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

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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.

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.

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.

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

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[1] Emma Farge, Michael Shields, "This virus may never go away,' WHO says", *REUTERS,* May 13, 2020, *available at* https://www.reuters.com/article/us-health-coronavirus-who-briefing-idUSKBN22P2IJ (last visited on May 14, 2021).
[2] Claire Felter "A Guide to Global COVID-19 Vaccine Effort", *Council on Foreign .Relations*. 8 (2021).

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.

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'.[3] 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.[4] 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*',[5] 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.[6]

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

[3] Dr. Amir Khan, "What is 'vaccine nationalism' and why is it so harmful?"*, ALJAZEERA,* February 7, 2021, *available at* https://www.aljazeera.com/features/2021/2/7/what-is-vaccine-nationalism-and-why-is-it-so-harmful (last visited on May 14, 2021).
[4] Oxfam International, *available at* https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19, (last visited on May 14, 2021).
[5] PTI, "Rich countries hoarding COVID-19 vaccines, says South African President, Cyril Ramaphosa"*, THE HINDU*, January 27, 2021, *available at* https://www.thehindu.com/news/international/rich-countries-hoarding-covid-vaccines-says-south-african-president-ramaphosa/article33671697.ece. (last visited on May 14, 2021).
[6] International Covenant on Economic, Social and Cultural Rights, 1966, art. 12.

their population,[7] due to which now they are comfortable in easing the restrictive measures,[8] whereas the developing and least-developed ones are still battling and losing thousands of lives each passing day.

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.*[9] Intellectual property is protected by law through patents, copyright, trademarks, industrial designs, geographical indications (GI), and trade secrets,[10] 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.

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.[11] 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. Article 7 of the TRIPS Agreement describes the objectives of the IP system in terms of a balance of rights and obligations,[12] 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.

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

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[7] Our World in Data, https://ourworldindata.org/covid-vaccinations?country=OWID_WRL, (last visited May 16, 2021).
[8] PTI, "Covid-19 | U.S. allows fully vaccinated people to forgo masks indoors"*, THE HINDU*, May 14, 2021, *available at* https://www.thehindu.com/news/international/covid-19-us-allows-fully-vaccinated-people-to-forgo-masks-indoors/article34553190.ece (last visited on May 16, 2021); *see also* Francesca Gillett, "Covid-19: Lockdowns ease in England, Wales and most of Scotland"*, BBC*, May 17, 2021 *available at* https://www.bbc.com/news/uk-57136140 (last visited on May 17, 2021).
[9] WIPO, *available at* https://www.wipo.int/about-ip/en/, (last visited May 17, 2021).
[10] WIPO, "What is Intellectual Property*?*", *available at* https://www.wipo.int/edocs/pubdocs/en/wipo_pub_450_2020.pdf (last visited May 18, 2021).
[11] Hilde Stevens et al., "Vaccines: Accelerating Innovation and Access", *available at* https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_16.pdf. (last visited May 18, 2021).
[12] Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, [*hereinafter* TRIPS].

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,[13] 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.

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 developed immunity*".[14] The proposal was supported by a majority of middle-income countries but the developed nations have categorically rebuffed the proposal,[15] however, the US under the newly elected President has recently changed its stance but not the others,[16] 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).[17]

South Africa,[18] Brazil and Thailand,[19] have been victims of these rigid patent laws to face the ire of developed countries. Such events can stall a country's efforts for a mass immunization

[13] Anna Lanoszka, "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries", 24 (2) *International Political Science Review* 190 (2003).
[14] James Bacchus, "An unnecessary Propsal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines"*, Cato Insitute*, December 16, 2020, *available at* https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines (last visited on May 18, 2021).
[15] Ann Danaiya Usher, "South Africa and India push for COVID-19 patents ban", 396 *The Lancent* 1790 (2020)
[16] Ministry of External Affairs, *available at* https://www.mea.gov.in/press-releases.htm?dtl/33848/Sta0tement+on+the+US+support+for+TRIPS+Waiver, (last visited on May 18, 2021).

[17] *Supra* note 13, at 187; *see also* Office of the United States Trade Representative, *available at* https://ustr.gov/issue-areas/intellectual-property/Special-301, (last visited on May 19, 2021).
[18] Lee Gillespie-White et al., "Patent process and access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa", *International Intellectual Property Institute* 14 (2002).

program for years. 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.

WHY PATENT WAIVER WILL NOT SOLVE THE CRISIS?

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,[20] 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.[21] 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,[22] 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

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[19] 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 *Journal of International Economic Law* 980 (2007).

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

[21] VMPA Study, "Vaccine Manufacturing and Procurement in Africa", *available at* https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf (last visited on May 20, 2021).

[22] Nicole Lurie, Jakob P. Cramer & Richard J. Hatchett, "The Vaccine Revolution", 100 *Foreign Affairs* 129-130 (2021).

capability, supply chain, quality check, availability for cold chain system for live virus vaccines,[23] 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:

1.1. 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.[24] 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.[25]

The American pharma industry, alone, spends more than $70 billion every year in R&D,[26] and the stance of a patent waiver will put such countries at odds with the pharmaceutical industry.[27] 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.

1.2. 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;

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[23] Ana Santos Rutschman, "The Intellectual Property of Vaccines: Takeaways From Recent Infectious Disease Outbreaks", 118 *Michigan Law Review Online* 174 (2020).
[24] Stephen Ezell and Nigel Cory, "The Forward for Intellectual Property Internationally, Information Technology and Innovation Foundation", *Information Technology and Innovation Foundation,* April 25, 2019, *available at* https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally (last accessed on May 23, 2021).
[25] *Supra* note 14.
[26] Congressional Budget Office, *available at* https://www.cbo.gov/publication/57126, (last visited May 24, 2021).
[27] Saeed Shah, "Developing Countries Push to Limit Patent Protection for Covid-19 Vaccines", *Wall Street Journal*, September 17, 2020, https://www.wsj.com/articles/developing-countries-push-to-limit-patent-protections-for-covid-vaccines-11600355170 (last visited on May 24, 2021).

waiver will make it more difficult for distribution of vaccine.[28] The protection of IP not only provides incentives for 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.

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,[29] 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.

1.3. 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,[30] and it will be further dragged on to the next meeting. So far, in the past 7 months, there have been 10 rounds of inconclusive meetings,[31] 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

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[28] U.S. Chamber of Commerce, *available at* https://www.uschamber.com/press-release/us-chamber-statement-proposed-wto-ip-rights-waiver, (last visited on May 24, 2021).
[29] Jamie Grierson, "Fake Covid vaccine and test certificate market is growing, researchers say", *The Guardian,* May 16, 2021, *available at*: https://www.theguardian.com/world/2021/may/16/fake-covid-vaccine-and-test-certificate-market-is-growing-researchers-say (last visited on May 27, 2021); *see also* AFP, "Pfizer confirms fake vaccine shots on sale in Mexico Poland: Reports*"*, *Deccan Herald*, Apr 22, 2021, *available at*: https://www.deccanherald.com/international/world-news-politics/pfizer-confirms-fake-vaccine-shots-on-sale-in-mexico-poland-reports-977126.html (last visited on May 27, 2021).
[30] Craig VanGrasstek, "The History and the Future of the World Trade Organization", *available at*: https://www.wto.org/english/res_e/booksp_e/historywto_e.pdf. (last visited on May 27, 2021).
[31] Philip Blenkinsop, "Explainer: COVID-19 vaccine patent waiver talks could still take months*"*, *Reuters,* May 6, 2021, *available at*: https://www.reuters.com/business/healthcare-pharmaceuticals/covid-19-vaccine-patent-waiver-talks-could-still-takemonths-2021-05-06/ (last visited on May 27, 2021).

highly sophisticated facility,[32] *inter alia*, moreover, building those facilities and making them certified and operational will take time, money, and precious expertise.

HOW COMPULSORY LICENSING IS A FEASIBLE ALTERNATIVE?

Instead of patent waiver, some experts are in favor of compulsory licensing for ramping up the production,[33] Article 31 of the TRIPS, allows a member country to opt for compulsory licensing,[34] 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,[35] which paves the way for early access to the license. Earlier, there used to be few limitations in the article which curtailed the countries with a license to supply only within the domestic limits,[36] 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,[37] 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

[32] Professor V.K. Unni, "Covid-19 and Vaccine Equity: Does a patent waiver matter*"*, *Forbes*, May 20, 2021, *available at*: https://www.forbesindia.com/article/iim-calcutta/covid19-and-vaccine-equity-does-a-patent-waiver-matter/68039/1 (last visited on May 28, 2021).
[33]. Kirtika Suneja, "Must open license regime to push vaccine, drug supply: Experts*"*, *The Economic Times*, May 3, 2021, *available at:* https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/must-open-licence-regime-to-push-vax-drug-supply-experts/articleshow/82360413.cms?from=mdr (last visited on May 28, 2021).
[34] *Supra* note 12, art. 31.
[35] *Ibid.*
[36] *Ibid.*
[37] World Trade Organization, *available at*: https://www.who.int/medicines/areas/policy/doha_declaration/en/, (last visited May on 28, 2021).

major generic producers,[38] 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.[39] 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.[40]

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 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,[41] the patent holder AbbVie, an American based manufacturer, denied to sue the country in the light of pandemic.[42] Vaccine giant Moderna has already refused to enforce its patents during the ongoing pandemic,[43] it is seen as an attempt to not discourage others who are willing and have the expertise to make similar technology-based vaccines.

THE WAY AHEAD

[38] World Trade Organization, *available at*: https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm, (last visited on May 28, 2021).
[39] World Trade Organization, *available at*: https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm, (last visited on May 28, 2021).
[40] Monirul Azam, *"*Has the TRIPS Waiver Helped the LDC's Progress Towards Innovation and Compliance*?"*, 1 *Open Book Publisher* 246 (2016); *see also* 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 *University of Missouri-Kansas City Law Review* 286-88 (2007).
[41] Thiru, "Israel issues compulsory license to allow the government to import generic versions of Kaletra"*,* *Knowledge Ecology International,* March 23, 2020, *available at*, https://www.keionline.org/32503 (last visited on May 28, 2021).
[42] Ed Silverman, "AbbVie will allow generic copies of HIV pill in Israel after the government approved a license*",* *Stat*, March 20, 2020, *available at*: https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/ (last visited on May 28, 2021).
[43] Reuters Staff, "Moderna will not enforce COVID-19 vaccine patents during pandemic*"*, *Reuters*, Oct 8, 2020, *available at*: https://www.reuters.com/article/health-coronavirus-moderna-idUSL4N2GZ2D6 (last visited on May 28, 2021).

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",[44] 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,[45] this task force is well-funded and has a long list of billionaire CEO's, founders, of big tech conglomerates and from other businesses, such as Google, Apple, Amazon, Walmart International, etc.[46] 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.

Voluntary licensing

[44] U.S. Chambers of Commerce, *available at*: https://www.uschamber.com/international/international-policy/global-task-force-pandemic-response, (last visited on May 29, 2021).

[45] PTI, "Sunder Pichai, Punit Renjen and Shantanu Narayen join steering committee of Global Task Force on Pandemic Response*", The Economic Times*, May 7, 2021, *available at* 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 (last visited on May 29, 2021).

[46] Businesswire, *available at*: 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 on May 29, 2021).

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.[47] 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.[48]

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),[49] Fiocruz (Brazil),[50] and R-Pharm (Russia).[51] More emphasis should be

[47] U.S. Food & Drug Administration, *available at*: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment (last visited on May 30, 2021); European Medicines Agency, *available at*: https://www.ema.europa.eu/en/news/first-covid-19-treatment-recommended-eu-authorisation (last visited on May 30, 2021).
[48] Gilead, *available at*: https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir, (last visited on May 30, 2021).
[49] Astrazeneca, *available at*: 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 on May 30, 2021).
[50] Marcelo Rochabrun, "Brazil sign agreement to produce Astrazeneca's experimental COVID-19 vaccine", *Reuters*, June 27, 2020, *available at*: https://www.reuters.com/article/us-health-coronavirus-brazil-vaccine-idUSKBN23Y0NB (last visited on May 30, 2021).

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.

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. [52]

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.

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.[53]

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[51] Reuters Staff, "Russia's R-Pharm signs deal to make UK-developed COVID-19 vaccine", *Reuters*, July 17, 2020, *available at*: https://www.reuters.com/article/us-health-coronavirus-cyber-russia-vacci-idUSKCN24I1XF (last visited on May 30, 2021).
[52] COVID-19 Clinical Research Coalition, *available at*: https://covid19crc.org/, (last visited on May 30, 2021).
[53] Opinion, "Shortage and wastage: On cutting vaccine wastage", *The Hindu*, April 29, 2021, *available at*: https://www.thehindu.com/opinion/editorial/shortage-and-wastage-the-hindu-editorial-on-cutting-covid-19-vaccine-wastage/article34433580.ece (last visited on May 30, 2021).

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 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.[54] 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.

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,[55] 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.

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

[54] Nimi Princewill, "African countries have struggled to secure enough Covid-19 vaccines. So why are thousands of doses going to waste?", *CNN*, May 19, 2020, *available at*: https://edition.cnn.com/2021/05/19/africa/covid-19-vaccine-wastage-africa-intl-cmd/index.html (last visited on May 30, 2021).
[55] *Supra* note 46; *see also supra* note 40 at 243.

for waiver, though highly optimistic but is not feasible in its approach, as it will 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,[56] 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.

[56] Times Now Digital, "Compulsory licensing in COVID-19: Does it differ from the global HIV/AIDS pandemic?", *Times Now News*, June 16, 20201, *available at*: https://www.timesnownews.com/international/article/compulsory-licensing-in-covid-19-does-it-differ-from-the-global-hivaids-pandemic/607451 (last visited on May 30, 2021).