A COMPREHENSIVE EXCURSUS OVER THE CASE OF INTELLECTUAL PROPERTY PROTECTION WAIVER FOR COVID-19 VACCINES

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The indispensable advent of proven and efficacious vaccines against Covid-19 - which has claimed over 4.16 million lives so far, emerged as an ebullient source of light holding the greatest promise to resolve the darkness of this pandemic. However, the insurmountable task of inoculating millions around the globe will need pre-eminent measures in the sectors of vaccine production and their equitable distribution. A great encumbrance to such recourse in the present setup of vaccine production-distribution lies in the form of Intellectual Property Rights (IPR) which the developers of already a handful of vaccines, avail themselves of. Apart from this, the post-introductory, nascent stage of vaccines has indicated towards a deepened self-interest of developed countries resulting in accumulation of essential raw elements and in the biased distribution of the same, defeating the statesmanship of solidarity and multilateral cooperation which can assure better accessibility to all. In this regard, the set of proposals moved by India and South Africa to waive certain provisions of the TRIPS agreement around Covid-19 related the rapeutics, emits the possibility of an institutionalized response with the greatest potential to upscale the productive-distributive facilities allowing the developing countries to adopt a much comprehensive strategy ensuring sufficient and

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affordable access to vaccine technologies. This article, while making the case for such a waiver, sets out to ascertain and explain various dimensions including its desiderium, feasibility and implications amidst the ongoing consideration by the TRIPS Council.

Keywords: IPR, TRIPS Agreement, WTO, COVID-19 Vaccines, Vaccine Nationalism

I. Introduction

Following the zenith of Uruguay round of trade talks, the World Trade Organization ("WTO") came into existence in January 1995 along with many trade-related agreements on goods (General Agreement on Tariffs and Trades, "GATT"), services (General Agreement on Trade in Service, "GATS") and other relevant attributes of international trade with the aim to narrow down the gaps in cross-border trade practices.[1] The Uruguay negotiations also saw discussions over Intellectual Property Rights ("IPR") as with the changing idea of trade attributable to the inclusion of innovation, creativity and branding; the contemporary significance of the knowledge economy and private intellectual property also came to be recognized making it another component of international trade.[2] While the developing countries did not display any token of interest, the developed countries, by the likes of their chemical, pharmaceutical and entertainment transnational corporations, aggressively pushed for a similar agreement as the two mentioned above, acting in a more national sense believing the effectively monitored and increased cross-border protection to bring in greater revenues through the channels of and for their corporations.[3] The developed nations compelled the developing nations to acquiesce to an agreement

[1] Peter Van den Bossche & Werner Zdouc, The Law and Policy of the World Trade Organization, 42-47 (3rd ed. 2013).
[2] Peter Drahos with John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? 2-3 (Earthscan Publ' 2002).
[3] Susan Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights, 9-12 (Cambridge University Press 2003).

over the same through various means which also included economic coercion-threats of hefty restrictions and allurement of handsome concessional access to textiles and agricultural trade sectors, resulting in the introduction of the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS") in 1995.[4]

Thenceforward the TRIPS agreement, which was initially conceived just as a peripheral agreement, mainly relating to cross-boundary enforcement against fraud imitation and piracy, has become a comprehensive legal instrument harmonising the IP protection around the world and emerged as the third pillar of the global trading system, adding new dimensions to conventional regulations as they were known under the GATT.[5] This emanation could be accounted to the agreement's bounding obligations on member-countries offering a global baseline enforceability and dispute settling capabilities. However, since its inception, the TRIPS agreement ("The Agreement"), has also been a subject of intense criticism owing to obvious reasons which imbalance the nexus between the private rights of ownership and the public good of shared knowledge over certain areas such as public health and education, as required by the generality for a broader welfare.[6] It is most-often argued that the agreement offers an unbefitting and invariable standard for all versions of diverse states forcing the developing and the least developed countries ("LDC") to invest heavily in raising domestic standards or to incur heavy costs from the developed world rights-holders for technology and service transfers of crucial sectors.[7] The proponents, on the other hand, believe that by instituting legal protection on the disclosure of information, creativity and innovation is both rewarded and encouraged on multiple levels contributing directly to development of global trade and commerce.

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[4] Simon Lester, Bryan Mercurio & Arwel Davies, World Trade Law: Text, Materials and Commentary 804-805 (Hart Publ'g, 2018).

[5] T. Cottier, *The Agreement on Trade-Related Aspects of Intellectual Property Rights,* in The World Trade Organization: Legal, Economic and Political Analysis 1041 (Macrory P.F.J et al. eds., 2005).

[6] S.K. Sell & A. Prakash, *Using Ideas Strategically: The Contest between Business and NGO Networks in Intellectual Property Rights*, Int'l Stud. Q., 143-175 (2005) [hereinafter 'Sell'].

[7] H.J. Chang, *Intellectual Property Rights and Economic Development – Historical Lessons and Emerging Issues*, J. Hum. L. Rev. 287 (2001) (hereinafter 'HJ Chang').

This tussle owes its existence to several complex disparities between multiple perspectives and seems unending; but a part of this debate which concerns the impact of the agreement on public health is, specifically, a constant variable of utmost severity which hits its crest during a global exigency or health crisis. While the proponents apply the same set of arguments to defend the agreement, critics refine their contentions explaining the impediments in the introduction of affordable and quick facilities of drugs, vaccines and other therapeutics in the developing and least developed countries due to barriers erected by IP protection.

This altercation is again brought to fore in the light of pandemic *de nos jours* which has grappled the world in an uptight manner, claiming almost over a hundred-million lives, overloading national health systems and inhibiting sufficient access to public services leading to an acute socio-economic crisis within a couple months of the Corona virus outbreak.

II. The Waiver

With the toll escalating on a daily basis and the virus variant proliferating incessantly, the urgency to respond to the current pandemic clearly indicates towards the dire need for a broader collaboration of solidarity and are liable global health system in response to complexities emerging out of crises, like the ongoing. The disproportionate availability of essential medical equipment and supplies; therapeutics; their raw components and technology, marks one such complexity highlighting the importance of such a need. The introduction of Covid-19 vaccines did bring along with them the glimmers of hope and heartening and probably the only way out of this fatal position but also became locus of the same debate as they form a factor subject to IP protection under the TRIPS agreement as well. The vaccine developers, going by the law, like any other, enjoy an exclusive right to produce and vend for the entire term guaranteed by patent protection i.e., a period of 20 years from the date of patent, against unfair competition.[8] There is a school of

[8] The Agreement on Trade-Related Aspects of Intellectual Property Rights art. 28, art. 33, Apr. 15 1994,1869 U.N.T.S. 299.

thought which suggests that such protection, in a global crisis like this, can impede wider accessibility of vaccines and neutralize the effect of the process. The answer lies in not just the introduction of the vaccines but in successful and timely inoculation of the masses.

Furthermore, the development in the area of vaccines has indubitably achieved a great feat, but the effects of such developments and of Covid-19, are unequal and non-resonant which do not garner similar benefits to every world-country simultaneously. This adversity has impacted and continues to impact populations in dissimilar manner, imposing a vicious social and economic burden on the most impoverished and already extremely vulnerable LDCs. The initial waves of devastation have already accentuated the lack of coordination between counties over development, production and diffusion of vaccine and vaccine technologies which can deteriorate, even more due to the robust stockpiling of doses by every other capable country. Apparently, it was reported by a coalition of campaigning bodies that most of the developed countries, representing only a 13 percent share of the global population had bought up to 51 percent of promised doses[9] by policies such as advance-purchase agreements, along with secured and priority access to vaccine technology and manufacturing capacity.[10] The glaring extent of disparity is such that while countries like America and many from the European bloc have fully vaccinated almost a half of their population, the LDCs have failed to secure sufficient doses for even an acknowledgeable share of their people[11]. In addition to this, the existing market space, and its functioning, in a setting which under sheer and continued pressure is collapsing has also failed to maintain correct standards of production and distribution.

The most pressing need right now is to deploy a comprehensive strategy so as to guarantee widespread, timely, baseline-sufficient, and affordable access to people in every corner of the world. The contemporary demand requires commitments and obligations which

[9] *Rich Countries Hoarding Covid Vaccines, Says People's Vaccine Alliance*, BBC Health, BBC (Dec. 9, 2020), https://www.bbc.com/news/health-55229894.
[10] Alexandra L. Phelan, *Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access*, 396 Lancet (2020).
[11] *Id.*

limit unilateralism and ensure equitable distribution of vaccines. It is within this frame of reference when the "vaccine nationalism" has deepened that India and South Africa together made a proposal to WTO's TRIPS Council, requesting all its member countries to allow "a waiver from the implementation, application and enforcement of several specific provisions of the TRIPS Agreement for the better prevention, containment and treatment of the Coronavirus disease", temporarily until widespread vaccination has taken place globally and majority of the world populace has developed an immunity. These provisions under the proposal comprehensively cover four sections of Part II of the TRIPS Agreement – Section 1, Section 4, Section 5 and Section 7 which provide protection on copyright, industrial design, patents and on undisclosed information, respectively.[12] Waiving off these specific provisions, as argued by the proposal, could help to negate barriers to the timely access to the indispensable vaccine technology ensuring a scale-up in production, distribution and research and development as well. The prospect of the proposal is such, that if accepted, the various and in fact every possible measure(s) taken by local government will become legitimate and immune from the claims of illegality under the WTO law.

If the waiver is granted, the member-countries will not be temporarily under an obligation, to either grant or enforce rights related to IP in case of Covid-19 drugs, vaccines, and other therapeutics.

The proposal displays the same essence as of the resolutions approved by the World Health Organisation and United Nations and aligns with other schemes, which intend to guarantee access to reliable and affordable technologies for the agenda of global immunization.[13] WHO's Covid-19 Technology Pool Access (C-TAP) which was introduced in association with the Government of Costa Rica, proposed to create a "pool for voluntary licensing on a non-exclusive basis for technologies

[12] *Id.*

[13] *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of Covid-19*, Communication from India and South Africa, IP/C/W/669, *Council for Trade-Related Aspects of Intellectual Property Rights*, World Trade Organization, (Oct. 2, 2020) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

that support the diagnosis, prevention and treatment of the virus"[14]; Access to Covid-19 Tools (ACT) Accelerator, a collaboration of global health actors including, again the WHO, to accelerate the development, production and access to Covid-19 treatments and strengthening of global health system; and Covid-19 Vaccines Global Access (COVAX), co-led by WHO, CEPI and Gavi are among the examples of such initiatives which directly or indirectly strive for the similar aim.

However, the actuality of such initiatives has turned out to be completely divergent on all levels in view of the intense and wide spectrum of problems faced by these programs, ranging from lack of funds to different multiplexities involved in supply and distribution around the globe.[15] While "Advance Purchase Agreements" and other licensing agreements between countries and developers show the potential to meet specific demands and standards, the exorbitant exploitation of the same to reserve a substantial amount of vaccine doses by countries with greater purchase capability, is widening the access gap by manifolds defeating the purpose of these programs.[16]

The Proposal, over the time has been supported and co-sponsored by a number of countries but obviously with a polarised outlook. A group of small but influential and developed countries, which include, mainly, Japan, Australia, Canada, the European Union ("EU") and the United Kingdom downrightly opposed it. The argument put forward by them contends that IP Protection promotes research and innovation and that suspending such rights will not necessarily scale up the production-distribution of the vaccines.[17] Moreover, on a different front, it is also contended that the existing exceptions provided under and around

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[14] Sudip Chaudhuri, *Making Covid-19 Medical Products Affordable: Voluntary Patent Pool and TRIPS Flexibilities*, South Views 200 (2020).

[15] Francesco Guarascio, *Exclusive-WHO Vaccine Scheme Risks Failure, Leaving Poor Countries No COVID Shots until 2024,* Reuters (Dec. 16, 2020), https://www.reuters.com/article/health-coronavirus-who-vaccines-exclusiv/exclusive-who-vaccine-scheme-risks-failure-leaving-poor-countries-no-covid-shots-until-2024-idUSKBN28Q1LF.

[16] Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, Mich. L. Rev. Online 118 (2020).

[17] *Rich, Developing Nations Wrangle Over COVID Vaccine Patents*, Health and Pharmaceuticals, Reuters (Mar. 10, 2021), https://www.reuters.com/article/us-health-coronavirus-wto-idUSKBN2B21V9.

the TRIPS agreement are sufficient to cover most of the concerns highlighted in the proposal.[18]

Recently, these non-cumulative contiguous events saw a great turmoil when, United States made a substantial shift in its policy by offering, in principle, a text based support for the waiver but only limited to protection around vaccines.[19] Following this, the co-sponsor countries introduced a revised proposal which expanded the scope of the proposed waiver from only vaccines and technology around Covid-19, as earlier, to "health products and technology" in general along with addition of a section to specify the duration of the proposed waiver, i.e., three years.[20]

Subsequently, the EU, placing its opinion in the TRIPS council, submitted an alternative proposal which offered alleviation in supply chains, export limitations and treatments to encourage and increase the cross-border access, while retaining IP protections. The EU, with backing of the UK has suggested a cooperative approach to solve this crisis as it is believed that even if the IP protection is waived off, the problem of accessibility cannot be worked out with the same ease.[21]

Agreed over the series of previously held meetings of the TRIPS Council in the month of June, the member-countries decided to hold text-based negotiations focusing over the set of proposals put forward by the member-countries. The last round of sittings, held late in the month of July and during the first week of August saw a split of opinions

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[18] James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for Covid-19 Vaccines*, CATO Inst. Free Trade Bull., 78 (2020).

[19] *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, Office of the United States Trade Representative, Executive Office of the President (May 5, 2021).

[20] *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, Revised Decision Text, IP/C/W/669/Rev.1, *Council for Trade-Related Aspects of Intellectual Property Rights*, World Trade Organization (May 25, 2021).

[21] *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property, Communication from the European Union to the Council for TRIPS*, IP/C/W/680, *Council for Trade-Related Aspects of Intellectual Property Rights*, World Trade Organization (June 4, 2021); *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic*, Communication from the European Union to the Council for TRIPS, IP/C/W/681, Council for Trade-Related Aspects of Intellectual Property Rights, World Trade Organization (June 18, 2021).

between the developed and developing countries, halting the talks, and missing the July end deadline.[22]

III. The Exceptions in and around the TRIPS Agreement

In accordance with Article IX.3 and Article IX.4 of the Marrakesh Agreement - the apogee of Uruguay and many other round of trade talks, the Ministerial Conference of the WTO is allowed to waive an obligation on any member-country by any multilateral trade agreement under the organisation in cases of "extraordinary circumstances", provided that it is supported by three-fourths of the member-countries. While such a term is nowhere defined in the agreement, its inclusion, in the mentioned article acknowledges the case of certain exigent situations resulting in extreme adversities upon a country, where compliance to many trade-related norms may not be viable.[23] For any member-country to avail a waiver, it is initially required by them to submit a request to the relevant WTO body for further consideration as put out by Article IX.3 (b), wherein the bodies stated are, namely, the Council for Trade in Goods, the Council for Trade in Services and the TRIPS Council.

Moreover, the TRIPS Agreement, in itself, includes many flexibilities keeping in mind and taking in account, the possibilities of such adverse exigencies. These flexibilities are handed out generally in the form of licensing arrangements and research exceptions as mentioned in Article 30 and Article 31 of the said agreement. While Article 30 provides for limited exceptions to the exclusive rights conferred by a patent without prejudice to the legitimate interests of the patent owner but on the other hand, Article 31 puts out a detailed set of exceptions, including "compulsory licensing" which can be employed even without the authorization of the patent holder, provided that certain conditions stated therein are met. Compulsory Licensing can, more accurately be described as a regulatory tool used by governments or third parties

[22] Kritika Suneja, *A Few Member Countries Ensured Deadline on Covid Vaccine IP Waiver Talks was Missed: India to WTO,* Econ. Times (July 28, 2021), https://economictimes.indiatimes.com/news/india/a-few-member-countries-ensured-deadline-on-covid-19-vaccine-ip-waiver-talks-was-missed-india-to-wto/articleshow/84812454.cms.
[23] Isabel Feichtner, *The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests*, Eur. J. of Int'l L.(2009).

backed by the governments to produce-distribute products under patent protection without the advance permission of the rights holder. This exercise, in general, is only allowed in exceptional circumstances such as national emergencies and health crisis.

Furthermore, the Declaration on TRIPS Agreement and Public Health, adopted at the fourth ministerial conference held in Doha, 2001 ("The Declaration"), which provides "the mandate for negotiations on a range of subjects including issues revolving around the implementation of present agreements," also recognises a multitude of exceptions in light of the several circumstances as discussed hereinabove. To provide one as an instance, the long transition period made available to the LDCs for compliance with the TRIPS Agreement stands out tall.

There are 144 instances of the WTO actually considering a waiver during the span of 15 years from 2001 to 2016, out of which 100 were of compulsory licensing or non-commercial use to ramp up the production and accessibility to public health measures.[24] In 2003 when many LDCs and developing countries were dealing with concerns of accessibility to generic medicines due to lack of the manufacturing ability, the General Council, out of the recommendation provided by the TRIPS Council, waived off certain obligations contained in Article 31 of the TRIPS Agreement.[25] Article 31(f), which states that any such use of the compulsory license should be authorised predominantly and on a case by case basis for supply of the domestic market, was waived off for exporting countries but under conditions which limited the supply only up to the extent necessary and only to the number of eligible countries.

This decision by the General Council was made permanent in 2005 by bringing around an amendment in the TRIPS Agreement which included the essence of the decision by introducing Article 31 *bis* in the agreement. Although being amended in 2005, its effect took place only after 12 years in 2017.

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[24] Ellen Fm't Hoen et al., *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001-2016*, 96(3) Bull. of the World Health Organization [WHO] 185 (2018), https://apps.who.int/iris/bitstream/handle/10665/272240/PMC5840629.pdf.

[25] General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 (Aug. 30, 2003).

Moreover, the international community in general, rests with it, the responsibility to prevent and contain the spread of transmissible diseases and has often takes the side of a justified system of extraterritorial application of the rights ensuring accessibility to medicine and technology amidst the spread of one.[26] There are many provisions from around the corners of distinct sectors of socio-economic constructs, agreements and accords which hint towards the primacy of shared cooperation in areas like public health during a transboundary crisis. For instance, Article 12 of the International Covenant on Economic, Social and Cultural Rights puts its member-countries under the obligation to give health rights the foremost importance, including access to essential drugs and healthcare facilities.[27]

Indeed, the element of morality sees itself surpassing the abstract normative principles of law during the periods of grave plight but if we get to the grass root level and are to believe the naturalists, then this set of principles is nothing but a rational ordinance which concerns the common good of the community, promulgated by the authority in charge.[28] Similarly, Article 7 of the TRIPS Agreement reads that, "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Thus, it would not be grossly unjust if passing of such a waiver, not completely but even slightly contributes against and answers the call of repercussions of the current crisis.

IV. Analysis of the Dialogues Over the Insufficiency of the Flexibilities

The only thing to constantly keep in mind while assessing the dimensions and aspects of the said proposal, is the severity and

[26] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant), (Jan. 12, 2006).
[27] International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966.
[28] St Thomas Aquinas, *Summa Theologica, Treatise on Law Q90, art. 4 para F.*

exceptionality of the current pandemic. Covid-19 is without any doubt, amongst the worst global health crises which has caused unprecedented socio-economic destitution and it would be highly erroneous to compare its factors with the standards of any other in the past. The repercussions of such a pandemic need to be tackled with measures beyond the set frameworks of existing socio-political determinants of health. The principal objective behind the proposal is to permit the countries to efficiently address the urgency of the current situation by allowing them to manufacture their own vaccines and scale up the production capabilities. The proposal indeed rings the bells of morality and seems like a legible tool which can help and speed up the fight against the pandemic but considering the amount of complexity involved herein this extensive process of negotiation, especially after the revised proposal with broader aim, any contention on this front falls contrary to its primordial purpose. On the other hand, those against the proposal similarly need to understand the insufficiency of any kind of pre-existing flexibilities, provisions, or exceptions in and around an atypical pandemic as massive as the current one. The efficacy and utility of these flexibilities vary for every individual country. Numerous developing countries having the manufacturing ability, with certain insight can effectively employ these flexibilities but compared to such countries, a larger number of LDCs do not have the necessary proficiency or ability to execute many of these flexibilities.

Besides this, the great reliance placed particularly over compulsory licensing is proving to be of very little value in the current setting, given the numerous and different constraints it has even in general and their effects over the license's efficiency in practice. The pre-condition of an existing negotiation with the patent holder and the establishment of adequate remuneration, license for particular products in individual cases are some of the strands which add upto the stack of such constraints. Proponents believe that, owing to the reasons of these complexities, the issuance of compulsory licenses in events of serious health crises like the one existing, also limits the prospect of technical

coordination between companies aiming to achieve higher margins of incentives and countries stockpiling the vaccines.[29]

Additionally, the complication of restriction over the export of generic medicines manufactured under a compulsory licensefoisted by Article 31(f) of the TRIPS Agreement, which was touted to have solved the problem of countries with insufficient manufacturing capabilities by inclusion of Article 31 *bis,* still leaves behind several concerns regarding the cumbersome process of import and export of such medicines and technology. The procedure consists of a lot of complexities which defer as well as disincentivise the exporting companies and manufacturers to participate and produce products under a compulsory license.[30] The leading and general reason behind this marks the lower levels of economies of scale/cost advantages reapable in order to induce the interests of companies and manufacturers for them to voluntarily engage in the practice.[31]

Opponents of the waiver, including many developed countries whether or not acting in a self-centred manner, have put forward their arguments which contend the merit of the waiver, solely to be very less significant in the current situation and assert that the existing flexibilities in and around TRIPS agreement have always been sufficient to address and tackle exigencies even of the gravest nature. However, there are instances from the very short history of TRIPS Agreement which suggest the contrary. Before the agreement over TRIPS, many of the countries either did not patent medicines and related technology or imposed a robust 20-year protection over them. However, under the contemporary provisions of the TRIPS Agreement, the developers and manufacturers keep with them the ability to drive up the costs of their product to generally unaffordable levels by exercising monopoly pricing and keeping out the alternative of cheaper generic substitutes citing poor

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[29] Henrique Zeferino de Menezes, *The TIPS Waiver Proposal: An Urgent Measure to Expand Access to the COVID-19 Vaccines,* South Ctr. (Mar. 2021).

[30] Donald Harris, *TRIPS after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, J. of Intell. Prop. L. 18 (2011). *see also*, Frederick M. Abbott and Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions*, J. of Intl. Econ. L., 10, 921 (2007).

[31] Holger P. Hestermeyer, *Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, American Soc. of Int'l L, 11 (2007).

quality standards. In 2001, after South Africa passed and enacted the Medicines and Related Substance Act of 1997 invoking the compulsory licensing provision to produce-distributeand parallelly import affordable generic drugs in light of the HIV/AIDS crisis culminating in the country then, many of the world's most dominant and influential pharmaceutical developers and manufacturers dragged the South African government to court in order to prevent the use of compulsory licensing for cheaper generics, which according to them was a violation of the TRIPS agreement.[32] While the immense pressure and public condemnation received from the generality forced these manufacturers to abandon the case, they still succeeded in lobbying developed counties to impose bilateral trade sanctions against the country.[33] In a similar instance, the Swiss-based multinational pharmaceutical company Roche imitated patent infringement proceedings against the Indian drug manufacturer Cipla for its decision to launch a generic version of a cancer drug which was based upon a compound named Erlotinib Hydrochloride, patented to and sold by the former.[34] Delhi High Court, citing "public interest" and the "affordability factor" initially ruled out in Cipla's favour but after a prolonged round of litigation involving several appeals, reviews and the ball changing courts due to heavy influence of the companies, both the parties withdrew all the pending litigation against each other. The matter was ultimately settled out of the court but only after leaving a worrisome mark which left many to ponder upon the nature of influence and monopolistic dominance these pharmaceutical companies maintain over such a primary sector.

Taking a transient digression from the core upshots of the abovementioned instances,the recent case of "Remdesivir" reveals a typical and adverse effect of IP protection over therapeutics during a transboundary health crisis. The patent for base compound of the drug is enjoyed by a single bio pharmaceutical company named Gilead in more than 70 countries, which means that when countries are

[32] Sell, *supra* note 6.
[33] M.J. Rotheram-Borus & M. Tomlinson, *Not Remembering History, Dooms Us to Repeat It: Using the Lessons of the Global HIV Response to Address COVID-19*, AIDS Behav. 3288-3290 (2020).
[34] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 SCC OnLine Del 382 : (2008) 148 DLT 598.

not under the blanket of voluntary licensing or do not deploy other measures to overcome the IP protection, they may not be able to get the access to generic alternatives until the expiry of the protection period, i.e., 20 years.[35] The public outcry against the strict enforcement of its patent rights over the drug forced Gilead to sign voluntary licensing agreements, which it did but with only a handful manufacturers of its choice. This led to nearly half of the world's total population to be excluded from direct access to the drug or to the affordable generics, including a multitude of countries with manufacturing capacity.[36] This exactly displays how multinational corporations venture to use the provisions of TRIPS in order to pursue private gain at a very clear cost of public good and health.

Subsequently, it has been argued that, though the development of various Covid-19 vaccines and related technology have been carried out by private pharmaceutical companies, a lion's share of public sector resources and philanthropic funding have been put behind to finance the research and development behind the same.[37] Commercializing the such vaccines and medical technology would infringe the public right to shared medical and scientific breakthroughs.

Proponents recognise and question the masked potential social cost of TRIPS Agreement for poorer countries and the dominance of private manufacturers in crucial sectors, particularly over the issue of accessibility to basic drugs and healthcare technology.[38] Plus the inequity over the share of vaccines among the countries possess not only a morally indefensible threat but also insufficiency in global vaccine production-distribution, making them ineffective eventually. The continuance of the prevailing situation can result in increased costs, greater inequity, and delayed protection at a global level. Moreover, the handful of flexibilities that are granted are believed to be far too

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[35] *India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19-related Medical Technologies*, Briefing Document, Médecins Sans Frontières (Nov. 18, 2020).
[36] *Id.*
[37] Ruchir Agarwal & Patrick Gaule, *What Drives Innovation? Lessons from COVID-19 R&D*, Int'l Monetary fund (Working Paper No. 2021/048).
[38] G. O'Farrell, *One Small Step or One Giant Leap Towards Access to Medicines for All?,* Eur.Intell. Prop. Rev., 30, 6, 211-215 (2008).

restrictive due to numerous limitations and for a good part, insufficient, especially in cases of grave transboundary crisis. This limited freedom in interpretation of the agreement in the light of public health often remains unexercised owing to complexity, cost and threat of retaliation in the form of trade restrictions and sanctions as evident from the provided and many other strikingly similar instances.[39] Certainly, this patent waiver is not the comprehensive solution which can cover, address and tackle the ripples of this pandemic solely but is definitely amongst the ones which can contribute significantly and urgently in the fight against it.

Contrastingly, the ones who oppose the waiver, do so on a consistent point which goes in consonance with and revolves around the foundation of the TRIPS Agreement. They argue IP protection to be the incentive of the innovation, which if undermined could worsen and jeopardise the affairs around future research and development by forcing the developers and innovators to restrain themselves from further contributing.[40] They also press upon the indisputable and indispensable role and attributes of the TRIPS Agreement which enabled the development of vaccines in a very short time and is still contributing to their further development.[41] In the current setting, opponents of the waiver, which include countries like Japan and Brazil, believe that the waiver alone cannot effectively address the crisis even if allowed because of numerous other bottlenecks such as large scale technology transfer, low availability and processing of raw materials, lack of technical know-how and required environment, training of individuals and dependence on handful of suppliers for related components and technology, all of which could become a load of tedious tasks for the least developed and developing countries, due to institutional and infrastructural deficiencies. In addition to this, a waiver in the contemporary-nascent stage of the vaccine development and production (where the new strains of the Coronavirus are evolving with every passing day), could lead to an

[39] *Id.*
[40] Paul Belleflamme, *Patents and Incentives to Innovate*, Ethical Perspectives 13(2), 267-288 (2006).
[41] Mahoney R.T., Pablos-Mendez A., & S. Ramachandran, *The Introduction of New Vaccines into Developing Countries. III. The Role of Intellectual Property,*22 Vaccine 786-92 (2004).

increased possibility of a global ramification, especially in the absence of liability of the private entities. It could also risk and divert raw materials and supplies away from well established, efficient and effective supply chains to the ones less coherent,imperilling the standards and quality of vaccines and therapeutics. Furthermore, case for voluntarily licensing is not of the same substandard as claimed. The number of voluntary licenses is indeed low, but they are so only because of the lesser number of countries and manufacturing houses currently having the required standards, technology, and technological insight in and for large scale vaccine production. Only in India, for instance, most of the pioneer vaccine developers have extended their license to almost all the capable manufacturing facilities such as Serum Institute of India, Cipla, Dr. Reddy's and many more, allowing them to produce and distribute their respective vaccines.[42]

To put it concisely, the IPR advocates believe, primarily in IP protection as a strong tool of encouragement for promoting innovation and for bringing in investment for advance research and development which can further facilitate the vaccine production-distribution; and secondarily in a bigger picture of associated technology and know-how transfer which lies beyond the position of the proposed waiver. The only setback in their beliefs comes in the form of time constraint and the urgency to address this crisis effectively. For any of the above to take place effectively and on a sufficiently large scale, ample of time will be required compared to the proposed waiver.

V. Epilogue

The proposed waiver and the existing flexibilities provided in and around the TRIPS Agreement are not mutually exclusive.

The proposal for a waiver on certain IP provisions offers a comparatively expedited and widely open global solution that will undoubtedly allow for a greater and unhindered collaboration in

[42] Manoj Sharma, *Apart from Serum, Bharat Biotech, these 5 Vaccine Makers are India's Hope against Covid-19,* Bus. Today (May 17, 2021), https://www.businesstoday.in/coronavirus/story/apart-serum-bharat-biotech-5-vaccine-makers-india-hope-against-covid-19-296312-2021-05-17.

development and scale-up of vaccine production and supply. However, before the same could be done, a foundation needs to be laid for counties without a proper infrastructure and adequate mode of technology transfer. This obviously is not an efficient strategy fit for the contemporary crisis but is necessary to maintain the standards of quality and effectiveness which can in turn contribute significantly and maybe completely in the near future. Countries with the apt manufacturing capabilities, meanwhile should consider and continue to use the flexibilities provided, to instantly safeguard public health at all levels, including issuing compulsory licenses and placing limitations on or making exceptions to exclusive rights. In light of the same, the practice of voluntary licencing along with voluntary schemes and efforts for equitable vaccine, treatment, diagnostic and technology distribution like COVAX and C-TAP should be strongly encouraged. Whereas for the developed countries, them being the world leaders, initiatives for greater transboundary cooperation and justified pooling of resources and equitable distribution of the same should be undertook and uplifted by them as "obligations of developing countries and the rights of developed are enforceable to a far greater extent compared to the rights of the developing and the obligations of the developed."

The duality around the sphere of IP rights encompasses enough potential to justify the arguments from either side of the proposed waiver. The demand for a broad-blanket waiver seems not only problematic but also robust as it could, in fact seriously disrupt the urge to further research and innovate, even in crucial health sectors such as public health. The same is with the "one size fits all" provisions of the TRIPS Agreement for every country whether developed or developing and for every bracket of circumstances, which poses a great threat to proper execution and efficient exercise of the agreement and of the flexibilities provided therein.[43]

Similarly, the additional limitations associated with Compulsory Licensing such as the "case by case" or "product by product" approach, can be relaxed even more, especially considering the state of LDCs during a crisis which already suffer through several self-imposed

[43] H.J. Chang, *supra* note 7.

limitations due to lack in practical and institutional capacity. Keeping in mind the enormous demand, the production of vaccines needs to be increased by manifolds and should be followed by equitable distribution running on a dynamically strict pattern. Steps should be taken against the practices which promote disparity in vaccine shares, including unjust accumulation of resources and vaccines through the medium of Advance-Purchase Agreements. Trade barriers, lack of raw materials and technological insight and bottlenecks in the supply chain are some of the aspects over which direct talks should be held.

At last, considering the aspects of the alternate proposal put forward by the EU, the bloc seems to be right in its approach as the accessibility and transfer of technology along with the insight cannot be worked out as easily even if the waiver is allowed. Moreover, between the ongoing series of sittings, so as to take stock of text-based negotiations and given the complexity of the matter, the likelihood of reaching to a conclusion over the waiver seems to be too little. For anything to happen, all 164 member-countries need to find a consensus.