"PATIENTS AND PATENTS" – NAVIGATING THE GLOBAL IP LANDSCAPE IN THE COVID-19 PANDEMIC[*]

Vidisha Singh[†]

ABSTRACT

The COVID-19 pandemic has had a ravaging impact on lives and economies all over the world. There is clear consensus among nations that no one is safe till everyone is safe. The last year has witnessed the rapid development of health technologies such as diagnostics kits, contact tracing applications and vaccines et al, which have the potential to overcome this pandemic. However, the rise of 'vaccine nationalism', as well as the lack of equitable global distributional frameworks for such technology have thwarted the global effort to succeed against COVID-19. The reasons for these problems are twofold – production incapacity and accessibility; both of which have Intellectual Property Rights (IPR) at the heart of it. This paper examines the different IPR issues involving COVID-19 health technologies and their impact on equitable access to such technologies. It draws a comparison between Low and Middle Income Countries and High Income Countries to demonstrate the disparity in the present regime and its impact on the global fight against COVID-19. In light of the proposal at the WTO to enact a temporary waiver of the Trade Related Aspects of Intellectual Property Rights Agreement [TRIPS Agreement], it analyses the different exemptions under TRIPS – Compulsory Licensing, National Security Exemption, Patent Pooling - and their impact on bridging the disparity between different nations. Following a detailed analysis of the different exemptions, it analyses the anticipated effect of the waiver on the equitable dissemination of health technologies to conclude that, in the absence of technology transfers and stronger supply chains, a waiver alone is unlikely to achieve this goal.

[*] This article has been commissioned for LAWASIA by the Anil Divan Foundation. It reflects the position of law as of 31st July, 2021.

[†] The author is a fourth year student of the B.A. LLB. (Hons.) Programme at National Law School of India University, Bangalore. She can be reached out at vidishasingh@nls.ac.in. The author would like to acknowledge and extend her heartfelt gratitude to Prof. Kishu Daswani for guiding the development of this paper with his helpful insights. The author would also like to thank Ms. Ragini Shah and Mr. Aditya Phalnikar for their valuable comments on earlier versions of this article. All errors remain mine.

I. INTRODUCTION

In December 2019, an outbreak of the novel Coronavirus in Wuhan soon manifested into a global health tragedy affecting all.[1] The World Health Organization announced COVID-19 to be a public health emergency on 30th January, 2020 and a pandemic on 11th March, 2021.[2] Various countries around the world imposed severe lockdowns to contain the virus and channelled their resources towards the development of health technologies that could detect, control and - maybe one day - put an end to this health crisis.

Less than a year from when it was officially declared as a pandemic, several vaccines against the COVID-19 pandemic had been developed by pharmaceutical companies and governments

[1] World Health Organization, 'Archived: WHO Timeline – COVID-19' available at <https://www.who.int/news/item/27-04-2020-who-timeline---covid-19> accessed on 8 July 2021.
[2] Jamie Ducharme, 'World Health Organization Declares COVID-19 a 'Pandemic.' Here's What That Means' (*TIME*, 11 March 2020) available at <https://time.com/5791661/who-coronavirus-pandemic-declaration/> accessed on 8 July 2021.

across the world. The last year has spurred the creation of numerous technologies for detecting COVID-19 infections, studying its transmission and using a variety of existing medicines to help critical patients recover. The ability to ramp up the supply of such materials, as well as developing new technologies and vaccines to combat the virus, is testament to what can be accomplished by human inventiveness and by extensive public support to the private-sector.

Yet, the present global production capacity for these vaccines and health-technologies falls short in comparison to the requirement of these goods around the world. The public-health benefits accruing from this technology are undermined by inequitable distributional frameworks. Higher Income Countries [HICs] have taken majority of the world's supply of these vaccines and other health technologies to inoculate and protect their own nations before extending help to the Lower Income Countries [LICs].[3] The pandemic is unlikely to end unless everyone, in all countries, has some form of inoculation and achieves herd immunity. This premise is already weakened by the appearance of new virus mutations, specifically in LICs, which threaten to limit the progress made so far to contain the virus. While there is no denying that the equitable distribution of health technologies is in the moral, political and economic interests of the world order, the phenomenon of 'vaccine nationalism',[4] where countries with access to these health goods reserve the bulk of the vaccines for themselves, raises serious concerns about the present legal and political frameworks for equitable distribution of health technologies.

At the heart of it, the problem with equitable distribution is two-fold – production of such technologies and access to such technologies. The present structure of global intellectual property law is inextricably linked towards solving both of these problems. The unprecedented challenge brought on by COVID-19 has led to unprecedented measures. In October 2020, India and South Africa submitted a proposal to the World Trade Organization [WTO] for a temporary waiver of all IP rights under the WTO Agreement for Trade Related Aspects of Intellectual Property Rights Agreement [TRIPs Agreement].[5] This temporary waiver calls for allowing

[3] Bridget Kuehn, 'High-Income Countries Have Secured the Bulk of COVID-19 Vaccines' (*JAMA Network*, 16 February 2021) available at <https://jamanetwork.com/journals/jama/fullarticle/2776341> accessed on 8 July 2021.

[4] Ana Santos Rutchsman, 'The Reemergence of Vaccine Nationalism' (*SFS Georgetown Journal of International Affairs*) available at <https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/> accessed on 8 July 2021.

[5] Communication from India and South Africa, 'Waiver From Certain Provisions Of The Trips Agreement For the Prevention, Containment And Treatment Of COVID-19' WTO Council for Trade-Related Aspects of Intellectual Property Rights IP/C/W/669 (2 October 2020) available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> accessed on 8 July 2021.

WTO members to not apply, enforce or implement certain IP protections applying to all COVID-19 related health technologies for the duration of the pandemic.

This paper explores the present IP regime and how it has impacted the responses of different nations to the COVID-19 pandemic. It elaborates on how the present regime has fuelled the problem of inequitable access, using examples from the COVID-19 pandemic. It analyses the exemptions available in the present IP regime, such as voluntary pledges and licensing, compulsory licensing and security exceptions, exploring their applicability in this crisis. It finally discusses the framework of a temporary TRIPs waiver and endeavours to analyse its efficacy in resolving the problems of technology transfers, capacity building and equitable access in LICs.

II. AN OVERVIEW OF THE GLOBAL RESPONSE TO COVID-19

COVID-19 prompted varying responses from different nations, depending on the extent of infections.[6] The fight against the pandemic has exacerbated existing inequalities to an unprecedented level. Health inequality exists in terms of access to diagnostics and treatment, rates of recovery, death toll and social determinants like economic stability and community health.[7]

Statistically, countries with different income groups were impacted very differently. Studies have found economic status as a major determinant of health service resilience and testing capacity,[8] which justifies the difference in responses for countries with varying income levels. Due to the concentration of technological innovation and resources in HICs, their outbreak response was much stronger, with the rapid development of contact tracing applications and diagnostics for testing.[9] In contrast, the LICs have a lower capacity of outbreak response. This has resulted in lesser testing and muted numbers for death tolls.[10]

[6] FT Visual and Data Journalism Team, 'Lockdowns compared: tracking governments' coronavirus responses' (*Financial Times*, 24 June 2021) available at <https://ig.ft.com/coronavirus-lockdowns/> accessed on 8 July 2021.
[7] Myo Neyin Aung, Yuka Koyanagi and Motoyuki Yuasa, 'Health inequality among different economies during early phase of COVID-19 pandemic' (2021) Journal of Egyptian Public Health Association, 2.
[8] Marius Gilbert, Giulia Pullano, *et al*., 'Preparedness and vulnerability of African countries against importations of COVID-19: a modelling study' (2020) 395(10227) The Lancet, 10.
[9] *ibid.*
[10] Philip Schellekens and Diego Sourouille, 'The unreal dichotomy in COVID-19 mortality between high-income and developing countries' (*Brookings*, 5 May 2020) available at <https://www.brookings.edu/blog/future-development/2020/05/05/the-unreal-dichotomy-in-covid-19-mortality-between-high-income-and-developing-countries/> accessed on 8 July 2021.

However, there is evidence to show that the severity of the pandemic was felt more acutely in HICs than in LICs, with the reported mortality heavily tilted towards HICs.[11] These numbers, although likely to be misleading due to underreporting and reduced media coverage in LICs,[12] created significant pressure on HICs to mobilise their resources and scale their solutions. Coupled with their resources and innovative capacity, these countries have been the hubs for vaccine and cutting-edge diagnostics development.[13] The most widely acclaimed vaccines, in terms of efficacy against the virus, were all developed in HICs - Pfizer/BioNTech vaccine in USA and Germany, the Moderna and Johnson & Johnson vaccines developed in the USA, the Oxford-AstraZeneca vaccine in the UK, the Sputnik vaccine in Russia, Sinovac-CoronaVac in China and Covaxin in India.[14]

Now that vaccines have been developed, these HICs have procured the bulk of the doses, with LICs being relegated to lower priorities.[15] This prioritization of local markets by a sovereign nation is known as vaccine nationalism and has been rampant in the COVID-19 pandemic.[16] This is done through pre-purchase agreements between the government and vaccine manufacturers or through export bans. Vaccine nationalism runs counter to the principle of global public health by directly disadvantaging countries with fewer resources. It has led to the allocation of vaccines to moderately at-risk populations at the expense of populations at higher risk, leading to subsequent infection cycles.[17] Given that there is presently limited production of these vaccines, and other health technologies, it is imperative to establish frameworks of equitable access to prevent recurring infection cycles occurring throughout the world.

Vaccine inequality is widening with each passing day. While HICs have approximately 16% of the world population, they have partially inoculated 20-50% of the populations and secured

[11] *ibid.*
[12] Yasmin Jahan and Atiqur Rahman, 'COVID-19: Challenges and viewpoints from low-and-middle-income Asian countries perspectives' (2020) 1(2) Journal of Safety Science and Resilience, 72.
[13] Chloe Taylor, 'This map shows where coronavirus vaccines are being tested around the world' (*CNBC*, 5 June 2020) available at <https://www.cnbc.com/2020/06/05/this-map-shows-where-coronavirus-vaccines-are-being-tested-worldwide.html> accessed on 8 July 2021.
[14] World Health Organization, 'COVID-19 Vaccine tracker and landscape' (2021) available at <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> accessed on 10 July 2021.
[15] Kuehn *supra* note 3.
[16] Ana Santos Rutchsman, 'How 'vaccine nationalism' could block vulnerable populations' access to COVID-19 vaccines' (*The Conversation*, 17 June 2020) available at <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689> accessed on 8 July 2021.
[17] *ibid.*

doses to vaccinate their entire population several times over.[18] On the contrary, LICs have received less than 2% of the available vaccine doses. This glaring disparity has caused great alarm among international organizations and civil societies, who have been led a number of initiatives for equitable vaccine access. Further, pharmaceutical companies have been pricing vaccines differently in different countries, with HICs often paying lesser prices than LICs.[19]

While most of the data in this regard is about vaccinations, it is indicative of a general healthcare infrastructure gap. While the G7 is on track to achieve 70% inoculation by 2021, most LICs will reach that number by 2024 on current trends.[20]

Responses of countries in the Asia-Pacific Region

Countries in the Asia-Pacific region were some of the first nations to be hit by the pandemic breaking out in Wuhan, China.[21] However, most Asian nations were able to control their infection rates and death tolls with greater success than in many western nations. Countries like South Korea, Japan, Taiwan, Hong Kong and Singapore were able to flatten their curves by mid-2020 and prevent subsequent large-scale infection cycles.[22] The success of these countries can be attributed to their early and stringent measures,[23] as well as their prior experience with pandemics. Most of the East-Asian countries have been hit by pandemics in the previous century – SARS in 2003, H1N1 Influenza in 2009 and MERS in 2015.[24] This experience meant that these countries were better prepared to act swiftly, with legal and organizational infrastructures in place to enact nation-wide responses.

However, a global analysis of pandemic preparedness reveals that there are glaring vulnerabilities in the health system. The presence of an older population and the burden of a

[18] Stephen Hall, Leah Kaplow, *et al*., 'None are safe until all are safe': COVID-19 vaccine rollout in low- and middle-income countries' (*McKinsey*, 23 April 2021) available at <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/none-are-safe-until-all-are-safe-covid-19-vaccine-rollout-in-low-and-middle-income-countries> accessed on 8 July 2021.
[19] Owen Dyer, 'Covid-19: Countries are learning what others paid for vaccines' (*The BMJ*, 29 January 2021) available at <https://www.bmj.com/content/372/bmj.n281> accessed on 4 July 2021.
[20] Gordon Brown, Winnie Byanyima, *et al*., 'The G7 must act to vaccinate the world' (*Project Syndicate*, 15 April 2021) available at <https://www.project-syndicate.org/commentary/g7-must-finance-equitable-global-covid19-vaccine-access-by-gordon-brown-et-al-2021-04> accessed on 4 July 2021.
[21] Michael Penn, 'How Some Asian Countries Beat Back COVID-19' (*Duke Global Health Institute*, 12 August 2020) available at <https://globalhealth.duke.edu/news/how-some-asian-countries-beat-back-covid-19> accessed on 4 July 2021.
[22] Brian Y. An and Shui-Yan Tang, 'Lessons From COVID-19 Responses in East Asia: Institutional Infrastructure and Enduring Policy Instruments' (2020) 50(6-7) American Review of Public Administration, 792.
[23] *ibid*, 791.
[24] Penn *supra* note 21.

large number of non-communicable diseases means that these populations are susceptible to higher number of complications due to COVID-19 infections.[25]

Furthermore, in terms of development and dissemination of vaccines and health technologies, Asian countries may have fared worse than their western counterparts.[26] While different countries face different issues with vaccine roll-outs, the underlying problem is the shortage of vaccines. Although they have significant industrial productive capacity, capacity to produce pharmaceutical products is lacking – which makes them dependant on western nations to procure their required doses.[27]

There are several reasons for this struggle. The relative success of these nations in controlling COVID-19 has resulted in less political pressure to develop vaccines. The results of clinical trials have been slower due to fewer patients getting sick.[28] Notably, there is no global pharmaceutical company, unlike in the US and UK, and previously established pandemic infrastructure involves different technologies. Further, governments in countries like India and Japan did not invest into vaccine development early enough, which affects their supply in the present time. India's Covaxin is predominantly being used for the domestic population and countries in South East Asia are reluctant to accept Chinese vaccines due to regional security interests in the South China Sea.[29]

The problem in these countries is both of productive capacity and equitable access, which is exacerbated by their reliance on western nations to end the pandemic. While Asian countries are in the process of developing mRNA production facilities to prepare for future pandemics, it would do little to help in the present case.[30]

[25] Babu Giridhara, Sonalini Khetrapal, *et al.*, 'Pandemic preparedness and response to COVID-19 in South Asian countries' (2021) 104 International Journal of Infectious Diseases, 171.
[26] Robin Harding and Stephanie Findlay, 'Asia, the 'factory of the world', struggles to roll out Covid-19 vaccines' (*The Irish Times*, 25 May 2021) available at <https://www.irishtimes.com/news/world/asia-pacific/asia-the-factory-of-the-world-struggles-to-roll-out-covid-19-vaccines-1.4574989> accessed on 8 July 2021.
[27] *ibid*.
[28] Harding and Findlay *supra* note 26.
[29] Hannah Sworn, 'Global Health Security COVID-19 and Its Impacts – Vaccine Politics: Compulsory Licensing in SE Asia?' (2021) 67 RSIS Commentary, Global Health Security: Covid-19 and its impacts, 2.
[30] John Power, 'What Asia's scramble for mRNA production facilities means for the future of vaccine manufacturing in the region' (*South China Morning Post*, 15 May 2021) available at <https://www.scmp.com/week-asia/health-environment/article/3133547/what-asias-scramble-mrna-production-facilities-means?utm_source=pocket_mylist> accessed on 8 July 2021.

III. THE PRESENT IPR REGIME AND ITS INTERACTION WITH ACCESSIBLE HEALTHCARE

The WTO's TRIPS Agreement is the foundational multilateral agreement on IPR. Its framework harmonizes IPR across various WTO nations to guarantee certain minimum standards of IP protection, general principles for enforcing IPR and dispute resolution between WTO members. It aims to ensure the critical balance between promoting innovation through the exclusive rights conferred by IP regimes and disseminating technology for public welfare.[31]

Article 7 of the TRIPS Agreement, laying down its objectives, states that the protection of IPR should contribute to the promotion of technological innovation, leading to the transfer of technology to the mutual advantage of producers and users, in a manner conducive to social and economic welfare.[32] The TRIPS Agreement recognizes the need to adopt measures for public health and public interest in sectors of vital importance, as is evidenced in Article 8 of the Agreement.[33] The importance of public health is further highlighted by the Doha Declaration on the TRIPS Agreement and Public Health, which reaffirms the interpretation of TRIPS in a manner protecting public health and accessibility to medicines.[34] It is, thus, well-established that the TRIPS Agreement allows member states with wide latitude to take action for protecting public health.

The TRIPS Agreement allows for the development for a strong IP network that serves as a platform for information exchange. The registration of any IP requires the innovator or rights-holder to provide information about their IP-protected innovations. This allows third-parties to know of the existence of such goods and the identity of rights-holders, thereby facilitating licensing agreements and avoiding inadvertent violations of IP rights.

The TRIPS Agreement mandates the minimum protections to be conferred on various intellectual property, leaving the exact specifications of the same to the domestic law of every country. The main attraction for developing countries to join the TRIPS was the prospect of 'technology transfers' from the HICs to the LICs. However, different policy choices by different member states within the international legal framework have led to the concentration of innovation, investment and technology in countries regarded as having 'stronger' IP

[31] World Trade Organization, Information Note on 'The TRIPS Agreement and COVID-19' (15 October 2020) available at <https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf> accessed on 27 June 2021.
[32] Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement 1995, Article 7.
[33] Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement 1995, Article 8.
[34] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (20 November 2001), available at <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed on 27 June 2021.

protections - most often HICs.[35] This exacerbates the problems of equitable access to health resources between the Global North and Global South, where HICs have been able to support research through public funding while the LICs scramble to secure sufficient resources for their populations.[36]

While most debates around public health and IPR are centred around patents, other forms of IPR protection are also at play. Well-known trademarks play a valuable role in battling vaccine misinformation and ensuring accurate information for consumers and medical practitioners.[37] Various jurisdictions such as China and Chinese Taipei,[38] have introduced new guidance on trademark applications related to COVID-19. Similarly, copyright regimes assume importance in balancing the rights of copyright-holders and the public at large to access copyrighted works for R&D activities to develop digital solutions for diagnostics and treatments.[39] A number of publishers have made their COVID-19 related studies and publications freely accessible in public repositories to promote R&D.[40] Similarly, the European Committee for Standardization and the European Committee for Electrotechnical Standardization has made available certain copyrighted European Standards for medical devices and PPEs.[41] These measures demonstrate the variety of IP issues associated with a given medical product and the difficulty in navigating these IP thickets to ensure equitable access.

The contentious relationship between the TRIPS Agreement and public health concerns are best demonstrated in the field of patents and undisclosed information, which have been discussed in detail below.

---

[35] Stephen Ezell and Nigel Cory, 'The Way Forward for Intellectual Property Internationally' (2019) Information Technology and Innovation Foundation, available at <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> accessed on 27 June 2021.

[36] Edouard Mathieu, Hannah Ritchie, Esteban Ortiz-Ospina, *et al*., 'A global database of COVID-19 vaccinations' (2021) Nature Human Behaviour, 3.

[37] World Trade Organization, Information Note on 'The TRIPS Agreement and COVID-19' (15 October 2020) available at <https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf> accessed on 27 June 2021.

[38] Chinese Trademark Office Notice on Malicious Trademark Registration applications, (27th February 2020) available at <http://sbj.cnipa.gov.cn/gzdt/202002/t20200227_312227.html> accessed on 27 June 2021.

[39] *ibid*.

[40] Press Release, 'Publishers make Coronavirus (COVID-19) content freely available and reusable' (*Welcome.org*, 16 March 2020) available at <https://wellcome.org/press-release/publishers-make-coronavirus-covid-19-content-freely-available-and-reusable> accessed on 27 June 2021.

[41] European Commission Press Release, 'Coronavirus: European standards for medical supplies made freely available to facilitate increase of production' (20 March, 2020) available at <https://ec.europa.eu/commission/presscorner/detail/en/ip_20_502> accessed on 27 June 2021.

Patents in the Pandemic

A patent is a monopoly on an invention granted to the inventor for a certain period of time – 20 years under the TRIPS Agreement.[42] Patent protection is available for any innovation that is new, involves an inventive step and is capable of industrial application, by virtue of Article 27(1) of TRIPS.[43] Patent rights are considered to spur innovation in risky or time-and-resource-intensive areas by providing incentives for profit making through exclusive use.[44] However, it has been extensively argued that this incentives structure of patents was not conceptualised for a pandemic.[45] The core idea behind exclusivity rights is to reward inventors for undertaking risks by protecting their inventions from 'unfair competition' for a specified period of time. The current health crisis is clearly different from the competitive market behind the idea of exclusive rights and to that effect, the present patent regime warrants modification.

The effects of patents on production and access to public health goods are multiple and varied. The first issue is of the disclosure of information at the time of obtaining the patent.[46] The patent applicant is obligated to disclose information describing their invention for public knowledge in a manner that is sufficiently clear and complete, so as to allow the invention to be carried out by a person skilled in the art.[47] While the law requires honest disclosure of the patent, applicants often withhold crucial scientific and technical details of the innovation. This presents as a problem because the details of manufacturing processes may not be completely revealed in the application or are unnecessarily difficult to, thus making it harder to replicate the process.[48]

The second issue is the time-lag in the publication of patent applications. Within less than a year, there were a variety of diagnostic and preventative technologies developed to combat the pandemic, yet the details of such patent applications remain unpublished. This hampers the timely sharing of technical information with the scientific community, preventing further

[42] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 33.
[43] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 27(1).
[44] Ana Santos Rutschman, 'The Intellectual Property of COVID-19' (2020) 28 Saint Louis University School of Law Legal Studies Research Paper Series, 4.
[45] Mariana Mazzucato, Jayati Ghosh and Els Torreele, 'Mariana Mazzucato, Jayati Ghosh and Els Torreele on waiving COVID patents' (*The Economist*, 20 April 2021) available at <https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torreele-on-waiving-covid-patents> accessed on 27 June 2021.
[46] DL Burk and M Lemley 'Policy Levers in Patent Law' (2003) 89 Virginia Law Review, 1575.
[47] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 29(1).
[48] WN Price and Arti Rai, 'Manufacturing Barriers to Biologics Competition and Innovation' (2016) 101 Iowa Law Review 1031.

innovation or licensing practices.[49] Given the time sensitive nature of this pandemic, with the emergence of new variants of the virus, this is a major obstacle to knowledge sharing and technology transfer.

The third issue is the presence of patent thickets, which refer to situations where the various components of a product are protected under different IP rights.[50] In the COVID-19 context, this problem is best demonstrated in the mRNA field. mRNA technologies are being used to develop some recent COVID-19 vaccines.[51] However, due to the presence of patent thickets in the field, these vaccines are at the centre of a complex landscape of rights. The issue of patent thickets exacerbates the disclosure problem, given that different information will be disclosed in different patent applications, making it more difficult to enable production. Such thickets can also lead to opportunistic behaviour by patent owners, whose non-cooperation may frustrate the whole production process.

Undisclosed information in the Pandemic

Undisclosed information refers to trade secrets, clinical trial data and other exclusive information that is not disclosed in the public domain.[52] Such information is protected under the TRIPS Agreement from unfair commercial use, with the exception of situations where such disclosure would be necessary to protect the public.[53] However, this exception is rendered futile in many cases where this information may be protected under other laws such as contract laws through non-disclosure agreements and data exclusivity rights for clinical data.[54] This loophole is already being exploited by pharmaceutical companies in Malaysia, where the breach of the non-disclosure agreement protecting trade secrets and strategic information would lead to non-delivery of vaccines.[55]

While it has been unconventional in the past to share clinical trial data, such data becomes crucial in the present context for the timely scaling up of production, especially for vaccines.

[49] Ana Santos Rutschman, 'The COVID-10 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation' (2021) 64 Washington University Journal of Law and Policy, 178.
[50] MA Lemley and C Shapiro 'Probabilistic Patents' 19 Journal of Economic Perspectives 75.
[51] C Martin and D Lowery, 'mRNA vaccines: Intellectual Property Landscape' (2020) 19 Nature Reviews Drug Discovery 578.
[52] Michael Risch, 'Why Do We Have Trade Secrets?' (2007) 11 Intellectual Property Law Review, 1.
[53] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 39.3.
[54] Medicines Law and Policy, Data Exclusivity in the EU: A Briefing Document (June 2019) available at <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-incentives-Data-Exclusivity.pdf> accessed on 27 June 2021.
[55] Hana Naz Harun, 'Vaccine deal at stake if info revealed' (*New Straits Times*, 27 December 2020) available at <https://www.nst.com.my/news/nation/2020/12/652459/vaccine-deal-stake-if-info-revealed133> accessed on 27 June 2021.

Presently, only limited summary data is shared, with limited information about R&D costs.[56] If the clinical trial data is not shared, such trials will have to be conducted again which delays the dissemination of these vaccines. This is especially true for vaccines such as the Oxford-AstraZeneca vaccine, which use completely new technology. Further, there is an absence of a regulatory pathway for generic versions.[57] Even in mRNA vaccine technologies, apart from patent thickets, there is a growing body of trade secrets that guard the process of production against replication. Developing the process to reliably produce these new technologies takes years of research and experimentation with multiple variables. This information falls within trade secrets and is valuable for developing not just COVID-19 vaccines but also other therapeutics based on mRNA technologies.[58]

Despite these difficulties, some countries have adopted expedited approval mechanisms to meet the growing demand for vaccines. In April 2021, India approved COVID-19 vaccines for emergency use, which had already received approvals in the USA, EU, Japan or were listed in the WHO Emergency Use Listing.[59] However, this does little to assuage the problem of shortages in production and inaccessibility due to high prices that may be imposed by vaccine manufacturers.

While the aforementioned issues are unique to the different types of IPR, the cumulative effect of these regimes is amplified by these issues. The COVID-19 crisis is a global, borderless issue; yet we observe the development of R&D processes in a siloed fashion.[60] This has led to secrecy and lack of collaboration between different players, resulting in duplication, active non-cooperation and affordability issues. Secrecy about data and know-how impedes the manufacturing of public health goods, which restricts supply and promotes the commodification of such goods.

---

[56] Christopher Morten, Amy Kapczynski, *et al.*, 'To Help Develop The Safest, Most Effective Coronavirus Tests, Treatments, And Vaccines, Ensure Public Access To Clinical Research Data' (*Health Affairs*, 26 March 2021) available at <https://www.healthaffairs.org/do/10.1377/hblog20200326.869114/full/> accessed on 30 July 2021.
[57] Jacob Sherkow, Lisa Ouellette, Rachel Sachs and Nicholson Price, 'Are patents the cause of—or solution to—COVID-19 vaccine innovation problems? (No!)' (*Written Description*, 4 March 2021) available at <https://writtendescription.blogspot.com/2021/03/are-patents-cause-ofor-solution-tocovid.html> accessed on 27 June 2021.
[58] James Pooley, 'The Big Secret behind the Proposed TRIPS Waiver' (*IPWatchdog*, 25 March 2021) available at <https://www.ipwatchdog.com/2021/05/25/big-secret-behind-proposed-trips-waiver/id=133905/> accessed on 27 June 2021.
[59] Directorate General of Health Services, Government of India, Notice dated 15th April 2021, available at <https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/notice15april21.pdf> accessed on 27 June 2021.
[60] Santos Rutschman *supra* note 44, 6.

The excessive pricing of emerging technologies has a disproportionate impact on LICs, which have larger populations and are being charged higher prices, as was seen in the previous section. Even in HICs, while government funding has spurred existing R&D of these technologies, the ownership of the IPR has remained with the pharmaceutical companies, who continue to charge high prices.[61] Any attempt by other players in the market to replicate such goods is met with severe sanctions and liability for IP violations.[62] Thus, the present IP regime has been used as a garb to facilitate vaccine nationalism and inequitable access, which is detrimental to public health in a transnational problem like the current pandemic.

IV. The failure of exemptions under the TRIPS Agreement and collaborative efforts in achieving accessible healthcare

While advocating for strong IPR, the TRIPS Agreement recognizes the need to balance these exclusive rights with broader public interest considerations. The provisions of the Agreement enable certain flexibilities within the TRIPS framework to restore this balance. These provisions are above and beyond any voluntary agreements that different players might engage in. While a multitude of voluntary and TRIPS-enabled measures have been undertaken across the world, they have their own shortcomings in dealing with the complex nature of the COVID-19 pandemic.

Voluntary Licensing Agreements, Patent Pools and Pledges

Traditionally, although the IP holder has monopoly rights over the protected goods, they may enter into voluntary licensing agreements to enable manufacturing as well as accelerate R&D towards novel innovations on a larger scale. The large number of pre-orders received by pharmaceutical companies for vaccines by states and the generally growing demand for medical products in the COVID-19 pandemic can best be met by entering into voluntary agreements to scale up supply.[63] Such voluntary licensing agreements can either be through

[61] Nicole Wetsman, 'Health Secretary Alex Azar Won't Promise that a Coronavirus Vaccine Would be Affordable' (*Verge*, 27 February 2020) available at <https://www.theverge.com/2020/2/27/21155879/alex-azar-coronavirus-vaccine-affordable-insurance> accessed on 27 June 2021.

[62] Chloe Kent, 'COVID-19: Start-up that saved lives with 3D-printed valve may face legal action' (*Medical Device Network*, 18 March 2020) available at <https://www.medicaldevice-network.com/news/3d-printed-valves-covid-19-italy/> accessed on 27 June 2021.

[63] Mohammad Behnam, Marc Chelala, Tony Gambell and Miyu Toyoshima Galliart, 'Medtech's call to action: Meeting the demand surge caused by COVID-19' (*McKinsey*, 1 September 2020) available at <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/medtechs-call-to-action-meeting-the-demand-surge-caused-by-covid-19> accessed on 29 June 2021.

individual agreements between parties, or through voluntary licensing initiatives like patent pools and voluntary pledges.

A patent pool is an agreement between two or more patent owners to license their patents to one another and to third parties.[64] In March 2020, Costa Rica submitted a proposal to the World Health Organization for the creation of a patent pool involving voluntary assignments to provide free access or licensing on reasonable terms for member countries.[65] This led to the creation of the COVID-19 Technology Access Pool (C-TAP) to accelerate the public disclosure of critical information relating to COVID-19 treatments, vaccines and clinical trial data.[66] These patent pools help to reduce the transaction costs associated with obtaining a multitude of patents as well as accelerates the time-periods for R&D.[67] Patent pools for developing vaccines may also ensure that the same quality of vaccines are developed on a large scale to ensure safe inoculation. The rapid deployment of the C-TAP is reflective of the effort by various international players to expedite the development and equitable distribution of COVID-19 related health goods.

Another form of voluntary licensing initiatives are patent pledges. These are commitments made by patent holders to limit the enforcement of their patent rights against the public at large without any direct compensation to the patent holder.[68] The Open COVID-19 Pledge is a commitment, calling for its adopters to share their IPR for the purpose of ending the COVID-19 pandemic.[69] It has found great support in technology companies such as Facebook, Intel and Sandia National Laboratories.[70] The pledge allows its adopters to commit a range of licences and choose contractual frameworks that best suit their interests. This is a key example of how operating within the existing legal framework to further public interest.

---

[64] Ryan Lampe & Petra Moser, 'Do Patent Pools Encourage Innovation? Evidence from the Nineteenth-Century Sewing Machine Industry' (2010) 70 J. ECON. HIST. 898.
[65] Letter from Costa Rica to the World Health Organization, (2020) Knowledge Ecology International <https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf> accessed on 29 June 2021.
[66] World Health Organization, COVID-19 Technology Access Pool, available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool> accessed on 29 June 2021.
[67] Santos Rutchsman *supra* note 44, 14.
[68] Jorge L. Contreras, 'Patent Pledges' (2015) 47 Arizona State Law Journal, 543.
[69] Open COVID-19 Pledge, Frequently Asked Questions, available at <https://opencovidpledge.org/faqs/> accessed on 29 June 2021.
[70] Open COVID-19 Pledge, Make the Pledge to Share Your Intellectual Property in the Fight Against COVID-19, <https://opencovidpledge.org> accessed on 29 June 2021.

Voluntary licensing agreements are advantageous to patent holders as it allows them to set the terms and conditions of the license. These agreements and initiatives can be tailored to incorporate clauses regarding technology transfers, sharing of data and a predetermined value for royalties. Moreover, invocation of any flexibilities under the TRIPS Agreement may be met with challenges by patent holders, leading to delays in implementing these flexibilities.[71] The voluntary nature of these agreements and pledges are premised on consent and are likely to offer timely solutions – a facet crucial for mitigating the damage of COVID-19. Further, unlike the TRIPS flexibilities which are restricted to national levels and adopt a case-to-case approach, these voluntary agreements can be established on a global level and have a more expansive scope.[72]

However, these mechanisms are solely dependent on the consent of the patent holder. Despite the increasing pressure from states and international organizations for pharmaceutical companies to collaborate, the vaccine rights holders have largely ignored the C-TAP and the Open COVID-19 Pledge. Although these initiatives find support from other groups of IPR holders, the categorical lack of pharmaceutical entities significantly restricts the ability of these pools and pledges to achieve their goals of 'ending the fight against COVID-19'.[73]

Public Private Partnerships for Pooled Procurement: COVAX, GAVI and CEPI

These partnerships can be of various types, such as product development partnerships or access partnerships.[74] Product development partnerships aim to fund and coordinate R&D to produce technologies, while access partnerships focus on procuring these technologies through pooled procurement methods.[75] While these partnerships have benefits for all their members, their benefits are targeted towards economically disadvantaged markets and populations.[76]

These partnerships have been working to alleviate conditions in the health space since before COVID-19. Gavi is one such partnership that has been working on vaccine supply and procurement.[77] Similarly, the Coalition for Epidemic Preparedness Innovations (CEPI) was

[71] Aislin McMahon, 'Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance' (2020) Journal of Medical Ethics, 5.
[72] *ibid.*
[73] Katrina Perehudoff, Ellen Hoen, Pascale Boulet, 'Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too' (2021) BMJ Global Health, 3.
[74] Santos Rutchsman *supra* note 49, 87.
[75] *ibid.*
[76] Jon Merz, 'Intellectual Property and Product Development Public/Private Partnerships' (2005) World Health Organization Report, 12.
[77] Gavi, About our alliance, available at <https://www.gavi.org/our-alliance/about> accessed on 29 June 2021.

developed to address R&D gaps evidenced by the Ebola outbreak to develop vaccines for emerging infectious diseases.[78] The COVAX scheme was developed in the COVID-19 context as a global mechanism for states to come together to purchase vaccines.[79] COVAX allows its members to place advance orders for vaccine doses and promotes vaccine affordability by allowing participating countries to purchase doses at lower prices than they would pay through individual negotiations.[80] COVAX works with multiple vaccine manufacturers, which increases the chances for LICs to procure life-saving vaccines in a timely fashion.

Although these partnerships are doing a remarkable job at addressing the issue of equitable distribution, they have certain limitations. The first being the time-limited nature of these endeavours. While Gavi and CEPI are permanent organizations, COVAX is not a permanent structure. This highlights the lack of long-term structures for future pandemic preparedness, which perpetuates the pressure on product supply in times of crisis. Concerns have also been raised about the bargaining asymmetries within different players in these partnerships.[81] The large number of players and limited supply can lead to allocation issues and preferential treatment of some nations over the others. This is already seen by the COVAX allocation policy in 2020, which imposes different conditions on self-financing countries and countries funded to participate in COVAX, mainly LICs.[82] While these partnerships are slowly working on addressing issues of access to public health goods, they do not facilitate knowledge and technology transfers that would improve the productive capacity of these countries.[83] These partnerships, in fact, shift the conversation from the restrictive IPR regime hampering equitable distribution of vaccines.

Article 31 and Article 31bis: Compulsory Licensing

Compulsory Licensing is one of the most discussed provisions of the TRIPS Agreement. It is central to the Agreement's overall balance between promoting innovation and access.[84] While advocating for a strong IP regime, the TRIPS Agreement recognizes that patent rights are not

[78] CEPI, 'CEPI to Fund Three Programmes to Develop Vaccines Against the Novel Coronavirus, nCoV2019' (*CEPI*, 23 January 2020) available at <https://cepi.net/news_cepi/cepi-to-fund-three-programmes-to-develop-vaccines-against-the-novel-coronavirus-ncov-2019/> accessed on 29 June 2021.
[79] Jenny Ravelo, 'Is COVAX part of the problem or the solution?' (*Devex*, 11 March 2021) available at <https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334> accessed on 29 June 2021.
[80] Santos Rutschman *supra* note 49, 191.
[81] *ibid*, 197.
[82] *ibid*.
[83] Ravelo *supra* note 79.
[84] World Trade Organization, Information Note on 'The TRIPS Agreement and COVID-19' (15 October 2020) available at <https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf> accessed on 27 June 2021.

absolute and require curtailment in light of broader public interest. This was also affirmed by the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Article 30 of the TRIPS Agreement states that member states can provide limited exceptions to exclusive rights of a patent.[85] The exceptions under Article 30 – research and experimental use, and the bolar exemption – are not entirely relevant to the production and access issues relating to the COVID-19 pandemic. However, Article 31 and Article 31*bis* are key provisions that states may choose to rely on.

Article 31 allows for compulsory licensing and government use of a patent without the authorization of the right holder, subject to certain conditions. The process of obtaining a compulsory licensing may vary from country to country, but broadly requires the following features – that there must be a national emergency or other circumstances of extreme urgency, that the proposed user must have made other efforts to obtain authorization from the right holder on reasonable terms and conditions and such efforts should not have been successful for a reasonable period of time.[86] Further, the scope and duration of use should be limited to the purpose for which it is authorized and such authorization may be terminated if the circumstances warranting said authorization cease to exist.[87]

Compulsory licencing under Article 31 has been invoked in several Asian jurisdictions in the past to access life-saving drugs at affordable prices.[88] India's first compulsory license was granted to drug-maker Natco Pharma to make and sell a similar version of Bayer Corporation's Nexavar, an advanced kidney cancer drug after the conditions under Section 84(1) of the Indian Patent Act.[89] In relation to COVID-19, there has been increased conversation around invoking compulsory licensing, with the Indian judiciary questioning the Central Government on their stance to invoke compulsory licensing.[90] Similarly, Thailand has previously issued compulsory

[85] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 30.
[86] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 31(b).
[87] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 31(c)-31(g).
[88] Sworn *supra* note 29, 3.
[89] *Bayer Corporation* v. *Natco Pharma Ltd.*, Order No. 45/2013, Intellectual Property Appellate Board, Chennai.
[90] K.C. Gopakumar, 'Kerala High Court seeks Centre's response to invoke compulsory licensing of COVID vaccines'(*The Hindu Business Line*, 2 July 2021) available at <https://www.thehindubusinessline.com/news/national/kerala-high-court-seeks-centres-response-to-invoke-compulsory-licensing-of-covid-vaccines/article34534257.ece> accessed on 8 July 2021; 'SC asks Centre to consider revisiting vaccine policy; says illogical to impose obligation on state govts to source vaccines for 18-44 age group' (*The Leaflet*, 3 May 2021) available at <https://www.theleaflet.in/sc-asks-centre-to-revisit-vaccine-policy-says-illogical-to-impose-obligation-on-state-govts-to-source-vaccines-for-18-44-age-group-healthright/> accessed on 8 July 2021.

licenses against seven patented drugs to overcome issues of accessibility.[91] In the past, Malaysia granted a compulsory license for a hepatitis C medicine, Sofosbuvir, for treating HIV/AIDS,[92] following which Indonesia also granted seven compulsory licenses to increase access to cheaper medicines for HIV/AIDS and Hepatitis C.[93] Thus, invoking compulsory licensing in Southeast Asia is a practice with past precedent. Most developing countries have incorporated compulsory licensing provisions within their domestic laws, which provides greater certainty to the legal regime.

Given the existing manufacturing capacity in countries like Indonesia, India and Bangladesh,[94] the invocation of compulsory licensing regimes would enable Asian jurisdictions to utilize these facilities to ramp up production. Although compulsory licenses are authorized on a country-to-country basis, the introduction of Article 31*bis* to the TRIPS Agreement allows states with manufacturing capacity to issue a compulsory license to export the patented goods to countries without any manufacturing capacity.[95] The presence of this framework as well as its historical use has been one of the leading arguments against enacting a temporary TRIPS waiver. Further, the threat of invoking compulsory license is also an effective tool at negotiating voluntary licenses with patent holders. In India, Natco Pharma filed an application under the Indian Patent Act for issuing a compulsory license against Eli Lilly for a drug to treat COVID-19.[96] However, shortly after this application was filed, Natco and Eli Lilly signed a non-exclusive, royalty-free, voluntary licensing deal with the use of the drug in India.[97]

Yet the use of compulsory licensing has been riddled with problems and has been deemed unsuitable by many for dealing with the pandemic. The ultimate goal of ending the COVID-19 pandemic entails facilitating the production of 10-15 billion doses annually to maintain heard

[91] Inthira Yamabhai, Adun Mohara, Sripen Tantivess *et al.*, 'Government use licenses in Thailand: An Assessment of the Health and Economic Impacts' (2011) 7(28) Global Health, 3.
[92] Catherine Saez, 'Malaysia Grants Compulsory Licence For Generic Sofosbuvir Despite Gilead Licence'(*Intellectual Property Watch*, 15 July 2017) available at <https://www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence/> accessed on 2 July 2021.
[93] Dr. Germán Velásquez, 'Indonesia Government Granted 7 Compulsory Licences To Promote Access To HIV Related Medicines' (2012) 19(3) Revista De La Facultad De Química Farmacéutica, 248.
[94] Kerry Cullinan, 'Indonesia and Bangladesh Reveal Massive Untapped Vaccine Production Capacity at C-TAP Anniversary' (*Health Policy Watch*, 28 May 2021) available at <https://healthpolicy-watch.news/indonesia-and-bangladesh-reveal-massive-untapped-vaccine-production-capacity-at-c-tap-anniversary/> accessed on 2 July 2021.
[95] Livelaw News Network, 'Natco Pharma Files Application Seeking Compulsory License for COVID drug Baricitinib' (*LiveLaw*, 5 May 2021) available at <https://www.livelaw.in/news-updates/natco-pharma-files-application-seeking-compulsory-license-for-covid-drug-baricitinib-173627> accessed on 2 July 2021.
[97] Special Correspondent, 'Natco Pharma signs pact with Eli Lilly for Baricitinib' (*The Hindu*, 17 May 2021) available at <https://www.thehindu.com/business/natco-pharma-signs-pact-with-eli-lilly-for-baricitinib/article34582342.ece> accessed on 2 July 2021.

immunity worldwide.[98] While compulsory licensing has worked for nations in the past, there are three main reasons why it is bound to fail in this case.

First, the existing compulsory licensing regime is not fit to deal with a global pandemic. The procedure for obtaining a compulsory license will have to be carried out on a case-to-case and country-to-country basis. Not only do all nations have different legal regimes governing compulsory licenses, but the products sought to be licensed rely on complex supply chains. mRNA vaccines have 100 key components, which are produced in multiple jurisdictions and many of which have separate IP protections – creating a patent thicket.[99] In order to manufacture a generic version of the same, the producer would have to seek a multitude of licenses from the exporting countries. Further, Article 31(f) of the TRIPS Agreement allows the issuance of compulsory licenses for supply to domestic market. Given that present production capacity is limited to few countries, in order to export these products to other countries, the separate procedure would have to followed under Article 31*bis*. To invoke Article 31*bis*, the importing country will have to notify and prove its lack of productive capacity to the TRIPS Council, and the exporting country must agree to the same.[100] This significantly increases the time for obtaining these products. Nothing in the compulsory licensing regime addresses the issues of technology transfer or increasing production capacity in countries that lack them. This problem is exacerbated in the COVID-19 pandemic when the whole world needs large supplies of vaccines and simply improving access to public health goods is insufficient.

Further, compulsory licensing can only be applied for after a certain period of time – generally 3 to 4 years – from when the patent is granted; making it unfeasible for treating an imminent danger like COVID-19.[101] Since its introduction in 2017, Article 31*bis* has successfully only been used once – to export the drug, TriAvir, from Canada to Rwanda to cure HIV/AIDS.[102] This invocation of the Article exposed procedural fallacies that have deterred its use by other

[98] Public Citizen's Global Trade Watch Series on the TRIPS Waiver, 'Existing TRIPS "Flexibilities" Unworkable for Necessary Scale Up of COVID-19 Medicines Production' (2021) available at <https://mkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/TRIPS-waiver_Existing-TRIPS-Flexibilities-Unworkable-for-Scale-Up-of-Covid-19-Medicines-Production-.pdf> accessed on 2 July 2021.

[99] *ibid*, 3.

[100] Nicholas Vincent, 'TRIP-ING UP: The Failure of TRIPS Article 31*bis*' (2020) 24(1) Gonzaga Journal of International Law, 15.

[101] The Patents Act 1970 (India), S.84(1); The Patent Act, 1959 (Japan), S.83; The Intellectual Property Code, Act No. 8293 of 1997 (Philippines), S.94(1).

[102] Holger Hestermeyer, 'Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines' (2007) 11(28) American Society of International Law Insights, 1.

countries. It took Rwanda nearly three years to secure the requested shipments. While for diseases such as HIV/AIDS and Hepatitis C, this process may still be feasible due to the lower transmission rates, it is completely unsustainable for developing medical products relating to COVID-19 with its rapid transmission and mutation rates.[103] The recent case of Canadian firm, Biolyse, seeking to produce and export a generic version of the Johnson & Johnson adenovirus vaccine shows that obtaining a compulsory license is a tedious and unpredictable process.[104]

Second, compulsory licensing only applies to patent protection under various patent regimes. However, broad IP thickets of patents, undisclosed information, trademarks and copyrights surround medical technologies sought to be licensed.[105] Pfizer/BioTech and Moderna own over a dozen patents related to their respective vaccines,[106] and there are several copyright protections on software and algorithms, as well as undisclosed data and industrial design at play. This means that the issuance of a compulsory license would not prove to be effective enough against the effective replication and production of these products.

Third, while countries have historically relied on the compulsory licensing to procure affordable drugs, they have also faced severe political backlash for their actions, specifically from the USA.[107] For instance, when Thailand invoked compulsory licensing provisions in 2007 to procure drugs to cure AIDS, the United States Trade Representative retaliated by placing Thailand on its 301 Report's Priority Watch List.[108] The 2021 Special 301 submissions include explicit mention of invocation of compulsory licensing by certain states.[109] These

[103] Vincent *supra* note 100.
[104] Ryan Tumilty, 'Ontario company seeks licence to make generic Johnson and Johnson COVID vaccine for developing countries' (*National Post*, 25 March 2021) available at <https://nationalpost.com/news/politics/ontario-company-wants-to-make-johnson-and-johnson-vaccine-with-government-license> accessed on 2 July 2021.
[105] Médecins Sans Frontières Report, 'A Fair shot for Vaccine Affordability: Understanding and Addressing the Effects of Patents on Access to Newer Vaccines' (2017) available at <https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf> accessed on 2 July 2021.
[106] Mario Gaviria and Burcu Kilic, 'BioNTech and Pfizer's BNT162 Vaccine Patent Landscape' (*Public Citizen*, 16 November 2020) available at <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/> accessed on 2 July 2021; Mario Gaviria and Burcu Kilic, 'mRNA-1273 Vaccine Patent Landscape (For NIH-Moderna Vaccine)' (*Public Citizen*, 16 November 2020) available at <https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/> accessed on 2 July 2021.
[107] '2020 Special 301 Report' (April 2020) Office of the United States Trade Representative, available at <https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf> accessed on 2 July 2021.
[108] James Love, 'Thailand's Compulsory Licensing Controversy' (*Knowledge Ecology International*, 20 June 2007) available at <https://www.keionline.org/25989> accessed on 2 July 2021.
[109] Global Trade Watch Series on the TRIPS Waiver *supra* note 96.

sanctions have a debilitating effect on international trade and politics, which already stands compromised by the pandemic.

Compulsory licensing regimes have considerable merit to them, in having previously bridged the gap between access and innovation. However, the time-sensitive and global nature of this pandemic, coupled with the rapid deployment of new technologies render these processes futile. The two-pronged approach – increasing production and increasing access - needed to overcome the pandemic finds no space in the existing regime.

Article 73 of TRIPS Agreement: Security Exceptions

Article 73 of the TRIPS Agreement allows member states to take actions they would consider necessary for the protection of its essential security interests at a time of emergency in international relations.[110] Despite the broad discretion to invoke this exception, member states are under an obligation to do so in good faith and only undertake actions that are necessary for the protection of essential security interests in emergency situations.[111]

Therefore, the fundamental requirement for invoking Article 73 is an 'emergency in international relations'. The COVID-19 outbreak was declared a Public Health Emergency of International Concern on 30th January, 2020.[112] This provides objective evidence of an emergency in international relations. This is further evidenced by the effects of the COVID-19 pandemic, in the emergence of vaccine nationalism and the issue of allocating scarce resources on a global level.[113] Further, the slowdown in international trade has had a major economic impact across the world. There have also been escalations of terrorist activities and threats to peace,[114] which would justify the threshold for declaring the COVID-19 pandemic as an emergency in international relations.

Article 73 requires the action to be taken at the time of emergency to protect the state's essential security interests. One of the core obligations of the government is to protect and promote public health. The threat of the pandemic affects internal law and order in member states – the

[110] Agreement on Trade-Related Intellectual Property Rights Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, Article 73.
[111] Russia - Measures Concerning Traffic in Transit, Report of the Panel, WT/DS512/R, 5 April 2019; Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights, Report of The Panel, WT/DS567/R, 16 June 2020.
[112] WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV), 30 Jan. 2020, available at <https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-onnovel-coronavirus-(2019-ncov)> accessed on 3 July 2021.
[113] Frederick M. Abbott, 'The TRIPS Agreement Article 73 Security Exemptions and the COVID-19 Pandemic' (2020) Research Paper No. 116, South Centre, Geneva, 7.
[114] United Nations Security Council Resolution 2532 (U.N. Doc. S/2020/253, Mar. 31, 2020).

protection of which would qualify as essential security interests.[115] The action should also be considered necessary for the protection of essential security interests, in that the measure should be plausibly related to the emergency being addressed.[116] The member states have substantial discretion to determine necessary measures and the mere fact that the desired outcome could be achieved by alternative measures is irrelevant.[117] Thus, in the context of COVID-19, the act of a member state to override patent rights or exclusivity interests would be considered reasonable to combat the pandemic.

Despite the fact that the TRIPS Agreement contains other flexibilities that contemplate a public health emergency, the invocation of Article 73 by member states is beneficial for several reasons. Article 31 and 31*bis* are the only other articles in the TRIPS Agreement containing exemptions for public health emergencies and deal with compulsory licensing of patents. However, as demonstrated in the previous section, medical technologies for the prevention of COVID-19 also involve other IP protections such as undisclosed information protected under Article 39.3 of TRIPS. Further, trademark holders may attempt to stop distribution of products having the same shape and colour as their marketed products, while copyright holders may seek to block access and dissemination of research and content.[118] These protections do not have public health exceptions embedded in them, despite their potential to block equitable distribution channels. Article 73 may be invoked to address this web of protections by allowing governments to employ a variety of actions to address its essential security interests.[119]

While such acts of member states may be permissible under TRIPS, they may face scrutiny under their domestic IP regimes and other trade and investment agreements.[120] In fact, it has been argued that this exception may not be a realistic option for states in combatting COVID-19 for two reasons.

First, the exception under Article 73 is only effective for countries with domestic manufacturing capacity, as they can invoke Article 73(b)(iii) to justify the suspension of IPR

[115] Abbott *supra* note 113, 10.
[116] Russia - Measures Concerning Traffic in Transit, Report of the Panel, WT/DS512/R, 5 April 2019, ¶7.138.
[117] *ibid*.
[118] Abbott *supra* note 113, 18.
[119] Shirin Syed, 'IP barriers in tackling COVID 19: Anything in TRIPS to help out?' (*TradeRxReport*, 1 July 2021) available at <https://www.traderxreport.com/patents/ip-barriers-in-tackling-covid-19-anything-in-trips-to-help-out/> accessed on 29 June 2021.
[120] Henning Grosse Ruse-Khan, 'Access to Covid-19 Treatment and International Intellectual Property Protection – Part II: National security exceptions and test data protection' (*EJIL:Talk!*, 15 April 2020) available at <https://www.ejiltalk.org/access-to-covid19-treatment-and-international-intellectual-property-protection-part-ii-national-security-exceptions-and-test-data-protection/> accessed on 29 June 2020.

rights as a necessary action to protect security interests in the pandemic.[121] Thus, it would prove ineffective for LICs without the required production capacity. Further, while the emergency exception exists in domestic legislations of many LICs, it lacks the necessary governance to execute the suspension of IPR to manufacture goods.

Second, Article 31*bis* allows states to grant compulsory licenses for producing pharmaceutical products for the purposes of exporting it to an eligible country.[122] Article 31*bis* has proved to be of limited use, given the cumbersome process. However, Article 73 cannot be used to overcome these shortcomings because the 'necessity element' of Article 73 would not cover the suspension of IPR in one country to export protected goods to other countries.[123] Coupled with the lack of production facilities in LICs, this reduces the efficacy of Article 73 in addressing the current problem of inequitable access to vaccines.

Thus, it is seen that while a number of collaborative efforts and flexibilities under the TRIPS have been invoked in the pandemic, they all fall short of addressing a problem of this magnitude. While they may have worked in the past, the urgent and complex nature of this pandemic requires a different approach – one that focuses on technology and knowledge transfers to scale up protection in a timely fashion.

V. WAIVE YOUR IP GOOD-BYE: IS A TRIPS WAIVER SUFFICIENT TO BATTLE THE PANDEMIC?

The TRIPS waiver is at the heart of the recent clamour about IP rights as an impediment to equitable access. In October 2020, India and South Africa proposed a waiver from certain provisions of the TRIPS Agreement for the prevention, treatment and containment of COVID-19.[124] The waiver has been proposed not just in the context of vaccines, but for diagnostics, therapeutics and other medical products. The proposal for the waiver is grounded in two main arguments – *first*, that the rapid scaling up of the manufacturing process is crucial to address the timely availability and affordability of public health goods; and *second*, that other

[121] Emmanuel Kolawole Oke, 'Is the National Security Exception in the TRIPS Agreement a Realistic Option in Confronting COVID-19?' (*EJIL:Talk!*, 6 August 2020) available at <https://www.ejiltalk.org/is-the-national-security-exception-in-the-trips-agreement-a-realistic-option-in-confronting-covid-19/> accessed on 29 June 2021.
[122] Agreement on Trade-Related Intellectual Property Rights Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, Article 31*bis*.
[123] Kolawole Oke *supra* note 121.
[124] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, TRIPS Communication IP/C/W/669 available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> accessed on 3 July 2021.

intellectual property rights, beyond just patents, may also pose a barrier to the goal of equitable access and need to be waived in order to overcome COVID-19.[125]

The waiver proposal has had a divisive effect on the global community – with LICs supporting the waiver and welcoming relief from IP liabilities and HICs categorically rejecting a wholesale waiver of IP rights to propose either a narrower waiver,[126] or advocate for the use of flexibilities in the TRIPS Agreement.[127] The proposal for a waiver warrants close scrutiny to determine its legality and its efficacy in promoting increased productive capacity and access.

What does the TRIPS Waiver cover?

The exact scope of the TRIPS waiver has been a contentious issue between different members of the WTO. In the revised proposal put forth by India and South Africa,[128] the scope of the proposal was narrowed down from 'health products and technologies' to 'health products and technologies for the prevention, treatment or containment of COVID-19'.[129] The proposal mentions that the waiver shall be in force for 3 years from the date of the decision, after which the General Council shall review the existence of exceptional circumstances justifying the waiver to determine whether the waiver should be terminated.[130] In substantive terms, the proposal seeks the waiver of Sections 1, 4, 5 and 7 of Part II, dealing with Copyright and Related Rights, Industrial Designs, Patents and Protection of undisclosed information related to COVID-19 health technologies respectively.[131] It also seeks to waive the enforcement of these sections under Part III of the TRIPS Agreement.[132] The effect of such waiver is that it strips the monopoly rights enjoyed by pharmaceutical and other companies through all forms of IP rights.

---

[125] *ibid*, ¶8 and 10.
[126] Prashasti Singh, 'US backs Covid-19 vaccine patent waiver plan proposed by India, South Africa' (*Hindustan Times*, 6 May 2021) available at <https://www.hindustantimes.com/world-news/us-backs-covid-19-vaccine-patent-waiver-plan-proposed-by-india-south-africa-101620259025472.html> accessed on 4 July 2020.
[127] Michelle McMurry-Heath, 'Michelle McMurry-Heath on maintaining intellectual property amid COVID-19' (*The Economist*, 20 April 2021) available at <https://www.economist.com/by-invitation/2021/04/20/michelle-mcmurry-heath-on-maintaining-intellectual-property-amid-covid-19> accessed on 4 July 2020.
[128] Communication from India, South Africa and others, 'Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of COVID-19 – Revised Decision Text' WTO Council for Trade-Related Aspects of Intellectual Property Rights IP/C/W/669/Rev.1 (25 May 2021) available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True> accessed on 6 July 2021, [Hereinafter 'TRIPS Waiver Proposal'].
[129] TRIPS Waiver Proposal, ¶1.
[130] TRIPS Waiver Proposal, ¶2.
[131] TRIPS Waiver Proposal, ¶1.
[132] *ibid.*

Legality of enacting a TRIPS Waiver

The TRIPS Agreement has no express provision that allows the WTO Council to temporarily waive the Agreement. Despite that, the waiver is within the powers of WTO sovereign states. The TRIPs Council has jurisdiction over this waiver, as per Annex 1C of the WTO Agreement. Under the WTO Agreement, in '*exceptional circumstances*', the Ministerial Conference may decide to waive an obligation under any Multilateral Trade agreement, provided that this decision is supported by three quarters of its members.[133] Any such waiver should state the exceptional circumstances justifying this decisions, the terms and conditions of this waiver an the date of termination.[134]

Thus, despite the availability of flexibilities within the TRIPS Agreement, the Marrakesh Agreement contemplates 'exceptional circumstances' that warrant the temporary waiver of these provisions. None of the agreements define what constitutes 'exceptional circumstances', but the status of the COVID-19 pandemic as a 'global health crisis' by the World Health Organization may satisfy the threshold.[135]

Further, having illustrated the failure of the existing framework and its flexibilities in dealing with the pandemic, the proposal for a waiver of 3 years is considered a proportionate measure justified by the exceptional circumstances. The waiver only concerns health products and technologies for the prevention, treatment or containment of COVID-19, as opposed to an overbroad exception concerning all IP, for an initial duration of 3 years. At the present juncture, there are several mutations of the SARS-CoV-2 virus and the goal of universal vaccination is afar.[136] The waiver of IP related protections for health technologies aims to facilitate technology transfer from HICs to LICs, ramp up production in the available manufacturing facilities across the world and allow for access to life-saving, quality medicines to all.

[133] Marrakesh Agreement Establishing the World Trade Organization 1995, Article IX.3.
[134] Marrakesh Agreement Establishing the World Trade Organization 1995, Article IX.4.
[135] Andrew Joseph, 'WHO declares coronavirus outbreak a global health emergency' (*Stat*, 30 January 2020) available at <https://www.statnews.com/2020/01/30/who-declares-coronavirus-outbreak-a-global-health-emergency/> accessed on 2 July 2021.
[136] Centres for Disease Control and Prevention, 'SARS-CoV-2 Variant Classifications and Definitions' available at <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html> accessed on 4 July 2021.

Arguments in favour of the waiver

The waiver has found immense support in various member nations and international civil organizations.[137] The failure of patent holding companies of life-saving drugs and technologies to enter into voluntary pledges and agreements has impeded the accessibility of these products and prolonged the pandemic.[138] Further, the re-emergence of vaccine nationalism has delayed the supply of vaccinations to LICs and facilitated subsequent rounds of infections in the countries.[139] In the absence of alternatives to scale up production, the waiver is being considered as a necessary step towards improving global production and access to create a 'People's vaccine'.[140]

The most forceful argument in favour of the waiver is the evidence of IP bundles as a hurdle to scale manufacturing. According to one estimate,[141] in the absence of IP claims, it is possible to collectively mobilise the present manufacturing capacity in the world to inoculate 60% of the world by 2021 and the whole population by 2022. The proponents of strong IP regimes argue that the waiver is redundant in the absence of existing manufacturing facilities.[142] However, not only is there under-utilized production capacity in several countries, but there is evidence to suggest that intense patenting activity could potentially delay the entry of new manufacturers.[143] Thus, the temporary waiver of IP rights would break down the structural barriers that prioritize the profits of corporations over global equitable access of health goods.

Ordinarily, IPR is provided to the innovators or creators of technologies for their risky endeavour as an incentive to innovate. However, due to the sudden onset of the COVID-19

---

[137] Civil Society Letter to the WTO, Supporting Proposal By India And South Africa On Waiver From Certain Provisions Of The TRIPS Agreement For The Prevention, Containment And Treatment Of COVID-19, available at <https://www.twn.my/announcement/signonletter/CSOLetter_SupportingWaiverFinal.pdf> accessed on 4 July 2021.

[138] Prabhash Ranjan, 'The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines' (April 2021) ORF Issue Brief No. 456, Observer Research Foundation, available at <https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/> accessed on 4 July 2021.

[139] Chris Kay and Haslinda Amin, 'Vaccine Nationalism Threatens WHO's 2021 Goal of 2 Billion Doses' (*Bloomberg Quint*, 17 March 2021) available at <https://www.bloombergquint.com/coronavirus-outbreak/vaccine-nationalism-threatens-who-s-2021-goal-of-2-billion-doses> accessed on 6 July 2021.

[140] People's Vaccine Alliance, available at <https://peoplesvaccine.org/> accessed on 4 July 2021.

[141] Gordon Brown, Winnie Byanyima, *et al*., 'The G7 must act to vaccinate the world' (*Project Syndicate*, 15 April 2021) available at <https://www.project-syndicate.org/commentary/g7-must-finance-equitable-global-covid19-vaccine-access-by-gordon-brown-et-al-2021-04> accessed on 4 July 2021.

[142] Shivangi Mittal and Varun Ramdas, 'Why the TRIPS Waiver is unlikely to solve India's COVID-19 vaccine shortage' (*The Print*, 7 May 2021) available at <https://theprint.in/opinion/why-the-trips-waiver-unlikely-to-solve-indias-covid-19-vaccine-shortage/653979/> accessed on 4 July 2021.

[143] Shubhashini Chandrashekharan, Tahir Aman, *et al*., 'Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers' (2015) 33(46) Vaccine, 6368.

pandemic, the unprecedented research efforts have been a result of public sector funding and pooling of resources. For instance, the U.S. government funded the R&D and development of the Moderna COVID-19 vaccine,[144] while public money accounts for over 97% of funding for the Oxford-AstraZeneca vaccine.[145] This means that these companies' R&D efforts were supported by public funding, which makes giving them monopoly rights over these health goods unjustified. This is one of the most compelling reasons for the implementation of the waiver, because it seeks to provide the benefits of public spending to the actual public.[146]

While the proposal made by India and South Africa covers all IP waivers for all health technologies, the USA has recently pledged its support for a narrower waiver that covers only *vaccine patents*.[147] As explained above, these health products concern IP rights of various kinds and just a patent waiver would do little to assuage the present situation.

Given the present situation, where some HICs have better bargaining power and financial capacity, some have advocated a TRIPS waiver in the interest of transparency.[148] This is due to the fact that the opaque licensing agreements entered into, between the pharmaceutical companies and various countries, reflect different prices – with HICs paying significantly lesser for the same vaccine than LICs.[149]

Sceptics of the waiver would argue that the waiver harms innovation and is a bad precedent for any future epidemic responses. They fear that a waiver for COVID-19 may set a precedent for waiving IP rights concerned with health goods relating to other serious illnesses such as cancer, HIV/AIDS and diabetes. However, unlike in cases of aforementioned illnesses, the R&D for COVID-19 did not rely on classic market incentives that the patent system was envisaged as. Rather, government and philanthropic funding and increasing demand, seen through advance purchase commitments, have been the main drivers of the progress. Resultantly, the TRIPS

[144] Eric Sagonowsky, 'After nearly $1B in research funding, Moderna takes $1.5B coronavirus vaccine order from U.S.' (*Fierce Pharma*, 12 August 2020) available at <https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-moderna-takes-1-5b-coronavirus-vaccine-order-from-u-s> accessed on 4 July 2021.
[145] Samuel Cross, Yeanuk Rho, *et al*., 'Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology' (2021) MedRxiv, available at <https://www.medrxiv.org/content/10.1101/2021.04.08.21255103v1.full.pdf+html> accessed on 4 July 2021.
[146] Anthony D., 'WTO TRIPS Waiver for COVID-19 Vaccines' (*John Hopkins Bloomberg School of Public Health*, 10 May 2020) available at <https://www.jhsph.edu/covid-19/articles/wto-trips-waiver-for-covid-19-vaccines.html> accessed on 4 July 2021.
[147] AFP, 'US announces support for Covid-19 vaccine patent waiver' (*Hindustan Times*, 6 May 2021) available at <https://www.hindustantimes.com/world-news/us-announces-support-for-covid-19-vaccine-patent-waiver-101620243476047.html> accessed on 4 July 2021.
[148] Mazzucato and Ghosh *supra* note 45.
[149] Dyer *supra* note 19.

waiver is seen as the next step towards achieving the goal that propelled this progress in the first place – to end the pandemic.[150] Further, a TRIPS waiver does not mean that the companies owning the IP have to suffer losses. Any agreements to manufacture these products should include the payment of reasonable royalties to these IP holders to ensure that the companies are rewarded for their effort in scaling up production and access.[151]

On the argument of bad precedent, there is a clear distinction to be drawn between COVID-19 and the other illnesses. Although each of the aforementioned illnesses is grave and imperils public health goals, they are not as transmissible as COVID-19 has proven to be. The lag of inoculation in the LICs, as compared to the HICs, has spurred several mutations of the virus that threaten the global battle against COVID-19.[152] No one is safe till everyone is safe and that is a crucial distinguishing factor between why subsequent waivers for other illnesses will not be triggered.

The proponents of the waiver recognize that the waiver, while necessary for scaling production and access, is not sufficient by itself. It must be accompanied by speedy technology transfers and increase in manufacturing capacity. However, the waiver facilitates this process by simplifying the global rules governing IP and exports to give governments the freedom to collaborate on technology transfers without the fear of trade-based retaliation, as has been seen in the invocation of compulsory licensing in the past. Freeing up IPR for these health products would also catalyse support for platforms like the C-TAP.[153] There are multiple initiatives, such as the WHO mRNA vaccine technology transfer hub,[154] that provide channels to facilitate this technology transfer. If technology transfers are facilitated by WTO member nations, then the goals of the waiver can be met faster. This, in turn, means that the waiver shall terminate in time, which should assuage the concerns of opposing states and foster a commitment to sharing knowledge and know-how.

---

[150] 'Seven Reasons the EU is wrong to oppose the TRIPS waiver' (*Human Rights Watch*, 3 June 2021) available at <https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver> accessed on 6 July 2021.

[151] Mazzucato and Ghosh *supra* note 45.

[152] Damian McNamara, ''A Few Mutations Away': The Threat of a Vaccine-Proof Variant' (*Medscape*, 29 July 2021) available at <https://www.medscape.com/viewarticle/955691> accessed on 30 July 2021.

[153] Ommen C. Kurian, 'Patent Waiver as the New Pandemic Normal: India's Key Role in an Emerging Global Consensus' (*Observer Research Foundation*, 9 May 2021) available at <https://www.orfonline.org/expert-speak/patent-waiver-as-the-new-pandemic-normal-indias-key-role-in-an-emerging-global-consensus/> accessed on 6 July 2021.

[154] Expression of Interest, 'Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing' (*World Health Organization*, 16 April 2021) available at <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing> accessed on 6 July 2021.

Arguments against the Waiver

Given the unprecedented nature of this waiver, questions have been raised about its efficacy in achieving its goals. Negotiating the precise details of the waiver has seen the different factions in the TRIPS Council at loggerheads. While LICs have been supporting a waiver for all IP rights relating to the pandemic, the US has pledged support for a narrower patent waiver for vaccines.[155] The EU, Australia, Germany and Japan have opposed the waiver altogether.[156]

Staunch opponents of the waiver argue that nullifying IP rights only gives the illusion of solving the problem that exists. However, they argue that this stems from the misidentification of the problem itself.[157] They argue that a waiver of IP rights simply amounts to a waiver of the exclusionary rights of the IP holder, but makes no compulsion to share information with third parties. Rather, an IP waiver may destroy the formal platforms for disclosing information about inventions, designs and innovations for the public good. IP filings help manufacturers know the identity of the innovator and helps them contact the relevant authorities to negotiate licenses. In case of a waiver, temporary or otherwise, all of this information will become trade secrets, maintained under strict confidentiality. This prevents manufacturers and governments from rightfully obtaining enough information about the IP owners and their rights, either to negotiate licenses or to replicate the production of health goods. In essence, it would further slow down the equitable distribution of health goods.[158]

While individual countries may use coercive measures to compel a transfer of such information, that may result in legal action against these governments under domestic IP law, which does not automatically stand amended by a TRIPS waiver. Instead, the focus should be on establishing financial and other incentives to facilitate transfer of technology to other countries and third parties. Such incentives would allow them to transfer not just the IP-protected information, but other know-how and training required to produce these goods in a sustainable manner.

---

[155] Office of the United States Trade Representative, 'Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver' (6 May 2021) available at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> accessed on 30 July 2021.

[156] Reuters, 'Covid: Germany rejects US-backed proposal to waive vaccine patents' (*BBC News*, 6 May 2021) available at <https://www.bbc.com/news/world-europe-57013096> accessed on 30 July 2021.

[157] Ana Santos Rutschman and Julia Barnes-Weise, 'The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal' (*Bill of Health*, 5 May 2021) available at <https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/> accessed on 6 July 2021.

[158] Monica de Bolle and Maurice Obstfeld, 'Waiving patent and intellectual property protections is not a panacea for global vaccine distribution' (PIIE, 12 May 2021) available at <https://www.piie.com/blogs/realtime-economic-issues-watch/waiving-patent-and-intellectual-property-protections-not> accessed on 30 July 2021.

While the information gap is problematic, the two fundamental problems in the present pandemic are the extensive and time-taking regulatory approvals and the lack of know-how and raw materials to produce these goods. None of these are resolved by a TRIPS waiver. In the developing and delivering vaccines around the world, there are broadly seven steps in the supply chain – vaccine development, domestic approval for manufacturing, vaccine manufacture, domestic approval at the importing country, international distribution, border clearance and domestic distribution.[159] The initial phases require manufacturing capacity, supply of a variety of raw materials and technical know-how, while the transportation and distribution phases of the supply chain require certain minimum quality control and temperature standards for the effective dissemination of vaccines.[160] However, according to the WHO, less than 25% of countries meet the criteria for stock management, maintenance and distribution of vaccines, while around 29% of the countries meet the requirement of temperature control required to maintain these vaccines.[161]

Furthermore, each of these stages are governed by domestic regulations and clearances that have no uniformity amongst them. Regulatory requirements depend on the type of vaccine, manufacturing process, mechanism for action, the nature of the disease and the target population.[162] Due to the complexity of biotherapeutic products, their authorization on each stage of the supply requires more clinical study; thereby prolonging the time for approval. Further, different vaccines are produced using different technologies, which means that manufacturing units need to approved separately for producing different vaccines.[163] It is imperative to resolve this issue by adopting a uniform set of minimum approvals required for each type of vaccine that can be universally adopted to ensure that safety standards are uniformly followed across the world. In this regard, the WHO's Emergency Use Listing Procedure provides a global mechanism to streamline regulation.[164] However, a TRIPS waiver

[159] World Trade Organization Information Note, 'Developing And Delivering COVID-19 Vaccines Around The World' (22 December 2020) available at <https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf> accessed on 30 July 2021.
[160] *ibid.*
[161] World Health Organization, 'Immunization Supply Chain and Logistics: A Call-to-Action' (March 2014) available at <https://www.who.int/immunization/call-to-action_ipac-iscl.pdf> accessed on 30 July 2021.
[162] WTO Information Note, *supra* note 159.
[163] World Trade Organization, 'COVID-19 Vaccine Supply Chain And Regulatory Transparency Technical Symposium: Session 2- Mapping Vaccine Manufacturing And Trade' (29 June 2021) available at <https://www.wto.org/english/tratop_e/trips_e/techsymp_290621/summary_session2.pdf> accessed on 30 July 2021.
[164] World Health Organization Emergency Use Listing Procedure, available at <https://www.who.int/teams/regulation-prequalification/eul> accessed on 30 July 2021.

would do nothing to contribute to this, especially in light of domestic IP regimes continuing to operate as is.

On the issue of manufacturing capacity, countries opposing the waiver highlight how the presence of manufacturing facilities is imperative, but insufficient. This is because the components to manufacture any health good come from a variety of sources. Pfizer has attested that their COVID-19 vaccine supply chain relies on 280 components from 19 countries and that export restrictions in various countries can detrimentally impact production processes.[165] In fact, manufacturing companies have stated how the predictable system of IP rules laid down by the TRIPS Agreement accelerated the vaccine development processes by allowing manufacturers to locate patent holders and procure components for the final product.

Manufacturing COVID-19 health goods are complex and require specialised production capacity, especially with the use of mRNA technology which requires considerable technical knowledge.[166] Not only does there need to be a transfer of know-how of production, but it is imperative to ensure that trade restrictions do not restrict access to raw material. These supply chains are global in scope and IP waivers do not resolve export restrictions that countries impose.[167] Thus, instead of waiving IP rights, countries should focus on negotiating suitable trade measures to expedite these transfers. Given that major vaccine-developers have relied on government funding for support, governments should proactively engage in discussions on trade policy relating to COVID-19 related goods to scale supply while protecting IP rights.

If these infrastructural and contractual problems are not addressed, the only significant impact of the waiver would be to stifle innovation. While conceding to the use of government funding for their research, opponents of the waiver argue that the only reason that one can contemplate overcoming such a crisis is due to technological advancement and their underlying IP rights.[168] The waiver undermines the very system that has developed lifesaving science and destroys incentives for companies to continue developing these technologies.

Further, the argument that a waiver limited to COVID-19 related health products would not stifle innovation is flawed. A number of components of these technologies are used by these

[165] *ibid.*
[166] Prashant Yadav and Rebecca Weintraub, '4 Strategies to Boost the Global Supply of Covid-19 Vaccines' (*Harvard Business Review*, 6 May 2021) available at <https://hbr.org/2021/05/4-strategies-to-boost-the-global-supply-of-covid-19-vaccines> accessed on 30 July 2021.
[167] WTO Information Note *supra* note 159.
[168] McMurry-Heath *supra* note 127.

companies in developing other products and medicines.[169] Once third parties get access to these vaccines and health products, they can use the existing research of other companies to develop other products. Resultantly, pharmaceutical companies may lose their competitive advantage in other health-related technological fields as well.[170] This has a ripple effect on stifling innovation across the board, effectively depleting the standard of global healthcare.

It is also imperative to note that a TRIPS waiver does not automatically alter domestic IP laws. Even if the waiver is passed, HICs might adopt protectionist methods by invoking domestic IP laws or BIT protection to these companies.[171] They might follow a lower standard of disclosure than is necessary to replicate their products on a mass scale and may impose export restrictions on raw materials.[172] Thus, without a favourable domestic regulatory environment to facilitate transfers of technology and knowledge, there is unlikely to be a significant shift in the situation.

The exact scope of the waiver is central to its outcome. If a mere patents waiver is enacted, it does little to scale up production in the absence of trade secrets and transfer of know-how. This could also result in the production of substandard health products without an adequate understanding of the technology, having devastating effects on public health.[173]

It is also speculated that the negotiations for the waiver will take a substantial amount of time, should the waiver be enacted at all. If history is any evidence, it only demonstrates how negotiations at the WTO concerning the waiver are unlikely to yield results in the time-frame required to meaningfully battle COVID-19.[174] This is concerning in light of the various mutations of the virus that are already arising in different parts of the world. The Director General of the WTO has now suggested a deadline of December 2021 for the waiver

[169] Antonio Regalado, 'What are the ingredients of Pfizer's covid-19 vaccine?' (*MIT Technology Review*, 9 December 2020) available at <https://www.technologyreview.com/2020/12/09/1013538/what-are-the-ingredients-of-pfizers-covid-19-vaccine/> accessed on 7 July 2021.
[170] Gopakumar G Nair, 'Impact of TRIPS on Indian Pharmaceutical Industry' (2008) 13 Journal of Intellectual Property Rights, 437.
[171] Mansi Gupta, 'The TRIPS Waiver: A Necessary But Not A Sufficient Measure' (*IRCCL Blog*, 8 July 2021) available at <https://www.irccl.in/post/the-trips-waiver-a-necessary-but-not-a-sufficient-measure> accessed on 8 July 2021.
[172] 'American export controls threaten to hinder global vaccine production' (*The Economist*, 22 April 2021) available at <https://www.economist.com/science-and-technology/2021/04/22/american-export-controls-threaten-to-hinder-global-vaccine-production> accessed on 8 July 2021.
[173] Grady McGregor, 'Biden wants to waive patent protections for COVID-19 vaccines. We asked a patent lawyer what happens next' (*Fortune*, 6 May 2021) available at <https://fortune.com/2021/05/06/covid-vaccine-patent-waiver-protections-rights-waiver-biden-next/> accessed on 6 July 2021.
[174] De Bolle and Obstfeld *supra* note 158.

negotiations.[175] Whether this deadline will be honoured is tough to predict – despite the traction around the issue, it has been nearly 11 months since the initial proposal for the waiver was made in October 2020 and we are far from consensus.

VI. CONCLUSION

Talks about the waiver have already triggered a global discussion about the existing IP regime and its role in impeding accessible healthcare. The debate has already placed the obligation of transparency about production and pricing on pharmaceutical companies. The rising death tolls and emerging mutations of the virus show the dire consequences of insufficient production of and access to these health technologies. This virus knows no borders and neither should the fight against it. A globally coordinated multi-pronged approach towards developing an equitable production and distribution framework for these technologies is the need of the hour. The temporary waiver of IP under the TRIPs Agreement is not the panacea to this problem, but is considered by many to be a step closer to the goal of ending the pandemic.

This paper has demonstrated how the TRIPS waiver alone cannot help end the pandemic, yet the monopoly over production of these goods is a serious impediment in this endeavour. The threat of the TRIPS waiver can be used to facilitate multilateral voluntary agreements between companies and countries, just like the threat of compulsory licensing has led to voluntary agreements in the past. Apart from the monopolization of information, the problem is also one of matching supply with demand. The complicated manufacturing and distribution channels for public health goods needs to be uniformized to ensure that demand is matched by supply. The demand and supply of these health goods is unpredictable and with the emergence of new complications, vaccines and data on clinical trials, there is a high level of uncertainty about the goods to produce in the coming months. Such supply cannot be determined without knowing the different demand in different countries. In this regard, the establishment of a supply chain infomediary to help coordinate global supply and demand. Such an infomediary should be a neutral organization, serving as a repository of demand and supply data to help coordinate the needs of all players.[176] Given the opposition to the TRIPS waiver, such a proposal might serve as a middle ground for countries to agree upon while also going a long way in contributing to their mutual goals.

[175] 'WTO chief says hopes COVID patent issue will be settled by December' (*Reuters*, 10 May 2021) available at <https://www.reuters.com/business/healthcare-pharmaceuticals/wto-chief-says-hopes-covid-patent-issue-settled-by-december-2021-05-10/> accessed on 30 July 2021.
[176] Yadav and Weintraub *supra* note 166.

The promise made at the beginning of the TRIPs Agreement – that LICs would benefit from technology transfer and building of productive capacity – ought to finally be realised to end our fight against COVID-19 and hopefully, be better prepared against future health crises. It is important for nations across the world to commit to the goal of equitable distribution and take steps towards achieving it. This may or may not involve a TRIPS waiver, but certainly requires proactive steps towards strengthening supply chains and manufacturing capacities for health goods. Governments should consider negotiating trade measures to strengthen technology transfers while protecting the rights of innovators. This will go a long way in establishing a framework to better withstand future pandemics.