Covid -19 Vaccine: A Case of Compulsory Licensing for Social Utility!

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ABSTRACT & INTRODUCTION

After a long and tough battle with COVID-19, people were given a ray of hope with the emergence of vaccines across the globe. However, it is safe to say that things have not quite gone according to plan. Vaccine shortages, debates over patents, hoarding, re-infections despite vaccines etc. have taken over the discourse.

In this paper, the authors seek to examine one of these aspects: the need to treat vaccines as a "social utility" tool essential for saving lives worldwide. We will delve into the compulsory licensing prospects in India, the debate around the recent patent-waiver calls on vaccines, and the dilemma between IP rights and social utility for COVID-19 vaccines. India and South Africa have led the calls for this waiver based on concerns of supply and price affordability. In this backdrop, we shed light on the process and need for compulsory licensing for the vaccine in India and how, in a sense, India is contradicting its call on the international front and its efforts back home, domestically. *"Necessity is the mother of innovation"* – but what happens when that innovation does not reach those for whom it is a necessity? The legal dilemma arises when the jurisprudence of public welfare entangles with the jurisprudence of patent law under the principles of Intellectual Property Rights.

The epidemic of Covid-19 has led to the development of the Covid-19 vaccine. The pharmaceutical sector has been upfront to develop a cure to bring normalcy back into the world. There have been billions of dollars invested to develop the vaccine and the institutions have secured a patent on the technology and the formula. The conclusive standing shall be observed by understanding the legislative intent under the Indian Patents Act 1970 (hereinafter referred to as "the Act").

COVID-19 & TRIPS

The TRIPS Agreement, which was the fallout of the Uruguay Round of Negotiations (1986-94), was pushed by developed countries for the protection of IP rights. It was significantly pushed by the United States – who were backed, at the time, by their pharmaceutical corporations. Strong cross-border IP protection meant greater revenue for pharma and other IP protected corporations. Since these discussions, proponents for IP protection and the 'right to health' have held extensive debates and discussions. While the former states that IP protection incentivizes invention and progress; the latter contends that IP protection, especially patents in the pharma sector, leads to inaccessible and unaffordable vaccines and drugs in the developing South. Today, this same debate has ignited in the form of the COVID-19 vaccine. These vaccines are subject to the TRIPS Agreement and eligible for patent protection. It is because of this that India and South Africa, two 'developing' countries, have raised calls for patent waivers to the WTO.[1] In fact, under paragraph 4 of the *Declaration on the TRIPS Agreement and Public Health* (2001)[2], member-countries recognized that TRIPS does not and should not prevent hindrances in matters of public health. It acknowledges the need for increased accessibility for medicines and drugs for all in a public healthcare crisis. COVID-19 is the public healthcare crisis of the century!

TRIPS, in itself, have contingencies for public health emergencies that allow for waiver on patents. However, these contingencies have been largely branded as "insufficient" by experts. Article IX.3 of the Marrakesh Agreement establishes that any WTO and multilateral trade agreement imposed or backed by the WTO may be waived in "exceptional circumstances". Additionally, through Article IX.4, while granting the waiver the Ministerial Conference can note the "exceptional circumstances" – justifying the decision and conditions of the waiver. An end date has to be fixed and review annually by the Conference if the waiver is for over a year. This waiver may be granted to any one WTO member or all and there is precedent to support

[1] Prabhash Ranjan, 'The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines' (*ORF Foundation*, 06 April 2021) < https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/> accessed 26 May 2021

[2] Declaration on the TRIPS Agreement and Public Health, Paragraph 4

the same. In 2003, certain GATT provisions were waived on the export and import of "blood diamonds" from Africa. In the same year, accessibility to drugs and medicines in the Least Developed Countries (LDCs) was seen as a problem; they lacked manufacturing capacity as well. Thus, TRIPS conditions of remuneration to the patent country were waived for the importing LDCs after extensive discourse. Evidently, the COVID-19 pandemic – the world's worst health crisis in a century and possibly the biggest disruption and loss of life since World War II – falls under "exceptional circumstance", as defined under Articles IX.3 and IX.4 of the WTO Agreement. When nations are struggling for equitable distribution and manufacturing hindrances, upholding TRIPS seems insensitive and unnecessary. A waiver for a year can be implemented and reviewed once the year ends.[3] . A waiver for a year can be implemented and reviewed once the year ends.[4]

COMPULSORY LICENSING IN INDIA: A BRIEF

It is important to note that the Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement gives discretionary power to the government sector to license patented products under Article 31, TRIPS further stresses upon a condition precedent that such exercise shall only be performed in a case of national emergency or national crisis.[5] Further, Doha Ministerial Conference, 2001 acts as an embellishment to the rationale behind Article 31 of the TRIPS Agreement. Doha Declaration binds its members to act for public welfare to improve the social and the economic condition of a state.[6] The doctrine which aids the rationale mentioned above is compulsory licensing, in Indian jurisdiction it is stated under the Act. The provisions 84 and 92 of the Act enshrines the rationale and the spirits of Article 31 of TRIPS, section 84 of the Act

[3] Prabhash Ranjan, 'The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines' (*ORF Foundation,* 06 April 2021) < https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/> accessed 26 May 2021

[4] Prabhash Ranjan, 'The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines' (*ORF Foundation,* 06 April 2021) < https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/> accessed 26 May 2021

[5] Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement 1995, Article 31.

[6] Doha Declaration 2021, THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH.

states that a patent under Indian patent law could be used for the purpose of public welfare after 3 years of expiration if the conditions mentioned under 84(1) is satisfied.

"The conditions are as follows:

- The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
- The patented invention is not available to the public at a reasonably affordable price; or
- The patented invention is not worked in the territory of India."[7]

Furthermore, as per section 92 of the Act, Central Government can grant a compulsory license in national emergency or urgency, the provision enshrines the spirits of Article 31 of the TRIPS Agreement. The legislative intent has been crystal clear as the procedure mentioned under section 87 of the Act, ought to be ignored during a public healthcare crisis.

The judicial interpretation on the matters of principles of Intellectuals Property Rights and spirits of Public Healthcare have time and again inclined towards the latter in Indian jurisdiction. The first prominent case law to grant a compulsory license is *Bayer Corporation vs Union of India*,[8] herein the Patent Controller granted a compulsory license to Natco Pharma (an Indian-based company) to produce the medical drug treating cancer. The Intellectual Property Appellate Boards (IPAB) Coram observed that the facts of the case satisfied all the conditions stated under section 84 of the Indian Patent Act, 1970. The judgment has established that public healthcare under Article 21 of the Constitution of India[9] shall be respected in times of healthcare crisis.

Another important case in Indian jurisdiction is *Lee Pharma vs Astrazenca*[10] wherein the request for compulsory licensing was rejected by the controller of the Patent office on the grounds of failure to meet conditions elucidated under section 84(1) of the Act. Moreover, the Delhi Court has observed that in patent law, mere registration does not make the patent ironclad, factors like

[7] Indian Patent Act 1970, s 84(1).

[8] 0108, [2012] IC 74.

[9] The Constitution of India, Article 21.

[10] 1, [2015] CLA 1.

strength of the defense and public welfare shall also be taken into consideration.[11]

Ahead of the talk at the World Trade Organization regarding waiver of Covid-19 vaccine around the globe raises questions on which set of principles are required in the world as we know it, the principle of Intellectual property rights or the spirits of Public Healthcare? Assessing the legislative intent and judicial precedents in India, it is highly likely that compulsory licenses may be granted. World Health Organization has categorized the Covid-19 virus as a global pandemic, the uncontrollable increase in death rates is an indicator of a dire need for vaccines in poor countries for a reasonable price.

In India, as per section 92 of the Act, the central government has the power to categorize the Covid-19 pandemic under "national emergency" or "extreme urgency". Furthermore, under the Epidemic Diseases (Amendment), Ordinance 2020, a commutable virus is recognized as a deadly epidemic disease. The TRIPS Agreement along with Doha Agreement inclines towards spirits of public welfare, considering all the aforementioned aspects Covid-19 vaccine could possibly be the biggest case of compulsory licensing in India.

THE SOCIAL UTILITY FACTOR

COVID-19 vaccine, in our opinion, is now a necessity and a fundamental right for everyone. It could even be argued to denial of the vaccine is violative of the right to life because inaccessibility of the vaccine could lead to death. This is where the necessity and "social utility" argument for the vaccine comes into consideration. Public health considerations are at play now, even for the biggest pharma corporations, who are private entities having their own capitalist goals. The social utility, however, cannot be ignored even by them. Countries not in favour of the patent waiver, like Germany, are perhaps only risking their own populations with this decision. The B1617 variant is highly transmissible and will most definitely find its way across borders. In fact, it already has affected thousands in the U.K. and some other nations.[12]

[11] Ibid.

[12] 'B.1.617 Variant of Coronavirus Spreading at Frightening Speed Worldwide, Warn Experts' (*The Weather Channel*, 30 May 2021) < https://weather.com/en-IN/india/coronavirus/news/2021-05-31-b1617-variant-spreading-worldwide-at-frightening-speed> accessed on 31 May 2021

Mass global vaccination is the only solution to stop mutations and transmissibility of various variants found across the globe.

Germany, for instance, is against this waiver because innovation and information is a 'commodity'; a commodity that can provide a monopoly for a reasonable period of time. Other arguments are that a waiver would lead to unsafe and less effective vaccines if everyone starts to produce a certain kind with the information available. Not everyone has the manufacturing capacity and technology to produce effective vaccines in the manner patented by these big pharma corporations. Patents help cover development/manufacturing costs and encourage investment while driving research and development. But is this what we are concerned with when millions are dying every day?

Given the degree of uncertainty regarding the workings of the vaccine, pharma corporations rarely pump in the money for research and development (R&D). Their main investments incurred are for distribution and enhancing the production capacity rather than in the "invention" itself. R&D is largely funded by the governments, through taxpayer money. So, is it not only fair that everyone gets a share of the vaccine?[13] R&D is conducted through taxpayer money but then patents ward off accessibility to the common man. The "price" of the invention is the patent created on it. To ensure that this is common knowledge for higher production and accessibility, this "price" (patent) has to be withheld. The investment in COVID vaccines has been state-guided public investments – thus, the knowledge acquired through this investment must also be publicly accessible for the social utility it accrues. Otherwise, this is simply private monopolization of information funded by public investments at the cost of people's lives and well-being.[14]

A waiver of the vaccines ensures that power from the hands of big pharma corporations is taken away. They will no longer be able to control the manufacturing numbers, distribution, and pricing of the vaccine. Manufacturing units can invest in bulk to produce in bulk without the fear of

[13] Michael Safi, 'Oxford/AstraZeneca Covid Vaccine Was 97% Publicly Funded', (*The Guardian,* 15 April 2021) < https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded> accessed on 27 May 2021

[14] Deepanshu Mohan, 'In Discussions about COVID-19 Vaccine Patent Waivers, Social Utility Factors should be Prioritised' (*Scroll.in,* 19 May 2021) < https://scroll.in/article/995169/in-discussions-about-covid-19-vaccine-patent-waivers-social-utility-factors-should-be-prioritised> accessed on 27 May 2021

litigation. The argument that patents were never a barrier is not entirely true. Even those who have licensed with Indian manufacturers, for example, the *AstraZeneca-SII* tie-up, are conditional partnerships. The parent company places conditions on the licenses provided for manufacturing that need to be adhered to. A waiver will remove such barriers. In a public health emergency, no permissions must be required to save lives and produce in bulk. Licenses leave pharma corporations in charge – which are, despite common rhetoric, driven by capitalist interests. What remains to be seen is whether a waiver simply on the vaccines will be effective or not. It is widely believed, as we have alluded to earlier, that unless a waiver on all COVID vaccine-related raw materials and technologies is provided, a simple waiver on the patents held by corporations will be of little to no use.

INDIA'S CONTRADICTION: HOME & AWAY

After India's request at WTO made headway, experts were quick to point out their contradictory stance domestically. As discussed in the earlier section, the government has a statutory right to enforce compulsory licensing of COVID vaccines. But the central government has requested the Supreme Court to not question or discuss this State power to waive IP rights for an essential drug like the vaccine.

The vaccination program in India has got off to a woeful beginning owing to shortages. Calls for compulsory licensing were raised by many states to enhance production and ensuring timely availability. Once a compulsory license is granted, the permission of the patent holder is rendered useless. The reasons against this move are ambiguous and the Center has often used convoluted language to deflect such calls. In its affidavit, the Center said as follows: [15]

> *"It is earnestly urged that any discussion or a mention of exercise of statutory powers either for essential drugs or vaccines having patent issues would have serious, severe and unintended adverse consequences in the countries efforts being made on global platform using all its resources, good-will and good-offices though diplomatic and other channels."*

[15] Why is India Calling for a Global Vaccine Patent Waiver, but Against Discussing One at Home?' (*Scroll.in,* 13 May 2021) < https://scroll.in/article/994672/why-is-india-calling-for-a-global-vaccine-patent-waiver-but-against-discussing-one-at-home> accessed on 28 May 2021

Conversely, within the same affidavit, they have iterated that, in case an application for compulsory licensing is made under Section 92 of the Act, it will be considered. The rigidity to even consider compulsory licensing for the indigenously invented *Covaxin*, is startling, and largely, inexplicable. If granted the license, multiple public sector facilities are available to ramp up the production of at least one approved vaccine. Precedents show that big pharma corporations like Gilead and Merck granted patent licenses to pharma companies in India for diseases like HIV, Hepatitis and Diabetes. The only vaccine under the Indian IP regime is *Covaxin*. Covishield's IP rights are held by its parent firm *AstraZeneca* - who have sub-licensed these rights to manufacturing facilities across the globe and the Serum Institute in Pune, India. While it might be tough to gain a compulsory license for *Covishield*, since it is a British-Swedish company, such roadblocks will not be faced for *Covaxin,* which has been developed and manufactured under the Indian IP regime completely.[16] Those in opposition, including the pharma corporations, feel that simply handing over vaccine 'recipes' to countries without sufficient safeguards, technologies, and infrastructure will only further hinder the vaccination process globally and impact those in dire need. Lower and middle income countries have been questioned on their infrastructural capabilities in the case the waiver is provided. Trade barriers on raw materials required for these vaccines are also a concern.

CONCLUSION

The arguments from the legal standpoint oscillate between the jurisprudence of patent laws and spirits of fundamental rights in the course of a global pandemic. The former has originated from the need for the protection of innovation to promote healthy competition in the market and increase the accessibility for the masses. Whereas, the latter is an essential to the 'right to health' under Article 21 of the Constitution of India. The authors conclusively incline towards the spirits of fundamental rights; waiver-off the Covid-19 vaccine for the greater good of the world. It shall

[16] V Venkateswara Rao, 'The Case for Compulsory Licensing of COVID Vaccine' (*National Herald,* 01 May 2021) < https://www.nationalheraldindia.com/opinion/the-case-for-compulsory-licensing-of-covid-vaccine> accessed on 30 May 2021

be observed that the legislative intent of provisions 84 and 92 of the Act has established for a crisis like Covid-19 global pandemic.

Therefore, it is essential to recognize the legal rights created for a crisis like situations. Furthermore, the IP rights over the Covid-19 vaccine is not a subject of business anymore rather a subject of social utility to save the humanity and to protect the spirits of the fundamental rights enshrined in the Constitution of India.