The Clash Between Public Interest and Private Interest: A Critical Analysis of Intellectual Property Rights in the Vaccine Context

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Abstract

The underdeveloped states are facing bitter health outcomes. The social and economic systems are on the verge of breaking down. Even working at full exhaustion, the health care facilities have failed to fulfil the surging demands. The "global" pandemic calls for "global" action as each passing day is costing precious human lives. The deteriorating situation begs for humane and selfless action. This study highlights the inadequacies of the present-day intellectual property legal framework that has negated equitable access to vaccines. Public health concerns beg the waiver of intellectual property rights as the flexibilities offered by relevant law are symbolic when it comes to vaccine manufacturing. It is high time for world leaders to sit and formulate a viable solution and, till such time, intellectual property rights should be waived.

Introduction

The central issue in the fight against the COVID pandemic is an unrestricted demand for immunisation.[1] Seth Berkley, the CEO of Global Vaccine Alliance ("Gavi"),[2] expressed his concern about the inadequate supply of COVID vaccines to the underdeveloped world at the time when the outbreak was declared a public health emergency and not a global epidemic. He remarked: "The thing we have to think about now that's different is, how do we produce vaccines specifically for the developing world if this is a truly global epidemic."[3]

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[1] As quicker the substantial world populace gets immune, the better it will be to stop further spreading. For better understanding read, Gypsyamber D'Souza; David Dowdy, 'What is Herd Immunity and How Can We Achieve It With COVID-19?' (*Johns Hopkins Bloomberg School of Public Health Expert Insights*, last updated 6 April 2021) <https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html> accessed 7 July 2021.

[2] A public-private partnership, GAVI was established on the onset of the twenty first century with the aim of facilitating the access to crucial vaccine to (with an aim to facilitate access to) poorer nations as per the innovative model by supporting funds pooling and prioritizing national immunization efforts.

[3] Michael Igoe, 'Will vaccines reach low-income countries during a global pandemic?' *Devex* (Washington, 26 February 2020) <https://www.devex.com/news/will-vaccines-reach-low-income-countries-during-a-global-pandemic-96635> accessed 7 July 2021.

The present study first explains the internationally accepted innovation protection mechanisms that are relevant to vaccine development: patents and trade secrets. This is followed by an analysis of the shortcomings of the flexibility of compulsory licencing in the vaccine context which is argued by the opponents of waiver as being sufficient. Next, the foreseeable practice of the pharmaceutical industry, accounting for substantial vaccine development against the deadly pandemic if the current protection regime remains intact, is discussed.

The current pattern of vaccine agreements with pharmaceutical giants has ignited a debate over the consequential inequity resulting from unequal distribution.[4] On the one hand, giant economies have bound prominent pharmaceutical companies to supply vaccines on a priority basis to states which have already vaccinated half of their population. In contrast, there are states which have yet to report a case of vaccine administration. Such unequal distribution of vaccines will adversely affect the pace at which the world recovers from the COVID pandemic.[5]

The crucial issue attached to it is the mutations in the genetic makeup of the virus responsible for this communicable disease.[6] Mutations make even those vaccinated for one variant vulnerable to other variants, therefore making an end to pandemic unforeseeable.[7] The prevailing situation demands herd immunity at the international level, which, researchers believe is the only viable solution to get rid of this pandemic.[8] It is

[4] A recent book comprising the compilation of essays by various writers is a comprehensive study on the debate over the nexus between the IP regime and public health emergency. Srividhya Ragavan, Amaka Vanni (eds.), *Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals* (1st edn, Routledge 2021).

[5] The countries opposing the patent waiver are steady in vaccinating their populations. For example, the statistics of vaccinated persons (minimum of one dosage) per 100 persons for some of the waiver opponents are: UK= 119.6; Germany= 100.5; China= 98.28; European Union= 93.56; Canada=116.2; Switzerland=93.98. On the other hand, the statistics of some patent waiver proponents are: South Africa=7.65; India=28.36; Pakistan= 9.54; Afghanistan= 2.63; Bangladesh=6.14; Iran= 7.77. The disparity in the number of individuals vaccinated with the minimum of one dose per 100 persons in the countries quoted above highlights the shortcomings of the current distribution pattern. Source: *Our World in Data*: Statistics and Research – Coronavirus (Covid-19) Vaccinations, as updated on July 14, 2021.

[6] The vulnerabilities of administered vaccines to the viral mutations are highlighted in number of recent studies. See for example, Jiahui Chen; Kaifu Gao; Rui Wang; Guo-Wei Wei, 'Prediction and mitigation of mutation threats to COVID-19 vaccines and antibody therapies' (2021) 12(20) Chemical Science 6929.

[7] Studies suggests that the alpha variant proved to be less threatening than the currently rapidly spreading delta variant and research is underway for assessing the efficacy of the vaccines against it. The role of booster administration is also relevant here as is discussed by WHO in 'The effects of virus variants on COVID-19 vaccines' – A part of WHO's Vaccines Explained Series.

[8] In reaching the desired immunisation of eighty per cent of the world population the challenges involved are systematically highlighted by Roy M Anderson; Carolin Vegvari; James Truscott; Benjamin S Collyer, 'Challenges in creating herd immunity to SARS-CoV-2 infection by mass vaccination' (2020) 396 The Lancet, 1614-1616.

achievable when all the states, from developed economies to underdeveloped states (with or without the capacity to produce the vaccination), have equal access to the vaccines, leading to vaccine-induced herd immunity. Higher demand for vaccines by the world's largest economies has negated the supply to poorer states in practical terms.[9]

These correlated issues stem from the lack of bargaining powers held by poor economies, vaccine nationalism, and the inability of rampant vaccine production steered by the World Health Organisation ("WHO"). The Trade-Related Aspects of Intellectual Property Agreement ("TRIPS Agreement") is argued by majority states as a major clog to the equitable and expeditious access to vaccines.[10] The pharmaceutical giants have the patent protection under the said agreement that runs for twenty years,[11] within which they potentially make an exorbitant amount of profits on the actual investments spent on their first-time production.[12] The proponents of patent waiver argue that waiting twenty years for production to start at optimal levels, engaging all the producers to counter global demands of vaccines, is humiliating in the given situation where each passing day is crucial to the survival of human lives. One clear manifestation is India, which can cater to the substantial world demand for vaccines, as is called the pharmacy for the developing

[9] Romesh Vaitilingam, 'Vaccines for developing countries: the costs and benefits of waiving patents' *LSC Business Review* (London, 20 May 2021) <https://blogs.lse.ac.uk/businessreview/2021/05/20/vaccines-for-developing-countries-the-costs-and-benefits-of-waiving-patents/> accessed 22 June 2021; OECD, 'Coronavirus (COVID-19)vaccines for developing countries: An equal shot at recovery,' (4 February 2021) <https://read.oecd-ilibrary.org/view/?ref=1060_1060300-enj5o5xnwj&title=Coronavirus-COVID-19-vaccines-for-developing-countries-An-equal-shot-at-recovery&_ga=2.32886398.1780262466.1634965783-636226196.1634965783> accessed 25 June 2021.

[10] The proposal before WTO to waive some of the provisions of TRIPS Agreement was laid down by India and South Africa primarily and till date, more than 100 states have backed the waiver proposal. The recent US shift from anti-waiver to the pro-waiver state under Biden's administration is seen by many as an optimistic sign. Max Bearak; Emily Rauhala, 'Hopes surge for boosted vaccine supply after U.S. voices support for waiving patents, even as uncertainty remains' *Washington Post* (Washington, 6 May 2021) <https://www.washingtonpost.com/world/2021/05/06/vaccine-intellectual-property-world-reaction/> accessed 8 July 2021. The said pro-patent move is credited, to certain extent, to the joint effort of former world leaders and other eminent personalities who urged the Biden government to change its stance because they knew that the US stance is definitely going to impact the outcome of WTO Ministerial meetings. Less than a month later the US announced its support for waiver. Rebecca Trager, 'US urged to waive Covid-19 vaccine patents' *Chemistry World* (London, 22 April 2021) <https://www.chemistryworld.com/news/us-urged-to-waive-covid-19-vaccine-patents/4013574.article> accessed 9 July 2021.

[11] TRIPS Agreement 1995, art 33.

[12] For the want of the intrinsic motivation, the patent incentive has led to civic damage. Finding a solution for good of all is negated by the patent regime in the public health crises. Julia Kollewe, 'From Pfizer to Moderna: who's making billions from Covid-19 vaccines?' *The Guardian* (London, 6 March 2021) <https://www.theguardian.com/business/2021/mar/06/from-pfizer-to-moderna-whos-making-billions-from-covid-vaccines> accessed 9 July 2021.

countries.[13] Nevertheless, India is incapable of playing the role and one reason for its incapacity is the patent restriction (except for some like the SERUM Institute agreement with AstraZeneca, but with the licensor controlling the recipients). India is miserably affected by the lack of a sufficient number of vaccines since vaccine centres have to shut their doors for the public after every few days for want of more vaccines.

Thus, this sparks a debate amongst members of the World Trade Organisation ("WTO") to waive the intellectual property ("IP") rights during the emergency whereby developing states would be able to produce generic versions of vaccines in their domestic markets without fear of reprisal from patent owners. Unanimous approval is needed from one hundred and sixty-four WTO members whereby every member state will be allowed to play the role they are capable off but to date are cuffed by the IP system. The waiver demand has the backing of international organisations like Médecins Sans Frontieres, that are stressing the need to take steps which allow rapid mass production of COVID vaccines for catering to global demand.[14]

"It is about saving lives at the end, not protecting systems."

Dr Maria Guevara – Doctors without borders

There are different protective mechanisms for innovations under the TRIPS Agreement. The most debatable in terms of COVID vaccine manufacturing are patents, data exclusivity, and trade secrets. The patent is a monopoly granted to the inventor for the invention for twenty years.[15] The trade secrets are, unlike patents, not made public due to their nature and include the know-how of the invention, which the owner intends to keep a secret. Such protection is permanent (unless disclosed) and is carried out usually by non-disclosure agreements.[16] Though the debate mostly surrounds the patent waiver, yet the writer believes the disclosure of otherwise protected trade secrets is essential for getting the intended benefits from patent waiver. It is not possible to cook something without knowing the ingredients or recipe. To avoid reverse-engineering which can be done easily to form replicas, patents play a key role. However, where the good is manufactured in a way that the reversal is not enough to understand the method of

13 Lahariya, C., 'A brief history of vaccines & vaccination in India' ([2014]) 139(4), 491-511, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078488/ accessed 25 September 2023.

[14] Global solidarity as has been so often declared during current pandemic must be delivered on as is asserted in a press release by Médecins Sans Frontières, 'Countries obstructing COVID-19 patent waiver must allow negotiations to start' (*MSF*, 9 Mar 2021) <https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations> accessed 10 July 2021.

[15] TRIPS Agreement 1995, art 33. The member states are debarred from refusing the registration of covid-19 related patents under Article 27 of said agreement.

[16] TRIPS Agreement 1995, art 39.

manufacturing, then trade secrets best serve the purpose whereby the essential know-how remains within few hands and is not made public.[17] Confidentiality pledge by key employees is one mode of maintaining such secrets. Trade-secret protection generally lasts longer than patent protection. These protections are obstacles during emergencies, as the world is witnessing today. Solely waiving the patent will not work as is evident from the 2020 Moderna decision not to enforce vaccine patent, as without technological transfer and share of know-how, such non-enforcement of the patent is futile.[18] This exhibits its symbolic and nominal empathy of not enforcing the patent.[19] The need is the waiver of both patent and trade secrets essential for scaling up COVID vaccine production.

Waiving Intellectual Property Rights: A Step in the Right Direction

The world is in dire crisis with the current terrible pandemic. Emergencies and unprecedented situations demand innovative solutions as old methods do not suffice. The current IP provisions in the TRIPS agreement have caused an "artificial scarcity" of vaccines for two main reasons: either the states cannot afford the prices at which they are sold (as the charitable initiatives are not sufficient) or the production of vaccines is slow compared to their exponential demand. Suspending IP rights is unusual but justified in accounting for the inadequate and inequitable supplies of vaccines to the developing and underdeveloped nations. Waving IP rights would enable countries around the globe to use patented invention in the making of generic bio-products without the fear of being sued by the pharmaceutical companies which own such patents.

Although waiving patent rights directly benefit the less privileged nations; it undoubtedly has an indirect benefit for even the richer states. This benefit is because when of the world population (eighty percent) is immunised, this will help achieve global herd immunity—the only way out from the novel pandemic situation that knows no boundaries.[20] Besides being the right thing to do, making vaccines available to poorer

[17] Michael Risch, 'Why Do We Have Trade Secrets?' (2007) 11(1) Marquette Intellectual Property Law Review.
[18] Zachary Brennan, 'Moderna CEO brushes off US support for IP waiver, eyes more than $19B in Covid-19 vaccine sales in 2021' *ENDPOINTS* (6 May 2021) <https://endpts.com/moderna-ceo-brushes-off-us-support-for-ip-waiver-eyes-more-than-19b-in-covid-19-vaccine-sales-in-2021/> accessed 14 July 2021.
[19] Carl O'donnell; Manas Mishra, 'Moderna sees no impact on COVID-19 vaccine from potential patent waiver' *Reuters* (London, 6 May 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-raises-2021-sales-forecast-covid-19-vaccine-192-bln-2021-05-06/> accessed 13 July 2021.
[20] Suneel Prajapati; Narasimha Kumar GV, 'Assumption of Herd Immunity against COVID-19: A Plausibility and Hope or a Terrible Thought in Modern-Day to Save the Life' (2020) 6(24) Journal of Infectious Diseases and Epidemiology 147.

countries is in the self-interest of First World countries. Furthermore, improving the manufacturing capacity of the developing world is another point of debate.

Extreme situations require extraordinary measures. It is also a fact that not enough vaccines are manufactured to cope with the surging demand,[21] and to waive vaccine-related IP rights is one step amongst many that should be taken to bring mankind out of the pandemic. Other measures include rectifying supply chains,[22] establishing complex bio-manufacturing facilities, transferring technology from companies, and so on. All these steps need to be cumulatively taken as a global collaboration to make it possible for all individuals around the world to get vaccinated in the fastest possible time.

There is an obvious tendency that states will prioritize looking after their own citizens who have elected them. Yet, humanity demands a collective fight against the deadly COVID pandemic. Viruses do not respect borders. Man cannot live in isolation in this increasingly interconnected and tightly knit world. With the contagious viruses, no one is protected unless and until the majority gets vaccinated.[23] The immunisation of the majority should be done, within the given time frame, to curb the mutating virus that potentially escapes the effect of a vaccine manufactured for a particular genetic sequence.

Five major COVID vaccine producers account for over ninety per cent of all vaccines produced globally.[24] Waiver proponents assert that production needs to happen faster for tackling mutating viruses. During emergencies like the COVID pandemic, IP rights should not be enforced, even under the TRIPS Agreement. The demand for waiving IP rights is to make sure that countries around the globe can increase production and manufacture enough supply to meet the ever-increasing demand.[25] Furthermore, more

[21] Rebecca Forman, Soleil Shah, Patrick Jeurissen, Mark Jit, Elias Mossialos, 'COVID-19 vaccine challenges: What have we learned so far and what remains to be done?' (2021) 125 Health Policy 553.
[22] Hannah Schofield; Lavan Thasarathakumar, 'Blockchain, COVID-19 and the Pharmaceutical Supply Chain' (*PharmExec*, 12 May 2021) <https://www.pharmexec.com/view/blockchain-covid-19-and-the-pharmaceutical-supply-chain> accessed 11 July 2021.
[23] The said need was emphasised by the President of European Commission Ursula von der Leyen at Brussels State of the Union conference of the European University Institute on 6 May 2021 (available at https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_2284) but his speech was essentially restrictive in a sense that it was unresponsive of the global effort needed.
[24] The supplies from pharmaceutical giants are limited for over-promised and under-delivered doses. The rich economies have dominantly been the recipient of such doses leaving poor nations to face the threats posed by ruthless virus. Mark Eccleston-Turner; Harry Upton, "International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility" (2021) 99(2) Milbank Quarterly 426, 428.
[25] The first and the foremost reason for the vaccine scarcity is the under production. Mario Gaviria; Burcu Kilic, 'BioNTech and Pfizer's BNT162 Vaccine Patent Landscape' (*Public Citizen*, 16 Nov 2020) <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/> accessed 11 July

manufacturers in more countries could drive prices down, though some manufacturers like AstraZeneca and Jonson & Johnson have vowed to provide vaccines on a non-profit basis during the pandemic. As of the time of this writing, some hundred countries, mainly led by India and South Africa, have demanded WTO to suspend certain patent rules contained in the TRIPS Agreement. [26] Such a waiver would overcome legal barriers that prevent manufacturers from producing generic versions of vaccines. The waiver can act as a stimulus for making availability of vaccines more equitable. More than eighty percent of vaccines produced go to rich and middle-income countries, leading to predictions that mass vaccination in underdeveloped countries may not occur until 2024 or later if the same distribution patterns continue.[27] The richer countries that have the capacity of bulk buying vaccines and even booking them in advance are the ones opposing the waiver. One of the reasons for the opposition is that these states are housing some giant pharmaceutical companies.

Shortcoming of the Existing Intellectual Property Legal Framework

The TRIPS Agreement came into force in 1995.[28] It was established after developed countries negotiated with developing and underdeveloped states to reach an agreement that allowed for the monetization of intellectual property rights.[29] Over time, as the provisions become clearer in their application, it faced criticism which it is still facing.

2021. For immunising majority of world citizens, the demand is of 11 billion doses while currently the capacity stands at less than 4 billion doses. Ellen't Hoen, 'Covid shows the world it needs new rules to deal with pandemics' (*Big Issue North*, 25 May 2021) <https://www.bigissuenorth.com/features/2021/05/covid-shows-the-world-it-needs-new-rules-to-deal-with-pandemics/#close> accessed 12 July 2021.

[26] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 'Waiver from certain provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19 Communication from India and South Africa' IP/C/W/669 – (WTO, 2 Oct 2020) <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>. Later on an amended proposal was put forward by number of states on 21 May 2021 (available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>. The later proposal acknowledged that patent waiver is not sufficient unless the essential know-how is transferred.

[27] Saeed Shah; Drew Hinshaw; Gabriele Steinhauser, 'Covid-19 Vaccine Patent Waivers Could Take Months to Benefit Developing Nations' (2021) The Wall Street Journal <https://www.wsj.com/articles/covid-19-vaccine-patent-waivers-could-take-months-to-benefit-developing-nations-11620332442> accessed 10 July 2021.

[28] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[29] The objective of TRIPS Agreement as laid down in Article 7 states "The promotion and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

The Doha Declaration of 2001 was a victory for the developing states and organisations that secured certain flexibilities in the TRIPS Agreement in the public health sector. Utilisation of patents was allowed to the states under certain conditions even where patent holders did not permit its usage - the compulsory licencing. Yet the scope of said mode is limited which will be discussed later in the article. The debate on the incompatibility between the TRIPS Agreement provisions and public health is old. Ban Ki-Moon, General Secretary of the United Nations, highlighted in his report of 2016 the disagreement between the public health policy and the practical application of innovation protection laws. The debate on the said agreement has once again ignited in the backdrop of a deadly pandemic as a compact IP web protects the vaccine and the vaccine-producing platforms.[30]

I. Limitations Imposed by Patents

The normative construction of the patent protection under the TRIPS Agreement does account for the disclosure of protected innovation, but its mechanism is insufficient and inadequate. The information disclosed in the patent application is, first, not technical enough to provide any assistance.[31] Secondly, such information is placed at the public disposal for "usage" in public health crisis once the patent life expires. The said limitation undermines the essence of the patent protection regime and undermines the intention of the Uruguay Round negotiators.

Moreover, once the patent is granted, no further revelation of adequate knowledge is demanded whereby the manufacturing process has improved. This inadequacy of the information disclosed is a clog to the COVID vaccine production. The problem is further aggravated by the gap between the filing of a patent application and the grant of a patent, during which time the public is unaware even of such inadequate knowledge. The manufacturers further employ different tactics to prolong the patent protection, such as modifying the original patent application with slight changes and filing modified applications from time to time, thus enjoying protection thereunder.[32] This makes the

[30] Mario Gaviria; Burcu Kilic, 'A network analysis of COVID-19 mRNA vaccine patents' (2021) 39 Nature Biotechnology 546.

[31] The practice suggests that the patent law is indifferent to enabling knowledge that is useful in actual production as is asserted in H. Samuel Frost, 'The Unique Problem of Inventions Which Are Fully Enabled and Fully Described, But Not Fully Understood (Merrell Dow's Terfenadine Revisited)' (2007) Intellectual Property Journal <https://www.bereskinparr.com/files/file/docs/PatentTerfenadineFrost.pdf> accessed 16 July 2021.

[32] For instance, 165 patent applications are associated with the cancer treating drug Imbruvica by AbbVie covering the identical essential content thereby exaggerating the duration of patent protection well beyond the twenty years. For details see, I-Mak, 'Overpatented, Overpriced Imbruvica's Patent Wall' (*I-Mak*. last

time-duration of patent protection doubtful for the competitors, especially in vaccine development which then becomes less attractive to them (though some other reasons are also responsible for making the vaccine market less attractive for investors).[33] Shortly, the extension of patent protection beyond the fixed timeframe and inadequacy of knowledge shared in patent application[34] hinders the COVID vaccine's swift development. This limits the capacity of capable manufacturers in a time where resources must be employed to their full exhaustion to defeat the pandemic that has miserably affected humanity.[35]

II. Disclosure of Know-How and Trade Secrets Inevitable

Vaccines are unique in comparison to medicines, and mere patent information does not suffice in their production.[36] Undisclosed information includes vaccine know-how, trade secrets, and clinical trial data, which the investor intends to hide from the outside world. It is essentially aimed at avoiding free riding on the energy, time, and money invested by the inventor in the research and development of the invention from scratch. If disclosed, this will tend to lower the cost of production for others. Unlike patents, the undisclosed information, as the term indicates, is not opened to the public at all. Such disclosure is the biggest concern in the rapid COVID vaccine development.[37] The reports suggest that

revised July 2020) <https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf> accessed 17 July 2021. Mark A. Lemley; Carl Shapiro, 'Probabilistic Patents' (2005) 19(2) Journal of Economic Perspectives 75.

[33] Olga Gurgula, 'Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies – Two Different Concepts Sharing Similar Features' (2017) 48 IIC - International Review of Intellectual Property and Competition Law 385.

[34] The debate over inadequacy problem linked to knowledge enclosed in patent application is old as is any other relevant issue that have surfaced again in the pandemic situation. Dan L. Burk, 'The Role of Patent Law in Knowledge Codification' (2014) 23(3) Berkeley Technology Law Journal 1009.

[35] The capable manufacturing states include India, Canada, Brazil, South Africa, Bangladesh, United Arab Emirates, Indonesia, Turkey, Ghana etc. as per Chelsea Clinton; Achal Prabhala, 'Biden Has the Power to Vaccinate the World' *The Atlantic* (Boston, 5 May 2021) <https://www.theatlantic.com/ideas/archive/2021/05/biden-has-power-vaccinate-world/618802/> accessed 17 July 2021. The said article was published before the announcement of Biden's Administration as to his support for patent waiver which will be a leverage for a pro-waiver stance in the upcoming WTO Ministerial Meeting. Biolyse, an Ontario based pharmaceutical company has attempted to obtain licence from J&J for producing generic version of its COVID vaccine comprising of single jab. Biolyse claims that it has the capacity to produce 2 million doses a month. The company has filed an application for compulsory licensing under the Canadian Access to Medicine Regime. Such efforts at national level will determine the state practice concerning compulsory licensing at this point of global public health crises. Arianna Schouten, 'Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law' (*Knowledge Ecology International,* 12 March 2021) <https://www.keionline.org/35587> accessed 17 July 2021.

[36] Mark Eccleston-Turner, 'Beyond patents: Scientific knowledge, and access to vaccine' (2017) 3(1) Ethics, Medicine and Public Health 64-73.

[37] A suggestion is made to pool up financial resources for buying the know-how to scale up vaccine mass

pharmaceuticals manufacturing vaccines have entered into confidentiality agreements that also halt their participation in global voluntary initiatives of pooling technology and know-how as a collective action (most notably COVID Technology Access Pool[38] and technology transfer hub).[39]

As discussed earlier, two main IP protections and their vitality in the construction of pharmaceutical companies need to be brought in conformity with public health policies. The said highlighting of shortcomings should not be construed to mean that the writer backs the non-waiver of IP rights claim, rather, it should be included as part and parcel of the overall bigger package, including technology share, know-how disclosure, and non-exclusionary policies at both the international and domestic level. The said package would allow manufacturers from around the world to freely engage in vaccine production, especially free from fear of the stopping of vaccines to their countries as a penalty for infringing IP protections.

The waiver proposal led by South Africa and India is a positive sign that even if the result is not the waiver, this will lead to the controlled voluntary licencing by pharmaceuticals. The absence of consensus on waiver within a reasonable time would compel joint action by WTO and WHO to address the problem that is worsening day by day.

Compulsory Licencing: An Insufficient Flexibility in a Vaccine Context

The capable producers are permitted to manufacture the product patented under the licence issued by the respective government. Compulsory licencing has been crucial in biomedical history when access to life saving "medicines" came under the limelight. The grounds for issuing such licence are not exhaustively listed in the TRIPS Agreement and are in the logical discretion of the member states. For instance, compulsory licence can

production. James Love, 'Buying Know-How to Scale Vaccine Manufacturing' (20 Mar 2021) <https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36> accessed 19 July 2021.

[38] Absence of collaboration from the manufacturers and technologically equipped countries led to the miserable failure of C-TAP. Henrique Zeferino de Menezes, 'The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines' (2021) 129 Research Papers 7 <https://www.southcentre.int/wp-content/uploads/2021/03/RP-129.pdf> accessed 17 July 2021. Ellen't Hoen, 'The elephant in the room at the WHO Executive Board' (*Medicines Law and Policy*, 22 Jan 2021) <https://medicineslawandpolicy.org/2021/01/the-elephant-in-the-room-at-the-who-executive-board/> accessed 20 July 2021.

[39] WTO, 'Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing' (16 Apr 2021) <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing> accessed 20 July 2021.

be issued for grave emergencies, where protecting the public interest is essential. Besides it, other factors can also trigger the application of compulsory licencing.[40]

TRIPS Agreement provides for resorting to compulsory licencing in situations of a grave emergency, but before that, an attempt to negotiate a voluntary licence agreement is a must. [41] Absence whereof, in the national interest, the government can issue a compulsory licence. But the layer and fragmentations of IP protections render the flexibility of compulsory licencing less suitable to vaccine development. There are other reasons as well that demand more than the mere compulsory licencing as its application limits in the context of rapid vaccine development. The overall procedure of vaccine development is not restricted to a single territory, and it is not possible to issue a blanket or an all-inclusive compulsory licence. Therefore, the said issuance needs to be country by country, and case by case, to be more impactful.[42]

The choice to impose additional requirements and criteria for compulsory licencing in domestic legislation can make the two-fold criteria more cumbersome. States are hesitant to issue compulsory licenses due to the fear of facing severe trade sanctions, as it has happened in the past. Additional protections at the regional and domestic level, such as exclusivity of clinical trial data, further obstruct vaccine development. This further prolongs the timeframe of protection.

Where a compulsory licence is issued, the inventor/manufacturer should be reimbursed adequately. It is unclear what constitutes adequate compensation in the context of vaccines. The licenced goods were, before the 2001 amendment in pursuance of the Doha Declaration, to be essential for domestic demands, yet, following the addition of Section 31 (b) in the TRIPS Agreement, the goods produced under compulsory licencing can be exported to member countries of WTO. Although reservations can be made for the said amendment, certain countries, such as the EU member states, have opted out of it.

The resort to compulsory licencing has rarely been made, for instance, when Rwanda obtained access to vaccines for AIDS, and Canadian companies exported it.

[40] MSF has very technically analysed the claims of EU as to the sufficiency of compulsory license flexibility instead of the need of COVID vaccine patent waiver and concluded that the said flexibility for number of reasons is insufficient to address the issue of mass scaling and EU should consent to patent waiver (document available at <https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF-AC_EU_CL_briefing-doc_ENG_May2021.pdf>.

[41] Article 31 of TRIPS Agreement.

[42] Siva Thambisetty and others, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end he covid 19 pandemic' (Law Society Economy Working Papers, June 2021) <https://ssrn.com/abstract=3851737> accessed 15 July 2021.

However, it is a burdensome and time-consuming step,[43] and is in no way suited to the present-day crises where each passing day is costing lives. The issue of transparency of patent protections has made it more difficult to assess the scope of applications seeking the issuance of compulsory licences. The one hope that the TRIPS Agreement waiver proposal has given is that the states are easing their domestic compulsory licencing regulations to make a case against waiver. Though it will help in the availability of diagnostic and therapeutic products, its role is limited in vaccine development. The present study suggests that compulsory licencing should not be employed as a substitution to the TRIPS Agreement waiver in addition to the waiver itself. There is no denying that in the containment of viral speed, sole compulsory licencing is insufficient, and that the advantage offered by the TRIPS Agreement waiver is multi-fold as compared to the compulsory licencing, which is limited in the ever-advancing field of technology.

Foreseeable Pharma Giants' Practices with Intact IP Protections

The goal to diminish the COVID pandemic with the least loss of lives is undermined by the monetary benefits yielded from the monopoly market. The issue is not as simple as it might appear. The wait for mass inoculation in under-developing countries might be prolonged even after the richer economies have fully vaccinated their populations because there are cases reported around the world where even vaccine administered individuals are ailing. Some are dying due to the transmission of the mutated virus that can suppress the effect of the administered vaccine. Here, the role of boosters comes into play. Some countries have even announced the booster shots administration starting from health care workers (for instance, Thailand).[44]

The foreseeable situation would be that, on the one hand, fully vaccinated will be given dosages of boosters and on the other extreme, the citizens of poorer nations will be dying for want of dosage of the vaccine in the first instance. If the IP waiver does not take place now, the world would probably see a decline in the manufacturing of COVID vaccines once their demand by prosperous economies is fulfilled. Waiving IP then would be the denial of equal human rights, especially when each passing day is critical. In the absence of any incentive from the poorer nations, the powerful pharmaceutical companies

[43] Holger P. Hestermeyer, 'Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines' (2007) 11(28) ASIL Insights <https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and> accessed 17 July 2021.

[44] In people with low immune response to Sinopharm vaccine (manufactured by China), UAE has offered a booster dose already. Sui-Lee Wee, 'The U.A.E. offers a third dose of Chinese vaccine to some with low immune response' *The New York Times* (New York, 22 Mar 2021 <https://www.nytimes.com/2021/03/22/world/the-uae-offers-a-third-dose-of-chinese-vaccine-to-some-with-low-immune-response.html> accessed 22 July 2021.

would then turn to the race of booster manufacturing by agreeing with giant bargaining powers.[45]

"To deny people their human rights are to challenge their very humanity."

Nelson Mandela

Impact of Waiver on Future Innovations: A Negation to Claims of Waiver Opponents

There is a dichotomy of expert opinions on the impact of the IP waiver. On one side, the opponents of waiver see it as a hindrance to future research and industrial development in vaccine production.[46] Placing advanced technologies in the public domain will undermine potential developments. While the other side argues that a temporary waiver is an ideal solution to convert the pandemic to an endemic without having many repercussions for pharmaceuticals.

Arguments for incentive-based innovation find little to no support from the existing literature. Even if one admits that innovation stems from the hope of profit, then the same cannot be said for COVID vaccines owing to the way they have developed. There is substantial public funding that has been invested into the research and development ("R&D") of COVID vaccines, and breakthroughs have taken place in universities and national health institutes.[47] This weakens the case for patenting the vaccines and the trade secrets specialised for vaccines manufactured on public subsidies. The specialization of COVID vaccines is not justified where there are zero risks for

[45] Nicky Phillips, 'The coronavirus is here to stay — here's what that means' (*Nature*, 16 Feb 2021) <https://www.nature.com/articles/d41586-021-00396-2> accessed 21 July 2021.

[46] Human Rights Watch (HRW) has come up with the reasons that why the claims of European Union, the major waiver opponent, are false. HRW argues that IP does clog rapid vaccine manufacturing, the patent serves as a stimulus for technology transfer, COVAX initiative or dose-sharing insufficient to meet global demand, a tentative waiver is not a clog on future invention and compulsory licensing is welcoming but not sufficient. Human Rights Watch, 'Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver' (*HRW*, 3 June 2021) <https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver> accessed 24 July 2021.

[47] For instance, more than 2.5 billion dollars is funded to Moderna by US government and thus US "has unique leverage" with it. James Krellenstein; Christian Urrutia, 'Hit Hard Hit Fast Hit Globally a Model for Global Vaccine Access' (*PrEP4All*, 2021) <https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/6054fdd855fb270753f4b0c9/1616182745295/P4A+-+Hit+Hard+Hit+Fast+Hit+Globally+Report.pdf> accessed 25 July 2021.

incentives and profits are attached to development as the governments have entered into advance agreements.[48] The COVAX initiative further secures the return on investments.

Monopoly is created by patent protection for a specified time, that prohibits any competition during such time. This implies choice as to the fixation of price and the dissipation of the technology shared with the patent owners, assuming dominance. Thus, the production of commodified goods can be restricted during the life of a patent. This is troublesome for public health policies. Pharmaceuticals are constructed on this patent protection system, and the outcomes of such basis are evident in the prevailing COVID crises.[49] The fact that the majority of WHO-approved vaccines had substantial reliance on public fundraising[50] makes a stronger case for the availability of the vaccine to the world population and that the manufacturers have no right to monopolise over what has not been economically afforded by them. The breakthrough in the duration in which these vaccines are made available for use is accredited to the integral role played by public sectors. The products are still specialised, which has adversely impacted the proportionate distribution of vaccines to every corner of the globe.

Therefore, the present time calls for treating the pandemic as exceptional, and its impact should not be underscored. The current pandemic is unique and unprecedented and thus should be handled extraordinarily. The TRIPS Agreement failed to acknowledge the varying socio-economic conditions of states in pragmatic terms. Under any circumstances, the vaccine market is less attractive than the medicine market due to their relatively lower demand in higher-income countries. Vaccines are produced to combat diseases in lower and middle-income countries and are often distributed on a non-profit basis. There were instances from the past when there was a sole need to deliver vaccines

[48] Even much before the clearance of final clinical trials richer countries had secured billions of doses. Some 3.7 billion doses, as declared by pharmaceuticals in the West, have been agreed to be provided to UK, Japan, USA and EU. Saeed Shah, 'In Race to Secure Covid-19 Vaccines, World's Poorest Countries Lag Behind' (2020) The Wall Street Journal <https://www.wsj.com/articles/in-race-to-secure-covid-19-vaccines-worlds-poorest-countries-lag-behind-11598998776?mod=article_inline> accessed 15 July 2021.

[49] Duncan Matthews; Olga Gurgula, 'Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines' (2016) European Intellectual Property Review < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2779014> accessed 15 July 2021.

[50] A significant study undertaken in this regard substantiates that covid vaccines are made possible only by international collaboration and public investment. Samuel Cross and others, 'Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine?' (*medRxiv*, 10 April 2021) (preprint version), <https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded> accessed 26 July 2021. Another study suggests a very practical solution to the investment-based claim that both private and public actors have contributed in covid vaccine development therefore the innovation policy in public health sector should be seen as co-shaping the markets actively and not the intervening or a regulating one. Mariana Mazzucato; Victor Roy, 'Rethinking value in health innovation: from mystifications towards prescriptions' (2012) 22(2) Journal of Economic Policy Reform 101.

to poorer economies. The markets have often failed, especially against an effort for containing the Ebola virus. It is the best time to devise a solution to the IP framework to tackle prevailing crises and prepare a plan to combat future inequity in vaccines and medicines.

Currently, very few markets are involved in COVID vaccine production, which impedes rapid production, and even the offers made by potential manufacturers for voluntary licencing are rejected.[51] Another step that can help mitigate the scarcity of vaccines is to introduce incentive-based global policies to allow the entry of competitors into the vaccine market, which would reduce the monopoly and will account for the demand for increased production.[52] Price fixation and lack of government seeking shares in private profits from vaccines as public commodities, as discussed before, have aggravated the issue for poorer economies, which are reported to have been charged higher than others. Pfizer is charging, as the researchers suggest, six percent of the unit production cost and justifies it by saying that this would have been exponentially high had there not been a pandemic environment.[53] The poor economies do not even have the negotiation power for that. AstraZeneca is selling at the production cost, but again the issue is that the company has contractual obligations towards the richer economies. Then there are reports revealing that despite claiming no profit, Astra Zeneca is selling its vaccines at higher costs to lower and middle-income countries than to the richer due to disparity in demand.[54] All in all, the manufacturers' powers to decide the production

[51] Voluntary licensing, even where granted by pharmaceuticals, are inherently restrictive in a sense that the manufactures control autonomy over the agreed terms and conditions.

[52] Burak Kazaz; Scott Webster; Prashant Yadav, 'Incentivizing COVID-19 Vaccine Developers to Expand Manufacturing Capacity' (*Center for Global Development,* 2021) <https://www.cgdev.org/sites/default/files/incentivizing-covid-19-vaccine-developers-expand-manufacturing-capacity.pdf> accessed 24 July 2021. Subhashini Chandrasekharan and others, 'Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers' 33 Vaccine 6366-6370.

[53] Pfizer vaccine is mRNA vaccine the production cost of which is less than $3 and selling it at $19.5 during the public health emergency and yet intending to raise prices further once the acute phase of viral spread is over. Christopher Rowland, 'Pfizer coronavirus vaccine revenue is projected to hit $26 billion in 2021 with production surge' *The Washington Post* (Washington, 4 May 2021) <https://www.washingtonpost.com/business/2021/05/04/pfizer-covid-vaccine-revenue/> accessed 21 July 2021.

[54] Nick Dearden, 'AstraZeneca must justify 'unequal' vaccine pricing after bumper profit' (*Global Justice Now*, 11 February 2021) <https://www.globaljustice.org.uk/news/astrazeneca-must-justify-unequal-vaccine-pricing-after-bumper-profits/> accessed 2 July 2021. In the words of Director of GJN: "AstraZeneca's bumper profits today show the company can easily afford to provide its Covid-19 vaccine at cost price during the pandemic and beyond. But despite this pledge, it has yet to address the question of why lower-income countries like South Africa and Uganda are paying several times more per dose than the

matters, price fixation, and endemic declaration for purposes of aggravating prices when deemed suited, are less likely to solve the grave concern of vaccine equitable distribution.

It is high time to move on to think about *lex feranda* instead of continuing and defending the existing legal framework (*lex lata*) that has always been debated for its inadequacies in a public health crisis. The need of formulating alternative policies as a solution to current public health concerns and as preparedness for future public health crises is inevitable. The argument that the waiver would not be effective for want of capacity requirement is baseless as there are demands for licences by governments that do have manufacturing capacity, but the innovation protection mechanism renders the specialization of such capacity a failure. The First World countries are under the obligation to specialize the technology transfer to developing states.[55] Any reluctance, thereof, is in direct conflict with the very spirit of the TRIPS Agreement.

Burden sharing is the need of the hour, and this is not possible without a TRIPS Agreement waiver.[56] The doubtful quality of prospective generic versions of COVID vaccines, if allowed, is falsely debated by waiver opponents to be connected with IP waiver. There is no nexus between the two independent issues, and it is just being employed as a scapegoat for waiver.[57] The TRIPS Agreement waiver should also negotiate on waiving protection over raw materials necessary for vaccine production as it will then be a challenge once vaccine patents and trade secrets are removed. There is a dire need to reformulate the IP framework connected with public health emergencies in WTO, but till such time, the waiver is essential.

Resolving the issue of inequitable and inadequate distribution of COVID vaccine is essential. Besides being a public health concern, the gap in supply and demand increases the room for corrupt practices – the crimes committed in the dark – which is another challenge to tackle due to the complex processes involved down till the distribution phase.

European Union. This is not the "equitable access" AstraZeneca has been trumpeting in its press releases." South Africa is reported to be paying per dose $5.25, Uganda $7 as compared to EU $2.16.

[55] The term "shall" is used in article 66 clause 2 of TRIPS Agreement thus the provision is mandatory in character. Jayashree Watal; Leticia Caminero, 'Least-developed countries, transfer of technology and the TRIPS Agreement' *WTO Economic Research and Statistics Division* (22 February 2018) Staff Working Paper ERSD-2018-01.

[56] India is called the pharmacy for third world countries, but the facts dictate that to survive against the deadly pandemic poor nations' reliance on the generic versions of vaccines produced by Serum Institute does not suffice. Achal Prabhala; Leena Menghaney, 'The world's poorest countries are at India's mercy for vaccines. It's unsustainable' *The Guardian* (London, last updated on 23 Apr 2021) <https://www.theguardian.com/commentisfree/2021/apr/02/india-in-charge-of-developing-world-covid-vaccine-supply-unsustainable> accessed 22 July 2021.

[57] For example, successful production of Remdesivir of exportable quality in India despite the prior speculations on to the quality of it.

The secrecy of the terms and conditions of the agreement relevant to the procurement of COVID vaccines and conflicting interests are some of the aggravating factors for the risk of corrupt practices that undermine the effective implementation of emergency policies, as is reminded by the United Nations Office on Drugs and Crimes.[58] This includes, but is not limited to, the misuse of public funding that has given in huge amounts to the development of a vaccine, counterfeited vaccines, nepotism, and favouritism. The dismissal of Zimbabwean top governmental medical officials on similar grounds has heightened the risks.[59] While writing this, news from Pakistan surfaced on the detention of some suspects for allegedly plundering Pfizer vaccines from governmental stock with the aid of a vaccine administrator employed by the government and selling it for financial gains.[60] This further aggravates the artificial scarcity of the COVID vaccines. There are risks involved in the entire chain from procurement to the distribution of COVID vaccines.[61] Time is of much essence when these risks are highest because the supply is substantially low compared to the demand. The alleged corruption undermines public confidence in governmental efforts during public health emergencies.[62] Mitigating corruption risks, both at an international and domestic level, is another challenge in the equitable access to the vaccine. Transparency in the agreements over COVID vaccines is achievable through open contracts, which will minimize the corruption risk in the procurement stage.[63] At the domestic level, the viable proposal is that specialised

[58] United Nations Office on Drugs and Crime, 'Covid-19 Vaccines And Corruption Risks: Preventing Corruption In The Manufacture, Allocation And Distribution Of Vaccines' (*UNDOC Policy Papers*) <https://www.unodc.org/documents/corruption/COVID-19/Policy_paper_on_COVID19_vaccines_and_corruption_risks.pdf> accessed 27 July 2021.

[59] Matt Smith, 'The Global Vaccine Rollout Means Heightened Corruption Risk. Here's What to Know' *Barron's* (New York, 27 Mar 2021) <https://www.barrons.com/articles/the-global-vaccine-rollout-means-heightened-corruption-risk-heres-what-to-know-51616796521> accessed 27 July 2021. Zimbabwe is just one example; many other states or state individuals are targeting the vulnerabilities in the vaccine chain. Corruption is the gateway to other evils that destroys the socio-political and economic makeup of a country.

[60] Naeem Sahoutara, '3 suspects, including ex-army officer, remanded to police custody in 'illegal' Covid vaccination case' *DAWN* (Karachi, 29 July 2021) <https://www.dawn.com/news/1637619/3-suspects-including-ex-army-officer-remanded-to-police-custody-in-illegal-covid-vaccination-case> accessed 29 July 2021.

[61] J. C. Kohler; Deirdre Dimancesco, 'The risk of corruption in public pharmaceutical procurement: How anti-corruption, transparency and accountability measures may reduce this risk' (2020) 12(1) Global Health Action. The study divides the procurement system in to three phases viz pre-biding, bidding and post-bidding phase for systematically analysing the possible room form corruption in each stage.

[62] Taryn Vian, 'Review of corruption in the health sector: theory, methods and interventions' (2008) 23(2) Health Policy and Planning, 83-94.

[63] For further reference see, UNDOC, 'Guidebook on anti-corruption in public procurement and the management of public finances: Good practices in ensuring compliance with article 9 of the United Nations Convention against Corruption' (*United Nations,* September 2013) <https://www.unodc.org/documents/corruption/Publications/2013/Guidebook_on_anticorruption_in_public_procurement_and_the_management_of_public_finances.pdf> accessed 29 July 2021.

committees should be established for monitoring the entire distribution and deployment process.[64] Several guidelines have already been issued in this regard.[65] To address the scourge of corruption globally, especially during a public health emergency, United Nations Convention Against Corruption (entry into force 2005) demands international cooperation in the fight against corruption.[66] Furthermore, it is high time to strengthen the anti-corruption national legislation and fill in the gaps in the laws to mitigate any chances of manipulating the law for personal gains.

Conclusion

The world is indulged in a race to accumulate as many COVID vaccines as they can.[67] This has led to the inequitable distribution of vaccines through advance purchase agreements. One big reason is the IP protection that prevents the capable manufacturers from producing their domestic versions of vaccines which is the need of the hour as depicted by the facts. The relevant stakeholders are not serious about a consensual resolution to the problem. Therefore, mandatory action is a must to address the grave issue of the pandemic.[68] End to COVID is not just a public health concern but a socio-economic and moral concern too.[69] Demand for a patent waiver does not tantamount to asking for charity, rather it asks for an entitlement to manufacture the local vaccines without being

[64] United Nations Office on Drugs and Crime, 'Accountability and the prevention of corruption in the allocation and distribution of emergency economic rescue packages in the context and aftermath of the COVID-19 pandemic' (*United Nations*, accessed 29 July 2021) <https://www.unodc.org/documents/Advocacy-Section/COVID-19_and_Anti-Corruption-2.pdf>.

[65] For instance, UNDOC's Good Practices Compendium on Combating Corruption in the Response to COVID-19 prepared on October 16, 2020, in the G20 Saudi Arabia 2020 Riyadh Summit.

[66] The said Convention is further complemented by the United Nations Convention Against Transnational Organised Crimes enforced in 2003.

[67] Stockpiling is another grave concern as the states are entering into agreement for increasing their vaccine intake more than what is need to vaccine whole of their population amid uncertainty as to the duration of immunity and the potential escape of variant from the protective immune response. Zain Rizvi, 'Not Enough: Six Reasons Why COVID-19 Vaccine Manufacturing Must Be Rapidly Scaled-Up' *Public Citizen* (Washington, 13 May 2021) <https://www.citizen.org/article/not-enough-six-reasons-why-covid-19-vaccine-manufacturing-must-be-rapidly scaled-up/> accessed 29 July 2021.

[68] The pharmaceuticals are not interested in voluntary licensing in the first place and in the rare circumstances agreements under free licensing have led to complex issues especially when the licensee state (as India) had to divert the intended distribution of vaccine produced under such license to meet its own national demand amid the spike in viral spread.

[69] The term vaccine apartheid has also surfaced amid the unequal vaccine distribution, and "Vaccine for All" is the ultimate solution to covid vaccine and related technology hoarding. On invitation, 'Mariana Mazzucato, Jayati Ghosh; Els Torreele on waiving covid patents' *The Economist* (Washington, 20 April 2021) <https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torreele-on-waiving-covid-patents> accessed 29 July 2021. Nancy S Jecker; Caesar A Atuire, 'What's yours is ours: waiving intellectual property protections for COVID-19 vaccines' (2021) Journal of Medical Ethics <https://jme.bmj.com/content/medethics/early/2021/07/06/medethics-2021-107555.full.pdf> accessed 30 July 2021.

sued by the patent owners. The pledge made by developed countries during the Uruguay Round Negotiations of 1994 to ensure the provision of benefits of technology transfer and capacity building at the disposal of developing economies has been sabotaged by their hoarding of COVID vaccines.[70] The race for buying vaccines and even booking future production has been termed by WHO director-general Tedros Adhanom Ghebreyesus as "catastrophic moral failure," which is self-defeating, not just economically but also epidemiologically,[71] and depicts that the pandemic has unveiled the inadequate provisions of the IP mechanism.

Currently, the capacity of global production of the COVID vaccine stands at 3.5 billion doses per annum. But the required capacity is 10 billion doses per annum to immunise seventy percent of the world population. Only radical expansion of the current production capacity can meet the demand. Countries housing pharmaceutical giants are the main opposition to the waiver which have entered into advance purchase agreements with richer economies having the bargaining power. Developing and under-developed states are left to wait for the supply of a limited number of vaccines under the COVAX scheme, which is insufficient in terms of roll-out and supply to cater to the surging vaccine demands there.[72] This is a do-or-die situation. As early as the world realises it, it will be better for this planet prone to critical survival challenges. It is high time to find plausible solutions to the clash between private monopolistic gains and public health interest. The lack of empirical study on the impacts of IP rights on vaccine production is a major obstacle in reaching a logical and reality-based decision on whether it is essential to waive COVID vaccine IP rights or not, which the writer believes will help the countries in substantiating their claims in WTO meetings.

In the event of failure of the agreement on waiver demand, aggrieved states can take collaborative action under Section 73 of the TRIPS Agreement as the last option. The richer economies, most notably the United States, now supporting the waiver should also join in. The exceptional situation of pandemic and the repercussions, thereof, fit into the said section and are equal in effect to waiver. However, invoking it may face

[70] Anne Orford, 'Broken Bargains' *London Review of Books* (London, 5 May 2021) <https://www.lrb.co.uk/blog/2021/may/broken-bargains> accessed 30 July 2021. This news article highlights the way historical negotiations led to the adoption of TRIPS Agreement despite a pre-TRIPS reluctance of rich economies like EU of enforcing patents.

[71] WHO, 'WHO Director-General's opening remarks at 148th session of the Executive Board' (WHO, 18 January 2021) <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board> accessed 30 July 2021.

[72] As per UN press release the actual delivery predicted will be less than even half of the WHO intended 100 million doses by the end of 2021. Economic and Social Council, Special Meeting on Vaccine for All (ECOSOC/7039) (16 April 2021) <https://www.un.org/press/en/2021/ecosoc7039.doc.htm> accessed 30 July 2021.

challenges in resolving disputes, yet it is a strategy that merits consideration. Dr Tedros Adhanom Ghebreyesus, DG of WHO, has demanded states to be “on war footing” if they want to defeat this unprecedented pandemic. It is still not too late to take a step in the right direction of bringing global health imperatives within the sphere of international law.