



Equitable access to medicine and covid-19 vaccines: Global initiatives and legal challenges

Wasif Reza Molla

Assistant Professor, Department of Law, University of Calcutta, West Bengal, India

Abstract

In 2020, the world faced an unprecedented threat when the COVID-19 epidemic swept the planet and distorted our way of life. Since the pandemic engulfed the world, the question of how to manage it and which vaccines to use has remained debatable ^[1]. But one lesson the pandemic has taught us is the need for universal, timely, equitable, and affordable access to medicine and vaccines, because no one is safe until everybody is safe. Unfortunately, what we experienced is the lack of equal, cheap, fair, safe, on-time, and universal access to medicine and vaccinations, which had a direct effect on the right to life and the right to the best possible health care for millions of people. It also caused many hospitalizations and deaths that could have been prevented. However, despite the fact that we are fortunate enough to have COVID-19 vaccinations produced in a short span of time, a strange and unwanted circumstance arose because of the unequal distribution of vaccines among different nations. It has been observed that wealthier countries acquire a significant quantity of vaccines in excess of what is required. This attitude made the pandemic even more devastating, particularly for less developed and more marginalised countries and regions. The shortages of essential medicines during the COVID-19 pandemic in various nations resurfaced the debate on universal access to medicines and patent rights. Some have blamed the unexpectedly high demand for certain medicines for the shortages. However, several thinkers in the field of global health have contended that the patent system is to blame for the legal impediments to universal access to affordable medical treatments around the globe, which is a major reason for the scarcity of medicine. This issue reached its peak after the second wave of Covid-19, when vaccines and drugs like Remdesivir, received FDA approval for Covid treatment, and it intersected with the exclusive rights of the patent owner of this medicine ^[2]. This again sparked the same global debate on patent laws and public health.

Focusing on this conceptual notion, this paper examines, from the perspective of the COVID-19 pandemic, the ethical obligations of the pharmaceutical industry during times of emergency, as well as the international effort to provide universal access to medicine and COVID-19 vaccines within the field of pharmaceutical patents. It then turns to the second issue regarding building harmony in the cause of public health and welfare, with a focus on the field of patent law and it concludes by suggesting some points essential for a broader approach to tackling these issues of the critical lack of life-saving treatments, medications, and diagnostic kits during pandemic.

Keywords: Covid-19, compulsory licensing, access to medicine, global initiatives, trips flexibilities, WTO waiver decision

Introduction

"Someone's doom is someone's blessing." This ancient proverb seems fit to describe the role played by multinational pharmaceutical companies during the COVID-19 pandemic. The COVID-19 pandemic has emerged as an unprecedented global health crisis. A menace for which the world was not prepared, nor was it supposed to be. It was just like a surprise attack from an unknown alien called the Corona Virus. We know that in any crisis we should fight together, and those who have more responsibility should come forward to resist the danger. In this case, multinational pharmaceutical companies could shoulder such responsibility. Several multinational pharmaceutical companies have worked at a breakneck pace to produce a wide range of vaccines, and their efforts have paid off with an earlier-than-anticipated rollout of vaccines ^[3]. But unfortunately no collective effort was made by the pharmaceutical companies to curtail their claim of patent right over their patent medicines to facilitate access of necessary medicines, vaccines or medical kits to fight COVID-19 pandemic and that's led to an unequal production and distribution of COVID-19 vaccines and medicines around the world which casts a cloud over their efforts to fight COVID-19 pandemic ^[4]. On the contrary, recently, Gilead Sciences, a biotechnology company based

in the United States, filed a case challenging the legality of a Russian government decision that allowed a Russian pharmaceutical company to produce a generic version of Gilead's antiviral medicine Remdesivir without the company's permission. The Supreme Court of Russia ruled against Gilead and held that, due to the emergency generated during the COVID-19 pandemic, the government's decision to allow Russian company Pharmasintez authorization to develop and market the anti-COVID-19 medicine without the consent of the patent owners was legitimate. This is not the only case where, in a shameful manner Gilead filed a case to exploit its patent right on Remdesivir. There are numerous such instances where multinational pharmaceutical companies, in a brutish way, remained stuck to their policy of profiteering even in such a life or death situation ^[5]. Several large pharmaceutical corporations, including Pfizer/BioNTech and Janssen, have strongly opposed any waiver of global intellectual property rights while the World Trade Organization considers whether to accept a proposal from India and South Africa to do so. The two companies argue that giving up their IP rights will only make the situation worse. They said it might disrupt raw material distribution and make people wary of taking chances. Instead of this approach, there should have been an international consensus

of multinational pharmaceutical companies on prioritising the most affected countries, treating all people fairly, valuing and rewarding hard work, and maximising the returns on scarce resources. And most importantly, to design a plan that makes financial conditions irrelevant to people's ability to stay alive. Despite the fact that in many third-world nations, only the wealthy have access to modern medical care.

Access to medicine and COVID-19 vaccines: Ethical Obligations of the Pharmaceutical Industry

Given their unique position to develop, manufacture, and distribute COVID-19 vaccines, pharmaceutical companies have sole responsibilities in this emergency situation. However, pharmaceutical companies are free to decide which therapies to develop, how to price and distribute their products, and whom to supply through bilateral agreements^[6]. It is a matter of fact that there are no legal obligations for pharmaceutical corporations to develop vaccinations or treatments for infectious diseases. On the other hand, patents and exclusive rights help pharmaceutical firms to charge higher prices than they would be able to under normal circumstances^[7].

In the absence of any international coordination or subsidised purchase, uniform pricing standards, and market-driven distribution, vaccines have been made available and successfully delivered in wealthy countries^[8]. As a result, developing nations with fewer resources had to wait longer for aid. Many pharmaceutical companies, including COVAX, and governments have already deviated from the market approach in response to these issues, as evidenced by their donations of vaccines to COVAX and low-income countries, pledges to sell vaccines at marginal cost during the pandemic, and, in the case of some companies, their refusal to enforce vaccine patents. However, there has been a lack of coordination in these efforts, making it utterly impossible to ensure that everyone benefits equally^[9].

The international effort to universal access to medicine and COVID-19 vaccines

As happened many times in the past, in the event of an emergency, many incentives were taken by the international community. The COVID-19 epidemic is not exceptional. Many of the global initiatives for strengthening global cooperation in dealing with the COVID-19 pandemic were considered and adopted by many international organisations like the United Nations and the World Health Organization. These initiatives include the supply and support of developed countries in the administration of safe and effective COVID-19 vaccines, including the Global Access (COVAX) facility^[10]. On April 21st, 2021, the WHO reported that out of the more than 700 million doses of COVID-19 vaccine administered worldwide, more than 87% went to richer nations or regions, while only 0.2% of vaccines manufactured so far went to lower-income countries or areas^[11]. Dr. Tedros, the Director-General of the World Health Organization (WHO), reportedly claimed on March 22nd, 2021, that the world has done very little to fix the unequal distribution of the COVID-19 vaccines so far, and that the world is on the edge of a terrible human rights violation^[12]. When it comes to issues of human solidarity, many promises have been made by developed countries, but developing and undeveloped regions have no idea if the so-called developed world will actually follow

through on their words. On the contrary, some affluent nations or regions have been in a mad rush to acquire anti-pandemic resources, such as masks, ever since the start of the COVID-19 pandemic in the spring of 2020^[13].

COVAX Initiative

COVID-19 Vaccines Global Access, also known as COVAX for its abbreviated form, is a global initiative conducted by the GAVI vaccine alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO), with UNICEF serving as a key delivery partner. Its primary objective is to ensure fair access to COVID-19 vaccines^[14]. It is one of the four pillars of the Access to COVID-19 tools accelerator, which is a project initiated in April 2020 by the World Health Organization (WHO), the European Commission (EC), and the government of France as a response to the pandemic caused by COVID-19. COVAX integrates worldwide resources to provide low-to-middle-income nations fair access to COVID-19 diagnostics kits, medicines, and vaccines. As the biggest buyer of vaccines in the world, UNICEF is a key partner in getting vaccines to people who need them^[15].

COVID-19 Technology Access Pool

The World Health Organization (WHO), the Government of Costa Rica, and other partners kicked off the COVID-19 Technology Access Pool (C-TAP) in May of 2020 in order to make it easier for people all over the world to have faster, more equal, and more inexpensive access to COVID-19 health products^[16]. The C-TAP was developed as a response to the global solidarity call to action and is currently supported by 45 states that are members of the WHO. Its initial partners are the United Nations Development Programme (UNDP), the Medicines Patent Pool, the United Nations Technology Bank, and Unitaid. The main objective of C-TAP is to make technology available to manufacturers of COVID-19 medicines, diagnostics kits, vaccinations, and other health products. In addition to this, it offers assistance for technology transfer agreements.

Intellectual Property waiver proposal

Legal conflicts over intellectual property (IP) that protects life-saving COVID-19 vaccines and medicine persist despite the fatal and widespread spread of COVID-19. There have been thousands of preventable deaths because of the delay attitude of governments worldwide^[17]. Vaccines and other medical supplies are desperately needed to combat the epidemic, so it is crucial that the international community quickly reaches consensus on the best course of action. On October 2, 2020, South Africa and India put forth a proposal with the intention of easing "quick access to cheap medicinal products." After a substantial amount of discussion on the 21st of May, 2021, a revised plan was presented in response to the feedback received from other WTO members, such as the observation that the initial proposal was too comprehensive. This updated version addresses "health products and technologies," which include diagnostics, therapeutics, vaccines, medical devices, and personal protective equipment, as well as their materials or components, as well as their methods and means of manufacture for the purpose of preventing, treating COVID-19^[18]. It has been suggested that the exemption would

remain in effect for a period of at least three years from the date when the resolution was passed. This proposition has garnered support from a large number of people, including support from the United States. It is possible that the IP waiver will be able to circumvent some of the restrictions that are imposed by the compulsory licensing system. These include the product-by-product requirement of compulsory licensing, which restricts the effective and speedy application of this mechanism, as well as the need to spend time identifying the patents that cover the products in question prior to the issuing of a compulsory licence. Both of these requirements restrict the effectiveness and speed with which this mechanism can be applied. These problems would be over if the IP waiver were put into effect. Furthermore, the hurdle of marketing approvals would also be removed. At the same time, the question of compensation wouldn't come up either unless there was an agreement to do so. Both the compulsory licencing of patents and the IP waiver, now under discussion at the WTO, have advantages and disadvantages. While the existing process of compulsory licensing of patents is plagued with problems, the IP waiver may be able to solve some of them. Nonetheless, it should be reinforced with another mechanism that permits involuntary technology transfer through compulsory licensing of trade secrets.

In addition, while discussions continue at the WTO, governments are urged to revise the intellectual property laws in their respective countries. This should include making the currently available mechanism of compulsory licensing of patents more effective by removing all bureaucratic hurdles and enabling the prompt and timely grant of such licences when they are required. In addition, the waiver would eliminate the need to comply with the burdensome procedure of Article 31bis TRIPS in the event of COVID-19 vaccines or medicines being exported to other nations that lacked or had limited production capacity. It is essential to have a solid understanding of what the IP waiver entails. If the waiver is agreed upon at the WTO level, WTO members would not be able to sue another WTO member for TRIPS non-compliance in the event that it waives IP rights at the national level.

This would be the case only if the waiver was agreed upon. In turn, the effect of the IP waiver at the national level is that once the IP waiver is enacted into domestic IP legislation, IP rights would not be enforceable against third parties. To be more specific, the national adoption of the IP waiver would necessitate suspending the enforceability of intellectual property rights, which would include obligations arising from free trade agreements, and declaring that the manufacture of IP-protected products and other activities that fall within the exclusive rights of the IP owner by third parties without their permission would not be considered an infringement of those rights. This, however, would only be applicable if the objective is to eradicate the COVID-19 epidemic. As a result, it is recommended that this clause be drafted in a manner that would minimise misuse by third parties. Every other usage would constitute an infringement of several patents and intellectual property rights. A further implication of the suspension of enforceability is that injunctions cannot be issued against the aforementioned third parties. Additionally, such a suspension of intellectual property rights would be transitory, for example, during the time that the IP waiver is in effect.

Compulsory licensing

When it comes to getting patents for their COVID-19 medical research, pharmaceutical companies have been very proactive. By virtue of their ownership of these exclusive rights, they are able to set the terms and conditions of sale, including the price and availability of the products. But the TRIPS Agreement has a unique way to limit the use of a patent's exclusive rights. This is done through something called "compulsory licensing." Many scholars and activists recognise that compulsory licensing as a helpful approach to increasing access to patented medicines. If a Government of developing country issues a compulsory license for the production of a patented drug, then generic drug makers are legally allowed to manufacture and sell the patented drug. Being excluded from patent protection, the drug are often produced at comparatively low price by generic drug manufacturers and so be obtainable at low price to those who want it within the country. All WTO countries have the right to give such licences, and the Doha Declaration on the TRIPS Agreement and Public Health 2001 reaffirmed that compulsory licensing is one among the flexibilities under the TRIPS Agreement. This system has been adopted by the many countries around the world; therefore it can be relied on to meet the demands of public health. "Government use" licences, or "public non-commercial use" licences as they are referred to in TRIPS, are a specific sort of compulsory licence that allow governments to provide permission for their own use, including manufacture, importation, and distribution of the protected products. Government use may be a useful instrument in public health since governments can take the initiative in this area by licensing the use of patented pharmaceuticals and thereby facilitating access to cheaper drugs. Furthermore, in the case of "public non-commercial use," prior negotiations with the patent owners may be waived in accordance with Article 31(b) of the TRIPS Agreement ^[19]. Compulsory licences provided to third parties to meet a national emergency or other exceptional urgency do not necessitate any prior negotiations under the same law. As can be seen in table 1 below, some developed as well as developing countries have already granted Compulsory Licenses or Government Use Authorisation for Covid-19 medicines ^[20].

Table 1: Compulsory Licenses/ Government Use Authorisation: (as of 2 March 2021) ^[21]

Country	Drug	CL/GU	Year (granted /filed)
Ecuador	Raltegravir	Compulsory Licenses	2021
Russia	Remdesivir (for Covid-19)	Compulsory Licenses	2021
Hungary	Remdesivir (for Covid-19)	Government Use	2020
Israel	Lopinavir/ritonavir (for Covid-19)	Government Use	2020

National Security Exception in the TRIPS Agreement

In light of the current COVID-19 pandemic, several experts and intellectuals have proposed that states can suspend patent regulations by invoking the national security exception in Article 73(b) (iii) of the TRIPS Agreement. This would allow for the production and importation of patented medicines and vaccines ^[22]. In cases when a member state's essential security interests are threatened, the

exception grants the state the right to take any action, including the suspension of IP rights and the disclosure of information. To handle a public health crisis, it can be used for any sort of intellectual property, including copyrights, industrial designs, and trade secrets. In addition, there are no procedural requirements for invoking Article 73, so there is plenty of discretion to act in the event of any emergency. India has incorporated Article 73 into its IP legislation in Section 157A of the Patents Act 1970^[23]. Although the provisions of "government use" and "compulsory licence" in the Patents Act have their own limitations, such as the usage being restricted to only authorised entities, a cooling period of three years, a time-consuming process of granting, and excess discretionary powers to the Controller of the Patent Office, the whole process is a time-consuming exercise that will not be relevant in an emergency situation such as the pandemic that is currently occurring. Hence, the blanket provision for all IPs, such as the security exception, would be more effective.

Conclusion

Affordability and accessibility of medicine and COVID-19 vaccinations are major global health concerns and will increase as more sophisticated medications and vaccines are introduced. Although steps have been taken by the international community to ensure vaccines are distributed fairly, such as the creation of COVAX, more has to be done. The issue of inequitable vaccine distribution was a result of a number of factors, including a lack of public disclosure of clinical data and vaccine supply agreements; a lack of engagement through multilateral arrangements such as COVAX; and a lack of adequate corporate strategies (e.g., fair pricing, IP strategy, manufacturing agreements). In this regard, the pharmaceutical industry as a whole should take a hard look in the mirror and consider their responsibility to society^[24]. It is necessary for pharmaceutical companies all across the world to come forward and implement CSR principles. Some TRIPS flexibilities, such as compulsory licensing, could be used as a legal tool to lower the cost of some medications. But there are a number of legal and procedural hurdles that need to be cleared before the government may begin using this instrument. The patent system should be reformed using a combination of legal and administrative measures, government incentives like grants, subsidies, and rewards; and public-benefitting initiatives like private-public partnerships, patent pools, and patent promises should be adopted. In addition to the IP waiver, a more effective approach is necessary to ascertain an appropriate allocation of vaccines during the pandemic, and a more long-term, sustainable, and development-friendly solution is required for developing countries^[25]. In the event that the request for a waiver is granted, it is imperative that pharmaceutical corporations do not dither about devoting research and development resources to the fight against the next pandemic. To offer the necessary degree of fair access to fight the worldwide pandemic, efforts should be undertaken to bolster supply chains, modernise infrastructure, and guarantee distribution.

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