IPR WAIVER FOR VACCINES: IS IT A ONE STOP SOLUTION FOR THE CRUNCH IN SUPPLIES

Suyash Shrivastava & Neelakshi Joshi, Indore Institute Of Law, Indore

ABSTRACT

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement was introduced after successful lobbying by the developed nations, in order to protect the creations of mind at the transnational level and upend duplication of their efforts in other countries. The debates over the provisions of this agreement revolve around the rights of a patent holder and the interests of the public. The agreement, though, offers flexibilities under Article 31 (compulsory licensing) but its application has always been contentious, as the rich nations have predominantly been against this provision. While there have been talks at some instances since the outbreak of the pandemic in March 2020, on the virtue of the TRIPS agreement, it intensified after India and South Africa proposed at the World Trade Organization (WTO) for waiver of patent rights on vaccines. The claim that a patent waiver is a prerequisite to resolve the vaccine crisis seems to be misguided as the real issue lies with the shortage of raw material and lack of know-how of manufacturing process, which is surely not going to proliferate in case of a waiver, instead, it will put the governments at odds with the developers. Invoking compulsory licensing will be a feasible alternative as it will be under the auspices of law and will ensure safe and efficacious vaccine, also deep cooperation with the vaccine developers will provide an insight into the manufacturing process and gradually will accelerate the production, as transfer of technology is the key and that remains in the hands of developers that have carried out the R&D.

Keywords: TRIPS, Compulsory Licensing, Waiver, Crisis, R&D.

1. INTRODUCTION

The ghastly nature of Coronavirus (COVID-19) has already ravaged millions around the world and the health infrastructure of even the developed nations crumbled against it. There is still no certainty whether the countries will be able to outweigh the virus or as World Health Organization (WHO) stated earlier that the virus *'may never go away'*.[1] These difficult times have also helped in accomplishing a miracle, developing a vaccine is a cumbersome process and it takes years to even reach the initial stage,[2] but owing to the global research and development efforts there is a list of ready to use vaccines in a record-breaking time. After the development of vaccine, came another challenge for the countries i.e. devising a procurement and distribution channel to inoculate the vaccines to its citizens. Surprisingly, it turned out to be more complex than even fighting an uphill war, as millions of doses have to be manufactured, and supplied with limited resources to all the countries. This challenge is more severe particularly for the developing and least-developed countries,[3] (LDC's) due to huge population and low purchasing capacity.

As the rich nations have already pre-booked the doses leaving a bare amount of vaccines for the majority of the world, the rest of the nations are forced to implore upon the ways to widen the availability of vaccines. In this quest, most of them have built a consensus on the patent waiver on vaccines, but this has sparked fierce debate between the developed nations and the developing and LDC's, even the professionals and laureates in the field of medicine have failed in reaching a common ground till now. There is a need to understand every facet of the reasoning provided by both sides and how their actions will entail a framework not just for the current situation but also for the health emergencies that may erupt in the future.

This research article attempts to articulate the circumstances that have led to the shortage of vaccines in the world except for the developed countries, followed by an overview of patent laws particularly the TRIPS Agreement, which has a binding effect on all the WTO members, and how the agreement seeks to establish a balanced approach between the rights of a patent holder and the interests of the public. Thereafter, the research article will give an account of some instances which followed the setting-up of the TRIPS agreement, and created a void

[1] Emma Farge, Michael Shields, *'This virus may never go away,' WHO says*, REUTERS (May 12, 2021, 6:30PM), https://www.reuters.com/article/us-health-coronavirus-who-briefing-idUSKBN22P2IJ.
[2] Claire Felter *A Guide to Global COVID-19 Vaccine Efforts*, COUNCIL ON F.R. 8 (2021).
[3] UNCTAD, https://unctad.org/topic/least-developed-countries/list, (last visited May 14, 2021).

between the developed nations on one side and developing and LDC's on the other regarding the effectiveness of patent laws.

In the later parts of research article the authors will give a brief background the reasons on why a patent waiver will fail to bring substantial changes in the current situation as the real hindrance is not the patent, but the availability of raw materials and the lack of know-how of the vaccine manufacturing process. Then the authors will try to provide more feasible suggestions to handle the crisis i.e. compulsory licensing under Article 31 of the TRIPS agreement, and other measures that are already in place and are striving to increase the availability of vaccines. The authors will conclude by asserting that a patent waiver will not turn out to be an effective measure to the unprecedented problem, and instead, deep and amiable coordination between the governments and manufacturers will resolve the crisis.

2. ALLEGED HOARDING OF VACCINES BY DEVELOPED NATIONS

While vaccines were still in the development stage during the year 2020, countries with huge funds were able to book the vaccines for their citizens while leaving other nations to continue their fight against the virus with whatever means they had at their disposal, this phenomenon is infamously called as 'vaccine nationalism'.[4] A recently conducted Oxfam study reflects a harrowing disparity that the wealthy nations represent just 13% of the world's population but they've successfully stocked roughly 51% of the vaccines.[5] The monopolistic attitude of some pharma companies backed by these wealthy nations is withholding them from diluting their manufacturing secrets to other nations or vaccine manufacturers in those countries. During a virtual conference of the World Economic Forum (WEF) in January 2021, the South African President Cyril Ramaphosa had to request the rich nations '*not to hoard vaccines*',[6] it conspicuously depicts the sobriety of the situation in parity with other similarly placed regions of the world. Needless to say, irrespective of the economic status it is everyone's right to enjoy the highest attainable standards of health.[7]

[4] Dr. Amir Khan, *What is 'vaccine nationalism' and why is it so harmful?,* ALJAZEERA (May 14, 2021, 7:28 PM) https://www.aljazeera.com/features/2021/2/7/what-is-vaccine-nationalism-and-why-is-it-so-harmful.
[5] OXFAM INTERNATIONAL, https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19, (last visited May 14, 2021).
[6] PTI, *Rich countries hoarding COVID-19 vaccines, says South African President, Cyril Ramaphosa,* THE HINDU (May 14, 2021, 7:28 PM), https://www.thehindu.com/news/international/rich-countries-hoarding-covid-vaccines-says-south-african-president-ramaphosa/article33671697.ece.
[7] UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, art. 12.

The WHO being at the forefront decided to manage this issue by way of initiating C-TAP (COVID-19 Technology Access Pool),[8] where countries and vaccine manufacturers were invited to share their expertise with other nations, but even after the passage of a year no significant development has taken place. The world is already witnessing the consequences of vaccine nationalism as countries like the United States (US), United Kingdom (UK), have already vaccinated a significant proportion of their population,[9] due to which now they are comfortable in easing the restrictive measures,[10] whereas the developing and least-developed ones are still battling and losing thousands of lives each passing day.

3. IP RIGHTS AND VACCINE

Intellectual Property (*hereinafter* IP) refers to *creations of the mind, such as invention; literacy, and artistic works; design; and symbols, names and images used in commerce.*[11] Intellectual property is protected by law through patents, copyright, trademarks, industrial designs, geographical indications (GI), and trade secrets,[12] which solicits inventors and creators to earn monetary value and recognition for their discovery. IP laws seek to maintain a balance between the rights of the creator and the interests of the public. IP rights have their history and have been recognized in various legal systems. Modern initiatives to protect IP through international law started with the Paris Convention for Protection of Industrial property (1883*)*,[13] and at present, there are over 25 International instruments that protect these rights.

The law governing vaccine's formulation, including the combination of medicinal components comes under the ambit of IP law. They also exist on a device for vaccine administration, for instance, an injection delivery system or a capsule constructed to release the product in a particular area of the human body.[14] Copyrights can protect the expression of ideas, and trade secrets including any information that the inventor has refused to publish, for example, any data of clinical trial. It takes heavy investments as well as profound research and development

[8] WORLD HEALTH ORGANIZATION, https://www.who.int/initiatives/covid-19-technology-access-pool, (last visited May 14, 2021).
[9] OUR WORLD IN DATA, https://ourworldindata.org/covid-vaccinations?country=OWID_WRL, (last visited May 16, 2021).
[10] PTI, *Covid-19 | U.S. allows fully vaccinated people to forgo masks indoors*, THE HINDU (May 16, 2021, 12:03 PM), https://www.thehindu.com/news/international/covid-19-us-allows-fully-vaccinated-people-to-forgo-masks-indoors/article34553190.ece; *see also* **Francesca Gillett,** *Covid-19: Lockdowns ease in England, Wales and most of Scotland*, BBC (May 17, 2021, 1:02 PM), https://www.bbc.com/news/uk-57136140.
[11] WIPO, https://www.wipo.int/about-ip/en/, (last visited May 17, 2021).
[12] WIPO, *What is Intellectual Property?*, https://www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf.
[13] *Id.*
[14] Hilde Stevens et al., *Vaccines: Accelerating Innovation and Access* https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_16.pdf.

(R&D) to develop a vaccine, and the ultimate role of IP rights is to encourage R&D investments required for their development. Article 7 of the TRIPS Agreement describes the objectives of the IP system in terms of a balance of rights and obligations,[15] and it can be inferred that the ultimate objective is to promote innovation for the benefit of both the developers, and the end users, while also contributing towards the social, and economic welfare.

In order to encourage the pharma companies to perpetually innovate, the provisions of patent law in the area of vaccines are essential and these provisions give them an impetus in exclusively reaping the economic reward of their invention. In the process of the development of vaccines, IP rights are highly prioritized as patent law gives the makers their desired award and recognition in society.

4. WHY HEALTH EMERGENCIES ARE WORSE FOR DEVELOPING & LDC's?

The patent laws concerning pharmaceuticals have been a bone of contention between the developed and LDC's/developing nations since the inception of the TRIPS Agreement in the year 1994,[16] the reason being that major pharma companies having huge manufacturing facility are established in developed nations owing to the, *inter alia*, infrastructural facilities, availability of raw materials, and when any exigencies arise, such as COVID-19 pandemic, these handful of companies come under immense pressure since now they have to supply their goods in a much larger quantity to various nations. Also, the dearth of funds makes it even more difficult for the least-developed ones to procure in bulk from these pharma companies.

The current scenario portrays a hindering structure where except for India and China, all the other Covid-19 vaccine developers are based in developed nations;[17] this tends to show that the rest of the world is relying on these countries for deciding the fates of their vaccination drive. Recently, in October 2020, India and South Africa provoked the already existing tussle over IPR on vaccines when they proposed in WTO to allow waiver of TRIPS agreement "*until widespread vaccination is in place globally, and the majority of the world's population has*

[15] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), [TRIPS].
[16] Anna Lanoszka, *The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries*, 24 (2) INTL' POLSCI REVIEW 190 (2003).
[17] REGULATORY AFFAIRS PROFESSIONAL SOCIETY, *https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker*, (last visited May 18, 2021).

developed immunity".[18]

The proposal was supported by a majority of middle-income countries but the developed nations have categorically rebuffed the proposal,[19] however, the US under the newly elected President has recently changed its stance but not the others,[20] this takes us back to the early 2000's when the developed and least-developed countries for the first time were up against each other on the IPR issue, at that time developed nations vehemently used these laws for filling their treasuries and if any country violates the IPR protection laws then that nation would invite trade sanctions from the US under the "Special 301" (an annual report which reviews the global state of IP laws and its enforcement).[21]

South Africa was one of the first victims of these rigid patent laws to face the ire of developed countries when their government passed the Medicines and Related Substances Control Act, 1997, to allow parallel imports and production of generic medicines in their country to fight the deadly HIV/AIDS which had already claimed thousands of lives around the country,[22] the major international pharma companies responded by filing lawsuits against the country in violation of the patent laws.[23] The law was somehow in consonance with the recently introduced TRIPS agreement but the US anxiously anticipated that it might create a dent in their monopoly,[24] so the US government jumped in and pressurized the country to every bit possible to repeal the law and they even included the country in the 'watch list' of Special 301, later in this campaign US was joined by a group of prosperous countries, the EU (European Union), but eventually, they all reached a consensus and South Africa was allowed to proceed with the law without any external influence.[25]

Such events can stall any country's efforts for a mass immunization program for years. Similarly, Brazil and Thailand have also been a part of the 'watch list' for violating the

[18] James Bacchus, *An unnecessary Propsal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, CATO INSITUTE (May 18, 2021, 4:25 PM), https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines.
[19] Ann Danaiya Usher, *South Africa and India push for COVID-19 patents ban*, 396 THE LANCENT 1790 (2020)
[20] MINISTRY OF EXTERNAL AFFAIRS, https://www.mea.gov.in/press-releases.htm?dtl/33848/Sta0tement+on+the+US+support+for+TRIPS+Waiver, (last visited May 18, 2021).

[21] Lanoszka, *supra* note 16, at 187; *see* OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, https://ustr.gov/issue-areas/intellectual-property/Special-301, (last visited May 19, 2021).
[22] Lee Gillespie-White et al., *Patent process and access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*, IIPI 14 (2002).
[23] Debora Halbert, "*Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*," 1 (2) SEATTLE J.R. FOR S.J. 257 (2002).
[24] *Id.* at 269.
[25] White, *supra* note 22 at 20-23.

American patent policy.[26] Past events conclude that in circumstances of an epidemic or widespread occurrence of infectious diseases, rich nations comfortably afford their treatment through better health infrastructure and well-established presence of pharmaceutical industries, while other countries have to survive according to the whims and fancies of rich nations.

5. WHY PATENT WAIVER WILL NOT SOLVE THE CRISIS?

The authors are of the view that the theory behind the proposal for waiver of TRIPS agreement is that all governments are facing challenges in ensuring sufficient quantity of vaccine timely, as patent grants a monopoly to the makers regarding supply, this monopoly becomes a hurdle for many middle and lower-income countries, which are apparently not deep-pocketed. The countries supporting waiver argue that the patents are the force behind the increase in price, and delay in availability of vaccines in the middle and lower-income countries. While theoretically waiving the IPR might bring desired results for developing and LDC's, but when this will be implemented in the real world, things will not be as favorable as it seems. If supposedly in the next WTO meeting countries unanimously vote for the waiver and remove the legal barriers for manufacturers around the world, these manufacturers then have to start reverse-engineering (a reproduction of the already existing product, by attempting to understand minute details) the vaccine development process and evolve a method to produce it. Thereafter, the production process will require raw materials and other logistics, and right now the bigger issue than patents is the availability of them and with more manufacturers moving in it will further disrupt the already strained supply chain,[27] and will dampen even the well-established facilities.

It takes years to strengthen and stabilize the edifices of pharmaceutical infrastructure for vaccine production, moreover, it is a much more complex process than manufacturing the generic versions of normal drugs,[28] a newly established facility without the technical know-how and expertise from the stalwarts will not serve the needs of a safe and efficacious vaccine, right from the research process, there are several quality checks, and standards that have to be maintained for minimizing the risks of a detrimental effect that a vaccine can have on the

[26] Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 980 (2007)

[27] Nikou Asgari, *Pfizer chief warns of 'scramble' for raw materials if patents waiver*, FT (May 27, 2021, 11:20 AM), https://www.ft.com/content/2f99beeb-e887-4c1e-977b-e5d334f7fd6a.

[28] VMPA Study, *Vaccine Manufacturing and Procurement in Africa*, https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf.

individuals. As the consequences of a faulty vaccine are grave and still haunt the Americans, when a polio vaccine manufacturer namely "Cutter Laboratories", in the year 1954, due to a flawed manufacturing process, developed and consequently administered these doses to roughly 120,000 children, it left 51 paralyzed, 5 dead, and around 40,000 got "abortive polio".[29]

The synthetic mRNA (messenger RNA), the technology behind the vaccines of Pfizer and Moderna, took scientists 60 years, countless failed experiments, and billions of dollars to come to light,[30] it would be naïve of someone to imagine manufacturing a safe and efficacious generic version of these vaccines in a short span of time. Production capability, supply chain, quality check, availability for cold chain system for live virus vaccines,[31] intricacies associated with the development of vaccines which are difficult to comprehend and replicate, are some of the factors that will huddle in the way of the production process and a patent waiver alone would not assure these. Instead, a waiver will have adverse consequences and some of them are stated below:

5.1. Effect of waiver on R&D

In every manufacturing process, the first stage involves profound research on the feasible ways of development and ascertaining the efficacy of innovation. One of the major factors for introducing these laws was to stimulate innovation by validating the developers or inventors to reap benefits proportionate to the amount of risk undertook by them.[32]

Diluting IPRs would eliminate the incentives that spark innovation, thus hindering the discovery and development of knowledge for new products, technologies, and would even undermine the research on diseases that might prove lethal in the future.[33] The American pharma industry, alone, spends more than $70 billion every year in R&D,[34] and the stance of a

[29] Michael E. Ruane, *The tainted polio vaccine that sickened and fatally paralyzed children in 1955*, THE WASHINGTON POST (May 21, 2021, 09:24 PM), https://www.washingtonpost.com/history/2020/04/14/cutter-polio-vaccine-paralyzed-children-coronavirus/.

[30] Nicole Lurie, Jakob P. Cramer & Richard J. Hatchett, *The Vaccine Revolution*, 100 FOREIGN AFF. 129-130 (2021).

[31] Ana Santos Rutschman, The Intellectual Property of Vaccines: Takeaways From Recent Infectious Disease Outbreaks, 118 MICH. L. REV. ONLINE 174 (2020).

[32] Stephen Ezell and Nigel Cory, *The Forward for Intellectual Property Internationally, Information Technology and Innovation Foundation*, ITIF (May 23, 2021, 11:24 PM) https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally.

[33] Bacchus, *supra* note 18.

[34] CONGRESSIONAL BUDGET OFFICE, https://www.cbo.gov/publication/57126, (last visited May 24, 2021).

patent waiver will put such countries at odds with the pharmaceutical industry.[35] Without the assistance on clinical trials, experiments, and viable ingredients required for moving on with the development process by the experts in the field, it will pose a great challenge for the new manufacturers, thus, would defeat the purpose of a waiver.

5.2. Neglecting IPR can concern safety

U.S Chamber of Commerce argued that, the proposal for waiving of IP rights is a distraction from the real work such as reinforcing supply chains and distribution of vaccine to the world. Waiver will make it more difficult for distribution of vaccine.[36] The protection of IP not only provides incentives to innovators to create, but also play crucial role in ensuring the safety of the vaccine and helps to prevent the importation of fraudulent and dangerous practices. Unlike typical pharmaceutical industry, the vaccine market is not a free and open market.[37] The exclusivity of the IP rights makes it an accountable task to keep a check on the safety standards of the vaccine.

Unarguably development of a vaccine is a long, meticulous, and costly process, a waiver might embolden the unauthorized manufacturers to access the markets, through forged documents, and supply the counterfeit vaccines in place of the generic ones, this has already started getting prevalent,[38] and will further open the floodgates for these illicit businesses to flourish, as in case of a waiver it will be a much more arduous task to catch hold of them.

5.3. A tedious process

The WTO is a member-driven, consensus-based organization, which means the waiver proposal will only be in effect after receiving the assent of all the 164 member countries, even a single veto of any member country can halt the process,[39] and it will be further dragged on to

---

[35] Saeed Shah, Developing Countries Push to Limit Patent Protection for Covid-19 Vaccines, WSJ (May 24, 2021, 09:39 AM), https://www.wsj.com/articles/developing-countries-push-to-limit-patent-protections-for-covid-vaccines-11600355170.

[36] U.S. CHAMBER OF COMMERCE, https://www.uschamber.com/press-release/us-chamber-statement-proposed-wto-ip-rights-waiver, (last visited May 24, 2021).

[37] VMPA, *supra* note 28.

[38] Jamie Grierson, *Fake Covid vaccine and test certificate market is growing, researchers say*, THE GUARDIAN (May 27, 2021, 07:19 PM), https://www.theguardian.com/world/2021/may/16/fake-covid-vaccine-and-test-certificate-market-is-growing-researchers-say; *see also* AFP, *Pfizer confirms fake vaccine shots on sale in Mexico, Poland: Reports,* DH (May 27, 2021, 07:21 PM) https://www.deccanherald.com/international/world-news-politics/pfizer-confirms-fake-vaccine-shots-on-sale-in-mexico-poland-reports-977126.html.

[39] Craig VanGrasstek, *The History and the Future of the World Trade Organization*, https://www.wto.org/english/res_e/booksp_e/historywto_e.pdf. (May 27, 2021, 08:04 PM)

the next meeting. So far, in the past 7 months, there have been 10 rounds of inconclusive meetings,[40] and the possibility is low for any unanimous decision in the upcoming meetings as European countries are relentlessly defending their stance against the waiver.

In case of a successful waiver, a new set of challenges in the form of logistics and raw material will further defer the vaccination program, as now countries that have clinched proficiency in manufacturing the generic version of medicines will have to set up a new or refurbish their existing facilities to make the high-end mRNA or vectored COVID-19 vaccines that require a highly sophisticated facility,[41] *inter alia*, moreover, building those facilities and making them certified and operational will take time, money, and precious expertise. Thus, the stakeholders should not forget that the capacity to build or convert new facilities of highest standards is very limited,[42] and exists with a few countries; therefore, it is hardly possible to build these facilities in months if not years.

6. HOW COMPULSORY LICENSING IS A FEASIBLE ALTERNATIVE?

Complete removal of the patent laws from the deliberations will never be a feasible solution, but in exceptional circumstances of exigencies when the world is battling against a virus, pharma companies or patent holders can adopt an approach that is suitable for promoting societal along with humanitarian interests and not serve a discriminative monopolistic structure. Instead of patent waiver, some experts are in favor of compulsory licensing for ramping up the production,[43] Article 31 of the TRIPS, allows a member country to opt for compulsory licensing,[44] a process in which the patented subject matter can be used without the authorization of patent holder to make the generic versions, but they need to strictly adhere to the provisions of Article 31. In case of "*national emergency or other circumstances of extreme urgency*" the TRIPS agreement, further, allows the proposed user to bypass certain obligations,[45] which paves the way for early access to the license. Earlier, there used to be few

[40] Philip Blenkinsop, *Explainer: COVID-19 vaccine patent waiver talks could still take months*, REUTERS (May 27, 2021, 08:04 PM) https://www.reuters.com/business/healthcare-pharmaceuticals/covid-19-vaccine-patent-waiver-talks-could-still-take-months-2021-05-06/.
[41] Professor V.K. Unni, *Covid-19 and Vaccine Equity: Does a patent waiver matter*, FORBES (May 28, 2021, 11:16 AM), https://www.forbesindia.com/article/iim-calcutta/covid19-and-vaccine-equity-does-a-patent-waiver-matter/68039/1.
[42] Hans Sauer, *Waiving IP Rights During Times of COVID: 'A False Good Idea',* IP WATCHDOG (May 28, 2021, 11:30 AM), https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/.
[43] Kirtika Suneja, *Must open license regime to push vaccine, drug supply:Experts*, THE ET (May 28, 2021, 12:52 PM), https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/must-open-licence-regime-to-push-vax-drug-supply-experts/articleshow/82360413.cms?from=mdr.
[44] TRIPS, *supra* note 15, at art. 31.
[45] *Id.*

limitations in the article which curtailed the countries with a license to supply only within the domestic limits,[46] this provision was counter-productive for the countries with no or limited manufacturing capacity as they might get the license but due lack of know-how they can neither produce nor import the much-needed pharmaceuticals.

The 2001 Doha Declaration (Doha Ministerial Declaration on TRIPS and Public Health) addressed this issue and proposed a solution by inserting Article 31bis,[47] an exception to the aforesaid article, and specifically designed for the Countries that do not possess the necessary manufacturing capacity, which will now allow them to import the patented products (the exporting country also needs to issue license) under the auspices of compulsory license from major generic producers,[48] such as India, Bangladesh, and Malaysia. Article 31bis, after several rounds of negotiations and discussions finally entered into force in the year 2017.

While in a patent waiver the inventor is stripped of his rights, compulsory licensing has a balanced approach which allows the inventor to continue with the possession of rights and even has the right to be fairly compensated.[49] There are various instances in the past when compulsory licensing turned out to be a lifesaver for millions of citizens residing in developing and LDC's, and made countries like Bangladesh, India, self- sufficient in the pharmaceutical sector.[50] Malaysia in the year 2004 became the first Asian country to be a beneficiary of the flexibilities offered after the Doha Declaration, and issued compulsory licenses to import antiretroviral drugs (ARV's) for HIV/AIDS from India after long but failed negotiations with the pharma companies,[51] as a result, several lawsuits were instituted against the country, but not being servile to the foreign pressure the country carried on with the imports and this helped them to expand their treatment base and significantly lowering the price of ARV's by 81%.[52]

In the case of compulsory licensing, after granting the agreed royalties to the companies, the governments can request the know-how of the manufacturing process, earlier these companies

---

[46] *Id.*
[47] WORLD TRADE ORGANIZATION, https://www.who.int/medicines/areas/policy/doha_declaration/en/, (last visited May 28, 2021).
[48] WORLD TRADE ORGANIZATION, https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm, (last visited May 28, 2021).
[49] WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm, (last visited May 28, 2021).
[50] Monirul Azam, *Has the TRIPS Waiver Helped the LDC's Progress Towards Innovation and Compliance?*, 1 OPEN BOOK PUBLR. 246 (2016).
[51] WHO, *Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context*, https://apps.who.int/iris/bitstream/handle/10665/204741/B5144.pdf?sequence=1.
[52] Sara Germano, *Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low-and Middle-Income Countries*, 76 UMKC L. REV. 286-88 (2007).

were harsh on granting of such licenses but there hasn't been any case during the pandemic and instead, they've been flexible. On 18th March 2020, Israel issued a compulsory license for lopinavir/ ritonavir (AbbVie's Kaletra), an HIV pill that the country believed to be effective in treating COVID, and turned to India for importing the generic version of the same,[53] the patent holder AbbVie, an American based manufacturer, denied to sue the country in the light of pandemic.[54] Vaccine giant Moderna has already refused to enforce its patents during the ongoing pandemic,[55] it is seen as an attempt to not discourage others who are willing and have the expertise to make similar technology-based vaccines.

7. THE WAY AHEAD

7.1 Global Task Force

The second wave of COVID-19 in India, which gradually grew around mid-March 2021 wreaked havoc around the country, as due to the rapid proliferation of trajectory it created a heavy shortage in the domestic supplies of all the essentials needed for the treatment of patients. As the dreadful visuals and editorial columns on the issue circulated the world, various foreign governments, civil society organizations, Indian Diaspora, *inter alia*, poured the supplies to help the country and in this process, an initiative based on public-private model emerged by the name of "Global Task Force on Pandemic Response",[56] which was tasked to check the gap between what is available and what might be needed.

The task force was quick enough to supply 1,000 ventilator beds, 25,000 oxygen concentrators, and other COVID relief material, in a phase-wise manner,[57] this task force is well-funded and has a long list of billionaire CEO's, founders, of big tech conglomerates and from other

[53] Thiru, *Israel issues compulsory license to allow the government to import generic versions of Kaletra*, KNOWLEDGE ECOL. INT'L (May 28, 2021, 07:45 PM), https://www.keionline.org/32503.

[54] Ed Silverman, *AbbVie will allow generic copies of HIV pill in Israel after the government approved a license*, STAT (May 28, 2021, 07:47 PM), https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/.

[55] Reuters Staff, *Moderna will not enforce COVID-19 vaccine patents during pandemic*, REUTERS (May 28, 2021, 11:09 PM), https://www.reuters.com/article/health-coronavirus-moderna-idUSL4N2GZ2D6.

[56] U.S. CHAMBER OF COMMERCE, https://www.uschamber.com/international/international-policy/global-task-force-pandemic-response, (last visited May 29, 2021).

[57] PTI, *Sunder Pichai, Punit Renjen and Shantanu Narayen join steering committee of Global Task Force on Pandemic Response*, ET (May 29, 2021, 11:05 AM), https://economictimes.indiatimes.com/nri/migrate/sunder-pichai-punit-renjen-and-shantanu-narayen-join-steering-committee-of-global-task-force-on-pandemic-response/articleshow/82449223.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst.

businesses, such as Google, Apple, Amazon, Walmart International, etc.[58] Since now India is witnessing a steady fall in the daily cases and consequently, the demand for COVID relief material is also decreasing, the task force has gradually steered its resources to other regions as well. The primary aim of the task force now should be on the production and availability of vaccines, with its diverse capabilities, reach to many nations, and abundance of resources, the task force has a great potential to somehow lower the vaccine crisis, and with new names adding to the list of billionaires their pooled resources are just going to amplify.

7.2 Voluntary licensing

Everyone, including international agencies and governments, should admire and underpin the efforts of pharmaceutical companies to shoot up the manufacturing capacity of COVID-19 vaccines by way of voluntary licensing, counting with terms of direct funding, assisting with the supply of raw materials, and overcoming production congestion. Voluntary licensing, in the context of pharmaceuticals, means when a creator or inventor holds any IPR over a product, it grants them exclusive right over that product and even authenticates to enter in voluntary licensing contract with any third party such as a generic producer based in another country, to produce and sell as per the agreed terms.

Voluntary licensing is a concept which is used to increase the production and availability of that product. This phenomenon has been practiced several times during the ongoing pandemic at both the national and trans-national levels, for instance, Gilead Sciences (GILD), the producer of antiviral drug Remdesivir was sanctioned for emergency use by the US Food and Drug Administration (FDA) and European Medicine Agency in 2020.[59] As the demand heightened worldwide, Gilead issued a non-exclusive voluntary license to producers in countries such as India, Pakistan, and Egypt to level up the production and supply in the low and middle-income countries, the producers, also, received the assistance and requisite know-how to seamlessly produce the drug.[60]

---

[58] BUSINESSWIRE, https://www.businesswire.com/news/home/20210505005914/en/Global-Task-Force-on-Pandemic-Response-Launched-by-Leading-Companies-and-Business-Associations-to-Address-Urgent-COVID-19-Surges, (last visited May 29, 2021).

[59] U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment (last visited May 30, 2021); EUROPEAN MEDICINES AGENCY, https://www.ema.europa.eu/en/news/first-covid-19-treatment-recommended-eu-authorisation (last visited May 30, 2021).

[60] GILEAD, https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir, (last visited May 30, 2021).

U.K. based developer AstraZeneca in partnership with Oxford University was among the first ones to roll out COVID-19 vaccines, and was also first the major producer to have voluntarily pledged to grant licenses in developing countries and signed sub-license agreements with Serum Institute of India (SII)[61], Fiocruz (Brazil)[62] and R-Pharm (Russia).[63] More emphasis should be on voluntary licensing since it is a tried and tested method that has accelerated vaccine supply in different regions, rather than on a principle that has no concrete studies. Coordination between governments and developers on rigid policy terms and the use of suitable persuasion techniques, coupled with a regular supply of raw materials will elicit more voluntary licensing contracts.

7.3 Sharing clinical data

The sharing of relevant clinical data and research knowledge will eliminate the doubling-up of efforts and consequently pace up the production. Yielding clinical data will also facilitate in abridging the timeline before the production process, as clinical experiments, review of the outcome by the central board, mandatory approvals by various committees, *inter alia*, can take several months and delay the production. There have been some instances of such voluntary collaborative efforts but limited to domestic boundaries. The 'COVID-19 Clinical Research Coalition' is the only major transnational coalition of scientists, policymakers, physicians, and funders, which promote open source sharing of research knowledge and data. [64]

The major focus of the coalition is to provide easily accessible clinical data in regions with fragile healthcare systems. Adding up more members and sustainable funding will help in bringing down the dependency on the countries with major pharmaceutical industries since now it will be relatively easy to produce antiviral medicines and other COVID relief material. The vaccine developers can also pool in their data and research in this initiative to stimulate the development process and the LDC's can, atleast, begin with the vaccination program,

[61] ASTRAZENECA, https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html, (last visited May 30, 2021).
[62] Marcelo Rochabrun, *Brazil sign agreement to produce Astrazeneca's experimental COVID-19 vaccine*, REUTERS (May 30, 2021, 08:01 PM) https://www.reuters.com/article/us-health-coronavirus-brazil-vaccine-idUSKBN23Y0NB.
[63] Reuters Staff, *Russia's R-Pharm signs deal to make UK-developed COVID-19 vaccine*, REUTERS (May 30, 2021, 08:04 PM), https://www.reuters.com/article/us-health-coronavirus-cyber-russia-vacci-idUSKCN24I1XF.
[64] COVID-19 CLINICAL RESEARCH COALITION, https://covid19crc.org/, (last visited May 30, 2021).

however, on a small scale until there is a sufficient supply of vaccines from other infrastructural capabilities.

7.4 Technology pools

Pooling technologies are new eye-catching solutions during pandemics. It can be stated as an agreement between at least two IPR holders to group their rights related to specific technology and grant license to use these rights to a third party.[65] The Medical Patent Pool (MPP) which was established in 2010 under the initiative of 'Unitaid' was the first of its kind. The MPP negotiates an IP license agreement with pharmaceutical companies holding patents, wherein the holder can allow MPP to grant sub-license to manufacture in low and middle-income countries to sell a generic version of medicines.[66]

A global call can be made to the big manufacturers and stakeholders to pool IP, relevant data, techniques of production, and knowledge of suitable manufacturing equipment to be used for the development of vaccines to combat COVID-19. The federal/central governments and manufactures can agree to voluntarily share the blueprint of the vaccine technology with some royalty for scaling up the production. One such agreement was signed by the WHO and the President of Costa Rica in May 2020, while urging other governments to pool data.[67]

7.5 Lowering vaccine wastage count

The rise in wastage of COVID-19 vaccines is a worrying trend that needs to be curtailed; however, it is inevitable that such wastage might not occur at all, but the judicious formulation and implementation of plans can lower it to a possible extent. There are various factors that lead to wastage such as exposing the vaccines to a temperature not prescribed, failure in reaching the destination before its expiry date, mishandling of vials during transportation or at the vaccination center.[68]

The actual data on this aspect remains unclear but some instances depict the situation, like recently an African nation South Sudan, which is majorly dependent on outside forces for its

[65] WORLD HEALTH ORGANIZATION https://www.who.int/initiatives/covid-19-technology-access-pool (last visited May 30, 2021)
[66] https://medicinespatentpool.org/what-we-do/strategy/
[67] WORLD HEALTH ORGANIZATION https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action (Last visited May 30, 2021).
[68] Opinion, *Shortage and wastage: On cutting vaccine wastage*, THE HINDU (May 30, 2021, 08:01 PM), https://www.thehindu.com/opinion/editorial/shortage-and-wastage-the-hindu-editorial-on-cutting-covid-19-vaccine-wastage/article34433580.ece.

vaccination, had to discard 59,000 doses out of 191,000 received as a donation because of the failure to reach before the expiry date.[69] Also, April 2021, the French Health Minister in a statement revealed that '*25% of AstraZeneca, 20% of Moderna, and 7% of Pfizer vaccines currently go to waste in France'*.[70] In order to reduce the wastage, it is imperative to ensure that vials are not broken at any stage before administering the vaccine, moreover; a proper framework of resources is required to make sure that vaccines do not get out of their prescribed temperature bubble and reaches the destination before getting expired. It is, also, the duty of a responsible citizen to not turn away from vaccination after booking for the same; only a collaborative effort will successfully lower the wastage count.

7.6 Serious enforcement of Article 66(2) and 67 of the TRIPS

The TRIPS agreement mandates the developed countries to take measures to '*promote and encourage the transfer of technology to the LDC'* in order to set up sophisticated facilities, and for ensuring smooth implementation of this agreement, as per Article 66(2) and 67 of the TRIPS,[71] respectively. However, despite the existence of the provisions since the very beginning, developed countries have failed to provide the same. The current crisis has highlighted the need for strict interpretation and serious enforcement of these provisions, to prepare them for the uncertainties in the future.

8. CONCLUSION

The world was unprepared for the sudden outbreak of COVID-19, and the only way to mitigate its intensity is to inoculate a sizeable proportion of people around the world. The shortage of vaccines arose because of two major factors; one, developed nations have been able to stock the majority of the vaccines, and two, there is a limited supply of raw materials required to manufacture more doses. Some other factors associated are low manufacturing capacity, obsolete distribution network, lack of training of human resources, and presence of few highest levels of bio-safety facilities. As per many middle and low-income countries, the visible solution is a waiver of IPR's, namely patents, copyrights, trade secrets, and industrial designs. This demand for waiver, though highly optimistic but is not feasible in its approach, as it will

[69] Nimi Princewill, *African countries have struggled to secure enough Covid-19 vaccines. So why are thousands of doses going to waste?*, CNN (May 30, 2021, 10:16 PM), https://edition.cnn.com/2021/05/19/africa/covid-19-vaccine-wastage-africa-intl-cmd/index.html.

[70] Annabelle Timsit, How many vaccines go to waste, QUARTZ (May 30, 2021, 10:20 PM), https://qz.com/2013918/some-countries-are-wasting-more-covid-19-vaccines-than-others/.

[71] TRIPS, *supra* note 46; *see also supra* note 50 at 243.

not magically increase the access of COVID-19 vaccines, but will affect the willingness of the pharmaceutical industry to resolve the issue. A waiver might guarantee the seamless production lines but not the manufacturing know-how, as no treaty or law binds the manufacturers to reveal them. Moreover, there is no theory which substantiates that patent waiver will bring the desired results.

There has also been a major shift in the outlook of manufacturers towards the patent laws, leaving few, as the industry which was known for using all sorts of tricks to protect their patents irrespective of the situation, has been firm during the ongoing crisis, and took humanitarian steps like voluntary licensing to accelerate and diversify the manufacturing units to different regions of the world. Recently, countries like Canada and Germany,[72] have relaxed the provisions for compulsory licensing without any resistance from the pharmaceutical industry.

It has already been more than 7 months since the waiver proposal at the WTO but still, there are no signs of consensus, instead of indulging in this maze the main focus should be on ramping up the production and availability of raw materials and establishing more manufacturing facilities with the assistance of medical professionals, as they will play a pivotal role in increasing the supply. Only a united effort by all the governments, medical professionals, and citizens will help in surviving the ongoing pandemic, as no one is safe until we all are safe.

[72] Times Now Digital, *Compulsory licensing in COVID-19: Does it differ from the global HIV/AIDS pandemic?*, TN NEWS (May 30, 2021, 05:00 PM), https://www.timesnownews.com/international/article/compulsory-licensing-in-covid-19-does-it-differ-from-the-global-hivaids-pandemic/607451.