10] European Patent Office, 'European Patent Office - A hub for innovation and - enhancing Europe's competitiveness' <https://www.epo.org/news-events/press/background/epo.html> accessed 20 June 2021
[11] Ibidem.

The EPO receives up to five hundred patent applications per day and almost 134 thousand patents were granted in the year 2020 alone.[12] Even though the EPO is a European patent office, over half of the patent applications come from outside the EU. The headquarters of the EPO are in Munich and offices can be also found in Berlin and Hague and in addition, an information center in Vienna.[13]

The European Patent Convention (EPC) was established in 1973 and based on this convention, an uniform application procedure was created. At the beginning, there were sixteen states and now there are thirty-eight countries including Norway, Switzerland, and the United Kingdom which are outside of the European Union.[14] The Convention includes the main text of the Convention on the Grant of European Patents and different implemented regulations, rules and protocols on top of that.[15]

1.4. Blocking Patents and the Reasoning behind Them

As discussed earlier, the role of patents is to provide exclusive power to the patent holder in a use of that particular invention and. However, there are also rare situations, where certain patents are being filed by rival companies to prevent others the right for the patent.[16] Normally this is not the case and these kind of actions are usually strategic and used as an obstacle for the competitors as they would try to enter the same markets.[17] In cases like this and many others, the main goal for the patent is to block other similar patent applications, hence the used term 'blocking patents'. However, the term is quite controversial as it is very difficult to actually get a blocking patent for a certain product. Patents prevent direct copying and might make it more difficult for the rivals to patent their technology. It would be more problematic if the patent would go too broad and make

[12] European Patent Office, 'European Patent Office - A hub for innovation and - enhancing Europe's competitiveness' <https://www.epo.org/news-events/press/background/epo.html> accessed 20 June 2021
[13] Finnish Patent and Registration Office PRH, 'European Patent and European Patent Convention (EPC)' <https://www.prh.fi/en/patentit/applyforapatentoutsidefinland/europeanpatent.html> accessed 20 June 2021
[14] Ibidem.
[15] European Patent Convention (17th edition)
[16] Andreas Heinemann, 'Blocking Patents and the Process of Innovation'<https://www.ius.uzh.ch/dam/jcr:66f8a3a6-8876-4cd4-bf68-e09022a75930/Heinemann_Blocking_Patents.pdf> accessed 1 July 2021
[17] Ibidem.

the competition uneven as the company with the broad patent could dominate the field. That would not be good either for the economical or the political side of things.

The blocking patents have of course a possibility to be granted but sometimes they are withdrawn before the decision if the goal has just been to create prior art which would affect the patentability of the competitors' inventions.[18] This might still not affect the competitor's plans for the invention, it would mainly just weaken its chances in gaining patent protection.[19] Patent applications that are focused on blocking others have been increasing in the past years, which shows that patents have a growing role in the companies' market and technology strategies.[20] On a more broad level that also means that people are taking the IP protection more seriously and are directing more resources towards them and applying for a lot more regular patents as well.[21]

Blocking at the marketing level can happen if the main invention needs other complementary inventions to commercialize itself and in that situation one patent holder of the subsidiary patents can block others with that even though the others would have rights to the main invention as well.[22] In the technological level, there can be overlapping within the new technological inventions and that can cause a situation where the parties block each other out mutually. Therefore, in some cases, it can be solved by mergers and acquisitions that would help with the enforcement of the patent rights.[23] In other situations, companies solve these issues by cross-licensing and they will discuss the case and solve the issues with a licensing contract that would allow the use of the invention in exchange for the financial reward. Most of the times litigation is expensive and licensing is an effective way to go around it.

[18] Dominique Guellec, Catalina Martinez, Pluvia Zuniga, 'Blocking patents: What they are and what they do?' (2008) <https://ftp.zew.de/pub/zew-docs/veranstaltungen/innovationpatenting2008/papers/GuellecMartinezZuniga.pdf> accessed 1 July 2021
[19] Ibidem.
[20] Ibidem.
[21] Ibidem.
[22] Andreas Heinemann, 'Blocking Patents and the Process of Innovation'<https://www.ius.uzh.ch/dam/jcr:66f8a3a6-8876-4cd4-bf68-e09022a75930/Heinemann_Blocking_Patents.pdf> accessed 1 July 2021
[23] Dominique Guellec, Catalina Martinez, Pluvia Zuniga, 'Blocking patents: What they are and what they do?' (2008) <https://ftp.zew.de/pub/zew-docs/veranstaltungen/innovationpatenting2008/papers/GuellecMartinezZuniga.pdf> accessed 1 July 2021

The strategic patents, which also include the blocking patents, can be either offensive or defensive by nature. Patenting is offensive when it is created to threaten or weaken the other patents.[24] This form of strategy with granted and enforceable patents can affect to competitors and issue them restraints and prevent them the usage of their technology. In addition, it can establish a positive leverage and advantage on time for closing deals and settlement decisions. In business world, companies that practice this kind of action and patent technologies to obtain licenses from others, are being called patent trolls.[25] However, defensive patenting works to keep other competitors off of a certain inventions and diminishing their profits that are to be expecting after their investments.[26] The defensive way looks more into the future as usually the filing company wants to ensure that there will not be any risks for the competitors patenting the same idea. This method also provides help for the company in lawsuits about patent infringements.

Blocking patents can cause both positive and negative things to social welfare. They are initially a creation that is established due to a growing amount of bad patent applications and the threats they put up. Usually, the applications designed to prevent others from obtaining patents are withdrawn because they do not fulfill the basic elements of the patent application such as the novelty or the inventive step of the invention.[27] A better patent system would be reached, if the blocking patents solved the issue regarding some insufficient novel applications that notably weaken the system. However, they push the patent inflation onwards at the same time and cause unnecessary competition and counter-blocking. All in all, nothing ever is as black and white as it might seem on paper at a first glance.

[24] Ibidem.
[25] Dominique Guellec, Catalina Martinez, Pluvia Zuniga, 'Blocking patents: What they are and what they do?' (2008) <https://ftp.zew.de/pub/zew-docs/veranstaltungen/innovationpatenting2008/papers/GuellecMartinezZuniga.pdf> accessed 1 July 2021
[26] Ibidem.
[27] Ibidem.

II. THE COVID-19 PANDEMIC AND THE PATENTABILITY OF THE VACCINES

The second chapter focuses solely to the COVID-19 pandemic. This virus is currently the one thing that is affecting the life of everyone in this world. It has caused infections, deaths, pain and sorrow among the population and has changed the world into a very different place than it has been known. A new normal has in the meantime been deployed and people need to adopt to a new way of living. To fight this pandemic, there has been massive investment, research, and development into the vaccines against SARS-CoV-2 infection by academic institutions and pharmaceutical companies that are determined to put a stop to this disease or at least make it less deadly and thus manageable. However, as the income is not distributed evenly, there has been unequal distribution of the COVID-19 supplies and vaccines between countries. The developed countries are on a mission to get their whole population vaccinated whereas the low and middle income countries are still waiting for the aid that would give them also a chance and access to the vaccines in order to fight the virus equally to wealthier countries. Patents may protect most of the invented vaccines in some countries in the future as there is currently no granted patents yet and the pharmaceutical companies have not granted permission to third parties to start the manufacturing of the vaccines as they want to hold onto their profits earned and the knowledge and process behind the effective vaccines.

2.1. The COVID-19 Pandemic

At the end of the year 2019, the news about a new unknown, easily spreadable virus in China, got a threshold and spread rapidly in the news internationally and slowly new incidents of the contagious virus were noticed in other countries as well due to travelling. In March 2020, the coronavirus had an outbreak and it became an international health concern, declared by the World Health Organization.[28] The virus, called SARS-CoV-2 reached quickly the levels of the pandemic and the cases increased rapidly and more

[28] WHO Regional Office for Europe, 'Coronavirus disease (COVID-19) Pandemic' <https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/novel-coronavirus-2019-ncov> accessed 5 July 2021

deaths started to occur as well. During the outbreak, countries introduced a lot of heavy actions trying to slow down the spreading. Countries closed their borders, travelling and tourism were completely at halt, and some cities and countries ordered complete lockdowns that closed all the unnecessary services and restricted the movement of the people. Today, COVID-19 testing, social distancing, hand sanitizers and facemasks are a normal part of everyone's everyday life.

The statistics show that at time of this report over 198 million people have been tested positive for the COVID-19 virus and over four million people have lost their lives in the fight.[29]

2.2. The Research and Development of the COVID-19 Vaccine

Luckily in addition to all the health measures, the actions to develop a vaccine against the coronavirus began very soon by the academic and pharmaceutical and biotech industries. The first large scale vaccination program started at the end of 2020 and now there are at least thirteen approved vaccines in various parts of the world and many potential ones still in the development process.[30] After a vaccine has been proven to be safe and effective to combat the virus, it must fulfill the national regulations and meet the manufacturing and distributing standards. The WHO also sets out recommendations on the usage of each vaccine and national officials will base their policies to those.

There has been a short development period of a few months for the COVID-19 vaccines and therefore, it is still unknown what is the exact protective period for them even though, there is constant research on it.[31] In addition to the vaccines, people that obtained COVID-19 are protected for a while after the recovery from the virus. The vaccines' main goal is to stop the infection of the SARS-CoV-2 virus and with that ultimately the pandemic but that is a huge goal and there are a lot of steps in order to that being achieved. It is important that the vaccines are effective against the virus and that their approval,

[29] Our World in Data, 'Coronavirus Pandemic (COVID-19) – The Data' < https://ouworldindata.org/coronavirus-data> accessed 1 August 2021

[30] World Health Organization, 'Coronavirus disease (COVID-19): Vaccines' <https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines> accessed 14 July 2021

[31] Ibidem.

manufacturing and distribution is quick and efficient.[32] No vaccine is one hundred percent effective but the specialists are making sure that the vaccines would have the strongest impact on the pandemic as possible. However, there is a constant lack of supplies because the capacity needed right now is unheard of and the amounts cannot be compared to anything.[33]

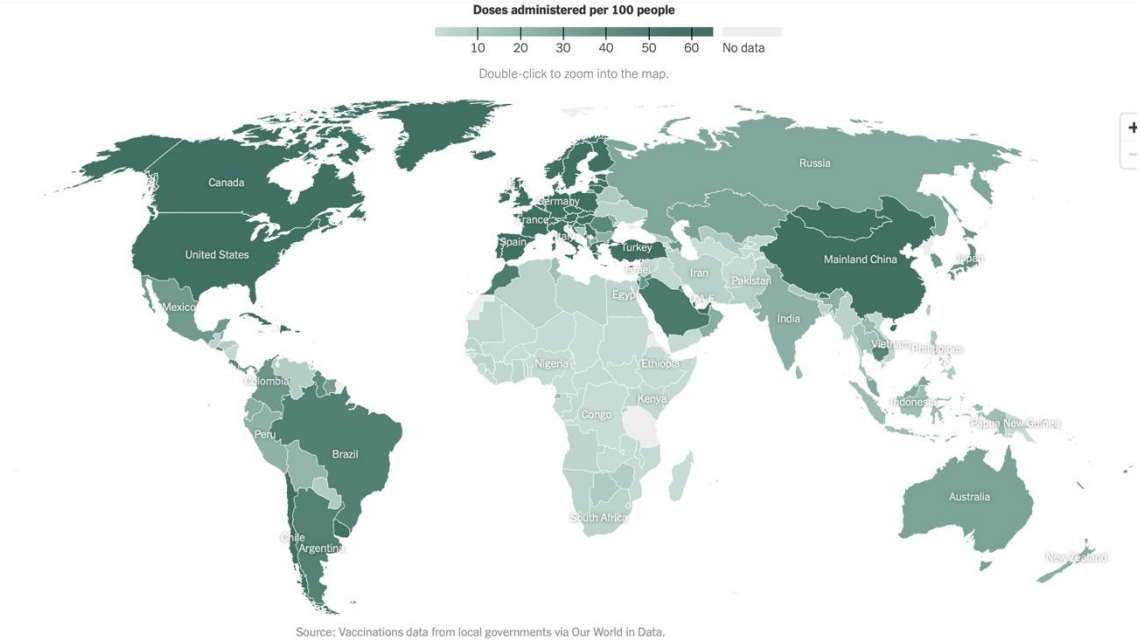
The vaccine is designed for people ranging from late teens to elderly. The vaccine is especially important for the elderly and people, who have to deal with some pre-existing conditions or disorders. The vaccine will protect from serious illness and death due to COVID-19 but as said it is still quite unknown, how far the level of effectiveness will reach. In ideal cases, it will even protect from minor and moderate symptoms that some people might face if infected with the virus. In addition, as the virus has progressed, it has created new variants of the virus that can act little differently than the original and it is not completely clear if the vaccine will be as sufficient towards these. Though, it has been proven that the vaccines will retain enough immunity towards the existing variants at least in terms of serious illness and death.[34]

2.3. How the Vaccines Have Been Distributed

In the beginning scientists estimated that the so called herd immunity for the COVID-19 pandemic is reached after seventy percent of the population have received the vaccination.[35] But now with the increase in variants, it is estimated to be close to eighty-five percent.[36] Thus it is considered as a milestone when countries are getting their population vaccinated. However, it is not completely sure whether that would be enough for the immunity. The herd immunity happens when most of a population is immune to an infectious disease, this provides indirect protection also to those who are not immune to the disease.[37] Now for the COVID-19, this situation is aimed to be reached through the

[32] World Health Organization, 'Coronavirus disease (COVID-19): Vaccines' <https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines> accessed 14 July 2021
[33] Ibidem.
[34] Ibidem.
[35] Carrie MacMillan, 'Herd Immunity: Will We Ever Get There?' <https://www.yalemedicine.org/news/herd-immunity> accessed 9 August 2021
[36] Ibidem.
[37] Gypsyamber D'Souza, David Dowdy, 'What Is Herd Immunity and How Can We Achieve It With COVID-19?' Johns Hopkins Bloomberg School of Public Health (6 April 2021)

vaccinations rather than an enormous amount of infections. In order to achieve the seventy percentage mark, 11 billion doses of vaccines must be produced for the whole world population.[38] At the moment in the beginning of August 2021, 4.2 billion doses have been administered and over twenty-eight percent have received at least one vaccine dose and fourteen percent of the world population are already fully vaccinated.[39] However, in low income countries, only one percent has received at least the first dosage. That clearly shows the unequal distribution of the vaccinations.[40]



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This picture is an effective reflection of the unfair distribution. Especially in Africa, Oceania and the Middle-East the vaccination rates are very low and some countries have not yet received vaccinations at all. When this is compared to the Europe, China, Japan and North America, where there might even be over one hundred doses towards one

<https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html> accessed 14 July 2021

[38] T. V. Padma, 'COVID vaccines to reach the poorest countries in 2023 – despite recent pledges' (2021) 595 Nature <https://www.nature.com/articles/d41586-021-01762-w> accessed 16 July 2021

[39] Our World in Data, 'Coronavirus (COVID-19) Vaccinations' < https://ourworldindata.org/covid-vaccinations> accessed 1 August 2021

[40] Ibidem.

[41] Josh Holder, 'Tracking Coronavirus Vaccinations Around the World' *New York Times* <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> accessed 14 July 2021

hundred citizens, which means excess doses that could be guided towards the countries desperate for them. It is understandable though, to vaccinate their own citizens first and after that help the others.

2.4. Patenting of the COVID-19 Vaccines

Patenting a vaccine is a complex process. A modern vaccine may be protected at many levels of its development. Usually these levels available for protection include the formulation, the process of making the vaccine, the antigen, and sometimes the dosing system and schedule. There is many parts for example the DNA base of the vaccine, the antigen and the adjuvant. Then the vaccine itself, the protection can be granted to the process of making the vaccine of the device inside which the doses are made.[42] The delivery system, usually an injectable with a syringe, of the vaccines play also important role in the timeline.

Compared to medicines, vaccines are complex drugs that cannot be tested that simply.[43] That is partly because drugs are formulated towards people with an illness but vaccines are meant to be applied to healthy people instead. It requires more expertise, previous data, and the costs in production and investments are a lot higher. Some basic vaccines to a long existing disease cannot enjoy intellectual protection as the manufacturing, usage and sales are already known and in addition the existed patents have already expired.[44] However if some vaccine is improved to be more effective, the new formula can receive protection.

Completely new vaccines are continuously under development and there is patent applications for those as has been the case for the COVID-19 vaccines. Nowadays, new vaccines that come into the markets are likely to have broad patent protection around them and usually recognize a wide geographical scope as well.[45] This is especially the case for the mRNA technology that is used in few of the COVID-19 vaccines. Investments

[42] Martin Friede, 'Intellectual Property and License Management with respect to Vaccines' <https://www.who.int/phi/news/Presentation15.pdf?ua=1> accessed 17 July 2021
[43] Ibidem.
[44] Ibidem.
[45] Ibidem.

are fundamental grounds when developing new innovations and they allow the crucial research and development stage to be as comprehensive as needed. Intellectual properties are usually not an issue but their management can easily cause more problems. Sometimes the existing patents may be infringed if they are not respected enough.[46] Also licensing patents is fairly common and then there might arise issues in the license agreements or in the license negotiations.

[46] Martin Friede, 'Intellectual Property and License Management with respect to Vaccines' <https://www.who.int/phi/news/Presentation15.pdf?ua=1> accessed 17 July 2021

III. THE WAIVER AGAINST THE PATENTS FOR THE COVID-19 PANDEMIC

The main thing in the third chapter is the Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment And Treatment Of COVID-19. The chapter introduces the waiver in detail and explains the reasoning behind it and all the issues and problematics it has faced during it time existing. The discussion of the waiver tries to gain trust from different countries, companies and organizations in order for it to be accepted. This chapter has information about who are all for the waiver supporting it fully and who are against it and try to prevent it ever being enforced. The reasoning behind these opinions are also stated after the basic information.

3.1. What the Patent Waiver Is All About

On October 2, 2020, India and South Africa submitted together an IP waiver proposal to the World Trade Organization (WTO). It was made to allow WTO members the option not to enforce patents or any other intellectual property rights regarding the COVID-19 vaccines, drugs, technologies and materials under the international trading regulations for the period of the pandemic.[47] This waiver refers to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and it was titled "Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19."[48]

On May 21, 2021, India and South Africa submitted a revised version of the waiver that in addition, has the decision text of the draft and the reasoning for the waiver. This update was made to specify the scope of the proposal and to move forward with the negotiations. The newer proposal defined that it will be applicable to health products and technologies for the prevention, treatment or containment of COVID-19. These include, but are not

[47] Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19 (2 October 2020) IP/C/W/669 Section 3

[48] Médecins Sans Frontières, 'India and South Africa proposal for WTO waiver from IP protections for COVID-19-related medical technologies' <https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies> accessed 16 July 2021

limited to, diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture."[49]

The waiver has especially gained publicity due to the patents existing in the vaccine manufacturing but it is also important to acknowledge all the other important parts of the waiver that relate to other Intellectual Property Rights including copyright and trademarks. However, this thesis will mainly focus on the issues surrounding the patents. The new waiver states that these unordinary proposals would be in force for three years minimum after the decision is made by the WTO General Council.[50] This means that the waiver is not by any means permanent and will only exist in exceptional circumstances that would justify these measures. To reach a decision, whether to adopt the waiver or not, it can be made based on the mutual decision of all the WTO members. However if there is not a common result, the decision can be reached by voting as well. A seventy-five percent majority is needed to make the waiver through voting if the situation comes to that.[51]

3.2. Where Everyone Stands with the Waiver

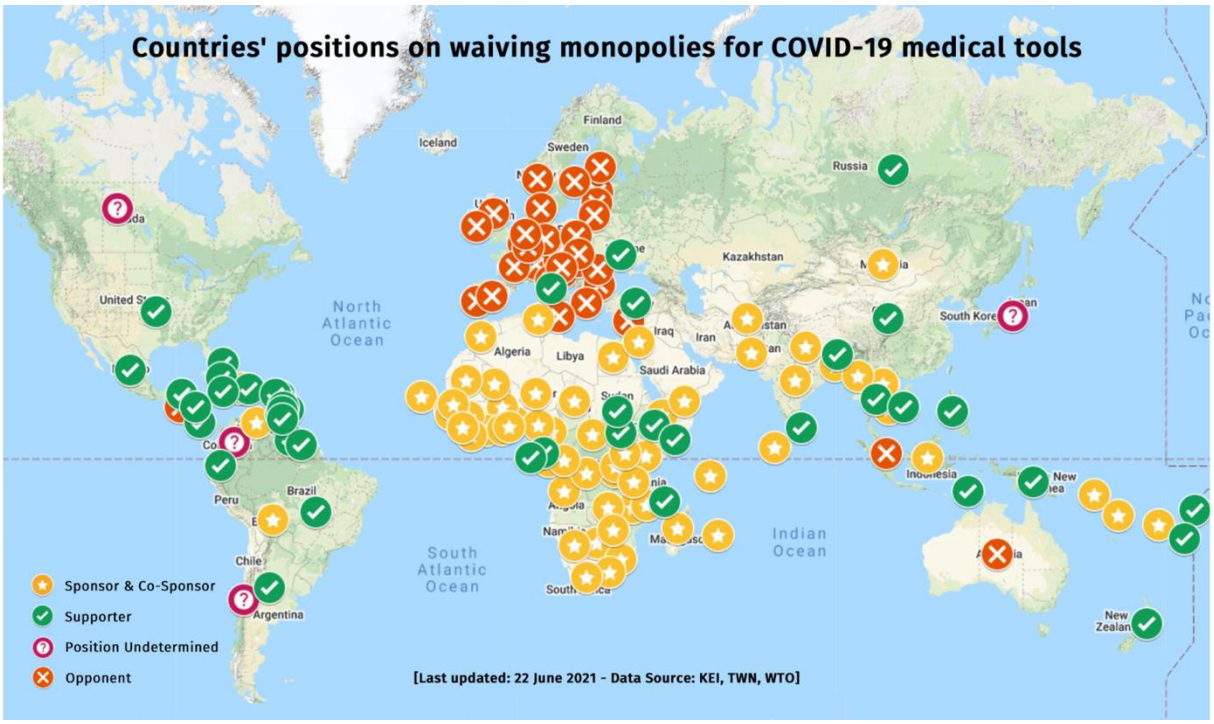
The waiver has divided countries, organizations, companies and even individuals in half. The other half supports the waiver and believes its abilities to ease the current situation and then with those changes provide help and the vaccinations quicker to the places in need of them. The other side that is strongly against the patent waiver believes it being only a setup with a lot of fancy suggestions and solutions against the pandemic but the actuality of this waiver do not have the means to execute the promises stated to the level planned. And they also believe other paths might have the same result and no intellectual protection needs to be lifted and leave inventions without the protection they could enjoy.

[49] Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19 (25 May 2021) IP/C/W/669/Rev.1 Annex
[50] Ibidem.
[51] Médecins Sans Frontières, 'India and South Africa proposal for WTO waiver from IP protections for COVID-19-related medical technologies' <https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies> accessed 16 July 2021

One of the main arguments against the waiver is that there is no proof that patents are slowing down the supply capacity. Moreover than the patents, the raw materials and small manufacturing capacities and the difficulties trying to grow them issue the problems. In addition, there is fear that if the patent system is weakened, the support of the private investors diminishes and that it would become harder in the future to find investors to support public health projects.

3.2.1 The Involvement of the Countries

The current situation in regards to the waiver is that over sixty countries have promised to co-sponsor the waiver and in addition, over hundred countries have showed their support for it.[52] The supporting countries are mostly developing countries.



53

[52] Médecin Sans Frontières, 'Countries obstructing COVID-19 patent waiver must allow negotiations to start' <https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations> accessed 17 July 2021
[53] Ibidem.

The picture is providing some illustration about the situation at hand. It can be seen that the European Union is the main opposing party against the waiver together with the United Kingdom, Switzerland and Australia. After the United States announced their support to the waiver at the beginning of May, Japan, Australia, Switzerland and the United Kingdom are expected to announce their standings soon as they have been uncooperative in the previous discussions.[54] However, Canada has stated that they will actively take part in the negotiations even though they have not clearly stated their standings. In consequence, it can be seen from the picture that the countries that are sponsors or co-sponsors of the waiver, are the countries that would benefit from the waiver the most as it would ease their situation with the pandemic.

However, the waiver is not only supported by countries, but also by hundreds of organizations and individuals have shown their support across the world. Some important and known organizations that are all for the waiver include Amnesty International, the World Health Organization (WHO) and many public heath associations.

3.2.2. The Situation with the United States

The waiver was originally opposed by the United States among the other wealthy nations. But after a while, the United States chose to give the emergency waiver its support. In the season of Donald Trumps' time, the negotiations with the WTO were completely at halt but now that Joe Biden is in charge things have started to change.[55] The United States have promised to take part in the waiver negotiations and they aim to help all the possible partners to expand vaccine manufacturing and delivery. Also, now that they have secured vaccination supply for their own people they will also donate vaccine doses and try to increase the production of raw materials needed for vaccine production.[56]

[54] David Ljunggren, Steve Scherer, Canada ready to discuss COVID-19 vaccine IP waiver, 'not interfering or blocking' – Trudeau' < https://www.reuters.com/world/americas/canada-willing-discuss-covid-19-vaccine-ip-waiver-statement-2021-05-07/> accessed 17 July 2021

[55] Médecin Sans Frontières, 'Letters to US President and Trade Representative to swiftly implement IP waiver of all COVID-19 medical tools' < https://msfaccess.org/letters-us-president-and-trade-representative-swiftly-implement-ip-waiver-all-covid-19-medical> accessed 17 July 2021

[56] Office of the United States Trade Representative, 'Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver' <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> accessed 17 July 2021

After the United States declared their participation to the waiver, other main countries have also followed their example and accepted the waiver. Some organizations send an official letter to the White House to the president, where it was stated how important and honorable it was that the United States decided to change their point of view. In the letter, the parties urge the United States to do everything in their power to get the European Union on board with the waiver and that they would start to consider their minds changed.[57] However, the US does not support the waiver fully, it only gave its support in regards to the patent issue and not to all of the intellectual property rights.[58]

3.2.3. The Opposing Position of the European Union

On 10 June, 2021 the European Parliament released a press statement that they reached a resolution in the matter of the a temporary waiver of the WTO TRIPS Agreement on patents to improve global access to affordable COVID-19-related medical products and to address global production constraints and supply shortages.[59] The waiver was adopted by 355 votes in favor, 263 against and 71 absent.[60] Those in favor think the waiver is an important element when planning to distribute the vaccine doses to the low and middle income countries. The MEPs, who argued against, believe the waiver would not speed the vaccine deliveries and in addition it could have harmful consequences to the innovation of the COVID-19 products.

The EU criticized the United States and the United Kingdom that have a lot of excess doses at hand that they have not donated forward as the EU, according to the press release, have exported nearly half of its vaccine products to the countries desperately in need.[61] This action is completely different compared to the US, where they took care of their own population first and only after that, started to distribute the excess doses.

[57] Médecin Sans Frontières, 'Letters to US President and Trade Representative to swiftly implement IP waiver of all COVID-19 medical tools' < https://msfaccess.org/letters-us-president-and-trade-representative-swiftly-implement-ip-waiver-all-covid-19-medical> accessed 17 July 2021
[58] Ibidem.
[59] European Parliament, 'Parliament calls for temporary COVID-19 vaccine patent waiver' <https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver> accessed 17 July 2021
[60] Ibidem.
[61] Ibidem.

Now that the Parliament has favorable result from the voting, it will put pressure to the Commission that is in charge of the strategy, to which now they will have pressure to make changes and updates.[62] Some professionals think that the vote acts like a strong signal to the Commission and that it was a huge win for the possibility to ensure that the vaccines are easily accessible globally one day.[63] Therefore, it can be seen that that the steady opposing status of the EU might be slowly weakening as people's heads have turned. However, no final decision concerning the waiver have been made, it is interesting to see does the whole world come together for this proposed waiver in order to guarantee equal circumstances in every country in the near future.

3.2.4. The Opinion of the Companies in the Pharmaceutical Industry

During the pandemic, various companies and scientists have made big achievements as they have been able to create and deliver vaccines against the virus. Their goal has been to be able to produce as much of the doses of the vaccine as possible in order to save lives and protect the global economy at the same time. But now their works are under attack as many organizations and countries are ready to lift the intellectual property protections that have enabled companies to make the vaccine at the fast speeds until this moment in time. Therefore, some that are opposing the waiver state that patents are partly the reason why we have vaccinations existing today and the world is slowly overcoming the crisis.[64] There is no denying that nearly everyone, who believes in the modern health care, believes that vaccinations are the best and most effective way to end the pandemic and that international collaboration is in the key role as more developed countries have the means to invest and provide help.[65]

[62] European Parliament, 'Parliament calls for temporary COVID-19 vaccine patent waiver' <https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver> accessed 17 July 2021
[63] Ibidem.
[64] The Economist, 'Michelle McMurry-Heath on maintaining intellectual property amid covid-19' <https://www.economist.com/by-invitation/2021/04/20/michelle-mcmurry-heath-on-maintaining-intellectual-property-amid-covid-19> accessed 18 July 2021
[65] Ibidem.

However, the pharmaceutical companies believe that the waiver and its proposal to nullify the patents is a rushed decision to a very difficult issue. That is because the underlying reason for the vaccines being developed so soon by the big vaccine companies are the technologies behind the vaccines they have been inventing for years. For example the mRNA technology in part of the vaccines that have been a trial and error for years in covers of the patent protection.[66] And now, when the research was successful they are able to commercialize the technology for a limited time before it is for all to use. The companies also want to bring the real situation behind them to everyone's knowledge. Nearly nine out of ten potential vaccine and medical experiments do not make it out of the clinical trials.[67] Therefore, the few main successful firms and investors do not support the waiver because it would give their years of effort for everyone to use even after this pandemic ends, meaning the precise technology behind the patented vaccinations.

As the intellectual properties are the driving force for the companies, they support other means in regards to the distribution than the waiver. For example making signed deals and agreements with manufacturers in other countries. However, when making these decisions, they are only licensing their product to be manufactured somewhere or distributed to a low income country, not diminishing the patent that the invention already has.[68] These licensing deals might not be the most profitable but they guarantee that the vaccination doses are properly transferred as the complex technology of them requires special conditions.

[66] The Economist, 'Michelle McMurry-Heath on maintaining intellectual property amid covid-19' <https://www.economist.com/by-invitation/2021/04/20/michelle-mcmurry-heath-on-maintaining-intellectual-property-amid-covid-19> accessed 18 July 2021
[67] Ibidem.
[68] Ibidem.

IV. DISCUSSION ABOUT THE FUTURE AND THE OTHER MEANS OF HELP

The last chapter of this thesis continues to analyze the waiver and offers speculations from more positive as well as negative points of view. It tries to look a little into the future and offer reasoning that might have something to do regarding the decision whether the waiver gets accepted or not and what are the most important factors for protecting the patents and the various aspects they bring into the discussion concerning the pandemic. This chapter also presents some options to the waiver that could also provide positive acts and help to the pandemic situation by providing help with the manufacture and distribution of the vaccines. The intellectual property licensing is a known way to involve third parties into the production or delivery process of the invention without lifting the protection that is established through patent. After that the chapter presents two very important collaborations that have a strong link between them. This global cooperation aims to increase the needed knowledge, vaccines, treatments and economic level and through those fight towards a more equal and equitable situation across the world.

4.1. The Speculation Surrounding the Lifting of IP Rights in the COVID-19 Vaccines

When it comes to the waiver, as so many countries, organizations and people have shown their support towards it, it is likely that the WTO will approve some sort of version of the waiver based on the discussions made about the topic. However, the scope of the likely accepted waiver remains unknown for as long as there is no decision.

Also one might argue that the scope of the waiver is weakened by the fact that there is no possibilities that all important patent applications have been published during these months of COVID-19. The time for patent applications to be published takes about eighteen months.[69] As the virus itself just lasted a year and a half, it is unlikely that all the publications made would even be open for everyone to see. Therefore, also it is not

[69] WIPO, 'WIPO Guide to Using Patent Information' <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_l434_3.pdf> accessed 18 July 2021

guaranteed if the information about the patented vaccines would be relevant enough and that would also weaken the waiver's power. If the published applications do not give enough information and the pharmaceutical companies oppose the waiver until the end, there is no way the needed information is able to be collected. In addition, it is important to find out which patents are causing the blockages and if those include enough knowledge to be distributed to third parties, such as manufacturers so that they would be able to start making the vaccines. But these issues do not have a clear answer until the correct and relevant applications are made public and they have been handled by the WTO decision makers. However, it is unlikely that the companies would start suing other companies for the patent infringements during this pandemic and so far there has been no such cases.

There should also be more research done for the capacities of the current manufacturers and how much vaccines they are able to produce when working at full speed. It is also important that countries would not make orders that are overly excessive compared to their population. Unless of course if they would then be willing to distribute them through some collaboration to the countries in need. As seen earlier from the maps, some countries have made orders that crosses their population excessively. There should also be research to be done for the future regarding the right amount of capacity to be able to manufacture and produce billions of vaccine doses if there ever is next pandemic. For the COVID-19 this would already be inefficient as the building of the capacity takes time.

The main question surrounding this patent topic relating to the pandemic is whether the waiver is necessary for this time. There is already article 31 in the TRIPS Agreement that includes provisions when "the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government"[70] This flexibility of the TRIPS agreement might have success if someone would use it but at the same time, it cannot be predicted whether there would be a case filed after that kind of move. To that kind of situation, the waiver would bring safety and additional backing for the use of the patented information.

[70] Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 31

What can be noticed, when looking more closely on the COVID-19 vaccines and other vaccine manufacturing also in this matter, is that usually the research and development is funded by the governmental or public investments in the beginning and when there is more hope for that vaccine to break through and succeed, the big market forces jump along and collect the rights to the product. The developing of the vaccines is relatively expensive and with the public support reasonably priced vaccines can be offered. This way more revenues are flowing in but at the same time it might cause unnecessary slowing when it comes to the distribution and manufacturing of the vaccines. This could be one situation, where change could be made more toward the nationally funded projects in the countries that are able to do so. Because now the private sector is able to produce vaccines more efficiently for a better quality than the public side.

This pandemic has brought up many points that have now put on the table to be solved. After this pandemic and the issues and problems arising from it, the world has a lot more important data they are able to use if ever something similar would happen. There could be more research and predictions done on the possible next pandemic and make sure that the existing capacity and agreements will then support the future situation better. Of course we all hope that day never comes and that this current pandemic will also fade away quickly. If one thing is sure after this, it is that we all are more alert and ready for strict measures and even faster emergency response.

4.2. The Benefits of an Effective Patent System in the Pandemic

The opposite view to the discussion on the previous chapter argues that the intellectual property rights do not hinder the distribution of the COVID-19 vaccines. Patents have allowed a fast development of quality vaccines that are safe and most importantly effective against the virus. The control of the IP rights that the companies have, allow them to be critical and work only with the most reliable suppliers and partners. If those were to be lifted and everyone could distribute and manufacture the vaccines, there would not be any certainty on the safety and correct protocols regarding the quality procedures.[71]

[71] Britain Eakin, 'J&J's Chief Patent Atty Says COVID IP Waiver Won't Work' <https://www.law360.com/articles/1375715/j-j-s-chief-patent-atty-says-covid-ip-waiver-won-t-work?nl_pk=f5ddc5d0-4e30-4002-b379-61134416adc9&utm_source=newsletter&utm_medium=email&utm_campaign=special> accessed 28 July 2021

Even though against the waiver, those people still see it as a huge problem that circa four hundred million people from the priority groups have not yet been vaccinated in the low and middle income countries.[72] It is understandable that countries who invented the vaccines and have funds to purchase them, do take care of their own population first but now that many countries have vaccinated most of their people, they would be able to help others. Instead of accepting the waiver, patents might act quite efficiently to help licensing and distributing the donated vaccines. Also the process could be made more equally fair if some organizations could participate in the costs and that way ease the burden from the developing countries.

Most of the pharmaceutical companies state that the patent protection provides protection towards the innovation and investment aspects of the invention. They are more motivated to put the know-how and the money in if they have the security from the fact that they are able to develop and maintain it instead of it going straight to be produced by someone unknown.[73]

The production times and the timelines for approvals of new inventions are discovered to cause more issues than the IP rights themselves.[74] There would still be too little raw materials and some possible ignorance within the manufacturers in the developing countries that would have to authorize the vaccines they manufactured in a rather lengthy qualification process. The Patent system is based on agreements and it is known for its predictability and publicly shared contractual base.[75] Politics should not weigh down the strong status of patent protection. There are multiple other ways to tackle the issues during this pandemic as stated.

[72] Britain Eakin, 'J&J's Chief Patent Atty Says COVID IP Waiver Won't Work' <https://www.law360.com/articles/1375715/j-j-s-chief-patent-atty-says-covid-ip-waiver-won-t-work?nl_pk=f5ddc5d0-4e30-4002-b379-61134416adc9&utm_source=newsletter&utm_medium=email&utm_campaign=special> accessed 28 July 2021
[73] Michael Safi, 'Covid vaccines: what is patent waiving and will it solve the global shortage?' *The Guardian* < https://www.theguardian.com/world/2021/may/06/covid-vaccines-what-is-patent-waiving-and-will-it-solve-the-global-shortage> accessed 28 July 2021
[74] Kolster, 'Removing the patent protection of COVID-19 vaccines will not solve the vaccine shortage' <https://www.kolster.fi/en/blog/removing-the-patent-protection-of-covid-19-vaccines-will-not-solve-the-vaccine-shortage> accessed 28 July 2021
[75] Ibidem.

4.3. COVAX – The Vaccine Pillar

COVAX' aim is to guarantee fair and equal access for every country and speed up the development and manufacture of the COVID-19 vaccines. COVAX is led together with the Coalition for Epidemic Preparedness Innovations (CEPI), the World Health Organization (WHO), and Gavi – the vaccine alliance.[76] UNICEF also acts as an important delivery partner alongside the others. It is the largest vaccine procurement and supply operation in history.[77]

COVAX has a few goals it works towards and wants to achieve. The main one is to provide vaccine doses for at least twenty percent of every countries' populations.[78] The vaccines are distributed mainly to the 92 lowest income countries. Another goal is to provide two billion doses of the vaccine by the end of 2021.[79] That way they are making it more possible to end the acute phase of the pandemic. They are ready to deliver new vaccines constantly, as soon as the doses are being manufactured and available. In addition, they take part also to help countries to rebuild their economies and make sure the pandemic would have the least amount of impact to the economies.[80]

When providing the vaccines, COVAX will follow the same hierarchy as it has been seen in many other countries. The first focus groups are the health and social care workers and straight after that the people at a higher risk groups and people that are over 65 years old. That will approximately cover the twenty percent of the people in one country and after every country in need has reached the goal of twenty percent of the population is vaccinated, can the distribution continue to cover more people.[81]

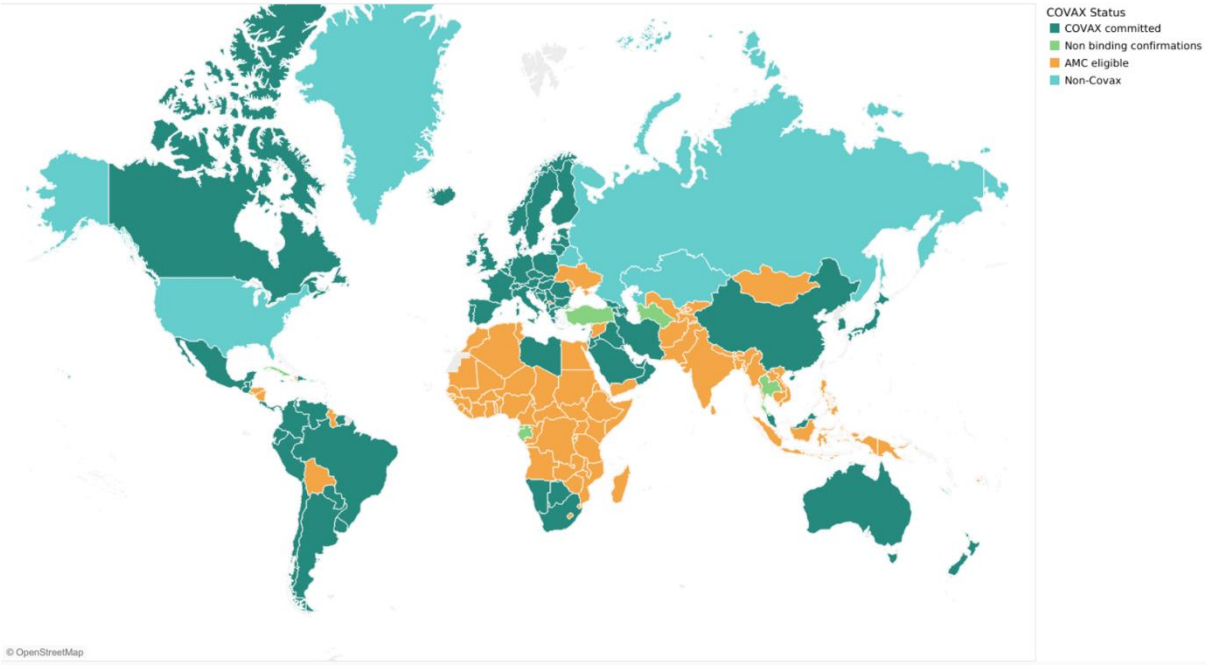
[76] WHO, 'COVAX - Working for global equitable access to COVID-19 vaccines' <https://www.who.int/initiatives/act-accelerator/covax> accessed 19 July 2021
[77] UNICEF, 'COVAX information centre' <https://www.unicef.org/coronavirus/covax> accessed 19 July 2021
[78] Gavi, 'COVAX' < https://www.gavi.org/covax-facility> accessed 19 July 2021
[79] UNICEF, 'COVAX information centre' <https://www.unicef.org/coronavirus/covax> accessed 19 July 2021
[80] Gavi, 'COVAX' < https://www.gavi.org/covax-facility> accessed 19 July 2021
[81] BBC News, 'Covax: How many Covid vaccines have the US and the other G7 countries pledged?' <https://www.bbc.com/news/world-55795297> accessed 19 July 2021

The topic of the donation of the vaccines has been presented and talked about among the G7 group of countries that include Canada, France, Germany, Italy, Japan, the United Kingdom and the United States. The countries were very cooperative and the countries plus many others have decided to help and donate both the overflowing vaccine doses from their supplies and also money.[82] Also the EU together has promised to help with 500 million euros and additional loans while the European countries have together promised aid for worth more than 1 billion euros.[83] It is important to receive help from the G7 countries as they have together taken more than a third of all the vaccine doses in the world, while only having thirteen percent of the population in the world.[84] Together, they would have a lot of power in this situation and could really make a difference.

The COVAX program has received some criticism for being slow as some initial goals were not met in time according to the original plan. Some targets got delayed because of the poor conditions of the countries and their undeveloped health infrastructure.[85] COVAX has also witnessed some hesitance towards the vaccines and that has also been partly an issue concerning the delays. In addition, six vaccines against the COVID-19 have been authorized for emergency use and distribution via COVAX but only two of them have been successfully delivered so far.[86]

And even though COVAX will eventually be able to reach its goal to vaccinate twenty percent of people in each country, it is still far from gaining an immunity against the virus. Some researchers state that over seventy percent of the population must receive the vaccine doses in order to gain the immunity.

[82] BBC News, 'Covax: How many Covid vaccines have the US and the other G7 countries pledged?' <https://www.bbc.com/news/world-55795297> accessed 19 July 2021
[83] Ibidem.
[84] Ibidem.
[85] Ibidem.
[86] Ibidem.



Source: Duke GHIC, Launch & Scale Speedometer

[87]

This map here shows the effects of COVAX. The dark turquoise shows the countries, which have offered to help distributing the excess vaccine doses. After this map was constructed, the United States has also joined in and now provides help through COVAX. The orange color reflects the countries, that are offered the help by COVAX and have the biggest need for vaccines at this moment.

4.3.1. The Access to COVID-19 Tools Accelerator

The Access to COVID-19 Tools (ACT) Accelerator is a worldwide collaboration that concentrates to speed up the development, production and fair access to COVID-19 tests, treatments and vaccines.[88] The ACT-Accelerator was established in April 2020 and it is supported by governments, companies, scientists, civil societies and various global health organizations.[89] COVAX, mentioned in the previous chapter is actually a so-called vaccines pillar of the ACT-Accelerator and it solely focuses on the issues regarding the

[87] Launch & Scale Speedometer, 'Weekly COVID Vaccine Research Update' <https://launchandscale-faster.org/blog/us-formally-joined-covax-will-it-matter> accessed 19 July 2021
[88] WHO, 'What is the ACT-Accelerator' <https://www.who.int/initiatives/act-accelerator/about> accessed 19 July 2021
[89] Ibidem.

vaccines. Together, these are a large group aiming to put an end to the pandemic and trying to rehabilitate the social and economic levels.

The ACT-Accelerator is associated with four main topics that are diagnostics, therapeutics, vaccines, health system strengthening.[90] Each of the main topics needs concentration, work and cooperation among the involved parties. Diagnostics focus on bringing rapid tests into the market, educating thousands of healthcare professionals and arranging 500 million COVID-19 tests to low and middle income countries.[91] Therapeutics is involved in all stages of the virus. It aims to prevent infections, diminishing the spreading, treating the infected and the recovered.[92]

The aim is to manufacture and deliver 245 million treatments to countries in need.[93] Maybe the most important one, the vaccines pillar is already stated in detail in the previous chapter. And the topic of health systems is working towards quality health care systems making sure that there are enough tools and products to help the patients.[94]

4.4. Overlook to the Measures of the U.S. Food and Drug Administration

The U.S. Food and Drug Administration (FDA) fight an important fight against the COVID-19 in the United States. The main aspects the FDA is focused are the availability of the coronavirus tests, therapeutics, vaccine project and other COVID-19 related issues.[95] It is important to ensure reliable, fast and available COVID-19 tests that provide accurate results. In addition to the issues relating to the pandemic, the FDA also monitors domestic and imported foods and inspects exported products coming to the U.S.[96]

[90] WHO, 'What is the ACT-Accelerator' <https://www.who.int/initiatives/act-accelerator/about> accessed 19 July 2021
[91] Ibidem.
[92] Ibidem.
[93] Ibidem.
[94] Ibidem.
[95] FDA, 'FDA COVID-19 Response' <https://www.fda.gov/media/137005/download> accessed 28 July 2021
[96] Ibidem.

The vaccines undergo a very thorough review where they are examined for their quality, safety and effectiveness.[97] The FDA is in charge of this process and regulates the approval of the vaccines. For some of the COVID-19 vaccines it has issued and Emergency Use Authorization (EUA) which can be achieved if the benefits surpass the risks.[98] The FDA also grants so called priority review vouchers that are created by the U.S. Congress and these vouchers entitle their owners to have a review of the treatment after six months instead of the standard ten months.[99] This voucher program motivates more treatments towards more rare diseases and of course in this situation, towards COVID-19 as well. It also speeds up the approval of the pharmaceuticals and allow a faster access for the American population.[100] However, not all companies are able to receive the voucher and therefore it creates a competitive situation among the applicants and the winner party has a chance to sell the voucher forward and that way may activate the whole system.[101] This way of doing does not harm the intellectual property rights of the inventions and offers a different, competitive scene to create pharmaceuticals.

[97] FDA, 'COVID-19 Frequently Asked Questions' < https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions> accessed 28 July 2021
[98] Ibidem.
[99] David Ridley, 'Priority Review Vouchers' <https://sites.fuqua.duke.edu/priorityreviewvoucher/> accessed 28 July 2021
[100] Ibidem.
[101] Ibidem.

CONCLUSION

The research is coming towards the end and it is time to collect some key points together and analyze whether the core information of this thesis has brought answers to the questions that were mentioned in the introduction.

Patent protection is an essential right to new inventions and it gives the patent holder the right to prevent others from using, manufacturing or spreading the invention as set out in granted claims of a patent. Because the patent holders are in charge for all of those aspects, all of the profits come straight to them and to the investing parties, who took a business risk by investing in advance. Therefore intellectual property rights have an important meaning nowadays as the world involves at a fast speed and misuses and infringements happen more commonly.

Sometimes patent applications are filed for the competitive advantage. Because the patentable invention has to be novel and it has to include some completely new aspect of innovation, some companies use subsidiary patents or clashing patents as means to prevent other competitors' rights to their patent as the new broad patent applied would in different possible ways make it more difficult for the competitors now to process and advertise their invention as the holder of the broad patent has a powerful status impacting to the market field and its pricing for example.

The issues around patents have now made their way into the pharmaceutical world as the world is globally suffering from the COVID-19 virus. The vaccines against it are ensured with patent protection and therefore, a lot of pharmaceutical manufacturers do not have the knowledge to process the vaccines that the world currently desperately needs. But as said, the companies that are covered with patents want to gain all of the profits from their invention and also in the pharmaceutical world it is not that simple to give rights to the vaccine contents. The much needed additional capacity is being built for the wider production and that is a step towards the right direction as it would not be ethical to take away pharmaceutical companies' knowledge and make them share it without any concerns about the protection of it.

As said previously the patents offer some positive effects, security and profits to the patent holder. However, during this pandemic, there are also some negative side effects that are believed to be caused by the strong patent protection. As the manufacturers all over the world cannot make the vaccine doses, the distribution of the vaccines has been extremely slow to the developing countries especially and that is bad situation to be in, when everyone wants to have an end to this pandemic. The low income countries are relying to the help of the wealthier countries from which many have announced that they would be donating vaccines and loaning money to purchase the vaccines and other supplies against COVID-19.

A patent waiver was proposed during last year, that brought together most of the countries in the world including also various and organizations and their goal is to get the waiver approved by the WTO, which would mean that the intellectual property rights, including patents to the vaccines, could be lifted of for the duration of the pandemic. This caused a big discussion on the internet and the opposing side is slowly diminishing as the European Parliament voted for the waiver and now the situation is handled by the Commission. The question whether the patents and the protection they receive in the middle of the global pandemic is suitable is clearly arguable but most of the involved countries agree that the patents do slow down the vaccination process and that they do not have the strong support line behind them when the issues are concerning COVID-19. However the European Union and the field of vaccine experts disagree strongly against this view.

A subsidiary issue in this thesis has been the equality of the countries and the equitable access to vaccines and products needed during the pandemic. As the maps showed the collected data, the countries who have the least amount of people vaccinated, not only support the waiver and are one of the main characters in it, but also are one of the main targets of the COVAX program which intends to distribute billions of vaccines to the poorer countries with the help of international organizations. The vaccines should not be a privilege to the people living in the wealthier countries but on the contrary, it should be a necessity to all populations across the world since everybody is fighting the exactly the same battle no different where one might live. Thankfully, the issue has been noted and it has become one of the key focus points among the decision making authorities. Even though the work has already been started, there must be a detailed plan that needs to be followed in order to reach the goals everywhere and diminish the pandemic for good.

Unfortunately, since the COVID-19 is a fairly new issue in the world, not all the problems could be solved or even analyzed with this thesis. In addition, the waiver awaits its final verdict and before that, it is impossible to say any outcome for sure. The battle against the virus remains still ongoing and therefore, the situations are uncertain and new issues might arise in the future as well. All in all, the most important thing is to make decisions for the common good and for the health of the people.

BIBLIOGRAPHY

Referenced Academic Materials

D'Souza G, Dowdy D, 'What Is Herd Immunity and How Can We Achieve It With COVID-19?' Johns Hopkins Bloomberg School of Public Health (6 April 2021) <https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html> accessed 14 July 2021

Dominique Guellec, Catalina Martinez, Pluvia Zuniga, 'Blocking patents: What they are and what they do?' (2008) <https://ftp.zew.de/pub/zew-docs/veranstaltungen/innovation-patenting2008/papers/GuellecMartinezZuniga.pdf> accessed 1 July 2021

European Parliament, 'Parliament calls for temporary COVID-19 vaccine patent waiver' <https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver> accessed 17 July 2021

FDA, 'COVID-19 Frequently Asked Questions' < https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions> accessed 28 July 2021

FDA, 'FDA COVID-19 Response' <https://www.fda.gov/media/137005/download> accessed 28 July 2021

Friede M, 'Intellectual Property and License Management with respect to Vaccines' <https://www.who.int/phi/news/Presentation15.pdf?ua=1> accessed 17 July 2021

Gavi, 'COVAX' <https://www.gavi.org/covax-facility> accessed 19 July 2021

Heinemann A, 'Blocking Patents and the Process of Innovation'<https://www.ius.uzh.ch/dam/jcr:66f8a3a6-8876-4cd4-bf68-e09022a75930/Heinemann_Blocking_Patents.pdf > accessed 1 July 2021

Josh Holder, ‘Tracking Coronavirus Vaccinations Around the World’ *New York Times* <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> accessed 14 July 2021

Padma T, ‘COVID vaccines to reach the poorest countries in 2023 – despite recent pledges’ (2021) 595 Nature < https://www.nature.com/articles/d41586-021-01762-w> accessed 16 July 2021

UNICEF, ‘COVAX information centre’ <https://www.unicef.org/coronavirus/covax> accessed 19 July 2021

WHO Regional Office for Europe, ‘Coronavirus disease (COVID-19) Pandemic’ <https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/novel-coronavirus-2019-ncov> accessed 5 July 2021

WHO, ‘COVAX - Working for global equitable access to COVID-19 vaccines‘ <https://www.who.int/initiatives/act-accelerator/covax> accessed 19 July 2021

WIPO, ‘WIPO Guide to Using Patent Information’ <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_l434_3.pdf> accessed 18 July 2021

World Health Organization, ‘Coronavirus disease (COVID-19): Vaccines’ <https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines> accessed 14 July 2021

Referenced Non-Academic Materials

BBC News, ‘Covax: How many Covid vaccines have the US and the other G7 countries pledged?‘ <https://www.bbc.com/news/world-55795297> accessed 19 July 2021

Eakin B, ‘J&J's Chief Patent Atty Says COVID IP Waiver Won't Work‘ <https://www.law360.com/articles/1375715/j-j-s-chief-patent-atty-says-covid-ip-waiver-won-t-work?nl_pk=f5ddc5d0-4e30-4002-b379-

61134416adc9&utm_source=newsletter&utm_medium=email&utm_campaign=special> accessed 28 July 2021

European Patent Office, 'European Patent Office - A hub for innovation and - enhancing Europe's competitiveness' <https://www.epo.org/news-events/press/background/epo.html> accessed 20 June 2021

Finnish Patent and Registration Office PRH, 'European Patent and European Patent Convention (EPC)' <https://www.prh.fi/en/patentit/applyforapatentoutsidefinland/europeanpatent.html> accessed 20 June 2021

Finnish Patent and Registration Office PRH, 'Patents' <https://www.prh.fi/en/patentit.html> accessed 15 June 2021

Kolster, 'Removing the patent protection of COVID-19 vaccines will not solve the vaccine shortage' <https://www.kolster.fi/en/blog/removing-the-patent-protection-of-covid-19-vaccines-will-not-solve-the-vaccine-shortage> accessed 28 July 2021

Launch & Scale Speedometer, 'Weekly COVID Vaccine Research Update' <https://launchandscalefaster.org/blog/us-formally-joined-covax-will-it-matter> accessed 19 July 2021

Ljunggren D, Scherer S, Canada ready to discuss COVID-19 vaccine IP waiver, 'not interfering or blocking' – Trudeau' <https://www.reuters.com/world/americas/canada-willing-discuss-covid-19-vaccine-ip-waiver-statement-2021-05-07/> accessed 17 July 2021

MacMillan C, 'Herd Immunity: Will We Ever Get There?' <https://www.yalemedicine.org/news/herd-immunity> accessed 9 August 2021

Médecin Sans Frontières, 'Letters to US President and Trade Representative to swiftly implement IP waiver of all COVID-19 medical tools' <https://msfaccess.org/letters-us-president-and-trade-representative-swiftly-implement-ip-waiver-all-covid-19-medical> accessed 17 July 2021

Medecins Sans Frontieres, ‘India and South Africa proposal for WTO waiver from IP protections for COVID-19-related medical technologies‘ <https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies> accessed 16 July 2021

Office of the United States Trade Representative, ‘Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver‘ <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> accessed 17 July 2021

Our World in Data, ‘Coronavirus (COVID-19) Vaccinations’ <https://our-worldindata.org/covid-vaccinations> accessed 1 August 2021

Our World in Data, ‘Coronavirus Pandemic (COVID-19) – The Data’ < https://our-worldindata.org/coronavirus-data > accessed 1 August 2021

David Ridley, ‘Priority Review Vouchers’ <https://sites.fuqua.duke.edu/priori-tyreviewvoucher/> accessed 28 July 2021

Safi M, ‘Covid vaccines: what is patent waiving and will it solve the global shortage?‘ The Guard-ian < https://www.theguardian.com/world/2021/may/06/covid-vaccines-what-is-patent-waiving-and-will-it-solve-the-global-shortage> accessed 28 July 2021

The Economist, ‘Michelle McMurry-Heath on maintaining intellectual property amid covid-19‘ <https://www.economist.com/by-invitation/2021/04/20/michelle-mcmurry-heath-on-maintaining-intellectual-property-amid-covid-19> accessed 18 July 2021

WIPO, ‘What is intellectual property?’ < https://www.wipo.int/edocs/pub-docs/en/wipo_pub_450_2020.pdf > accessed 15 June 2021

Referenced Normative Materials

Agreement on Trade-Related Aspects of Intellectual Property Rights

European Patent Convention (17th edition)

Universal Declaration on Human Rights (adopted 10 December 1948) 217 A(III) (the United Nations General Assembly)

Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19 (2 October 2020) IP/C/W/669

Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19 (25 May 2021) IP/C/W/669/Rev.1

ABSTRACT IN ENGLISH

As the world is constantly evolving, the competition for market space and making profit out of it become harder and harder. Nowadays new technologies and innovations are invented constantly and luckily there are rights to protect their development and value. Intellectual property rights allow the inventors and creators to enjoy from their achievements reasonably and making sure the rewards are going to the right persons instead of misuse and unlawful actions of others.

Usually, when markets get tougher, also the means to reach the top might become questionable. This thesis will concentrate on patent legislation and how patent applications can exercise many other variations, not just the typical protection to the new, novel inventions. Patents are sometimes used to better the applicant's standings compared to their competitors as means to block the competitors invention from being produced or marketed even though it might already be patented. These actions are made if the company applying the blocking patent knows they cannot make their invention without infringing the already existing patent and therefore they find means to block that one out of the way.

During the past couple of years, the whole world has been fighting over the COVID-19 pandemic. It has caused exceptional loss and health issues in waves all over the world. People have lost their lives and economies have suffered as the borders have been closed off and lockdowns have been arranged. Now there might be some light at the end of the tunnel, as the vaccines have made it to the most countries and immunity is slowly and steadily forming. However, there is a huge gap to be seen between the developed countries and the low-income countries. The rich states have been able to reserve vaccines to all of their people while the less fortunate ones have to wait and rely that at some point other countries provide them help and start distributing vaccines to them as well.

The waiver to lift the intellectual property protection during the pandemic has been issued and many countries and organizations now stand behind it to enable faster production and distribution of the vaccines and other medical equipment to the countries in need. The European Union and the pharmaceutical companies oppose this waiver strongly as the

patents are on their place for a reason to ensure just profits and revenues to the investors and manufacturers who are the makers of the product. For another option, they suggest licensing the patents to the manufacturers in order to provide help into this situation.

The aim of this thesis is to explain the current situation among the patent protection issues and problems in correlation to the COVID-19 and also analyze the different situations and the reasoning behind them and provide some clarification to all available possibilities and solutions during the pandemic.

ABSTRACT IN GERMAN

Unsere Welt befindet sich in permanenter Entwicklung. Im Zuge dessen wird der Kampf um Märkte und Profitmöglichkeiten immer härter. Es werden ständig neue Technologien und Innovationen entwickelt, deren Schutz glücklicherweise gesetzlich geregelt werden kann. Immaterialgüterrechte gewährleisten, dass Erfinder einen angemessenen Nutzen aus ihren Leistungen ziehen können und die richtigen Personen vergütet werden und verhindern rechtswidriges Verhalten und Missbrauch durch Dritte.

Infolge des verschärften Wettbewerbs wird gewöhnlich auch zunehmend mit fragwürdigen Mitteln gearbeitet, um Erfolg zu haben. Der Fokus dieser Abschlussarbeit liegt auf dem Patentrecht und darauf, wie Patentanträge neben dem Schutz einer neuen Erfindung auch für andere Zwecke verwendet werden können. Patente dienen in manchen Fällen dazu, die Stellung eines Antragstellers gegenüber Wettbewerbern zu stärken um zu verhindern, dass die Erfindung der Konkurrenz produziert oder auf den Markt gebracht wird, selbst wenn diese bereits patentiert ist. Derartige Maßnahmen werden eingesetzt, wenn das Unternehmen, dass ein Sperrpatent beantragt, sich darüber im Klaren ist, dass die eigene Erfindung nicht ohne eine Patentverletzung realisiert werden kann. Aus diesem Grund ist das Unternehmen bestrebt, Mittel zu finden, das bereits existierende Patent zu blockieren.

Die gesamte Welt kämpft gegen die COVID-19-Pandemie, deren Wellen den Verlauf der letzten zwei Jahre geprägt und hohe Verluste und schwere Gesundheitsprobleme verursacht haben. Die Pandemie hat nicht nur unzählige Menschenleben gefordert, sondern in Folge von Grenzschließungen und Lockdowns zu wirtschaftlichen Schäden geführt. Mittlerweile ist am Ende des Tunnels ein Licht zu sehen, da in den meisten Ländern Impfstoffe verfügbar sind und nach und nach eine Immunität aufgebaut wird. Es besteht jedoch eine riesige Kluft zwischen entwickelten und einkommensschwachen Ländern. Reiche Staaten sind in der Lage, für ihre gesamte Bevölkerung Impfstoffe zu besorgen, während ärmere Länder warten müssen und irgendwann auf die Hilfe anderer Länder angewiesen sind, um Impfstoffe bereitstellen zu können.

Es wurde vorgeschlagen, während der Pandemie auf die geistigen Eigentumsrechte für die Vakzine zu verzichten. Zahlreiche Länder und Organisationen unterstützen einen solchen Verzicht, um Produktion und Distribution von Impfstoffen und sonstiger medizinischer Ausrüstung in solchen Ländern zu beschleunigen, die diese benötigen. Die Europäische Union und Pharmaunternehmen lehnen einen solchen Verzicht strikt ab, da die Patente gewährleisten, dass Investoren und Hersteller als Schöpfer der Produkte angemessene Einnahmen und Gewinne erzielen können. Alternativ schlagen diese Seiten vor, Herstellern Patentlizenzen zu gewähren, um Abhilfe in der aktuellen Situation zu schaffen.

Ziel dieser Abschlussarbeit ist, die gegenwärtige Lage zu beleuchten, was das Verhältnis von Patentschutz und COVID-19 angeht, die verschiedenen Situationen und deren Hintergründe zu analysieren und einen Erklärungsansatz bezüglich der in der Pandemie verfügbaren Möglichkeiten und Lösungen zu liefern.