Alternative Protection of Intellectual Property Rights in Vaccine Production and Use under Covid-19

Ling Jin*

Department of Cognitive Science/Political Science, University of California San Diego, San Diego, U.S

*Corresponding author: lij001@ucsd.edu

Abstract. For the past three years, Coronavirus-19 (Covid-19) has become one of the major global health problems. Unlike any previous virus in the past decades, Covid-19 has shown its unprecedented spreading speed, infection rate, fatality rate, etc. Under this urgent disease outbursting event, scientists around the globe, through the myriad of research and experiments, successfully developed effective vaccines. However, like many other medical innovations, Covid-19 vaccines are categorized as intellectual properties and a scarce resource. As a consequence, the citizens of developed and developing countries face an imbalanced distribution of affordable vaccines. The formation of this issue is not only due to manufacturing, transportation, and other infrastructures, but also strongly correlated with aspects in the legal field, such as intellectual property rights (IPRs). With a humane common sense of vaccination many people, through comparative research method, this article aims to discuss the conflicts between the global crisis of Force Majeure and the interests of certain countries or corporations, possible solutions to resolve this conflict, and future coping strategies that ought to be published.

Keywords: Covid-19 Vaccines, Intellectual Property Rights (IPRs), Patent Laws, Force Majeure.

1. Introduction

As soon as multiple brands of Covid-19 vaccines were introduced at the end of 2020, the entire world was overjoyed, whereas issues that could not be ignored also arise. Vaccines, especially vaccines for this global pandemic, are scientific creations that must be treated as intellectual properties (IP) [1]. Therefore, intellectual properties rights (IPRs) ought to protect the IP and future inventions by proving market exclusivity, which is usually through patenting. However, misuses or under certain circumstances, patents could result in unnecessarily high prices for the target buyers [2]. In other words, some IPRs protection might be totally deviated from its original purposes, creating extra inconveniences for people instead. Unfortunately, the distribution of Covid-19 vaccines has been highly uneven between wealthier countries and low-income countries, and only as low as 0.2% of the total 1.3 billion doses had been given to the latter countries by the end of April 2021 [3]. To resolve this unbalanced administration, South Africa and India submitted a petition to the World Trade Organization (WTO) about waiving the IPR of Covid-19 vaccines aimed at making the vaccines more accessible to some countries. Requiring all the 164 members of the WTO to establish a consensus, this petition evolved into a deadlock. Proponents and opponents of this proposal have been debating ever since, over problems that lie much deeper than they appear: Is it appropriate to amend the laws when the laws are no longer the best decisions to go with? Who is truly capable of and responsible for legislating? How do people deal with the possible unforeseeable consequences that might be followed by global pandemics? What are the liabilities of nations when facing Force Majeure and hardships that influence the entire human race in the future? This article is meant to dig into these questions, and to provide some new hindsight revolving around the issue of Covid-19 vaccine IPR protections.

2. Characteristics of the production of Covid-19 Vaccines during the Global Health Crisis Outbreak

Since the outbreak of Covid-19, the world has put on great efforts to fight against this global pandemic. Scientists, governments, health professionals, and every single person have been rushing the minutes to research finding remedies to the disease. Coronaviruses are RNA viruses, which mainly affect the human upper respiratory tract to the lower respiratory tract, and immunocompromised people like elders or patients would be more vulnerable exposed to this virus [4]. Covid-19 is caused by SARS-CoV-2 which shares many common characteristics with SARS-CoV-1 or SARS, another coronavirus found in 2003. Therefore, the initial approach to the development of vaccines was conducted with the previous experiences with SARS. At the end of 2020, Covid-19 vaccines were officially developed. Although these vaccines could not cure and completely protect people from being infected, they were able to effectively slow down the spread of the virus [5]. Soon there immersed many different sources of approved vaccines mostly coming from different countries, such as the United States, China, the United Kingdom, the European Union, etc [6]. Besides, 3 major measures were adopted by different countries during the process of accelerating vaccines research and development (R&D). The first model is the government-oriented model, which mainly depends on political mobilization and public resources. For instance, Gamaleya Institute, a state-owned institute in Russia, was the major contributor to the Sputnik-V vaccine. The second model is the market-oriented model, and the countries that adopted this measure were represented by the US. Before Pfizer and Moderna had been licensed and authorized by the Food and Drug Agency (FDA), they made commitments of millions of doses of vaccines, and this is because there were economic tools such as Advanced Purchased Commitments were used to spur the market competitiveness between private companies. The last measure is the state-driven collaborative model which was mainly adopted by China. This model demonstrates a combination of the previous two models, with both political mobilization and the use of economic instruments, and both public and private sectors [7]. No matter which of the above model was adopted, each country was choosing what was the best suited for their conditions, and through prioritizing vaccine R&D, approved vaccines were successfully made and soon put to the market.

3. Legal Issues Faced in the Process of Vaccine Distribution and Application

3.1. Introduction of Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Despite the fact that more and more eligible vaccines are developed and distributed widely, there are also countries that are incapable of independently conducting Covid-19 vaccine R&D, such as third-world countries in Africa and South America [8]. As a result, these countries heavily rely on importing foreign vaccines to meet the demands. As for now the total supply of vaccines is much shorter than the demands worldwide, and each state would first secure enough doses for the citizens and then consider other countries. Due to multifaceted reasons, a phenomenon called “vaccine nationalism” arose. Some rich states who are able to produce vaccines easily hoard large amounts of vaccines that could be enough to vaccinate 3 to 5 times their entire population [8]. For the purpose of ending the pandemic beneficiary to all humans, at the same time, it is essential to get as many people vaccinated as possible. Under these circumstances, a number of scholars believe that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the greatest obstacles to reaching this goal [9]. TRIPS, a multilateral agreement from World Trade Organization (WTO), is the bridge to balance trade and knowledge and creativity, supporting innovation and public welfare [10]. TRIP is able to authorize the patent protection for any pharmaceutical product for up to 20 years, which further frustrates the developing countries to vaccinate their citizens. With the persistence of patents of the vaccines from the major manufacturers globally, the pressure of some countries’ incapabilities of obtaining enough vaccines will not be released shortly without tremendous effort.

3.2. Petition to World Trade Organization (WTO)

After the seriousness and negative impact of this problem have been recognized by an increasing number of people, some organizations started petitions, campaigns, and appeals for a solution. For example, the People's Vaccine Alliance, argues that "pharmaceutical corporations must allow the Covid-19 vaccines to be produced as wide as possible by sharing their knowledge free from patents" [11]. There are three key points that they propose: the first one is to waive the IP protections on Covid-19 vaccines, the second is to transfer the knowledge from the global north to manufacturers in the global south, and the last one is to provide subsidization of the manufacturing industry in the lower-middle-income countries (LMICs) [11]. Besides the voluntary work of the non-official organizations, in October 2020, India and South Africa submitted a formal petition to WTO about the suspension of patent protection of Covid-19 related drugs and technologies [2]. Although this petition immediately won many supporters, some voices were against it as well, and it still hasn't been approved by WTO. The proponents believe that the monopoly of "Big Pharma" impedes the promotion of affordable and accessible vaccines that are necessary to beat Covid-19 because most vaccines institutions have gained a significant amount of funding from the government which is unfair in the free market. However, the critics debate that the problem is on the manufacturing industry and flawed healthcare system in LMICs instead of the vaccine companies. The intrinsic drawback of the lack of technologies and raw materials in these countries causes the relatively high learning curve of the manufacturing processes. For example, to produce mRNA vaccines, like Pfizer, actually requires a rather groundbreaking technology that even China have had not widely used in their vaccines, and thus some vaccines are hard to replicate in the first place even without patent protection. Furthermore, just because of the highly concentrated intellectual properties and investments in vaccine R&D, a waiver of the patent protection seems much more unrealistic and unreasonable [12]. The debate still goes on today, and from both grounds, logical statements are built and they are right and sense-making from either standpoint. However, a question comes forward: whether the world would be better off, in this case, every person is able to be vaccinated, when some laws were to be adjusted, modified, or amended?

4. Justifications for Waiving the Intellectual Property Rights

4.1. Balancing Corporation Interests to the Global Welfare

The outbreak of Covid-19 is well recognized as a global health pandemic, which is meant to request efforts from all human beings together to fight against the virus. The reasoning that backs up this statement is mostly that Covid-19 fits into the profile of a case of Force Majeure. Force Majeure, originally a legal clause concept, is directly translated into English as "superior force" from "vis major" in Latin.

The Force Majeure doctrine relates to supervening unforeseen events that make performance impossible. It covers cases of subsequent impossibility, i.e. external supervening events occurring after contract formation, that are beyond the control of the aggrieved party such as fires, floods, droughts, earthquakes, civil riots, terrorist attacks, etc., which render the performance of a party's contractual obligations not just excessively onerous as in hardship-type situations, but impossible, whether on a temporary or permanent basis [13].

According to this definition, Covid-19 as a global pandemic is an unpredictable, unsolvable (at least within a small time frame), and fast-spreading disease. Extending the general concept of Force Majeure, the solution to such problems should be considered independently and customized.

IPR protection, as mentioned above, is meant to protect the intellectual investments of the scientists and researchers who contributed to vaccine R&D. Without the restriction of patents, a third party can easily replicate similar products and enter the market, causing the original version uncompetitive, and is unfair to the inventor. However, besides preventing infringement, piracy, and unauthorized use, IPR also serves another important role, providing information to the general public

in an organized and secured way [1]. With all being said, one of the major beneficiaries is meant to be the general public at the first point. Nevertheless, the current situation is that in the pharmaceutical industry, IPR protection is uniquely solid and abused, at the expense of competitiveness and consumer welfare. It is widely recognized that any development of any scientific industry requires large amounts of research and experiments, which deserves to be recognized and protected, whereas the people ought not to be the one paying for it as well [1]. Circle back to the special condition of the Covid-19 vaccine, vaccines on the market have already been proven to be effective on the virus, the current state of corresponding IPR protection is making it difficult for many people to be vaccinated, and this is the point when extra legislation should be considered to improve the situation. Laws on public health and IP laws might be able to decide what could be an exception on IPR protections that can be waived, and Antitrust Law could check some business activities, such as mergers and acquisitions [1].

4.2. Economic Analyzation of the Outcomes of Waiving the IPRs

The Covid-19 Vaccines, despite their highly-concentrated intellectual value, merchandise desperately in need all around the world. Instead of only being honored and treated as an advanced scientific research product, the vaccines should be categorized as leaning more toward a global necessity or infrastructural merchandise. IPRs, unlike many other laws, are rights in abstract objects [14]. However, the value of the product itself can be separated from the intellectual value, and sometimes manufacturers are not benefited from IPRs as much as they intend to. Peter Drahos, in his book, A Philosophy of Intellectual Property, provides an example of a similar situation, of motor vehicle manufacturers and extended protections in the design law that cover spare parts of vehicles. One particular finding is that what motivates the manufacturer to develop new designs is mostly market pressure instead of the design protections. Also, the cost of the design investment makes up a relatively small part of the overall cost of manufacturing a car. Therefore, for some specific cases, at least from the perspective of the manufacturer, the protection of intellectual property is of minor consideration [14].

Currently, the cost of manufacturing Covid-19 vaccines has remained relatively a business secret among most vaccine companies, therefore, the applicable information primarily gathered from a few independent studies and Doctors Without Borders is scarce as well. With the premise that the vaccine manufacturers are unwilling to disclose the cost of manufacturing the vaccines, the pricing of vaccines is also incredibly varied among different brands and fluctuated among areas. For example, AstraZeneca is selling its Oxford-based vaccine for a higher price, $5.25 per dose, in South Africa than in Europe and the US for each $2.15 and $3-$4. On the other hand, Moderna and Pfizer are selling their vaccines at an even higher price in the rich regions, 10 times more expensive than AstraZeneca, up to $23 per dose [15]. It is reasonable for people to doubt whether manufacturers are charging excessively for the vaccines. Therefore, after calculations, researchers Light and Lexchin conclude the proximate cost of manufacturing vaccines to be less than $1.

Of course, the manufacturing cost of the vaccines does not include the cost of R&D at the early stage. However, when several vaccine manufacturers from different backgrounds are all able to develop some kind of effective vaccine, although perhaps a smart choice as a company, refusing to disclose any information about the manufacturing costs indicates the unfair prices on the market. At the beginning of the pandemic, in order to speed up the process of vaccine R&D, no matter it is indirectly from the taxpayers and donations, or directly from the government or other sources, millions of dollars have been given to the pharmaceutical corporations. Therefore, even in the most resource-consuming stage of the early development of the vaccine, the companies do not invest a whole lot. In another word, when the technology and knowledge of manufacturing the vaccine are no longer desperately in need, and the actual cost of manufacturing is not surprisingly high, It seems inappropriate for the vaccine manufacturers to set the price higher than what it should be even in a free market.

Human nature is, according to Drahos, intrinsically motivated and attracted to positive rewards, psychologically speaking [14]. Therefore, a higher net gain is what every business desires. However, IPR protections of such products of public good, are no longer apposite to some extent. IPR protections make sure innovations are continuously being created, and it is more towards the "abstract" property instead of the actual product [14]. When the value of new types of vaccines is not the primary pursuit anymore, the IPR protecting such property means less than before and brings less profit for the scientist as well. Thus, alleviating some constraints on Covid-19 vaccine IPR protections within an acceptable range is not going to hurt the creativity of scientists and researchers in the pharmaceutical industry, but what is more, if more factories are licensed, eligible, and capable of producing vaccines, the prices will decrease but the sales increase. As a consequence, the problem of vaccines being unequally distributed will also be eased, and the pharmaceutical companies, very possible, would not trade their profit in return. It will be a pretty much ideal win-win situation.

4.3. Historical Evidence in the Pharmaceutical Field

Waiving the IPR of certain medicines has historical precedent, even before the Covid-19 outbreak. How Penicillin was widely manufactured, distributed, and utilized during World War II (WWII) has set a great example of prioritizing the actual value of medicine over the intellectual value.

With the background of WWII, Penicillium notatum, a mold later evolved into the Penicillin we have today, was introduced in the lab by British scientist Alexander Fleming in 1928 [16]. This mold has been proved to effectively inhibit the growth of bacteria, and possibly could be medical and clinically useful. Fleming's finding was published and recognized within a small range in Britain, and 1940s, as the war escalated, the British government actively looked for new treatments for infections from injuries, which eventually attracted Howard Florey and Ernest Chain, who later purified the mold and connected with the scientists in the US [17]. The British scientists were unable to conduct human trials on a large scale, and they shared the technology with scientists in the US. It was later proved to be the right decision that the US government put on great effort to encourage pharmaceutical firms to share every progress about the development of penicillin with each other and the government, in order to mass-produce this antibiotic for the war. From 1941 to 1944, the military was successfully supplied with a great amount of penicillin, which influenced the course of the war. During this period, there was no active patent on penicillin, technology was widespread mandated by the US government, and the R&D process from manufacturers also profited considerably from the stable demands and government subsidies [17].

A great number of people who were supposed to die of infectious wounds during WWII survived, loads of money they were supposed to spend on patent disputes were saved, and the action of the US government questioned the applicability and definition of IPR in the pharmaceutical industry. Even almost a century ago, the revolution on saving lives over profits won, and today, with the lessons learned from a successful antecedent, why should IPR impede the Covid-19 vaccines from spreading worldwide? The pandemic has not been ended yet, waiving the IPR protection on the vaccines, however, could just be the key to the end.

5. Conclusions

This paper is designated to raise public awareness of the low vaccination rates in some regions and propose some plausible explanations for the problem. Without that being said, the current situation is, after almost three years since the outbreak of Covid-19, some countries have gradually lifted the face mask mandate and reversed the policies to a pre-Covid standard, while some still choose to remain exercising strict anti-epidemic guidelines including lockdown when necessary. However, no matter which strategies each country is practicing, the worldwide vaccination rate has barely reached 60%. Despite some countries like Chile and South Korea having almost 90% of the population vaccinated, dozens of developing countries have less than 20%, and in some extreme cases, only 4.9% of the South Sudanian received vaccines to date. It is a shocking fact that even after a year and a half

after the first Covid-19 vaccine came out, it has still barely reached some parts of the world. It is not because their people strongly oppose vaccinations or there are issues with the supply chain. The answer is coming at the sound of a whistle. Waiving the IPR protections of Covid-19 vaccines to some extent is a crucial factor to increase the global vaccination rate, without the cost of undermining the intellectual property rights to a threshold worth paying attention to.

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