The debate around the access to vaccine and licensing amidst second wave of COVID-19 in India

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Abstract
The guardian of global health signified a “global response” to contain COVID 19 utilising the platform of World Health Organization when the novel virus strain was spreading. The nature of “waves,” that is, variable epidemiological patterns and peaks in trajectory, have been inconsistent and myriad in different regions and countries. Many researchers and scholars have deliberated on the possible ways forward to curb or mitigate the effects of the virus; and one such means is through universal vaccination. Hence, this article explores the positions to achieve that goal by looking at the licensing aspect and IP waiver debate and suggests a fine-tuning which balances all the interests, amidst the second wave in India.

KEYWORDS
compulsory licensing, COVID-19, intellectual property, IP waiver, second wave of COVID-19

1 | INTRODUCTION

The World Health Organization (WHO) declared COVID-19 as a pandemic last year on March 11, 2020 (WHO, 2020). As on May 25, 2021, the pandemic has resulted in 167,011,807 confirmed cases including 3,472,068 deaths (WHO, 2021d). The “right to health” is a sacrosanct right under the Indian Constitution and almost all human right treaties/conventions to which India is a party and an active member. The COVID-19 has also impacted the socio-economic health of the world in general and caused huge losses (Gruszczynski, 2020). Every minute about nine people lose their lives to COVID-19 (WHO, 2021c). Even the World Trade Organization (WTO) recognised the unprecedented disruption to world trade due to pandemic (WTO, 2020a). Therefore the longer the virus stays the worse the impacts will be and it calls for swift response. It has been recognised in several studies published, that the vaccine is the most powerful tool to contain the spread and prevent casualties (WHO, 2021b). Without delving...
深人于医学科学的领域，下一个需要解决的问题是，如何在最短的时间内以最高的效率对人口进行接种。回到经济的最根本原理，疫苗的供应需要增加以满足需求，以避免短缺。

作者探索了印度法律与国际秩序的界面。因此，许可和知识产权的豁免被讨论，涉及到支持者和反对者的论点。在识别其缺点和不足之后，作者提出了某些建议，通过采取平衡的方法，满足所有利益相关者的需求，并专注于印度的视角（图1）。

1.1 | 事实

印度的COVID-19每日病例在2021年3月开始呈指数增长。曲线在2021年5月8日达到峰值391,232例，之后开始逐渐下降，由于限制和封锁。2021年5月7日，印度（282.37）超越法国（276.11）成为每日报告病例最多的国家（每百万人口）（Ritchie，2020）。类似的情况也发生在死亡人数上。的确诊死亡人数在2021年3月后迅速增加，印度从5月15日开始每天记录超过4000例死亡，这是自那时以来的最高死亡率——约每百万人口3例——是那时最高的。

1.2 | 情况严重性

缺乏对病毒的压制和时间的损失导致了因变异而反复出现的情况。在印度，第二波是由B.1.617（一种SARS-CoV-2变种）引起的，被世界卫生组织（WHO）宣布为“值得关注的变异”。印度卫生部长在27届COVID-19小组会议上承认，65%的病例是由于B.1.617（印度时报，2021）。科学家K Vijay Raghavan——印度政府首席科学顾问，预测如果情况得不到控制，印度可能会面临第三个波，这将对年轻人口造成严重影响，因为其传染性和严重性更高（金融时报，2021）。感染人数与后COVID-19病例数呈正比。

图1 | 来自John Hopkins University CSSE COVID-19数据（2021年）[Color figure can be viewed at wileyonlinelibrary.com]

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syndrome and mucormycosis (commonly called “black fungus”) which has a startling mortality rate of 50% (Biswas, 2021). Therefore, it calls for an overhaul of the whole process aimed to expedite production and make vaccines more accessible.

2 | VACCINES

Vaccines, unlike conventional drugs, require the highest standards of quality, efficacy and safety for satisfying the regulatory framework. The framework ensures that its benefits outweigh the risks (or side effects) in dealing with deadly infections like COVID-19 (WHO, 2021a).

2.1 | The commitment

The UN in 2015 formulated 17 Sustainable Development Goals (SDGs) under 2030 Agenda. COVID-19 falls within the 3rd SDG which deals with the health of people (UN SDGs, 2020). Further, the UN adopted “Comprehensive and coordinated response to the coronavirus disease (COVID-19) pandemic" and "United response against global health threats: combating COVID-19" (GA/12262), acknowledging the pandemic as a global concern and calling for collaborative efforts to deal with the virus (United Nations, 2020).

The ongoing 74th World Health Assembly (WHO, 2021e) has again highlighted equitable access to COVID-19 vaccines, especially to health and care workers like the previous 73rd World Health Assembly Resolution on "COVID-19 response," vide WHA 73.1.

2.2 | WHO’s vaccine proactiveness

The WHO assesses and evaluates the efficacy of the vaccine to combat COVID-19 outbreak from the global perspective while granting Emergency Use Listing (EUL). EUL is an exceptional mechanism invoked by WHO in public health emergencies where candidates propose their Expression of Interest before WHO for approval of an investigational vaccine. The process is fast-tracked on the principle of larger benefit to the target population that outweighs the risk of its use to make the vaccine more accessible. The respective National Regulatory Authorities (NRAs) aid WHO in assessment of the vaccine candidate. As yet, six candidates are approved under EUL (Table 1).

2.3 | Vaccine candidates in India

In India, nationwide vaccination drive was rolled out on January 16, 2021 (BusinessToday.In, 2021) after approval of two vaccine candidates on January 3, 2021 which need to be administered in two doses. First, Serum Institute of India, Pune, vaccine candidate “Covishield” (recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2) is a license and technology transfer from AstraZeneca/Oxford University candidate (AZD1222). Second, “Covaxin” (whole virion inactivated coronavirus Vaccine) is an indigenously manufactured candidate by Bharat Biotech International Ltd. in collaboration with ICMR and NIV (Pune). Notwithstanding the candidate not yet getting the EUL seal of the WHO, it is being used for inoculation in India and some other countries. However, the GoI aims to push for the same before WHO to instill confidence among people and other countries which are a bit sceptical (Parashar, 2021). Third, the emergency use approval by CDSCO was obtained recently for Sputnik V vaccine developed by Gamaleya Research Institute of Epidemiology and Microbiology in a tie up with local player Dr. Reddy’s Laboratories through the Russian Direct Investment Fund (Table 2).
| ID | Manufacturer | Vaccine name | NRA of record | Platform | Anticipated decision date |
|----|--------------|--------------|---------------|----------|--------------------------|
| 1  | Pfizer/BioNTech | BNT162b2/COMIRNATY/Tozinameran | European Medicines Agency | Nucleoside modified mNRA | December 31, 2020 |
| 2  | AstraZeneca/University of Oxford | AZD1222 | European Medicines Agency | Recombinant ChAdOx1 adenoviral vector encoding the spike protein antigen of the SARS-CoV-2 | April 16, 2021 |
| 3  | SK Bioscience - AstraZeneca/University of Oxford | AZD1222 | Korean Ministry of Food and Drug Safety | Recombinant ChAdOx1 adenoviral vector encoding the spike protein antigen of the SARS-CoV-2 | February 15, 2021 |
| 4  | Serum Institute of India | Covishield | Drugs Controller General of India | Recombinant ChAdOx1 adenoviral vector encoding the spike protein antigen of the SARS-CoV-2 | February 15, 2021 |
| 5  | Janssen | Ad26.COV2.S | European Medicines Agency | Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) spike (S) protein | March 12, 2021 |
| 6  | Sinopharm (CNBG) Beijing | SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) | China National Medical Products Administration | Inactivated, produced in Vero cells | May 7, 2021 |

Abbreviations: EOI, expression of interest; EUL, emergency use listing; NRA, National Regulatory Authority.
3.1 | Voluntary license (VL)

A VL, simply put, refers to a private contractual arrangement between IP holders and the manufacturers to develop a generic version of medicine in which the patent subsists. The idea behind this is that it is generally accompanied by the transfer of know-how by the licensor to the licensee as per the royalty/premium decided at the time of execution of the license. It may be a nonexclusive arrangement where such license rights are transferred to multiple players in the form of a patent pool.

Case study—Remdesivir, meant to treat Ebola virus was suggested to be effective against the current COVID-19 also- it dealt with a method for treating Arenaviridae and coronaviridae virus infection (Sheahanan et al., 2020). The parent Co. of the drug provided nonexclusive voluntary licensing agreements to generic manufacturers like Cipla Ltd., Dr. Reddy’s Laboratories Ltd., Eva Pharma, Ferozsons Laboratories, and so forth, which covered as many as 127 countries including India and Pakistan (Gilead, 2021). The cost factor also reduced due to this in developing countries because of generic players.

3.1.1 | Drawback of VL

However the drawback in this arrangement is the “voluntariness.” The IP holder holds discretion in terms of allocating licenses and undoubtedly profit making is the driving force for such negotiations to mature. FICCI said in a recent statement “facilitate technology transfer and VLs to Indian companies that have the capacity and capability for mass-production of COVID vaccines” (Saluja, 2021). But this, albeit ideal scenario, is a weak obligation on part of the IP holder without any bindingness further supplemented by the fact that licensees compete against each other and it is unlikely that a generic from a developing country can overpass the one from the advanced nations. Many had prebooked supplies and contracted for the licence through internal mechanisms much earlier at the development stage.

3.2 | Compulsory license (CL)

CLs, on the other hand, permit generic manufacturers to produce what can be called “copycat versions” of patented drugs which can be sold at much cheaper rates as compared to the patented drug in the event of

| S. No. | Country/territory | Approval date | Vaccine name | Vaccine developer | Manufacturer |
|--------|-------------------|---------------|--------------|------------------|--------------|
| 1      | India             | 03/01/2021    | Covaxin      | Bharat Biotech   | Bharat Biotech |
| 2      | India             | 03/01/2021    | Covishield   | AstraZeneca      | Serum Institute of India |
| 3      | India             | 13/04/2021    | Sputnik V    | Gamaleya Research Institute | Dr. Reddy's |
| 4      | India             | 13/04/2021    | Sputnik V    | Gamaleya Research Institute | Gamaleya Research Institute |

Abbreviation: EUA, emergency use approval.
exceptional circumstances like public health crises. The terms of license ensure the royalty/premium to the IP holder at a “fair rate” as per the local respective intellectual property office. The genesis of CL lies in the Doha Declaration (2001) on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement by WTO, which provides for emergency-like situations when CL can be invoked. More particularly, Article 31 of the TRIPS permits CL for WTO members.

In India, Bayer v Natco\(^5\) was the only instance of grant of CL in favour of Natco (generic Co.) with respect to the drug sorafenib tosylate (anticancer drug) on ground of nonworking of the patent, that is, less availability (Bonadio, 2012). More recently, Natco, has yet again filed a CL request under Section 92\(^6\) for “Baricitinib” (used for treatment of COVID-19) citing public needs, essentially the affordability and the access.

Notwithstanding the fact that CL brought down the price of the drug (after Bayer v Natco\(^7\)), Natco was capable enough to know the “technology” behind the drug which is not the case with vaccines as they are complex trade secrets especially in light of COVID-19 (O’Sullivan et al., 2021). Therefore invoking the provision only “for the sake” would do no good under the myth of “enhanced production” but instead harm innovation.

3.2.1 | Drawback of CL

Two essentials for success of CL (Hilty et al., 2021):

1. Actual manufacturing capacity and facilities
2. Necessary expertise

Even if India satisfies point 1 it perhaps falls short on 2. As it is not a simple small-molecule drug or traditional vaccines but messenger RNA (mRNA)-based candidate which pose bigger challenges (Stolberg, 2021). Further, political and internal calculations are involved in CL as it is a domestic call of respective govt. Therefore, given the position of India on the WTO forum for IP waiver, invoking CL would weaken the case of shortage and stifle drug manufacturers to negotiate voluntarily with IP holders abroad in future. This is due to determination of “fairness” of license fee which is comparatively low as the ultimate discretion lies with the domestic courts.

4 | THE WAIVER DEBATE

TRIPS flexibilities were highlighted in South Centre’s policy brief (Syam, 2020)—like Article 73(b)—any action under public emergency, Article 66.1—transitional waivers for LDC members of WTO, Article 6—parallel importation. Building upon Article 66 of the TRIPS Agreement, India-South Africa jointly proposed at the WTO for an IP waiver. In nutshell, it calls for nonenforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement for waiving off allied patents, industrial designs, copyright, and protection of undisclosed information etc. associated with the vaccines and other COVID-related drugs (WTO, 2020b). Thereupon, the situation would be reviewed annually to determine the time period of such waiver. Therefore two schools of thoughts primarily emerge—one, which considers IP as an impediment/wall blocking the ability of countries to rapidly procure and produce; and second, which backs the exclusive IP rights granted to the inventors for the progress of science.

4.1 | Discussion

The author believes that mere presence of a provision of IP waiver in TRIPS does not mean that invoking it ought to be beneficial much like the CL (drawing an analogy, *just because you have yogic flexibility does not mean you over-stretch lest it...*
may even cause injury. It is not justified and ethical to punish all innovators (IP holders) by threatening their investment for the wrongdoings of a few, who refuse licensing on "objective grounds" as such refusals are only exceptional (Hilty et al., 2021).

Notwithstanding Moderna's vaccine patent, it pledged not to enforce the same (Shores, 2020). However, roughly after 6 months, it's CEO Stéphane Bancel indicated in a conference that the waiver had nothing to do with the mRNA vaccine's access, as "people don't know how to make it" (Jimenez, 2021). This is in addition to repercussions which might occur if the IP holder/manufacturer reduces its own self-production. This directly conveys the message that if IP is waived, the holders would be reluctant to give marketing authorisation licence, that is, in terms of providing the safety and quality standards and sharing required data and know-how (Hilty et al., 2021). Therefore, the delay is imminent as the generics would have to de novo prove 2 things—first, the similarity with the reference vaccine candidate; second, rule out the differences (clinically) on counts of safety and efficacy.

Lastly, the disincentive effect would writ large in the minds of innovators and operate as a dangerous precedent for the future. As many vaccines were actually researched and developed before, not initially intended for COVID-19. Patents filed (for other diseases) indicate the development and research even before the virus news had spread to the world—Moderna filed as early as September 4, 2018, for Patent No.: US 10,064,959B2 (Moderna, 2021). Hence a delayed response (due to delayed research in future) than COVID-19 would not be surprising.

5 | SUGGESTIONS

5.1 | Other initiatives

The COVAX initiative launched in mid-2020 has proved as a major support towards equitable access to vaccines. It is a vaccine arm of the umbrella moment- Access to COVID-19 Tools Accelerator striving for affordable, safe and effective vaccines. Stakeholders include, CEPI, Gavi, WHO, UNICEF, the World Bank, respective member governments, and manufacturers. Over 70 million doses to 126 countries since February have been realised (Hatchett et al., 2021). Notwithstanding more countries supporting this initiative (France, Germany, Italy, New Zealand, Spain, Sweden, and the UAE), It is now time for other better-off ones to shun the "vaccine nationalism" and donate the doses for the vulnerable populace as a global public good. Recent Rome Declaration by G20 countries highlighting technology sharing via COVAX and pooling mechanisms indicate the commitment to end the pandemic (European Union, 2021).

C-TAP (WHO COVID-19 Technology Access Pool) along with Medicines Patent Pool, the Tech Access Partnership, or the Open COVID Pledge, aims to promote pledges for pooling the patent to make it affordable. "Solidarity Call to Action" is one such initiative for IP sharing (WHO, 2021f). All such initiatives are global voluntary efforts acting as a sharing mechanism meant to discourage selfish vaccine conservatism. Though they show what nations ought to do, they impose no bindingness as such. It is expected in good-faith that stakeholders come-forward to alleviate the spread and help the needy regions somewhat like the idea of Vasudhaiva Kutumbakam (a Sanskrit phrase meaning “The World is One Family”).

5.2 | Supply chain effectiveness

Effective and efficient supply chain is key to control the virus. This includes logistics, raw materials supply (upstream, downstream), local storages, other/ancillary supplies, ImpEx flexibility, removal of export restrictions, and so forth, under COVID-19 exemptions and levy. The more lubricated and well-managed the setup is, the better will be the production capabilities. This is attributed to "scaling up" and "speeding up" of the entire machinery which ultimately will shoot up the supply to meet the demand curve. It is not just essential, but need of the hour, because unlike other policy reforms for vaccine equitability, this can be implemented as soon as possible to mitigate the
deaths and cases and address challenges in the short-run, till a decision or consensus is reached wrt patent waiver or other suggested route.

Thomas Cueni, director-general of the International Federation of Pharmaceutical Manufacturers and Associations had also remarked these as “bottlenecks” (to "The Lancet"), created due to inefficient—"sourcing of scarce ingredients, trained technicians, necessary stringent quality checks, as well as other logistic and regulatory challenges (Zarocostas, 2021)."

5.3  |  The production triangle in Indian context

Last but not the least, today, transboundary companies or ventures are very common due to multilateralism and inter-connectedness. Fisher et al. (2021) gives examples of the Government of Uganda’s National Drug Policy, 2002, and National Strategic Plan (2007-2012) to locally produce drugs to tackle AIDS; similarly Ethiopia’s “Health Sector Development Plan” (partnered with the WHO); and Pharmaceutical Manufacturing Plan for Africa in 2008—all intended to revive local manufacturing of drugs by providing technical assistance, business linkage, Good Manufacturing Practice (GMP) and sustainability via strategic partnerships.

The idea here is that the external player possesses the same object as that of the local player. The profit/equity shares can be allocated and decided in the agreement. Thus, this objective can be achieved by “tactical alliance” or "Joint venture-JV" (a kind of “strategic partnership" with the local player). The IP holder can then provide the adequate technology transfer and utilise local player’s production capabilities. Cipla Pharmaceuticals-Quality Chemicals JV is therefore a template where even the government of Uganda possessed a stake in the first plant. Such an arrangement is referred to as “production triangle” as it involves three primary players in developing a world-class facility (Fisher et al., 2021).

In India, albeit in a different context, Hero-Honda (Hero Group and Japan-based Honda Motor Co.) was one such successful JV. The terms in such arrangement are governed by contractual obligations entered into by parties, as JV is not a company, as such. Such ventures after passing the scrutiny of a sectoral regulator like Central Drugs Standard Control Organization (India’s NRA under WHO) can come up with a local production hub with state of the art GMP and know-how. Other stakeholders like the Ministry of Health and Family Welfare, DCGI, and Invest India (Indian investment Agency) can act as a facilitator under this model to smoothen and fasten the process. This model is also in alignment with GoI’s “Vocal For Local” campaign. The idea is also in sync with the "third way," as suggested by Okonjo-Iweala (Director General-WTO), referring to equitable technology transfer that is ensured within the multilateral framework and commitment (Zarocostas, 2021).

6  |  CONCLUSION

Dr. Reddy’s Laboratories-Gamaleya Research Institute of Epidemiology and Microbiology tie-up for Sputnik V vaccine is a step in this direction (the production triangle), but the GoI needs to get proactively involved not just as a facilitator but also as a purchaser of the stocks/stakes for a designated locking period (a formula between the central and state govt. for purchases may be designed) to encourage such investments in future as it plans to administer doses free of cost/subsidised rates. These proposals without hampering innovation in the long run (the fact that COVID-19 is not the last such virulent disease), address access to healthcare via alternate means in a quick manner and perhaps entail lesser time for enforcement. Whereas IP waivers or CLs possess drawbacks and need global consensus or face local challenges which need time for enforcement.

Ricardian law of comparative advantage, in simple terms highlights the notion of- **do what you are good at**. In international trade, there exists no uniform production and in a world with diversified specialization, reward based technical transfer ought to entail minimum social cost and do overall public good. This is because, in such tie-ups,
the vaccine need not be reverse engineered (time, infra wastage due to resource misutilization) due to lack of know-how. India's generic manufacturing capability needs to be utilised for its own as well as overall global good (WION Web, 2021).

The extremist views either calling for a waiver/CL or a vaccine nationalism are both harmful (to be utilised only if all "other possible ways" are exhausted). Instead a synthesis between the two approaches (a hybrid model) which increases "voluntariness" of the IP holder to enter into a contract should be looked upon, as suggested from the discussions above. It is a win-win arrangement for all stakeholders as it results in—scale up, speed up, better marketing/advertisement, IP holders' interest fulfilling altruistic justifications of IP (Bonadio & Baldini, 2020) to establish favourable conditions for collaboration, exchange and for speeding up the process of scientific discovery. Such a cocktail of best practices from all available flexibilities can be a tailor made approach, acceptable to all, would strengthen Global Health Security (Assefa et al., 2020) and would act as a better precedent for future outbreaks. It would therefore balance relative opportunity costs of countries and companies towards an equitable and rewards based lucrative setup.

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CONFLICT OF INTERESTS
The authors declare that there are no conflict of interests.

NOTE
This article was written before May 2021 and the situation prevailing at that point in time. The facts and figures might have changed with passage of time when this article is accepted for publication. The author has declared that no competing interests exist that have influenced the text and this piece is his unbiased opinion.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the corresponding author upon reasonable request.

ENDNOTES
1 Article 21 of Indian Constitution includes "right to health" under the umbrella of "right to life or personal liberty" available at https://legislative.gov.in/sites/default/files/COI-updated-as-31072018.pdf.
2 Committee of Central Drugs Standard Control Organisation (CDSCO) approved the 2 vaccine candidates vide press statement released by Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID-19 virus vaccine on January 3, 2021. See https://www.unicef.org/supply/covid-19-vaccine-market-dashboard.
3 The domestic statute concerning Patents in India grants exclusive patent rights and lays down ways of licensing it on agreed terms. The Patents Act. (1970). (No. 39 of 1970). Retrieved from https://www.indiacode.nic.in/handle/123456789/1392?locale=en.
4 "Know-How, means all nonpublic technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, pracces, formulae, instrucrons, skills, techniques, procedures, experiences, ideas, designs, drawings, assembly procedures, soware, computer programs, apparatuses, specifications, data, results and materials, including: biological, chemical, vaccine-related, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays, and biological methodology, in all cases, whether or not copyrightable or patentable, in wrien, electronic or any other form now known or hereafter developed," quoted from Lonza Ltd. (2021, February 2). Global long term agreement, Exhibit 10.2. Retrieved May 28, 2021, from https://www.sec.gov/Archives/edgar/data/1682852/000168285220000023/lonzamodernagltafullye.htm.
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