# THE 2020 'IPR WAIVER' AND COMPULSORY LICENSING OF COVID-19 VACCINES: A CRITICAL ASSESMENT

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**Abstract**

*In October 2020, amidst the global COVID-19 crisis; South Africa and India submitted a proposal to the World Trade Organization (WTO) asking for a waiver of intellectual property rights (IPRs) in order to increase access to vaccines or other COVID-19-related technologies. This was done in light of the growing concern regarding global efforts to ensure equitable access to affordable COVID-19 vaccines and associated medical technologies. However, this proposal, which also seeks to provide for the use of compulsory licenses, became a contentious issue, over the time. This paper shall primarily assess if the proposed IP waiver on COVID-19 vaccines has been able to address the need for global access to vaccines. Moreover, the paper shall also talk about the possible challenges of authorization of compulsory licenses on the COVID-19 vaccines. The author proposes certain arguments against the IPR waiver, discusses possible demerits and also suggests other alternatives that could be adopted in lieu of the IPR waiver and compulsory licensing approach. Therefore, this paper analyses the legal jurisprudence behind IPR policies in relation to the right of a person towards 'access to vaccines'.*

**Keywords**: COVID-19, Vaccines, IPR waiver, Licensing, Access, Right

## 1. Introduction

The act of granting property rights to one's intellectual creation lies in the motive to encourage the creator by offering incentives and exclusive control over the utilization of their creation. The question to whether and to what degree intellectual property rights (IPRs) foster greater innovation as well as access to life-saving medical technology for all at an affordable rate has been answered by many in opposing yet debatable ways. It has been generally assessed that the current Intellectual Property Rights (*hereinafter* IPR) system permits medical corporations to dominate research and development (*hereinafter* R&D), manufacturing, and distribution of their pharmaceutical product, which can result in excessive pricing as it is supported by their monopolistic power of patent rights. There

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have been a number of ideas aimed to change this current system in order to offer less expensive medical treatments while still providing enough compensation, incentives and enticing additional investment in pharmaceutical innovations. Moreover, the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (*hereinafter* TRIPS Agreement) under Articles 28 and 33 mandate that nations must provide patent holders the sole authority to create, use, and market pharmaceuticals for a minimum of 20 years following the date of patent filing. Critics argue that this sole authority power can also be used to limit supply, alter market conditions and worsen manufacturing capacity which can ultimately result in exorbitant prices of medicines and pharmaceutical technology.

Hence, as a solution to this issue, the IPR system has built-in defenses against such exploitation, most notably in the form of government-issued compulsory licenses, which let someone other than the patent owner to create and/or use a patented good or method without the patent owner's approval under specific circumstances. Other ways are to offer affordable medicines to the poorer countries in need as voluntary direct donations or amend laws pertaining to the length of the patent protection. However, a new approach towards access to equitable and affordable medicines was taken in 2020, amidst the COVID-19 pandemic. India and South Africa submitted a proposal to the WTO requesting a complete waiver of the IPRs of vaccines in order to increase its access including other COVID-19 related technology in view of the international efforts taken to guarantee equal access to inexpensive COVID-19 vaccines in the hour of need. The WTO Members were asked to waive any patent and other intellectual property rights (IPRs) that would be relevant to or have an impact on the “prevention, containment, or treatment of COVID-19” in the proposal presented at a TRIPS Council meeting in October 2020.

There are currently not enough COVID-19 vaccinations available in many of the regions with the highest disease burden due to a number of obstacles in the manufacturing and distribution of the vaccines, including insufficient infrastructure. There are conflicting views among academics and medical professionals regarding the actual utility of patent liberalization. An exception to the agreements establishing the TRIPS Agreement has been proposed. This suggestion is based on the idea that vaccines against the Coronavirus during a pandemic should be regarded as a “common good.”

In this paper, the author considers the proposed waiver's merits in the context of removing proprietary restrictions but primarily demonstrates that there is a discrepancy between the mechanics of the waiver and the projected rise in the manufacturing and distribution of vaccinations on a worldwide scale. In conclusion, the paper argues that the proposed waiver mechanism does not solve the related issues of infrastructure deficiencies and transmission of implicit knowledge and could possibly hinder future R&D and innovation in the pharmaceutical sector.

## 2. IPR vis-a-vis Right to Health: Way(s) to strike a balance

Intellectual property, especially patents, is generally considered to be an empowering aspect for pharmaceutical innovations, but very often the strata of the society in the poor and least developed countries suffer adversely because they find it extremely difficult to obtain medicines as the patent laws enjoy monopoly rights. Public-health emergencies like recent COVID-19, HIV/AIDS, H1N1 Flu etc., raise the responsibility of the patent-owing pharmaceutical corporations residing mostly in the rich developed countries to strike a balance between their private commercial interests and public health interests, and help the community at large. It is because private rights result in competitive pricing that creates a rise in prices of essential medicines and constrain large-scale production globally; thereby negatively affecting equitable and affordable access to health technologies. This ultimately throws off the balance between intellectual property rights and the right to health. Moreover, it was only in the year 2001 when the issue of public health and related concerns were first addressed in the international level, during the ministerial conference at Doha. The Doha Declaration of 2001 upheld that states have an unalienable right to take measures to safeguard public health.

### 2.1. Current IPR System and Access to Medicine

The dissemination of technical knowledge is the primary objective of the patent system as intellectual property (*hereinafter* IP) protection helps in the growth of novel technologies. The development and research of novel medical technologies also require such incentives due to investments made towards it. IP protection can also prevent the acquisition of new technologies by other parties.

Prior to the TRIPS Agreement, pharmaceuticals were not even the ‘subject matters of patentable items’ in the domestic rulings of about fifty countries. In 1995,

intellectual property (IP) protection began to be attached with trade regulations and it led to the signing of the TRIPS Agreement. Under TRIPS, patent protection to inventions in all fields of technology included pharmaceuticals too. The 2001 Doha Declaration recognized public health in principles governing the TRIPS. However, it has been found that the TRIPS Agreement's *'one size fits all'* policy do not actually help in promoting fair and equitable access to medicines and that too in an inexpensive manner. The international IP policy does not acknowledge the multifaceted aspects of disparities and diversity present around the world. We see that countries with low income, weak socio-economic situations and poor infrastructure facilities in the pharmaceutical sector are less likely to innovate or build something extraordinary. There are lesser chances of maintenance of price equilibrium of both generic versions of medicines and the patented ones considering the global economy. In this regard, pharmaceutical patent protection is dynamic and strong in the powerful developed countries wherein big companies hold rights to medicines and drugs. When prices of patented medicine drops down, most of the patent-owning multi-national corporations take extreme measures to protect their 'private rights' as against public good.[1] Though the principles and objectives of the TRIPS Agreement explicitly recognize the need to promote social welfare and safeguard public health, the practicalities of implementing the TRIPS Agreement's regulations into effect appear to dodge the basic issue of access to affordable medicine and treatment in an equitable manner. Therefore, it is of utmost importance to bridge any gap between varied interests and seek a balance between IP rights and right to health *vis-a-vis* right to access of medicines.[2]

### 2.2. Key challenges to accessibility of medicines during COVID-19

The very onset of the Coronavirus pandemic has witnessed the significance of vaccines for human health and all countries globally have put forward a demand for it, which has led to the pharmaceutical companies trying hard to make sure that the production of vaccines can be as per the requirement even though to satisfy the worldwide arena, they had to enlarge the production of the same which is challenging in its part. The vaccines are being purchased by all states in order to satisfy their national needs which

[1] J. Sundaram, *Pharmaceutical Patent Protection and World Trade Law- The Unsolved Problem of Access to Medicines* 24 (Routledge, 1st Edn, 2018).

[2] J. Chen, "Balancing Intellectual Property Rights and Public Health to cope with COVID-19 Pandemic", *Senton Hall Law Libraries* 8 (2021).

results in vaccine nationalism. The developing countries however, have had a difficult stint at receiving the vaccines for their countries because the whole system of buying and distribution is done by bilateral agreements also accompanied by advance purchase agreements.

Moreover, it was stated that countries like Canada, United Kingdom which are financially at a greater front, had already bought a major share of total vaccine supply already. This creates an unequal situation where the developing countries are struggling to have access to vaccines and US, UK and other developed countries have it in surplus quantity. Further, it was witnessed that developing countries were lagging behind in their fight with COVID-19 because of unavailability or delayed process of distribution of vaccines and it becomes very essential to increase the production of the same. But in order to increase the production of vaccines and to provide a wide range of the same to as many countries as possible, an IP waiver with the goal of providing a free manufacturing arena and avoiding any hurdles in the legal front was proposed in 2020.

This proposal according to many, affected Article 28 of TRIPS Agreement which stated about the vaccines and medicines having patent protection. Thus a global consensus on this total IPR waiver on COVID-19 vaccines was yet to be achieved since there had been opposition by US, Switzerland and United Kingdom. In light of this opposition, India, European Union, South Africa and America came up with a similar amended compromise in March 2022 but faced heavy disapproval because of its insufficient ambit. Subsequently, there were several rounds of conferences and debates upon the terms of the proposed waiver. The debate on merits-demerits of securing the patent protection was prolonged. But, the impact of COVID-19 has been absolutely devastating in terms of public health and wellbeing accompanied with the mass economic destruction due to the lockdowns and this irked the urgent need for world vaccinations to save the countries from anymore ill effects of the pandemic. Thus, the waiver was sought as the best possible tool to meet the need of the hour – increased manufacturing and distribution of vaccines. The developing countries acquiring the vaccines for public health were also not opposed under the TRIPS Agreement. Thus, the member states were bound

to strike a balance between the protecting IP rights and protection of right to health as specified in Articles 7 and 8 provide of TRIPS Agreement.[3]

### 3. IPR Waiver on COVID-19 Vaccines: Not the lone solution

There is an impeding question based upon the role of intellectual property rights in the context of innovation, development and creating access to COVID-19 vaccines and drugs, that has come up in our minds. At the global level, people have witnessed shortages of drugs and vaccines associated to COVID-19 treatment and the horrific ravages of this lethal virus due to the lack in pharmaceutical supplies in all parts of the world. The primary concern of the world is to overcome the global pandemic as quickly as possible. The possible way is only to make the vaccines equitably available to all. Now, vaccines are not simple products; they are pharmaceutical inventions which call for clinical tests, quality control, efficiency checks, sophisticated manufacturing facilities and other requirements which take due time, effort and big financial investments. In this matter, IPR has also played a unique role in the said development and availability of vaccines in the public domain. Thankfully, as of 2022, we have 10 WHO listed vaccines that have been rolled out in the global market after being accepted for treatment. Nonetheless, global vaccine equity is indeed a matter of concern and the manner how we achieve it is a question to ponder upon.

In this spirit, India and South Africa came up together in October 2020 with a proposal to suspend all IP rights on medical products and technologies as far as COVID-19 treatment is concerned so as to generate immediate access to affordable medicines, especially the COVID-19 vaccine to all. Hence, it remains to be seen how suspension or waiver of intellectual property rights protection will help as well as affect countries. Moreover, the pharmaceutical companies that have produced the vaccine assumed a lot of risk in the process of innovation, which calls for valid legal protection (in the form of IPRs) as well. But, does this mean that in the quest to achieve "fair and equitable access to medicines and vaccines" at affordable prices for people, should we ignore that the labor and efforts put in by pharmaceutical companies through the waiver of their proprietary

[3] L. Davies, "Compulsory licensing: An effective tool for securing access to Covid-19 vaccines for developing states?", 43(1) *Legal Studies* 16 (2022).

rights over their vaccine technology? Does the idea of total IP waiver actually address issues like "vaccine equity" in a world of disparities?

### 3.1. Brief background of the IP waiver proposal

When the World Health Organization (WHO) announced COVID-19 disease as a pandemic in 2020, the only hope in the minds of people was to combat this virus as soon as possible. After a long fight, the introduction of vaccines and other COVID-19 medical products including therapeutics, technology, diagnostics to the public in the mid-2021 (after the introduction of first COVID-19 vaccine- *Pfizer-BioTech* vaccine in 2021) stood up as a silver lining as this increased the chances of survival of the people affected or not, as mass immunization was the only way to fight this virus.[4] Following this many developed their own versions of the vaccine and sought respective IP protection for their investments in R&D. However, this action did not solve the problem of lack of access of vaccines at the global level. Only certain margins of the global population had access to vaccines, be it through national production and supply chain but it cannot be denied that people mostly from the LDCs were prone to this virus and this was due to the absence of manufacturing capacity of such a vaccine. In such a case a proposal was proposed to facilitate access to COVID-19 vaccines for all.[5] This view was supported as well as refuted by many.

In light of this, India and South Africa, on 2nd October 2020, proposed to WTO that intellectual property rights on COVID-19 be waived off/suspended. The reasoning behind this approach was to scale up production of vaccines. The proposal addressed that all countries who are equipped with COVID-19 treatment and related facilities should try to grant access to such COVID-19 resources to others by neither granting nor enforcing patents and other IPRs over their respective innovations for a temporary time-span i.e., until the global populace is immunized and free from the dangers of infection. They argued that the deficiency of equitable and affordable COVID-19 treatment, especially vaccination, put the low-income countries at risk.[6]

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4 World Trade Organization, "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19" 4 (September, 2021).

5 *Ibid*.

6 *Id*. at 6.

In the draft proposal, India and South Africa precisely suggested that there should at least be a three-year waiver period and the waiver of IP should entail all forms of vaccines, medical devices, therapeutic equipment, diagnostics and other such tools which will help in preventing the spread of the coronavirus. But these suggestions were opposed by the European Union and they submitted counter-claims to it. They called for voluntary licensing as an alternative as well as asked the WTO to limit export restrictions and allow countries to grant compulsory licenses depending upon the circumstances.

The 2020 proposal garnered official support from 62 WTO member-states including some LDCs like Indonesia and Pakistan. Subsequently, by mid-2021, this proposal had about more than 100 countries supporting it. The opposing parties were the US, Switzerland, Norway, United Kingdom and Brazil. By May 2021, after a series of discussions and conferences, a revised proposal was drafted. Even the US government, after Joe Biden took over as the President; announced that they supported the idea to liberalize IP policies with reference to COVID-19 treatment that too in the backdrop of the rise of the Omicron variant. However, they were stringent about relaxing their national law pertaining to data and transfer of knowledge. The revised proposal had support from 120 countries; yet opposed by 5-6 developed states in particular. Countries like Australia, France accepted the terms to relax patent rights of COVID-19 vaccines. "Among the companies which have licensed COVID-19 vaccines, Pfizer, Moderna, Johnson & Johnson, and AstraZeneca, only Moderna has for long been saying that it will not pursue rivals for patent infringement during the pandemic[7]." Pharmaceutical companies like Pfizer were skeptical whereas BioTech stated that a waiver of IP rights would delay the distribution of vaccines and "such a move would fail to supply bottlenecks[8]".

It was in the month of June 2022; the WTO members came to an agreement and announced that it will allow developing countries to permit the use of patented components or resources solely for the manufacture of COVID-19 vaccines through the mechanism of 'compulsory licensing' and such a measure will only be taken to provide for their domestic markets. This proposal now covers a 5-year span of time for waiver of IPR. WTO narrowed down the scope of manufacturing and distribution of COVID-19

[7] S. Dahiya, C. Sharma, *et.al.*, "Removing the Roadblocks in Equitable Global Access to COVID-19 Vaccine through IPR Waiver", 27 *Journal of Intellectual Property Rights* 168 (2022).
[8] *Id.* at 169.

treatment in the form of vaccines only. However, after the expiry of 6 months from June; WTO will consider including other technology and diagnostics in the proposal. This draft agreement had the support of the United Kingdom as they opined that this revised agreement did not portray IP rights as any barrier to accessibility of medicines in such times. Others also supported this new agreement for its role in enabling the diversification of vaccine manufacturing capability. However, entities like Oxfam and the International Federation of Pharmaceutical Manufacturers & Associations do not support this proposal and they reasoned it upon the idea that such waivers would fail to address the pandemic and its concerns over health threats. This is evident from the presence of gaps in infrastructural set-up and trade barriers of pharmaceutical products. By July 2022, 6 countries sought to extend the agreement into tests and since then, the waiver of IP has been invoked after mass acceptance at the WTO level, and this waiver strictly pertains to manufacturing and distribution of vaccines, either through collaborative efforts of countries altogether or by compulsory licensing mechanism.

### 3.2. Critical assessment of the proposed waiver

The opposing parties of this proposed IP waiver argue that even if waiving off certain IP rights may bring about changes in an amplified access to vaccines and other benefits accrued by low-income developing countries or LDCs; factors influencing this access to vaccines in adequate quantities- like infrastructure, production, supply and other such capacities prove to have weakened the distribution of vaccines. In the pursuit to uphold health and social facets of the pandemic; one must not disregard the role played by IPR in enabling investment, innovation, research and development of vaccines.

Thus, critics of this waiver argue that the waiver's effect would not bring in effective and affordable vaccines; instead such a measure would hinder future R&D in the pharmaceutical sector with the absence of IP rights and recognition.

The following enumerated points bring forth different views and arguments made against the imposition of the IP waiver on COVID-19 vaccines:

i. The waiver does not increase the speed of vaccine manufacturing and distribution. Instead IPRs are vital for sustainable manufacturing of COVID-19 vaccines.
ii. The disparity and deficiency of infrastructural capacities of nations cannot be neglected. It is mostly evident in the least developed countries. IPR is a vital tool

as it permits an innovator to select partners in higher manufacturing capacities of drugs and medicines as well as ensure safety and efficacy of such vaccines and simultaneously provide for the poorer nations.

iii. Since IP rights encourage and remunerates innovation, a waiver of such rights would weaken the spirit of innovation. Even if the existence of IP rights stimulated innovators to study, research and develop new items; the waiver on the other hand may quicken the supply of essential medicines but it will totally eliminate incentives for innovations and hinder the growth of knowledge and technology. Without the support of some IP protection, even pharmaceutical companies would resist themselves from taking up risks or even jeopardize their infrastructural capacity to produce a challenging medicine (in terms of R&D) such as COVID-19 vaccine. Thus, IPR played a substantial role in development of the treatment to COVID-19.

iv. Many would argue that IP rights have hampered the global access to COVID vaccines but this is not the case as such. However, in this situation, the flexibilities in national legislations are to be blamed as countries used these IP flexibilities to render their interests.

v. This has to be kept in mind that the competition of vaccines in the global market scenario will actually promote access as it will keep the prices affordable; not forced production of medicines in the domestic market. The waiver strike as an extreme measure to deal with. The parties opposing the waiver suggest that in lieu of the waiver mechanism, alternatives such as voluntary licensing and mechanism of pooling of data and knowledge for vaccines be taken up. For example, "AstraZeneca has committed to granting voluntary licensing in developing countries and signed sublicense agreements with several generic drugs producers to increase the supply of future vaccines, including with the Serum Institute of India and many more generic manufacturers of the world.[9]"

vi. Provisions of the TRIPS Agreement, precisely Article 7 and 8 provide for IPR protection as a means to acknowledge social and economic welfare; and the

[9] B. Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review" 62 *Virginia Journal of International Law Online* 21 (2021).

encouragement given to countries to adopt measures would come handy in the quest to protect public health in moments of catastrophes.

vii. The idea of 'global immunity' can only be accomplished within a short span of time if only governments ensure that there shall be global equitable access of vaccines to all people belonging from the deprived sections of the world population. Hence, it is the requirement of international fraternity to consider improving adequate access to vaccines and other COVID-19 medical products. This ultimately calls for the efficient public-health governance and diplomacy to provide better support in scaling up treatment facilities around the globe.

viii. Effective IPR enforcement will ensure that the risks of counterfeit and substandard medicines are mitigated easily and for that reason, waiver shall be a bad idea.[10]

### 3.3. Effect of the waiver so far

Many global health experts and researchers state that the proposed IP waiver, if managed properly, shall have a temporary yet significant effect over the manufacturing and distribution of COVID-19 vaccines and this waiver has to some extent in this short span of time shown results that are vital for maintenance of equitable and effective action in the fight against the novel coronavirus.

Due to the disparities in the manufacturing capacity and issue of lack of infrastructural facilities mostly in the LDCs there has been unequal supply-demand chain among the nations in relation access to COVID-19 medications and pharmaceutical products as well as technologies.

The waiver seeks to remove IP barriers and help in engaging a greater number of manufacturers in the market and ultimately produce more vaccines doses but faster. This waiver, during such a public health crisis, aims to enable low income countries to scale up production and administer adequate quantity of doses to its population as soon as possible. After the proposal of IP waiver, several governments have increased their manufacturing facilities, including technology and infrastructure.

[10] *Id.* at 29.

However, if we critically try to look into the practicality of this waiver though; this waiver would eventually fail to address some of these noteworthy issues. The first issue is that in the pursuit to share knowledge and technology; innovator companies would have to sell or disclose their trade secrets including confidential clinical data to new manufacturers which is actually prevented by the TRIPS Agreement. In such an instance, intellectual property could be compromised and it might eventually affect the efficacy of vaccines. The second issue is related to the lack of production abilities as well as storage and distribution logistics in many countries. The third issue is pertaining to the practice of developed countries like US who using the flexibilities in their domestic legislations block vaccine-related technology and know-how from being imported by some LDCs or low-income countries which ultimately affects the production of vaccines negatively, be it with or without IP protection. This practice may result in hoarding of vaccines and that will obviously affect the right to health and access of medicines at affordable prices of countless others. This puts the global community at stake and in this sense; such issues must be addressed as soon as possible in order to overcome all possible negative impacts of the IP waiver. IP protection is necessary however; they must not exploit human rights. Therefore, any step taken in this subject should ensure that adequate supplies are provided while still ensuring that IP issues are not neglected.

Amidst the proposals of IP waiver and the subsequent debates, countries have taken major efforts to increase the supply chain of vaccines in the global market via alternative approaches; such as vaccine donations by G7 Countries as an intense and collaborative international effort to immunize the world, COVAX Initiative (launched by the World Health Organization) with an aim to support equitable access to vaccines and the C-TAP (COVID-19 Technology Access Pool) mechanism which aims to endorse "pooling the patent" to make it affordable[11]. It basically allows voluntary licensing of medicines and technologies that too in an easy and transparent manner. These measures, unlike the proposed waiver, seem to positively impact the distribution of vaccines equitably around the globe.

[11] S. Sharma, "The debate around the access to vaccine and licensing amidst second wave of COVID-19 in India" 24 *The Journal of World Intellectual Property* 443 (2021).

## 4. Challenges to compulsory licensing of COVID-19 vaccines

On June 17, 2022, the WTO members took a ministerial decision on the TRIPS Agreement as a response to the circumstances of the COVID-19 pandemic. They announced a 'proposal' which actually narrowed down the aspects of the original 2020 proposal of the IPR waiver. Accordingly, it was announced in the ministerial decision that notwithstanding any of the provisions concerning the patent rights under a national legislation, the WTO member state can "authorize the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement[12]". This meant that the developing countries were allowed or authorized to use patented COVID-19 vaccines or any medical resource required for the production of such vaccines without the approval of the patent right owner. This declaration approved of what we know as compulsory licensing of COVID-19 vaccines for a period of 5 years, i.e. till 2027. In case a patent was authorized to be used, the right-owners will be remunerated adequately. Interestingly, this WTO Declaration also enabled use of compulsory licensing to such an extent that the member-state cannot only supply to its domestic market but let any amount of the patented product manufactured under this agreement to be exported to any eligible member-state, thus waiving the condition mentioned in Article 31(f) of the TRIPS Agreement.

Prior to this Ministerial Declaration by the WTO, there were multiple instances whereby countries took course to authorization of government use and compulsory licensing as legal tools to generate widespread access to COVID-19 related medical resources, technologies and products. For instance, in 2020 Hungary and Russia issued compulsory licenses for *Remdesivir*, and Israel authorized the same for *Lopinavir / ritonavir*. Countries including Australia, Canada, Brazil Germany, Indonesia, and Russia even reviewed their laws related to compulsory licensing of patented drugs only to facilitate access to COVID-19 resources amidst the tough times.[13]

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12 World Trade Organization, "Ministerial Decision of the TRIPS Agreement" 2 (June, 2022).

13 O. Gurgula, "Compulsory licensing v the IP waiver: what is the best way to end the COVID-19 pandemic?" 6 *The South Centre Policy Brief* 104 (2021).

### 4.1. Effect of compulsory licenses in the COVID-19 crisis

Few years ago, predominantly in the beginning of the 21st century, the world witnessed a pandemic-level public health crisis which is the lethal HIV/AIDS crisis, especially in the sub-Saharan countries. People who could not afford the costly HIV/AIDS drugs (patented by big pharmaceutical companies in high income developed countries) suffered severe consequences and the number of affected people took a high toll. The pharmaceutical companies resisted lowering their prices citing that they spent billions of dollars on developing the drugs and they owned exclusive rights over it. A controversy began to circulate amidst that crisis regarding the question "whether patent rights should take precedence over providing affordable medicines for people suffering from a fatal disease" There were discussions on it and subsequently this debate eroded the reputation of many including the companies and the WTO itself.

In the context of COVID-19 pandemic, we cannot possibly argue against public health considerations. The vaccines developed by different pharmaceutical companies and research institutes stands as a chance to fight this disease. Undoubtedly, vaccines are a public necessity today; the only way to stop the spread of possible variants of this lethal virus. The denial of this vaccine to a human violates his fundamental right to life.[14] Sadly, the demand for vaccines surpasses the availability and this shortage of the essential commodity creates further inequalities among nations in terms of access.

It has been estimated in some reports that till 30th June 2022, 16% of people in low-income, least developed countries (LDC) or developing countries have been fully vaccinated, compared to an estimate of 74% in the high income countries. As per the same reports, Africa has the lowest vaccination rates whereby till March 2022, only less than 15% of its population has been fully vaccinated with two or single dose of the vaccine.[15]

Hence, compulsory licensing of COVID-19 vaccines would effectively enable the government to invest more participants in the domestic market who will help in the

[14] *Ibid.*

[15] Our World in Data, "Share of people who completed the initial COVID-19 vaccination protocol", *available at:* https://ourworldindata.org/grapher/share-people-fully-vaccinated-covid?country=Upper+middle+income~High+income~Low+income~Lower+middle+income~OWID_WRL (last visited on January 27, 2023).

manufacture and development to ensure vaccines doses are largely produced. This will eventually boost the supply and assist in the even distribution of vaccines and other therapeutics to other countries that lack the same. Such licenses are authorized to fulfil the public need at large. For this reason, the European Union in the original waiver proposal of 2020 opposed the idea of complete IP waiver and instead argued for the grant of compulsory licenses by the countries, without the consent of the right-holder in certain circumstances. According to them, it would ensure vaccines and therapeutics are distributed in a global level. They also encouraged upon voluntary licensing and transfer of knowledge to support the manufacturers in countries with minimum or zero vaccination production facilities.

The time when COVID-19 was declared as a national health emergency by several countries, national governments were ready to grant authorization of license for 'public non-commercial use' (a special form of compulsory license) of a patented vaccine without the need for prior approval from the original patent owner. For instance, in 2020 the Russian government sought to issue a compulsory license on *remdesivir* to a local company, an anti-viral medicine prepared by an US-based pharmaceutical company 'Gilead Sciences'. It was aftermath the patent-owning company refusal to grant the license voluntarily to the Russian manufacturer and exclusion of the country from receiving the generic version of the medicine. The prices of the Gilead's product originally were exorbitantly high and supplies are restricted by the company's exclusive patent rights. Later, after the licensing of *remdesivir*, it was easily available and relatively affordable for citizens of Russia. Thus, compulsory license can be an effective option to license the production of medical products when negotiations have failed. Similarly, on March 2020, Israel handed out or granted compulsory license to import COVID-19 medications called *lopinavir/ritonavir*.

However, this measure can be badly politicized and is determined on a case-by-case basis. The grant for such a license can take a lot of time to process which is cumbersome. As the American idiom states that there are "two sides of a same coin", compulsory license as a course of action in regards to balancing of IP rights and access to medicines proves to be little problematic and chaotic and this has also been witnessed in the COVID-19 scenario. It cannot be considered as the ultimate solution. Several research studies and reports show that the effect of compulsory licensing has not been

that successful in establishing equal global access to vaccines and related resources especially between the rich developed countries and the poor third world, low income countries.

### 4.2. Challenges and complications to compulsory licensing: COVID-19 vaccine context

There are certain challenges within the dimensions of the COVID-19 scenario which has hampered the effective utilization and functioning of the compulsory licensing mechanism. The barriers of securing access to vaccines on a global scale are highly concerning which ultimately questions the credibility and effectiveness of the system and incites this particular thought in the minds of people which is "if not compulsory licensing, then which is the best alternative?"

One problem with compulsory licensing of vaccines is that, under Article 39.3 of the TRIPS Agreement[16] a pharmaceutical company is protected from disclosure of clinical test data of the patented product to others while marketing since it protects from "unfair commercial use". Thus, even after a manufacturer receives the license to make the generic version of the vaccine dose; they are required to generate their own data about the efficacy and safety of the generic copy, which ultimately increases the cost and time involved in producing generic versions of the vaccine. Vaccines need to have full clinical capacity and 100% efficacy and safety standards which consume a lot of time and money too while undergoing trials. Many companies therefore would use this flexible provision of compulsory licensing and this further delays 'access to medicines'.

Since compulsory licenses are allowed on a case-to-case basis which also differs from country to country, it is evident that one compulsory license would take account of one specific vaccine or a therapeutic equipment; not all COVID-19 vaccines at once. The paucity of vaccines thus, does not get addressed properly, when vaccines are covered by a complicated web of patents belonging to different right-holders or when they are licensed to a number of companies.[17]

Another complication to the use of "compulsory licensing" is that there are trade-restrictions that bar the export of vaccine components and inputs required for

[16] The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, art. 39.
[17] *Supra* note 13.

manufacture. These components of vaccines which needs to be acquired, maybe from different number of suppliers at once may also be protected by different patents and trade laws of different countries. If we see that there is only one producer (a big pharmaceutical company) who can actually manage to create 100% efficient vaccines and facilitate the supply of the vaccine, it is crucial that the vaccine is quickly accessible to people in substantial quantities; but then again this is unlikely to happen with just one supplier of that vaccine.[18]

Another important challenge that needs to be addressed is that only a considerable amount of knowledge or know-how of COVID-19 vaccines can be shared via compulsory licenses. If a pharmaceutical company does not voluntarily share the knowledge related to production of the vaccines, it will pose as a barrier to the manufacturing capacity and as a result; less people will be vaccinated and many will not be able to access the required amount or doses of vaccines.

TRIPS Agreement, under Article 31*bis* states that, a country that needs a specific pharmaceutical product but lacks the manufacturing capacity to generate it is allowed to import the medicine from a country that produces it, under a special compulsory license. This has not been helpful in mitigating COVID-19 crisis *per se*. The license allows only a specific amount or quantity to be produced and shipped accordingly after following the procedures laid down. In a situation like COVID-19 pandemic when there is a public need for a huge number of vaccine supplies and countries are under pressure to mobilize supplies to in all capabilities, the requirements under Article 31*bis* seems unrealistic.

Countries are discouraged from the issuance of compulsory licenses as it invites unnecessary pressure at global platforms. It is difficult for the countries to coordinate with others owing to different municipal jurisdictions and determination of the license and remuneration if they (generic manufacturers) don't want to attract a lawsuit on infringement of trade and IP rights. Issues like necessity for cold storage and sufficient transportation to assure safe delivery associated with the vaccination supply cannot be accomplished just by a compulsory licensing measure.

[18] E. Urias, S. Ramani, "Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence", 3 *Journal of International Business Policy*, 382 (2020).

Compulsory licensing, in a nutshell, does not provide an effective remedy against patent and non-patent barriers to 'access', even in the case of transfer and sharing of COVID-19 vaccines and 'technical knowledge'. The existing mechanism may not empower states to perform all their international legal obligations under the TRIPS, regarding access and availability of COVID-19 vaccines. Therefore, we should look for other alternatives, tools, mechanism or approaches to meet the global need for access to COVID-19 medicines and pharmaceutical products; such as, amendments of various IPR rules in order to simplify requirements and circumstances for compulsory licensing (looking at the current COVID-19 pandemic scenario) and effective implementation of Article 31*bis* [waiver to Article 31(f) TRIPS] including proper diplomatic negotiations.

## 5. Conclusion

We have witnessed how the development of vaccines by pharmaceutical companies became a priority, when the world was battling the ravages of COVID-19 pandemic. Abundant amount of money and resources was invested by them to research upon and develop an efficient and effective treatment against the COVID-19 infection. But, the IPR waiver proposed by countries amidst the situation does not actually help essentially in abridging the global disparities among countries concerning dissimilarities in capacity to manufacture and distribute vaccines. A complete IPR waiver upon these vaccines does not succeed in addressing the issues concerning vaccine-scarcity. There are intrinsic issues in the system itself, including the infrastructural shortcomings; administrative actions which we need to take into our consideration, if we seek to solve problems related to "access of vaccines". In certain situations, trade-barriers and statutory exceptions to transfer of technical-knowledge in the IP regime (such as, provisions for "data exclusivity") create "problems of access" and then tend to overshadow the damage it causes to countries that are deprived of the capacity of manufacture medicines and vaccines.

Also, it has been witnessed that the proposed IP waiver, mandatorily allowing for compulsory licensing, should be carefully reviewed as it has several implications that need to be addressed. This licensing arrangement, over time, has proved to be less effective and is very much prone to administrative and technical hitches, owing to several flexibilities in the TRIPS Agreement.

Hence, in this situation, alternative approaches to generate and distribute COVID-19 vaccines should be instated; encouraged and necessary amendments and revisions to the "waiver proposal" should be made, in order to give effect to global concerns for "vaccine-equity". The IPR waiver is not the lone means to provide for global access.