



## EXEMPTING COVID VACCINES FROM IPR LAWS : ITS IMPACTS AND HOW FAR CAN IT BE EFFECTIVE

By Krishnaveni A. Panicker  
From Reva School of Legal Studies

### ABSTRACT

The developing countries specifically and undoubtedly were in a very precarious situation throughout the pandemic, considering the availability of vaccines. To equalize the huge disparity in the vaccination rates between the advanced and developing countries, it is very necessary that IPR laws be compromised with, and situation be handled with equal access to the vaccine given to everyone. This paper emphasizes on the need to temporarily do away with IPR laws that ensures free flow and timely access of vaccines. Nevertheless, this can be a hindrance to research and can incentivize innovations in the field. Moreover, the suspension of IPR laws is necessarily coupled with compromise in the TRIPS agreement, whose legal implications are discussed herein. WTO, being the international body authorized for these negotiations related to waiving of IPR laws do not contain specified deadlines for the completion of these procedures and can go on for lengthy bouts of time. This paper also aims to throw light on the degree of effectiveness that can be instilled in the production of vaccines by waiving of IPR. Mere waiving of patent rights are not enough to kick-start production in developing countries because it is not humanly possible to replicate pharmaceuticals even if they are not protected by IPR. Therefore, it is not only necessary to remove the hurdles presented by patents removed but also to ensure that

appropriate tech transfers are in place. The former without latter is meaningless and this paper discusses about the same in brief and also about the complications possessed by the waiving of IPR in brief. Therefore, entirely stressing on dissolving patent rights is not sufficient for ensuring equitable distribution of vaccines and equal production of vaccines.

**Keywords:** waiving of IPR, patent rights, compulsory licensing, TRIPS Agreement

### NEED TO EXEMPT VACCINES FROM IPR LAWS

Equitable healthcare to address the Covid-19 crisis requires a multi-level, multipronged approach and it is important to achieve equitable healthcare because as said and believed “no one is safe till everyone is safe” and undoubtedly intellectual property rights play an important role in the process of achieving equitable and uniform healthcare.

The disparity that exists between vaccination rates in under-developed countries, developing countries and developed countries is appalling. It makes us ponder as to what are the actual reasons behind these differences that exist in vaccination rates, in the rate of production of vaccines, between the said categories of countries and to what extent do IPR laws have a role to play in them. Once a vaccine or any drug is newly developed, the developer firm is given the IP rights that allow it to solely control the retailing and manufacturing of the drug. This assigning of intellectual property rights, therefore, directly delay its production process which needs to be ramped up instead. Moreover, the vaccines are not readily available in middle and low income countries as it is available in the high income



and developed countries, because firstly, the high-quality infrastructure that for developing drugs is mainly available in high income countries and the high prices that the developer of vaccines sets, claiming it to be reasonable to cover the costs of developing the vaccine, makes it unaffordable for the LMIC's to purchase them. But, the interesting fact is, these drugs are mostly developed through public fundings, i.e, the taxpayer money. Despite this, the government is providing exclusivity to the private companies to develop these drugs, without ensuring that these vaccines are sold at affordable rates.

A report suggests that over 1.3 million doses of vaccines had been administered by April 2021 worldwide but a mere 0.2% of vaccine doses had only been given in low income countries<sup>1</sup>. The proposal made by India at the WTO, backed by over 120 member countries, though unofficially, to waive the intellectual property rights would turn out to be beneficial, by wiping off the disparities, if necessary steps are taken. If this proposal is negotiated successfully the manufacturers will be unable to hinder the production of finished goods and the availability to raw materials for production of Covid 19 technologies. Secondly, the waiver can prevent the companies from charging unaffordable prices due to the competition resulting from the waiver. A general consensus can be seen amongst the health scholars in our society and its advocates that the persisting system of

patent administration is enabling the companies to exercise control over Research, Development and manufacturing, distribution and when granted with monopoly, leads to fixing of prices extremely high<sup>2</sup>. For instance, the manufacturers of human papillomavirus exercised a duopoly by holding patents that made low income countries pay ten times the estimated cost of these vaccines. Therefore, IP rights encourages monopolies, by giving vaccine producers the unchecked power to charge exorbitant prices, thereby resulting in inadequate and unequal access to vaccines.

#### WAIVING OF IPR AND THE TRIPS AGREEMENT

Article IX.3 of Marakesh Agreement that establishes WTO states that in cases of "exceptional circumstances", an obligation on a WTO member country arising due to any multilateral agreement, like the TRIPS Agreement in the current scenario, may be waived. The term "exceptional circumstances" is not defined anywhere in the WTO agreement. In other words, this hands over adequate powers to the appropriate authority of WTO to adopt certain measures by relaxing obligations in situations of urgency that can be unlawful under normal circumstances as it contradicts the WTO Law. Therefore, WTO by virtue of Articles IX.3 and IX.4 of the agreement may grant this waiver to all the low and middle-income countries in the wake of Covid 19 pandemic.<sup>3</sup>

<sup>1</sup> *Suspend Intellectual Property Rights for Covid-19 vaccines*, THEBMJ,(June.28,2021, 1:00 PM)

<https://www.bmj.com/content/373/bmj.n1344>

<sup>2</sup> *The Need for Global Negotiations on Agreements to Fund R&D within the Context of a Progressive De-linking of R&D Costs from Product Prices*,

*Submission to UN High Level Panel, THE HEALTH IMPACT FUND* (Aug.2,2021,3:28 PM) <https://www.unsgaccessmeds.org/inbox>.

<sup>3</sup> Prabhash Ranjan, *The case for waiving Intellectual Property Protection for Covid-19 vaccines*, ORF (Jun. 26, 2021, 10:05 AM) <https://www.orfonline.org/research/the-case-for->



The 1995 agreement on Trade- Related Aspects of Intellectual Property Rights is a key legal instrument that “harmonizes intellectual property protection by imposing binding obligations on member countries to ensure a minimum level of protection and enforcement of IP Rights in their territories”. As part of the WTO’s legal regime, the TRIPS agreement also includes policies for an enforceable mechanism through which IP rights can be enforced. Since the inception of the TRIPS agreement, its impacts on people’s health have always been a hot potato. Subject to the TRIPS agreement, the Covid 19 vaccines and other related technologies developed are under patent production which gives the patent holders the exclusive right to “manufacture, sell and use the vaccine for the entire term of patent protection of 20 years”. At the same time, the TRIPS agreement provides flexibilities to relax rules pertaining to patent in certain circumstances.

Therefore, the waiver proposed by India and South Africa proposes the WTO’s TRIPS Council to recommend to the General Council “a waiver from the implementation, application and enforcement of ” certain provisions of the agreement for the prevention, treatment and containment of Covid 19. Article 31(b) of the TRIPS agreement provides for the waiving of patent rights held by the right holder in situations of ‘national emergency or circumstances of extreme emergency’.<sup>4</sup> This amounts to a

compulsory licensing by the government. But Article 31(f), reduces the wide ambit that can be attributed to Art.31 (b) on a plain reading of it as Art. 31(f) states that a compulsory license shall be predominantly issued to meet the needs of the domestic market of the member country authorizing such use. Therefore, this does not alter the status quo of LMIC’s or LDC’s with regard to the availability of the vaccines as compulsory licensing does not talk about exporting the vaccines. Therefore, merely exercising these flexibilities are not sufficient to tackle the disparities in vaccination rates and unequal access to the vaccines existing between the countries.<sup>5</sup> As pointed out earlier, the drugs and vaccines produced under compulsory license are predominantly for domestic market and are not subject to export. But, in the year 2001, this problem was recognised in DOHA Declaration, and it further instructed the TRIPS Council to come up with solution for the same. Consequently, the General Council of WTO set aside the obligations imposed on member countries for exporting products and subsequently the TRIPS agreement was amended in 2005.

In compulsory licensing, the patent holder still owns the right to get compensated for the product copies made considering the economic value of the authorization. At the same time, the amendment of 2005 has led the countries to export the drugs produced by compulsory licensing to the less developed countries. Therefore, this has ultimately led

waiving-intellectual-property-protection-for- covid-19-vaccines/.

<sup>4</sup> AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, amended on 23 January, 2017.

<sup>5</sup> *WTO members divided over India-South Africa proposal for TRIPS waiver during Covid-19*, THE HINDU BUSINESS LINE, (June.30,2021,11:00PM) <https://www.thehindubusinessline.com/economy/wto-members-divided-over-india-south-proposal-for-trips-waiver-during-covid-19/article32878713.ece>.



the LMIC's to obtain the vaccines at affordable prices.

### HOW EFFECTIVE IS THE IP WAIVER?

Waiving patent rights can be a way of dealing with the pandemic but this merely cannot ensure that it will be the ultimate solution required to eradicate the virus by inoculating the population. Moreover, a waiver can be considered as an extreme measure and should only be used as a last resort, when all the persisting obligations of the WTO will prove inadequate. Article 31 of the TRIPS Agreement though shows flexibility on the face of it in the utilization of vaccines, as we have seen above, the flexibility would only benefit the domestic market of the country until the amendment was made. But, despite the amendment, not many of the member countries in WTO have issued compulsory licensing. Even if they issue, we do not know how many manufacturers are ready to come forward, all equipped to produce the vaccines.<sup>6</sup> In fact, it can make the world turn a blind eye towards the actual problems that have to be dealt with by distracting us from addressing the real challenges faced in scooping up the production and the distribution of Covid-19 vaccines globally, majorly being addressing the bottlenecks in supply chains, the elimination of trade barriers, lack of raw materials and ingredients in the supply chain and the rich countries' willingness to share and giveaway doses with the poor countries.

<sup>6</sup> Sisule.F Musungu and Cecilia Oh, *The Flexibilities in TRIPS by developing countries: Can they promote access to medicines?*, South Centre and World Health Organisation( June.30, 2021,12:19 PM).

### I ) COMPULSORY LICENSING

Making use of compulsory licensing coupled with enabling of the export of the vaccines, certainly proves to be beneficial, but the problem lies with the fact that for any member country to export its products to the LMC's, the following are some of the conditions that have to be met:

- 1) The country intending to import shows that it lacks the capacity to manufacture the product and notify the same to the WTO Council. The names and the quantities required should also be informed.
- 2) The importing country should show that it has issued or intends to issue a compulsory license.
- 3) The exporting country should only manufacture the exact amount required by the importing country
- 4) Such products manufactured for the purpose of exporting should be clearly identifiable for being produced for such arrangement
- 5) It must be limited to the purpose for which it was granted and must be subject to legal review and for a specified time-period.<sup>7</sup>

Adhering to the above-mentioned prerequisites and strict standards of the TRIPS Agreement is not a feasible option in times of urgencies like the current pandemic. The export further includes procedural difficulties and is undoubtedly a cumbersome process. The lengthy procedures that the exporting country has to

<sup>7</sup> WORLD TRADE ORGANIZATION, [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm) - :~:text=Compulsory%20licensing%20is%20when%20a,the%20patent%2Dprotected%20invention%20itself,(last visited June.3,2021).



undergo including ensuring that the vaccines are transferred to the intended importing country and that too in specified quantity, identifiable by a different shape and colour; all these disincentivise the manufacturers to produce the vaccines under compulsory licences. Therefore, this cannot serve as an ideal process employed for waiving of the patent for equal access to vaccines.

## II ) VOLUNTARY LICENSING

A voluntary license is an authorization given to a generic company by the patent holder, permitting the former to produce the patented product. India's Serum Institute is producing the Covishield vaccine which is another version of the AstraZeneca vaccine developed by Oxford University and licensed to the Serum Institute through a voluntary license.<sup>8</sup> But since this sort of licensing is based on a contract between two parties, the patent holders have all the rights to decide on all important aspects of the selling of the vaccines. Therefore, this method of licensing does very little to ramp up the production of vaccines as this sort of licensing is subject to an exclusive deal.<sup>9</sup>

Waiving of IP rights can mean nothing at all or nullify the effect if the innovator company is not willing to partner and help the other companies in doing the technology transfer and help develop the processes. Patent specifications are merely not enough to realise production because it is not humanly possible to replicate pharmaceuticals even if

they are not protected by IPR. Therefore, it is not only necessary to remove the hurdles presented by patents removed but also to ensure that appropriate tech transfers are in place. The former without the latter is meaningless. In the context of Covid-19 pandemic, the people who pushed on waiving IPR rights intended to also exclude tech transfers from the rights. Sole patent waivers if not hinged with tech transfers are inadequate in serving the sole purpose of manufacturing the vaccines.

But another problem with the sharing of tech transfers is that they might not be feasible because technology used for the development of vaccines falls within the domain of trade secrets that are shared only if the sharing is appropriately incentivised.

## CONCLUSION

If we take a close look at the domestic platform of manufacturing in India, Section 84 of the Patents Act, 1970 contains provisions relating to compulsory patent licensing. But, at times of pandemic, compulsory licensing can be effectuated by virtue of Section 92, that relaxes the stringent requirements that has to be undergone as per Section 84, for licensing. But, relying only on the vaccines developed in our country is not sufficient because the development of a vaccine is a long and time consuming process. After the completion of the development, for the vaccines to be used and available in the market, they have to be

<sup>8</sup> AstraZeneca takes next steps towards broad and equitable access to Oxford University's potential COVID-19 vaccine, AstraZeneca, (Aug.3, 2021, 3:00 PM), <https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-university-potential-covid-19-vaccine.html>

<sup>9</sup> Sara Jerving, *Gilead's closed door deal sets precedent for Covid-19 drug access*, DEVEX (Aug.1,2021, 4:16 PM) <https://www.devex.com/news/gilead-s-closed-door-deal-sets-precedent-for-covid-19-drug-access-97214>.



licensed by WHO and the same is again a lengthy procedure. Therefore, it is necessary that we do not only rely only on the vaccines produced in our country, as this might lead to a prolonged pandemic with vaccination rates gaining a very slow momentum. Support from countries who have already developed the vaccines is a necessity arising from herein, therefore. But we have already looked into the problems that accompany the exporting of vaccines already produced in other countries using compulsory licensing. But, of course, after the government of a country issues a compulsory license, the rate of the vaccines comes down, as there exists a competition in the market now as the monopoly enjoyed by the vaccine developer company is no more in existence. This can certainly prove beneficial for countries who intend to import vaccines, especially to those LMIC's and LDC's who entirely lack manufacturing capabilities. But this cannot be an ideal solution for every country. In the case of India, the major vaccine produced and administered to people is the Covishield, which is another version of the AstraZeneca vaccine. As we have seen, this is produced by India using a voluntary license. For this to happen, the developer of the vaccine had to share all the technologies used in the making of the vaccine. Not all companies are willing to do this until appropriately incentivised and also, since voluntary licenses involves a one to one contract between two companies, it is not a dependable option, as in that case, every country would have to enter into a private contract with the other country.

And we must still bear in mind that, the IP

waiver proposed by India and South Africa are still not approved by many of the member countries of WTO as they feel that this can disincentivise corporate investment and Research and Development sector. One of the major reasons given by the proponents of IP rights all over the world is that it incentivizes innovation and therefore should be strengthened using a set of national and international laws. On the other hand, critics contend that patent rights on pharmaceuticals hinder the introduction of affordable vaccines and drugs in developing countries.

And last but not the least, IP waivers can be implemented only if all the countries agree to it, so that all the countries can make use of the vaccines without thinking about coming under any legal implications, unless the countries willingly provide the member nations with voluntary licences. But again, the TRIPS agreement do not provide for any specified deadlines, for these negotiations and therefore can go on for lengthy bouts of time.<sup>10</sup> Moreover, even if all the countries agree, time period required for ratification can be long. Therefore, we can conclude that patents are an obstacle to equitable healthcare but not the only obstacle. The other obstacles could render the patent waiving meaningless, if not coupled with adequate measures to tackle all the hurdles. In order to increase the development and equal access of the drugs, one solution is proposing an advanced market commitment mechanism, wherein international bodies and organizations commit to purchase certain specific amounts of the vaccines to distribute in LMIC's at the asking price. But

<sup>10</sup> *Lack of Political Will and IPr Rules stand in the way of mass vaccination for Covid-19*, THE LEAFLET (Aug.1, 2021,12:00 AM)

[theleaflet.in/lack-of-political-will-and-ipr-rules-stand-in-the-way-of-mass-vaccination-for-covid-19/](http://theleaflet.in/lack-of-political-will-and-ipr-rules-stand-in-the-way-of-mass-vaccination-for-covid-19/).



this mechanism cannot guarantee and does not ensure a low price as the prices can be equal to that of expensive drugs in high-income countries.

\*\*\*\*\*

## REFERENCES

### Articles

- 1) Silvia Salazar. Intellectual Property and the Right to Health.
- 2) K.Walsh, A.Wallace. Intellectual Property Rights Access in crisis.
- 3) Saipriya Balasubramanian. IP Waiver for Covid-19 vaccines in India.
- 4) Prabhash Ranjan. The Case for Waiving Intellectual Property Protection for Covid-19 vaccines.
- 5) Siva Thambishetty.2021.Vaccines and patents: how self-interest and artificial scarcity weaken human solidarity.
- 6) Oxfam Briefing Paper 95. 2006.Patents versus Patients.
- 7) Brink Lindsey.2021.Why Intellectual property and pandemics don't mix.
- 8) Christopher Garrison.2004. Intellectual Property Rights and vaccines in developing countries.

### Websites

- 1) Intellectual Property, Protection and Enforcement, World Trade Organization.
- 2) Compulsory Licensing of pharmaceuticals and TRIPS, World Trade Organization.

### Reports

World Trade Organization.2020. Waiver from certain provisions of the TRIPS Agreement for the Prevention, containment and Treatment of Covid-19:WTO.