IP AS AN END IN ITSELF?
THE CASE OF THE COVID WAIVER

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Abstract

This paper addresses distributive concerns regarding intellectual property (IP), particularly in the pharmaceutical realm, emphasizing the historical inequities in multilateral agreements and their implementation. The COVID-19 pandemic's stark impact on health access prompts a shift beyond IP internalism to scrutinize fundamental TRIPS-related disparities. Focusing on IP Gradualism, the paper underscores worldwide institutionalization disparities, delving into capability-building narratives, transition period hypocrisy, and their impact on global IP politics. The pandemic exposes longstanding skewed capabilities, prompting a region historically denied self-determination to request a waiver of the same agreement sustaining this inequity. Examining nations opposing the waiver, the paper reveals their imitation-based resistance, using time to highlight critical realities for waiver discussions, even diplomatically. The paper asserts that addressing the knowledge divide, decolonizing IP, and achieving distributive justice necessitate a geo-historically attuned trade perspective. Analyzing WTO Agreement waivers, the paper exposes interpretational hypocrisy in exceptional circumstances, further bolstering claims of inequity and advocating for global diplomatic restructuring. Ultimately, the paper underscores the need for conscious recognition of historical context and reasons behind

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present inequities, calling for global solidarity grounded in these realities.

Keywords: COVID Waiver, TRIPS, Access to Health, Pandemic, WTO, IPR in Pharmaceutical Industry.

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INTRODUCTION

Much has been spoken about the impact of Intellectual Property ("IP") on the distribution and development of vaccines essential to combat the menace of the COVID-19 pandemic. IP is often considered to be an essential enclosure on access to enable invention and creation in a capitalist society. In context of vaccines and therapeutics, these enclosures on knowledge and technology required for inventing and producing gain legitimacy through globally legitimized exclusionary norms of regulatory inducement. Negotiating a temporary waiver of those enclosures and exclusionary rights embedded within the Agreement on Trade-Related Aspects of Intellectual Property Rights ('**TRIPS Agreement**') at the World Trade Organization ("WTO") in interests of global solidarity towards accessibility of vaccines and therapeutics has been a mammoth task.

For context, India and South Africa had tabled a proposal titled "*Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19*" on 2nd October 2020,[1] before the Council for TRIPS, WTO emphasizing on World Health Organization's ("WHO") declaration of COVID-19 to be a "Public Health Emergency of International Concern", as well as on the WTO's

[1] World Trade Organisation, Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19- Communication from India and South Africa , Council for TRIPS of 2nd October 2020, IP/C/W/669 (2020), available at < https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf>.

own statement that the pandemic represents an unprecedented disruption to the global economy and world trade due to the growing supply-demand gaps. The aim was to avoid exclusionary rights over essential therapeutic products, processes, and their technologies to enable widespread development and use during the pandemic without exclusionary regulatory inducements.

The waiver proposal was not limited to vaccines. It aimed at scaling up research, development, manufacturing, and supply of all kinds of medical products that would be essential to combat COVID-19. It emphasized upon need for "rapid" access to affordable medical products like diagnostic kits, medical masks,[2] other protective equipment and ventilators, apart from essential medicines and vaccines for patients who were in dire need across the world. The focus of the proposal was on "capacity development" for timely and urgent access, without imposing barriers, especially in countries where technology could not have been developed from ground zero due to various historical reasons dictated by incongruent periods of freedom, of industrial transition, and its consequent effect on the global political economy of care.[3]

On use of internal safeguards within TRIPS– a prerequisite to overcome prior to requesting a waiver- the proposal highlighted that many nations without any manufacturing capacities might have had to rely on Article 31*bis* of TRIPS. This Article is a procedural labyrinth, a

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2 Morgan Watkins, 'Kentucky Gov. Andy Beshear calls on 3M to release patent for N95 respirator amid pandemic' *The Courier Journal*, (Louisville, 3 April 2020) <https://www.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/> accessed 19 May 2021.

3 For context on where I borrow the phrase "political economy of care" from, and the emerging scholarship around it, see Amy Kapczynski, 'Coronavirus and the politics of care' (*LPE Project*, 3 March 2020) < https://lpeproject.org/blog/coronavirus-and-the-politics-of-care/> accessed 17 June 2022; See also LPE Project, How to Vaccinate the World (13.08.2021) available at < https://lpeproject.org/events/how-to-vaccinate-the-world/>.

negotiation nightmare as well as an institutionally burdensome undertaking having immense implications on bilateral relations. This is relevant specifically in context of dependent countries with weak bilateral bargaining powers in relation to fulfilling their alternate, yet essential, needs. This would deter as well as take away the "rapidness" which could only have been enabled by a global collective waiver.[4] Accordingly, these 63 countries requested for a waiver of Section 1,4,5 and 7 of Part II of the TRIPS Agreement, for the purposes of therapeutics and research to be used for COVID-19's prevention, treatment and containment.

This proposal, however, ended as a significantly watered-down compromise, only taking force a couple of years after it was tabled, and three gruesome years into the pandemic- i.e., on 17th June 2022 (known as the Ministerial Decision of the TRIPS Agreement).[5] The final text of the Agreement to waive was limited to a non-waiver i.e., a compromise only applicable in case of patents on vaccines and use of protected clinical trial data for regulatory approval, and only limited to relieving proposers and sponsors of a few procedural burdens present

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4 Interestingly, Bolivia approached the WTO TRIPS council on February 17th, 2021, to use this provision and seek exports from Canada, and it notified the details of the drugs needed to be exported on 12th May. But there has been no notification from Canada on this, and no compulsory license had been issued. See World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Notification under the Amended TRIPS Agreement, Notification of intention to use the special Compulsory Licensing system as an importing member (19 February 2021), IP/N/8/BOL/1, 21-1434, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/N/8BOL1.pdf&Open=True>; See also Luis Gil Abinader, 'Bolivia seeks to import COVID-19 vaccines from Biolyse, if Canada grants them a Compulsory License'(*Knowledge Ecology International*, 11 May 2021) <https://www.keionline.org/36119> accessed 27 December 2021; See also Biolyse Pharma, 'Bolivia and Biolyse sign landmark agreement for export of COVID-19 vaccines' *News Wire* (Canada, 12 May 2021) <https://www.newswire.ca/news-releases/bolivia-and-biolyse-sign-landmark-agreement-for-export-of-covid-19-vaccines-832670191.html> accessed 2 September 2021.

5 Ministerial decision on the TRIPS agreement, Published June 22, 2022. Available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>.

in the *flexibilities* already present within TRIPS.[6] Essentially, there was waiver of the procedural burden envisaged under Article 31 (b)– requiring to seek right holder authorization (and government use, emergency decrees were allowed even if the said exporting/important had no compulsory licensing provision); and 31 (f) on export beyond domestic use– as against a *waiver* of any of the enclosures enabled through IP Rights. A pathetic picture that emerges out of this negotiation period of around two years is that while the so-called industrially supra-competent world was busy fighting with 63 nations– nations with histories of subordination and domination through colonialism- that sponsored the waiver proposal - more than 6 million people officially lost their lives to COVID,[7] despite a vaccine having existed and administered for the first time on 8th December 2020 in the United States.

What I seek to emphasize in this article is in fact something that was completely ignored during this long and myopic i.e., economically focused negotiation - The *context of the ask* of a waiver, and the histories leading to its *need*.

To make it clear, many have argued and continue to argue that an IP waiver does nothing to accelerate vaccine development and access, and it is rather manufacturing incompetence or bureaucratic unwillingness to quickly enter into licensing agreements that has largely contributed to loss of lives.[8] Many have also pointed out that India can reach a

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6 Tahir Amin and AS. Kesselheim, 'A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness' (2022) 59 INQUIRY < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9500257/#bibr2-00469580221124821> accessed 12 December 2022.

7 See World Health Organization, Coronavirus (COVID-19) dashboard <https://covid19.who.int/>; See also 'The pandemic's true death toll' *The Economist* (California, 2 November 2021) <https://www.economist.com/graphic-detail/coronavirus-excess-deaths-estimates> accessed 11 November 2021.

8 Prashant Reddy T and Yogesh Pai 'Why IP Waiver for vaccines is not so 'IP 'IP hooray at all' *The Economic Times* (New Delhi, 6 May 2021)

billion vaccinations without an IP waiver.[9] Many have argued that the waiver, even if it were granted as proposed, would have been insufficient as it does not ensure technology transfer of essential know-how important in the case of developing biologicals.[10]

These arguments ignore the context of the *need* to enter complex licensing arrangements, involving negotiations in lieu of every product (and a web of products and processes)[11] involved in producing the vaccine in a globally urgent situation. They also ignore the context of the *need* to make bilateral sacrifices in case a global waiver is not effectuated. They also completely ignore that optimal enablement for firms producing vaccines had already been provided through advanced payments, market orders and public subsidies, that substantially de-risked vaccine development, making further *need* of exclusionary rights for enablement of production an overkill.[12] The need to seek a license, however less formal that might be, should have been a *non-starter*.

<https://economictimes.indiatimes.com/opinion/et-commentary/why-intellectual-property-Waiver-for-vaccines-is-not-so-ip-ip-hooray-at-all/articleshow/82438489.cms> accessed 2 July 2022; See also Yogesh Pai and Prashant Reddy 'Even if WTO waives IP on vaccines, India will face challenge translating it into mass production' *Scroll* (New Dehi, 1 June 2021) < https://scroll.in/article/996079/even-if-wto-waives-ip-on-vaccines-india-will-face-challenge-translating-this-into-mass-production> accessed on 17 August 2022.

9 Ibid.

10 Prabhash Ranjan, 'A TRIPS Waiver is useful but not a magic pill' *The Hindu* (New Delhi, 10 May 2021) <https://www.thehindu.com/opinion/lead/a-trips-Waiver-is-useful-but-not-a-magic-pill/article62106288.ece> accessed 21 October 2022; Prashant Reddy, 'In India, COVID-19 faces a more urgent problem than IP' *Bloomberg Quint* (Mumbai, 20 April 2021) < https://www.bqprime.com/coronavirus-outbreak/in-india-covid-19-vaccines-face-a-more-urgent-problem-than-ipr> accessed on 3 March 2022; Praharsh Gour, 'A Recipe for Disaster: Export Bans, TRIPS Waiver and Hyper Nationalism' *SpicyIP* (New Delhi, 25 April 2021)< https://spicyip.com/2021/04/a-recipe-of-disaster-export-bans-trips-Waiver-and-hyper-nationalism.html> accessed on 7 December 2022.

11 Supply Agreement, dated as of October 9, 2020, by and among Pfizer Inc., BioNTech SE and TriLink BioTechnologies, LLC, Exhibit 10.26, (Justia Business Contracts), available at <https://contracts.justia.com/companies/maravai-lifesciences-holdings-inc-11469/contract/137780/>.

12 As reported by Guardian and the Wall Street Journal, the estimated remuneration in 2021, out of the doses already pre-booked by these vaccine candidates through pre-orders and public funding by Governments range between fifteen to thirty Billion Dollars in the case of Pfizer, eighteen to twenty Billon Dollars in the case of Moderna and Two to Three Billion Dollars in in the case of the Oxford-AstraZeneca's vaccine candidate. In the case

I argue that, even if insufficient, a waiver was definitely necessary to express social solidarity towards the urgency of saving lives, as well as to structurally assure oneself that our lives our not submerged under the logic of *compete or die*.

In any case, a detailed defense for the statement above has been offered by many. Much has already been written on the merit of the debates and its implications on pharmaceutical policy and access to therapeutics during a pandemic.[13] I only seek to highlight what has completely missed this debate, in two parts – Parts II and III.

Part II emphasizes on the historical context of Intellectual Property Gradualism which forms a reason for the *need* of the waiver. I highlight the global inequalities in administration of IP regimes for technological development – and show how *(un) freedom* to develop technology and be capable to produce one's own vaccine is embedded in historical social relations and power dynamics beyond any concept of *will* and *agency*. This important factor, which provoked the existence of the waiver provision in the global neo-liberal TRIPS regime, went completely un-acknowledged during negotiations.

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of India as well, SII has already received an advance purchase deal of Rs. 1732.50 crores for 11 Crore doses of Covishield and Covaxin, and an advance payment of Rs. 787.50 crores had been, admittedly released to Bharat Biotech for 5 crore Covaxin doses for the months of May, June, and July 2021.

13 See Siva Thambisetti *et. al.*, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic'(2021) LSE Legal Studies Working Paper 06/2021,43 < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737> accessed 21 December 2022; William W.Fisher, Ruth L. Okediji and Padmashree Gehl Sampath, 'Fostering Production of Pharmaceutical Products in Developing Countries' (2021) 43 MJIL 69; Cory Doctorow, 'Debunking the Arguments for Vaccine Apartheid' (*Medium Coronavirus Blog*, 21 May 2021) available at <https://coronavirus.medium.com/debunking-the-arguments-for-vaccine-apartheid-7466e4c5d242> accessed 17 September 2022; Brink Lindsay, (@lindsey_brink), Twitter (5th May 2021, 9:44 PM), available at <https://twitter.com/PharmaCheats/status/1390044539537211397>; see also, Matthew Lane, (@MattCameronLane), Twitter, (6th May 2021, 2:06 AM), available at https://twitter.com/MattCameronLane/status/1390042773731086341.

Part III then emphasizes upon the logic of the waiver provision in the Marrakesh Agreement and surveys its past practice, to highlight its essential ability to enable norm shifting and remedy circumstances of inequality provoked by a global neo-liberal and *market dependent* regime. I then argue that upon being mindful of this logic, the negotiations for waiving IP urgently for a short period to enable vaccinations and therapeutics across the world would have been unnecessary.

Finally, Part IV concludes the paper.

UNDERSTANDING IP GRADUALISM

The incorporation of Intellectual Property into the World Trade System through the TRIPS Agreement, in 1994, compressed 100 or more years of IP *'gradualism'*[14] for Europe and North America, to around 5 to 50 years for the rest of the world. The pre-TRIPS Intellectual Property policy in the now *developed* countries, were very different. Most prominently, foreigners' IP rights were deliberately left out for indigenous knowledge development and growth of domestic industries.[15] Japan, Korea, Taiwan,[16] Switzerland,[17] Germany[18] and the US had a pattern of copying and absorbing technologies through a liberalized foreign intellectual property regime, permissible in absence

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14 Graham Dutfield (@gmdutfield), Twitter (May 12, 2021, 11:25 PM), Available at <https://mobile.twitter.com/gmdutfield/status/1392539051798978562>- The phrase "IP Gradualism" coined by Prof. Dutfield and reiterated in this tweet.

15 Ha-Joon Chang, *Bad Samaritans: The myth of free trade and the secret history of capitalism* (*Bloomsbury Press* 2007) 119-122; See also Christopher May and Susan Hell, *Intellectual Property Rights: A Critical History* (Lynne Rienne 2006) 205-207.

16 May (n 15) 205; See also Nagesh Kumar, 'Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries' (2003) 38(3) EPW 209, 214-216.

17 Dominique S. Ritter, 'Switzerland's patent law history' (2004) 14(2) Ford, IP Media Entertainment L. J. 463, at 483-485.

18 Von Frank Thadeusz, 'No Copyright Law: The Real Reason for Germany's Industrial Expansion' *Spiegal Intenational* (18 August 2010) <https://www.spiegel.de/international/zeitgeist/no-copyright-law-the-real-reason-for-germany-s-industrial-expansion-a-710976.html> accessed on 22 November 2020.

of TRIPS.[19] This method of absorption by copying/reverse-engineering was followed until a point of knowledge development was reached that was voluntarily deemed to be enough to compete in the global knowledge market.[20] By the time TRIPS was signed, these nations possessed enough technological capability often induced by their sovereign ability. This technological superiority, due to their *ability* and *freedom* to do so, became a medium to enforce industrial superiority using IP to their benefit. The Swiss in fact emphasized that they were able to reach their industrial prowess only because of their *ability* to freely exact tribute from the foreigners, and if this was thievery, then all Swiss industries were thieves - although on the right side of moral conscience.[21] Even in Japan, an expansionary patent regime, including both product and process patents, was "voluntarily" adopted only in the 1970s when the Japanese enterprises had developed enough of their domestic knowledge capability, and now needed such protection to capitalize upon their own innovative activity abroad.[22] This translated to productivity defined *development*- something which would define the social *status* of global participants in relation to each other.

This transition period of *development* for these nations, *albeit* due to their early independence and political freedom, took more than a 100 years of flexible policy regimes prior to and since the Paris agreement.[23] Importantly, the Paris Agreement, often referred to as the "elite club" and touted in terms of harmonization, was conducive to the indigenous developmental needs of the members to the Agreement, as it provided legislative freedom by creating heterogenous patent rules

19 Thambisetti (n 13) at 43.
20 Graham Dutfield and Uma Suthersanen, 'Harmonization or differentiation in intellectual property protection? The lessons of history' (2005) 23(2) Prometheus: Critical Studies in Innovation 131, 135-136.
21 Ritter (n 17) at 489-490.
22 Kumar (n 16) at 214.
23 May (n 15) at 206-207.

wherein countries could adopt different standards of industrial property protection. For instance, Switzerland and Spain did not grant any patents on chemical products, and France and Italy did not grant any patents on pharmaceuticals, based on their indigenous productivity capacity, and needs at that point of time.[24] In the US, the patent provision was introduced as a *means* to an *end*, i.e., to promote the progress of sciences. International works were initially resisted from being protected, with a reasoning that it would hinder diffusion of knowledge, development of *bodily and mental power* and productive capacity of domestic industries.[25] Easy access was considered as a pre-requisite to knowledge absorption and copying was incessant to knowledge development, in a newly post-colonial American state, that was struggling to form its independent knowledge economy. This is exactly why the American committee of the Senate rejected various bills for protection of IP in foreign works. An international agreement like TRIPS, which significantly cut down this period of productive capacity building and policy freedom, would have had deleterious implications on the state of American industrialisation and productive capacity that we see today.

However, this was not deemed appropriate in the context of nations which were on the brink of independence or had barely completed half a century of sovereign existence, as TRIPS was brought in mandating a maximalist compulsory IP regime. Post TRIPS, if these countries (the ones who had been denied years of capability building) wanted to export their goods, agricultural or otherwise, they were essentially

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24 Surendra J. Patel, 'Intellectual Property Rights in the Uruguay Round: A disaster for the South?' (1989) 24(18) EPW 978, 980-982.

25 Balasz, 'A short history of book piracy' in J. Karaganis (ed.) *Media Piracy in Emerging Economies* (New York Social Science Research Council 2010) stating, "All the riches of English literature are ours. English authorship comes to us as free as the vital air, untaxed, unhindered, even by the necessity of translation; and the question is, shall we tax it, and thus impose a barrier to the circulation of intellectual and moral light? Shall we build up a dam, to obstruct the flow of the rivers of knowledge?".

mandated to protect foreign IP.[26] TRIPS placed important constraints on the sovereignty of countries of the "developing world" to implement innovation schemes and use absorption methods of reverse engineering for technological learning of their choice. The histories of inequity in bargaining towards a multilateral agreement in respect of intellectual property, as well as in its implementation has been widely documented.[27] In fact, TRIPS was a "package deal" for developing nations,[28] where consent, which was obtained, was governed by patterns of relationship which were largely non-voluntary from the point of view of the worse-off participants.[29] As has been recorded,[30] developing countries were reluctant, and in fact strongly resisted their inclusion in TRIPS to safeguard domestic industries. However, fear of trade sanctions, and a bargained exchange of concessions in textiles and agriculture were factors contributing to their consent. The concessions - promised for agreeing to sacrifice their IP and technological developmental interests - were increased market access for tropical products, agricultural output and export subsidies from the EU.[31] Due to the largely agricultural market then, this is what was deemed to be worth prioritizing by the developing

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26 Keith Aoki, 'Neocolonialism, Anticommons Property, and Biopiracy in the (Not-so-Brave) New World Order of International Intellectual Property Protection' (1998) 6(1) Indiana J. Global L. Stu. 18, 45.

27 For the history on TRIPS negotiations and their skewed nature, see Susan K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (CUP 2003); Ruth L. Gana, 'The Myth of Development, The Progress of Rights: Human Rights to Intellectual Property and Development' (1996) 18 (2-3) Law & Policy 315, 334-335.

28 Dominique S. Ritter, 'Switzerland's patent law history' (2004) 14(2) Ford. IP Media Entertainment L. J. 463, 483-485

29 Charles R. Beitz, 'Justice and International Relations' (1975) 4(4) Philosophy Public Affairs 360, 374.

30 Hamed El-Said and Mohammed El-Said, 'TRIPS, Bilateralism, Multilateralism & Implications for Developing Countries: Jordan's Drug Sector' (2005) 2(1) Manchester J. Int'l Eco. L. 59, 60-62.

31 Frederick M. Abbott, 'Commentary: The International Intellectual Property Order Enters the 21st Century' (1996) 29(3) Vanderbilt J. Trans. L. 471, 473.

nations.[32] However, the problem isn't this bargain, but rather the need to prioritize one or the other, and the need to have to make this trade-off or to choose, which can again be traced to historical inability and colonial suppression of these nations. TRIPS also promised to naturally foster technology transfers, to the benefit of the developing countries.[33] However, it is quite evident as to how that has panned out otherwise, we would not have had this debate during a global pandemic.

Estrangement of these *transitional periods* for many nation-states, which attained freedom around 50 years prior to TRIPS, and were subject to colonization prior to that, have had a huge role to play in undermining knowledge *capabilities*, and the freedom to use flexibilities. This has significantly affected their ability to be truly "free", and resist being dependent upon the dominance of a few. Continued dominance, through internationally harmonizing instruments like TRIPS, persists to widen this dependence gap by estranging capacity building and by normalizing the idea of dependence for development.

A critical take on analysing knowledge and industrial "capabilities", ought to be contextualized in light of prolonged colonial histories of the developing world. The period of development enjoyed by the free, non-colonized countries, or nations which gained early independence, were much longer than the developing world. This transition period has been "unprecedently short" for this part declining it the opportunity to equitably build its knowledge base by using and learning/absorbing from foreign works. In the case of India, which

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32 Rahul Rajkumar, 'The Central American Free Trade Agreement: An End Run around the DOHA Declaration on TRIPS and Public Health' (2005) 15 Albany L. J. Sci. Tech. 433, 459-460; See also J. H. Reichman & David Lange, 'Bargaining around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions' (2003) 5 Int'l IP L. Policy 9-1.

33 Fisher (n 13).

attained independence only in 1947, this period has not even been 60 years, given that India's voluntary ability to work through reverse-engineering was stripped away in 2005. It was even noted in the Ayyangar Committee report of 1959,[34] now that the patent system was supposed to ensure the fulfilment of the developmental needs of the domestic scientific and technological market, and hence an expansionary patent model, protecting product patents, and restricting reverse engineering was inappropriate for the research and health needs of the nation, and could even detrimentally affect the industrial and scientific/technological developmental process of domestic concerns. Within a short while, in the presence of a restricted regime of only process patents for pharmaceuticals limited for seven years which allowed for an environment of reverse engineering and developing pharmaceutical "products", India had a flourishing generic industry. This has supposedly been argued to be one of the reasons/ triggers for the inducement towards the TRIPS compromise.[35] Among various other reasons like development of research centres, investment in healthcare policy etc., this restricted patenting regime was instrumental in allowing the growth of the generic pharmaceutical industry. India had already reached the intermediate capability stage, through access to learning and imitative Research & Development, and was on the path to attain advanced capabilities in pharmaceutical development, in a relatively shorter transitional period of only about less than 60 years.[36] In fact, this is when the developed world, that had

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[34] Sh. Justice N. Rajagopal Ayyangar, *'Report on The Revision of the Patents Law in India*" (September, 1959), Available at: <https://ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-_Justice_N_R_Ayyangar_committee_report.pdf >[30-38, 180-181].

[35] Peter Drahos, 'Developing Countries and International Intellectual Property standard setting' (1995) 5(5) J. World IP 765, 772-773.

[36] Dinar Kale and Steve Little, 'From Imitation to Innovation: The Evolution of R&D Capabilities and Learning Processes in the Indian Pharmaceuticals Industry' (2009) 19(5) Tech. Analy. Strategic Mang. J. 607-608.

depended on over a century (as the transition period) of appropriation allowed by "independent" flexibilities with respect to their own suitable ideas of patentability (to support their domestic needs), started questioning the newly free, and developing/ transitioning nations as to whether the international system was tilted too far towards the appropriation of knowledge rather than its diffusion.

Interestingly, most of the exclusionary IP regimes in Africa and Asia were initiated by European colonies.[37] The 1852 Patent Law Amendment Act in Britain transformed the multiplicity-oriented system as in England, Scotland and Ireland, to a common streamlined and cheaper uniform patent system of a single British Patent.[38] To allow for wide industrialization, British colonies, by 1864, enacted patent laws[39] with an anomalous debate on whether all British patents should attain exclusionary privileges across the full stretch of the colony. The idea was to be able to locally patent inventions in all these colonies and earn from licenses and sales thereof.[40] The 1856 statute allowed importers (who were primarily colonizers, in the colonies) to earn the exclusive privilege accorded under the statute. This Act also allowed for special rights to British patentees, who were the inventors of the invention in Britain (and not the importers) to secure exclusive privileges for their invention within twelve months of securing their

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37 Honduras Patent Act, 1862; Cape of Good Hope Patent Act, 1860; Indian Patent Act, 1856; Indonesian Patents Act, 1844; Barbados Patent Act, 1852; Fiji Patent Act, 1877; Trinidad Patent Act, 1867.

38 Act for Amending the Law for Granting Patents for Inventions, 1852, 15 & 16 Vict. c. 83 (Gr. Brit.). - as in Lionel Bently, 'The "Extraordinary Multiplicity" of Intellectual Property Laws in the British Colonies in the Nineteenth Century' (2011) 12(1) Theoretical Enquiries in Law 161, 163.

39 Royal Commission, Report of The Commissioners Appointed to Inquire into the Working of The Law Relating to Letters Patent for Inventions, 1864, C. (1st Series) 3419, 30.

40 See Doris Estelle Long, 'Exposing the Processes of Empire in the International Protection of Intellectual Property in Intellectual Property in Context: Law and Society Perspectives' (Cambridge University Press 2015).

patents in Britain.[41] As has been accounted by Rajesh Sagar, in "Patent Policy in India under the British Raj", the total number of patents in 23 years of the initiation of the Patent Regime in India had a miniscule number of 2.63% native inventors.[42] There was a sheer lack of emphasis on any kind of knowledge or capability/capacity development of the colonies during these legislations, as is visible from the 1859 "Exclusive Privileges" grant[43] which required a domestic patent application to be novel both in India and in Britain (which was a much more developed nation in terms of the capability approach then) for it to be patentable. In fact, the Indian Patent Act during the colonial rule, of course, recognized the ability of foreigners to get patents in India and was a means to protect British patentees from colonies and their acts of imitating and learning out of the goods invented in Britain, which, paradoxically, is a strategy that was highly successful as a means of knowledge development in western independent nations. This lack of sovereignty, in effect, cut-short the developmental/transitional period for these colonies, as the focus of the colonizers was to build industries to support this colonization, rather than building indigenous capabilities of knowledge and technological development, through practices of access and absorption.

Getting rid of this knowledge and capability divide requires an alternate accent where global trade ought to be looked at from the eyes of geo-

41 Rajesh Sagar, *Patent Cultures: Diversity and Harmonization in Historical Perspective* (Graeme Gooday and Steven Wilf eds. (CUP 2022) 273, 274.

42 Ibid at 279.

43 Act V of 1859, Section XIX- "An invention shall be deemed a new invention within the meaning of this Act if it shall not, before the time of applying for leave to file the specification, have been publicly used in India or in any part of the United Kingdom of Great Britain and Ireland, or been made publicly known in any part of India or of the United Kingdom by means of a publication, either printed or written or partly printed and partly written".

historical attentiveness.[44] With the COVID-19 pandemic, and its gruesome impact on access to health, this narrative comes clearly into perspective, and the need to shift the conversation beyond IP internalism,[45] questioning the fundamental inequities which come with TRIPS in sovereign decision making and domestic implementation of constitutional rights, is imminent. IP cannot be *naturalized* and needs to be understood as a historically specific phenomenon arising out of the logic of a market society- an ensemble of social relations where humans are involuntarily subjected to commodity logics to fulfill basic including health.[46] Could the waiver have been an instrument to address these inequities and account for this challenge?

THE WAIVER PROVISION AND ITS EMPHASIS ON "EXCEPTIONAL CIRCUMSTANCES"

Part I of this paper highlighted the practice of granting *waivers* under Article IX.3 of the WTO Agreement, which is in fact a tool to protect conflicting sovereign priorities of nations part of the WTO Agreement.[47] International political processes and agreements often involve a conflict of values and "norms". In the case of WTO, the narrow economic focus on trade and IP protection[48] neglect the values which are prioritized by certain sovereign nations, including values

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44 Anjali Vats, *The Color of Creatorship: Intellectual Property, Race and the making of Americans*, (Stanford Uni. Press 2020) 206-207.

45 Amy Kapczynski, 'The Cost of Price: Why and How to get beyond Intellectual Property Internalism' (2012) 59(4) UCLA L. Rev. 970, 978-979, 999-1000.

46 See Oren Bracha, *The History of Intellectual Property as The History of Capitalism*, (2020) 71 Case W. Rsrv. L. Rev. 547, 574-575 for tracing the History of IP to the process of commodification which is an output of an ensemble of social relations that constitute capitalism and found specific phenomenological presence only during the 17th Century. The argument tries to denaturalize Intellectual Property law; See also Talha Syed, *Capital as a Social Relation* (unpublished), draft on file.

47 Isabel Feichtner, 'The Waiver power of the WTO: Opening the WTO for Political debate on reconciliation of Competing interests' (2009) 20(3), Euro. J. Int'l. L. 615-619 stating "Waiver power bears a specific potential to open the WTO for political debates on the coordination and reconciliation of competing norms and interest".

48 Chris Buccafusco (@cjbuccafusco), Twitter (January 13, 2021, 8:38 PM), Available at <https://twitter.com/cjbuccafusco/status/1349372696287735808>.

such as the human right to health care or protection of indigenous traditional knowledge,[49] not falling into the ossified norms of IP. These conflicts are structurally "value" and priority-oriented conflicts,[50] and are often overlooked in consensual negotiations by political organs, ignoring the priorities of domestic institutions and pressures involved.

The provision of a Waiver eradicates circumstantial rigidity and allows for accommodation to do away with the rigidity of the agreements when there is a change in context, affecting different members of the agreement differently or at different levels/intensities. Such ability holds all the more importance in the context of the global COVID-19 pandemic, which could never have been foreseen by the TRIPS delegates, and negotiators. The flexibility of a provision within the statute, which enables the possibility of a waiver from IP obligations, allows for an inclusive attitude towards social concerns of certain member states that may have been amplified due to the current context of the pandemic. It also helps bring into perspective, priorities of our society and the context-ridden-ness of the idea of global policy making.

The waiver power of the WTO is an internal and often fruitful solution to these underlying value conflicts as it allows for a mechanism of temporary modification of the treaty to take into account alternate *urgent* priorities.[51] This power helps contextualize the WTO legal framework,[52] and allows for flexibility in respect of values, especially when institutionally internal solutions do not have the proximate ability of resolving or acting as a resort to these context-ridden value

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49 Ibid at 616.

50 Ibid at 617.

51 Feichtner (n 47) 618 stating "Waiver power bears a specific potential to open the WTO for political debates on the coordination and reconciliation of competing norms and interest".

52 Robert Howse and Joanna Langille, 'Permitting Pluralism: The Seal Products Dispute and Why WTO Should Accept Trade Restrictions Justified by Noninstrumental Moral Values' (2012) 37 Yale J. Int'l. L. 368-369; See also Isabel Feichtner, 'Subsidiarity in the World Trade Organization: The Promise of Waivers' (2016) 79 L. Contem. Problems 75, 82.

conflicts. As Isabel Feichtner argues, the policy preferences of individual WTO members are highly context dependent and might not lend themselves well to generalization of fixated negotiations which were entered into at a particular point of time with certain prevailing circumstances and foreseeable consequences in mind.

WTO, in its decision making power, within the Marrakesh Agreement/ WTO Agreement, which was signed on 15th April 1994, by 123 nations (marking the culmination of the 8 year long Uruguay Round Negotiations on the future of GATT), has vested the sole authority with the Ministerial Conference and also the General Council (which conducts functions within conference meetings), to allow for a waiver of the obligations in the Marrakesh Agreement or its Annexed multilateral treaties, including the TRIPS Agreement- upon following the terms and conditions mentioned in the provision. This power is codified within Article IX (3) of the Marrakesh Agreement.

A waiver decision, firstly, is a move towards addressing allegations that argue WTO norms to be polarized- by modifying the said norms itself, *albeit* temporarily.[53] The point is that the flexibility of suspending certain norms, and not merely resorting to institutionally internal exceptions, allows the house to set its priorities in order, depending on the context or the proximate/urgent requirements of the situation.[54] Further, as against the case of enumerated exceptions, the deliberations during the waiver process allow for normative re-thinking, and institutional transformation, beyond legal arguments and arguments concerning trade, and towards contextual, ethical and non-economic considerations- that may be triggered due to certain unforeseen events, or even unpredictable/ unexpected developments in global scenarios. The waiver process, by itself, enables inclusive discussions at the WTO

53 Feichtner (n 47) at 638.
54 See Andreas F. Lowenfeld, *International Economic* Law, (OUP 2002) 41.

within its purported economic rationality,[55] giving heed to public interests which are non-economical but are incidentally affected by the framings of trade-based norms. It contributes to *embedding* the 'social' within the pure market logics of trade.

A. History

The provision for a waiver existed even under Article XXV of GATT, and had a similar substantive requirement of an "exceptional circumstance" warranting a Waiver from global trade obligations. During GATT deliberations upon the waiver provision, the drafting country- USA had clarified that the intent of the drafters was to ensure that the escapes mentioned in this provision were to "cover cases which were exceptional and caused particular hardship to any particular member", and importantly were "not covered by other escapes provided within the charter. The statement of the French delegate during GATT Negotiations crystallized the opinion of the western countries during these negotiations to the effect that – "No country should escape the obligations which it has undertaken…. All we suggest is that in more exceptional cases, temporary exemptions might be granted when the precise obligations of the charter would impose some economic hardships on some countries, those hardships being of a temporary character."[56]

"Exceptional circumstances" was not defined during the GATT regime, and having been left loosely open, the waiver provision has not been solely used in emergencies. 115 original waivers had taken place from 1947-1995, including as many extension waivers. In fact, one of the most controversial waivers was a waiver availed by the United

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55 Feichtner (n 47) at 634.

56 United Nations Economic and Social Council, Preparatory Committee of the International Conference on Trade and Employment, Verbatim Report of the Ninth Meeting of Committee V, Westminster (7 November 1946), E/PC/TC.V/PV/9. at 4-5, available at < https://www.wto.org/gatt-_docs/English/SULPDF/90230015.pdf>.

States to maintain import restrictions on Agricultural products' as against GATT disciplines. The only reason given, which was deemed to qualify as an exceptional circumstance under this provision, was the need to safeguard the domestic agricultural industry and to ensure that the US Department of Agriculture programs or operations with respect to agricultural commodities, were not rendered ineffective due to GATT norms.[57]

During the Uruguay Round of re-negotiations of the global trade treaties, this waiver power was substantially reviewed. The European Economic Community had suggested a reconsideration and reform to Article XXV paragraph V of the GATT, and the waiver proceedings, through their communication in the Uruguay negotiation on 18th May 1987. Their main claim was that the agreement was a collective contract between nations and a waiver of obligations had an adverse impact on the balance of rights and obligations of the subjects of the contract. The specific plea in the communication was to consider revising time limitations on waiver privileges, and to consider an annual review of waiver power. It finally added the caveat that the aim of this communication was to revise and limit this power, not to remove the flexibility, but rather to prevent the perpetuation of, or to forestall, permanently privileged situations.[58] Academics have argued that the trigger to this communication was the waiver granted to the

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57 Dale E. McNiel, 'United States' Agricultural Protectionism after the Uruguay Round: What Remains of Measures to Provide Relief from Surges of Agricultural Imports' (1997) 23(2) North Carolina Journal of International Law 296; See also General Agreement on Tariffs and Trade, Working Party 6 on the United States Waiver, Proposed Decision to Grant a Waiver to the United States in Connection with Import Restrictions Imposed Under Section 22 of the United States Agricultural Adjustment Act (of 1933) as Amended, (26th February 1955), W.9/228, available at <https://docs.wto.org/gattdocs/q/GG/W/9-228.PDF>.

58 Multilateral Trade Negotiations The Uruguay Round, Negotiation Group on GATT Articles, Communication From the European Economic Community (18th May 1987), MTN.GNG/NG7/W/4, available at <https://docs.wto.org/gattdocs/q/UR/GNGNG07/W4.PDF>.

US for import restrictions to be allowed,[59] however no discussions with respect to the interpretation of "exceptional circumstance" or to limit the same, was forwarded in this communication.

Because of this communication from the European Economic Community, the Negotiating group had requested the Secretariat to prepare a note on waiver powers and furnish before the group. The initial draft of this note was presented before the Negotiating group on GATT Articles on 4th September 1987.[60] The note provided for the history of the provision and clarified that "*exceptional circumstances*" had not been defined but were largely concerned with economic and legal hardships and not non-economic and geographical concerns. Reliance was placed on the working party reports during the application of the provision[61] in the previous GATT regime and the decisions thereto were quoted. There was a clear acknowledgment in the note that waivers have been granted for economic recovery of fragile economies, which required trade policies aimed at sustained investment and transitional growth, as was done in the case of United States Caribbean Basin Recovery Act on 16th February 1985.[62] The note also clearly recognized that contracting parties never made use of their power to define certain categories of "exceptional circumstances" to which other voting requirements would apply for waiver of obligations.[63] Finally the note also noted that out of the 61 waivers that were listed to have been granted by then, 57 waivers were granted to individual

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59 John Croome, Reshaping the World Trading System, A history of the Uruguay Round, (1st Edn, Kluwer Law Publications1998), 191-192; Feichtner (n 47) at 80.

60 Multilateral Trade Negotiations The Uruguay Round, Negotiation Group on GATT Articles, Article XXV:5 (Waiver Power), Note by Secretariat (4th September 1987), MTN.GNG/NG7/W/18, available at <https://docs.wto.org/gattdocs/q/UR/GNGNG07/W18.PDF>.

61 Ibid at 3.

62 Ibid at 3.

63 Ibid at 6.

members and 4 were "collective waivers", granted to a defined group of contracting parties.[64]

An addendum to this note was added by the Secretariat on 10th November 1988[65] clarifying the updated number of waivers that were granted, being 78, until 1988. Certain waivers were granted without an expiry date, but instead with a requirement of fulfillment of a specific condition, as in the case of the waiver granted to France and the Federal Republic of Germany in 1957 relating to trade with the SAAR- where the only condition of expiry was when intra-trade became duty free, which is in fact stated to have happened in 1970, i.e., after 13 years of the grant.[66]

The European Economic Community, further attempted to clarify its position and its request for changing the prevailing provision under the GATT regime, by issuing another communication dated 22nd February 1990.[67] It made a formal six-point request- (i) a maximum time limit for a waiver, although not a uniform one, but one that is deemed fit at the time of the waiver being granted; (ii) Clear, precise and economic justification being provided for the waiver; (iii) a reason ought to be given as to why the member(s) requesting a waiver are not resorting to internal provisions/ exceptions of the agreements for their policy goals; (iv) there shall be an annual review of all the waivers granted, as to whether the waiver is yet justified; (v) the waivers in existence during the commencement of the new agreement ought to be phased out and

64 Ibid at 6.

65 Multilateral Trade Negotiations the Uruguay Round, Negotiation Group on GATT Articles, Article XXV:5 (Waiver Power), Note by Secretariat, Addendum (10th November 1988), MTN.GNG/NG7/W/18/Add. 1, available at <https://docs.wto.org/gattdocs/q/UR/GNGNG07/W18A1.PDF>.

66 Ibid.

67 Multilateral Trade Negotiations the Uruguay Round, Negotiation Group on GATT Articles, Article XXV:5, Communication from the European Economic Community (23rd February 1990), MTN.GNG/NG7/W/69, available at <https://docs.wto.org/gattdocs/q/UR/GNGNG07/W69.PDF>.

(vi) a waiver does not preclude one from invoking dispute settlement provisions of the treaty, where it believes that the waiver is unjustifiably nullifying or impairing the benefits accorded to it by the agreement.[68]

In pursuance of this communication from the European Economic Community, a draft decision was developed, to govern all future waivers with clearer conditions and disciplines and was published on 23rd July 1990[69] for being forwarded to the negotiation committee.[70] The draft required a specific policy declaration for an extension of a prevailing waiver. It also required the nations seeking a fresh waiver to state the exceptional circumstances which justified the grant of a waiver, with a particular termination date. It further stated that all waivers were to be renewed annually, and that if a termination date was not provided, the waiver would automatically terminate within a specified period, however this time was left blank to be decided during negotiations.

This draft was thereafter sent to the negotiations committee and was negotiated in the early 1990s by the Trade Negotiations Committee at Ministerial Level, starting from December 1990, in Brussels.[71] Negotiations on this draft, took place without any difficulty. The final draft was released on 15th December 1993,[72] wherein it established the

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68 Ibid.

69 Multilateral Trade Negotiations The Uruguay Round, Negotiation Group on GATT Articles, Status of Work in the Negotiating Group, Chairman's Report to the GNG (23rd July 1990), MTN.GNG/NG7/W/73, at 2, available at <https://docs.wto.org/gattdocs/q/UR/GNGNG07/W73.PDF>.

70 Ibid at 15.

71 Multilateral Trade Negotiations The Uruguay Round, Trade Negotiations Committee, List of Representatives (10th January 1991), MTN.TNC/INF/11/Rev.1, available at https://docs.wto.org/gattdocs/q/UR/TNC/INF11R1.PDF.

72 Multilateral Trade Negotiations The Uruguay Round,Trade Negotiations Committee, Final Act Embodying The Results Of the Uruguay Round of Multilateral Trade Negotiations (15th November 1993), MTN/FA-1, available at <https://docs.wto.org/gattdocs/q/UR/MTN/FA.PDF>.

"Multilateral Trade Organization", later to be replaced with the "World Trade Organization".[73]

This was the draft which was to be signed at the Marrakesh Ministerial Meeting by all the participants. Interestingly, this draft scrapped off Article XXV of the GATT and the waiver provisions appeared twice. Once in the WTO Agreement at Article IX.3 and IX.4, and once within the GATT 1994, phrased as the 'Understanding in respect of waiver of obligations under GATT 1994'. Article IX.3 changed the voting requirement to the need for a three-fourth vote, as was the practice of the General Council's decision-making process.[74] The method of grant of a waiver was intended to firstly be consensual, and voting was only to be resorted to in the absence of a consensus.[75] However, the limitation on the vote requirement, in any case, was increased from a two-third vote, to a three-fourth vote.[76] The provision continued the requirement of an "*exceptional circumstance*", however with no details as to how to interpret the said phrase. It further established a time period of 90 days for the consideration of the waiver proposals by the Ministerial Conference. It procedurally established the requirement that

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73 Multilateral Trade Negotiations The Uruguay Round,Trade Negotiations Committee, Final Act Embodying The Results Of the Uruguay Round of Multilateral Trade Negotiations, Corrigendum (15th December 1993), MTN/FA/ Corr.1, available at <https://docs.wto.org/gattdocs/q/UR/MTN/FAC1.PDF>.

74 Feichtner (n 47) at 80.

75 World Trade Organization, Decision-Making Procedures Under Article IX and XII of the WTO Agreement, Statement of Chairman (24th November 1995), WT/L/93 (95-3663), available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/L/93.pdf&Open>.

76 United Nations Economic and Social Council, Drafting Committee of the Preparatory Committee of the United Nations Conference on Trade and Employment, Sub Committee on Tariff Negotiations, Suggested Amendments prepared by the Secretariat, (12th February 1947), E/PC/T/C.6/65/Rev.2, available at < https://docs.wto.org/gattdocs/q/UN/EPCT/C6- 65R2.PDF>; United Nations Economic and Social Council, Second Session of the Preparatory Committee of the United Nations Conference On Trade and Employment, Report of the legal drafting committee of the tariff agreement committee on Part III of the General Agreement, (19th September 1947), E/PC/T/209, at page 8, available at < https://docs.wto.org/gattdocs/q/UN/EPCT/209.PDF>.

the waiver request was first to be submitted to TRIPS, which would then refer it to the Ministerial Conference (inclusive of General Council as per the footnote 6. As per IX.4, in line with the communication from the European Economic Communities, the exceptional circumstance justifying the waiver was to be stated by the requesting parties, and the terms and conditions of the waiver, as also the time when it would terminate was to be clearly specified.[77] The waiver, if granted, was to be reviewed every year, as to whether it was to be continued or not, in terms of the exceptional circumstance mentioned.[78] In respect of waivers already granted under the previous GATT regime, an understanding was established mostly to govern extensions of waivers already existing, the reasoning thereto, as well as the dispute resolution mechanism that was highlighted in the previous draft, pursuant to the communication by the European Economic Community.[79]

B. Interpretation and Practice

Surveying the practice and use of the waiver power shows that the power has been used broadly, i.e., to allow for regional economic integration, as well as to justify import restrictions for domestic industrial development. The interpretation of "hardship" has been relatively liberal than is ideally conceived/ expected to be.[80]

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77 Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US*), (9th September 1997),WT/DS27/AB/RW2/ECU, at para [380] available at < https://www.wto.org/english/tratop_e/dispu_e/27abrw_e.pdf > The limited duration of the waivers as provided within Article IX.4 has further been judicially confirmed by the Appellate body in *EC Bananas -II,* where the Appellate Body held that the waiver ought to define the date of termination and can only be grated for limited period of time.

78 Multilateral Trade Negotiations The Uruguay Round,Trade Negotiations Committee, Final Act Embodying The Results of The Uruguay Round of Multilateral Trade Negotiations (15th April 1994), MTN.THC/W/ FA II.

79 Ibid at A l A-l (e).

80 For a table of Waivers granted in the WTO until 2015, see World Trade Organisation, General Council, Waivers 1995-2015, Note by the Secretariat (27th June 2016), WT/GC/W/718, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W718.pdf>. For a table of Waivers granted in 2019, see World Trade Organisation, General

i) In *Restrictions on the importation of Sugar and Sugar Containing Products- waiver extension*, that was sought by the US in 1991,[81] US vehemently argued the fact that Waivers were an essential tool for furthering the liberalization of trade by providing flexibility to accommodate the individual problems of the contracting parties in multilateral agreements. The US even pointed towards certain precedents where waivers were granted for indefinite periods, and were required so, due to the need of the individual contracting members at that point of time. The US's stand was vehement against a narrow interpretation of the waiver provision, which was opposed by the European Economic Community. The dispute resolution had ultimately decided in favour of the US, thus extending the waiver that was granted on 5th March 1955 and dismissing the complaints of the EEC.[82] As a result of this prolonged waiver and enactment of Section 22 of United States Agricultural Adjustment Act, where import restrictions were levied, US imports of sugar had declined from 5.3 million metric tonnes (raw value) in 1977 to 1.2 million metric tonnes (raw value) in 1987 and its production of sugar (beet and cane) had risen from 5.8 million metric tonnes (raw value) in 1977 to 6.6 million metric tonnes (raw

Council, Waivers 2019, Note by Secretariat (18th December 2019), WT/GC/W/795, available at <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=-259951&CurrentCatalogueIdIndex=0&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>; For a table of Waivers granted under the GATT 1947 see WTO, Analytical Index, Guide to GATT Law and Practice (1995), ii, at 892 -906, available at <https://docs.wto.org/gtd/analytical/AI_WTO_Vol_1.pdf>.

81 General Agreement on Trade and Tariffs, United States - Restrictions On The Importation Of Sugar and Sugar- Containing Products Applied Under The 1955 Waiver And Under The Headnote To The Schedule Of Tariff Concessions - Report of the Panel (7th November 1990), L/6631, 37S/228, available at <https://docs.wto.org/gattdocs/q/GG/L6799/6631.PDF>.

82 Ibid at 29.

value) in 1987.[83] Yet the waiver was deemed fit to be continued by the Committee, and the panel.

ii) In one of the earlier waiver requests, which was made by Belgium and Luxemburg, under Article XXV of the GATT, the scope of this adversity, and the meaning of exceptional circumstances was considerably examined, *albeit* in context. This request was also in terms of obligations under Article XI (quantitative restrictions) of the GATT in respect of agricultural products. The working party examined the request of both Belgium and Luxemburg and evaluated as to whether putting restrictions on import as against the provisions of Article XI of the agreement were necessary for the domestic industry of these nations or not.[84] Another question was as to whether alternate measures consistent with GATT obligations were possible to be taken instead of a waiver. Belgium in its request had pleaded that the Belgium agriculture industry comprised of very small enterprises that had an average area holding and were the smallest in Western Europe. The farms were also family run and there were no alternate qualifications that were enjoyed by these farmers, due to which they could not shift to alternate industrial activities. It was therefore essential to maintain import restrictions and allow for domestic farmers to run, for their income to be stabilized, and for them to not lose the 20 per cent share of income that was estimated to have been earned only on account on this import restrictions.[85] Apart from income concerns, the quality of life of these farmers also had to be

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83 Ibid at 4.

84 General Agreement on Trade and Tariffs, Belgium and Luxemburg Request for Waivers, Report by the Working Party (29th November 1955), Spec/382/55, at page 2, para 5, available at <https://docs.wto.org/gattdocs/q/GG/SPEC/55-382.pdf>.

85 Ibid at (6-7).

maintained for which the restrictions were argued to be necessary.[86] The Working Party, after analyzing the scope of internal subsidies and tariffs that could have been provided to Belgium, within the structure of the GATT, concluded that removing the restrictions was not practicable and allowed for the waiver on the condition that the restrictions were to be removed after a period of 7 years.[87] The Working Party concluded that this request satisfied the necessary requirements of Article XXV and qualified as an "exceptional circumstance", therefore allowing the waiver decision and submitting the same to the contracting party for their approval by vote.[88] On the request of Luxemburg as well, the reasoning that was given to justify the waiver was- (i) highly unfavorable natural factors for the domestic agriculture industry;[89] (ii) serious injury to the domestic producers in Luxemburg,[90] (iii) historical relevance of these restrictions and the long standing need for Luxemburg to provide special assistance to its agriculture industry.[91] The Working party considered the request and deemed the situation to be "Exceptional" due to the fact of the narrowness of the Luxemburg market and its less than significant impact on trade interests of other countries.[92] In accordance with this, the request for Luxemburg was approved and the Working Party had recommended the waiver for approval by the contracting states.[93]

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86 Ibid.
87 Ibid at (11).
88 Ibid at (14,17).
89 General Agreement on Trade and Tariffs, Report by the Working Party, Draft Section of the Working Party Report, II. Luxemburg Request (29th November 1955), Spec/379/55, available at <https://docs.wto.org/gattdocs/q/GG/SPEC/55-379.pdf>
90 Ibid.
91 Ibid at (3).
92 Ibid at (5).
93 Ibid at (6).

iii) Waivers, from the Most Favored Nation principle, have been granted merely on the basis of a need to maintain long standing relationships with countries. Canada in its CABIBCAN request for a waiver of this MFN principle[94] justified the same on the ground of the long-standing relationship in terms of trade between Canada and Caribbean Commonwealth nations.

iv) Another request by the France and European Economic Communities for a waiver to permit preferential trading with Morocco was granted/ recommended by the Committee merely on the ground of the existing "traditionally strong ties" between France and Morocco and the objectives of this arrangement being "sound economic development of Morocco and assistance thereto".[95]

v) Even in the case of the waiver request by the US for special trade preference to the Andean Nations, the reasoning was merely the need to curb the illicit drug production and trafficking in Andean nations, and to promote their trade and economic capability to overcome the need of drug trafficking.[96] This was primarily due to US's own interests of curbing the production of drugs that were being frequently transported to the US from these countries. This waiver request was also approved and

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94 World Trade Organisation, Council for Trade in Goods, CARBICAN Request for Extension of Waiver (3rd September 1996), G/L/100, available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/G/L/100.pdf&Open=True.

95 World Trade Organisation, Council for Trade in Goods, Trading Arrangements with Morocco, Extension of Waiver, Decision of Revision, (17th September 1996), G/C/W/59/Rev.1, available at < https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/G/C/W59R1.pdf &Open='True>, at page 1.

96 World Trade Organisation, Council for Trade in Goods, Andean Trade Preference Act, Request for Renewal of Waiver (4th September 1996), G/L/102, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/G/L/102.pdf&Open=True>.

recommended on the ground of the exceptional circumstance of a need for trade and economic development of beneficiary developing countries situated in the Andean region.[97]

vi) In a more recent instance, a waiver request that was made by Philippines, to waive off its obligations under Article 4.2 of the Agreement on Agriculture in order to maintain quantitative import restrictions on rice imports, for the need to protect domestic rice farmers from foreign competition, and for capacity building, was recommended and granted.[98] The said request was granted after a period of 2 years. Although the waiver was granted in 2014, yet the structure and scope of the negotiations that took place, did not focus on the "needs of the Philippines", which requested for the waiver, and the exceptional circumstances, if any, thereto, but rather on ensuring that the economic needs of the exporting western nations were not sacrificed/compromised upon. This was a significant departure from past precedents, where the subject of negotiation always for the *need* of the requesting nation/nations to have a waiver, as against the economic interests of other parties to the WTO Agreement.

Even Collective waivers have been adopted at WTO to suspend obligations for groups of members that are affected by onerous obligations in exceptional circumstances. They have been adopted to address claims by developing nations that GATT/ WTO take

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97 World Trade Organisation, Council for Trade in Goods, Andean Trade Preference Act, Draft Decision (4th September 1996), G/C/W/54, 96-3472, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/G/C/W54.pdf&Open=True>.

98 World Trade Organisation, General Council, Decision on Waiver Relating to Special Treatment for Rice of the Philippines, Waiver Decision, (24th July 2014) WT/L/932, 14-4313, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/932.pdf&Open=True>.

insufficient account of their developmental and survival-based needs,[99] with a few important ones being concerned with the enforcement of TRIPS, and obligations therein concerned with pharmaceuticals.

Decision No.	***Provisions waived***	***Beneficiaries***	***Grounds of the waiver***	***Duration***
WT/L/478	TRIPS Agreement Article 70.9 with respect to pharmaceutical products	LDC members	In accordance with Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, LDC members do not have to implement, apply or enforce Section 5 (on patents) and Section 7 (on protection of undisclosed information) of the TRIPS Agreement.	Until 1 January 2016 (about 13 years) Update: Extended to 1st July 2021
WT/L/540	TRIPS Agreement Paragraph 6 decision waiving Paragraphs (f) and (h) of Article 31	All WTO members except those who opted out	The need to implement Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health to find a rapid solution to help countries with insufficient or no manufacturing capacities in the pharmaceutical sector make effective use of compulsory licenses.	Until the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that member

[99] Feichtner (n 47) at 86-87.

WT/L /971	TRIPS Agreement Article 70.8 and 70.9 with respect to pharmaceutical products	LDC members	In line with the waiver decision WT/L/478, reaffirm that LDC members do not have to implement, apply or enforce obligations under Article 70.8 and 70.9 of the TRIPS Agreement with respect to exclusive market rights and mailbox obligations.	Until 1 January 2033, or until a country graduates from the LDC status (about 17 years)

Table: Examples of Article IX waivers granted with respect to provisions under the TRIPS Agreement as a collective measure.[100]

As can be seen from the above table, waivers, and extensions thereto, against the enforcement of their obligations under Articles 70.8, 70.9 of the TRIPS, have been granted to Least Developed Countries (LDCs) in the past for the purposes of transitional capability development. However, the narrow scope that has been adopted while defining LDCs[101] has left many developing nations, with much more proximate transitional need, begging for time. Especially nations, which had gotten independence and had started sovereign policy making in mid 1900s, thereby starting to develop capability and

[100] Table taken from MSF Access, "*India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19 related medical technologies",* Briefing Document , Medicines San Frontiers (8th October 2020), Table developed with the support of the Third World Network, at page 8, available at <https://msfaccess.org/sites/default/files/202010/COVID_Brief_ProposalWTO-Waiver_ENG_2020.pdf>.

[101] List of 49 nations including Angola; Bangladesh; Benin; Burkina Faso; Burundi; Central African Republic; Chad; Congo, Democratic Republic of the; Djibouti; Gambia; Guinea; Guinea Bissau; Haiti; Lesotho; Madagascar; Malawi; Maldives; Mali; Mauritania; Mozambique; Myanmar; Niger; Rwanda; Senegal; Sierra Leone; Solomon Islands; Tanzania; Togo; Uganda; Zambia. Nine additional least-developed countries are in the process of accession to the WTO. They are Bhutan; Cambodia; Cape Verde; Laos; Nepal; Samoa; Sudan; Vanuatu and Yemen. See more here: <https://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/brief03_e.htm>.

beginning to compete with the western market, have been eradicated from the use of this waiver, substantially cutting off at least a period of 20-30 years from their transitional development, as against centuries enjoyed by the western countries. In fact, the timing and scope of the TRIPS Agreement clearly shows that there was a deliberate effort by the west to cut-short the transitional period of developing economies like India, which had started intermediate development of a generic industry, thus cutting off the revenue capacities of the west.[102] To that extent, the enforcement of the waiver for LDCs has not borne any fruit *qua* those who already have the manufacturing capability to serve the needs of these LDCs at their economic level- due to the benefit of a prolonged tech-development period not having been extended to them, but rather only to a very narrow zone of nations which relatively still have a long way to go to reach any closer to the time/ volume of transitional periods enjoyed by the west.

The TRIPS waiver that was adopted on 30th August 2003, is an interesting historic instance at the WTO, as it was a collective waiver granted to all nations, against the enforcement of Article 31(f) and (h) of the TRIPS Agreement, apart from those who opted out from availing it.[103] The purpose of this waiver was to facilitate access to pharmaceuticals for those nations which did not possess manufacturing capabilities, and depended on export from nations which could invoke compulsory licenses and develop the same. Article 31(f) provided that upon the invocation of a compulsory license, the products that were manufactured could have only been used for domestic supply. This was deemed to be ineffective for nations which

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102 Kale (n 36) at 607-608.

103 World Trade Organisation, Implementation Of Paragraph 6 of The Doha Declaration On The Trips Agreement And Public Health, decision of 30th August 2003 (2nd September 2003), WT/L/540, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/L/540.pdf&Open=True>.

required access to pharmaceuticals but lacked the manufacturing capacity to produce the same, and depended on exports from developing nations like India, which could subsidize the same for them.

The TRIPS waiver of 2003 was symbolic, in the sense that it took into consideration, non-economic reasons for a waiver, and was a conscious attempt on the part of the Contracting parties to recognize conflicting norms (not associated solely with economic development) concerned with protection of health and healthcare, which were incidentally impacted by the trade and transitional restrictions that were imposed upon by the TRIPS Agreement. Upon the expiry of the transitional period for developing countries like India and South Africa, which were important producers of generics for the developing world and especially for the LDC's that lacked the manufacturing capacity to produce pharmaceuticals, it was argued in the request for a waiver - that TRIPS Agreement's restriction on access to affordable medicines for the developing world impeded the fulfillment of human rights such as the right to life, under Article 6 of the ICCPR and the right to health under Article 12 of the ICESCR. In this light, there was a debate on TRIPS and its role in impeding access to essential medicines inside the WTO, with arguments focusing on accessibility and domestic manufacturing capability, as well as the capability to export until manufacturing was possible- contested against the incentive (read: windfall) interests of the big pharmaceutical companies stationed in the west.[104] This debate took place from 18th – 22nd June 2001, in the TRIPS Council, Geneva, post which, on 14th November

[104] World Trade Organisation, Council for Trade Related Aspects of Intellectual Property Rights, Special Discussion on Intellectual Property and Access to Medicines, Held in the Centre William Rappard during the meeting of the Council from 18 to 22nd June 2001 (10th July 2021), IP/C/M/31, available at < https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/M31.pdf&Open=True>.

2001, the Ministerial Conference of the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health,[105] acknowledging the serious health problems that the developing and the LDC countries were facing due to insufficient or no manufacturing capacity, or tech/ know-how availability which was protected under Articles 5 and 7 of the TRIPS Agreement. The conference examined the provisions of Compulsory licensing that were present within the TRIPS Agreement and recognized its inefficiency for countries which did not have any manufacturing capability, and which depended on exports for access to essential medicines - perhaps due to their economic status, as well as the lack of a transitional period and the histories of suppression that are pertinent to our global civilization.

On September 19, 2001, the TRIPS council discussed two drafts of a proposed ministerial declaration:

i) The developing country draft asserted that the TRIPS Agreement does not pre- vent members from taking measures to protect public health. Thus, TRIPS does not remove a member's sovereign power to address public health emergencies within its own borders.

ii) The developed country draft argued that the most effective strategy for addressing public health emergencies is a combination of economic, social and health policies which require a strong patent regime for incentives and effective drug development.

Notwithstanding these divergent positions, a Declaration on TRIPS and Public Health was issued by a consensus of all WTO members at

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105 World Trade Organisation, Ministerial Conference, Fourth Session, Doha, Declaration on the TRIPS Agreement and Public Health, (20th November 2001), WT/MIN(01)/DEC/2, available at < https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/Min01/DEC2.pdf&Open=True>.

the Doha Ministerial meeting in Qatar in November 2001. The Declaration provides:

> *"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.*"[106]

Pursuant to this, a Draft waiver decision was forwarded to the conference for a consensus, in terms of the provisions under Article IX.3 of the WTO/ Marrakesh Agreement, showcasing "exceptional circumstances" i.e., the widespread issue concerning HIV/Aids, Malaria and other epidemics in developing countries and the LDCs - which lacked the manufacturing capacity to develop pharmaceuticals for the same. In lieu thereof, a draft of waiver of Article 31(f) (*Motta Draft)* - which posed restrictions on export after resorting to compulsory licensing for developing drugs, and Article 31(h) which required the nation issuing a compulsory license to pay adequate remuneration to the rightsholder, was put before the Contracting parties for a consensus. However, this draft was rejected by the United States, which was adamant on restricting the scope of the application of the waiver to HIV/Aids, Malaria and Tuberculosis, instead of the broadly worded "other epidemics".[107] Given the history of the interpretation and use of the phrase "exceptional circumstance", it was

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106 Ibid.

107 World Trade Organisation, Council for Trade Related Aspects of Intellectual Property Rights, Minutes of the Meeting, Held in the Centre William Rappard On 25th, 27th and 29th November and 20th December 2002 (5th February 2003), IP/C/M/38, at [34], available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/M38.pdf&Open=True>.

quite unreasonable of the United States to have raised an objection to an issue of epidemics and unavailability/ inaccessibility of drugs at affordable prices, citing it as unjustifiably vague, and wide-encompassing, however the draft was further deliberated upon, and was forwarded to the General Council for adoption on 28th August 2003.[108] The General Council proceeded to adopt this waiver on 30th August 2003- covering a waiver of Article 31(f) and 31(h) obligations on patents (products and processes) of the pharmaceutical sector that needed to address public health problems as recognized in the Doha Declaration.[109] Interestingly, the decision did not include a termination date in terms of Article IX.4 of the Marrakesh Agreement, but rather provided for termination when an amendment replacing the said decision would come into place in the TRIPS Agreement.

The deliberations on the date of adoption of the waiver clearly show the element of norm-shifting that was fostered by this waiver, moving away from the sole-economic focus of the WTO, and towards addressing "exceptional circumstances" of hardship which went beyond "economic needs" and were in fact incidentally affected by the global trade regime. The minutes of the meeting highlight this aspect of the Chairman's statement:

> *"He also found a special satisfaction because Members' action today in completing the Doha Declaration on the TRIPS Agreement and Public Health demonstrated for all to see that the WTO was committed to pursuing its trade mandate in a way which fully respected and protected humanitarian concerns.*"[110]

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108 World Trade Organisation, Council for Trade Related Aspects of Intellectual Property Rights, Minutes of the Meeting, Held in the Centre William Rappard on 28 Aug. 2003 (7th November 2003), IP/C/M/41, at [3] and [10], available at <https://docs.wto.org/dol2fe/Pages-/SS/directdoc.aspx?filename=Q:/IP/C/M41.pdf&Open=True>.

109 Ibid at 168.

110 World Trade Organisation, General Council, Minutes of the Meeting, Held in the Centre William Rappard on 25th, 26th and 30th August 2003 (13 November 2003),WT/GC/M/82,

The focus on public health needs of the developing countries and the LDCs and how these concerns were gravely impacted with the restrictive compulsory licensing provisions in the TRIPS Agreement was duly acknowledged by the WTO, showing a shift in norms and priorities from sole economic policymaking to socio-economic and well-being/health related concerns as well. This waiver was the first attempt to normatively shift focus towards addressing humanitarian concerns of the Developing countries and the LDCs, who have been denied their claim to a sufficiently long transitional period, and manufacturing capability- due to histories of colonialism, oppression, and global policy coercions, as can be seen from Part - I of this article.

This shows that the WTO has, in fact in the past, already ventured into intersectional policy making, and the COVID-19 waiver won't be an unprecedented arena for essential norm shifting.

On a consideration of these interpretations taken in the past, there can be no doubt that the COVID-19 situation is one that qualifies as an "Exceptional circumstance" for a waiver from IP obligations under the TRIPS agreement. TRIPS obligations themselves have played a role in denying domestic industries of developing countries the capability of knowledge development through reverse engineering, or a significant transitional period. Its impact has been significant in respect of the capability to produce vaccines, or other pharmaceutical products in situations of such urgencies.

Any debate on the grant of a waiver from IP obligations under TRIPS during this global pandemic should have, in fact, been a clear non-starter. The hypocrisy in the interpretation of "Exceptional Circumstances" under Article IX.3 of the WTO Agreement, further

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at [34], available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/GC>.

supports the normative claims of inequity and a need to fundamentally restructure the global diplomatic regime that govern indigenous capability building.

CONCLUSION

The core reflection from this part is – Why does a provision to "waive" off obligations even exist in the WTO Agreement? And if not now, then when? Prioritizing norm shifting in the context of a global pandemic, giving heed to historical inequality and oppression, is the basic core of Article IX.3 of the WTO Agreement, lest its symbolic existence in the Agreement should just be done away with.

I do not shy away from the fact that manufacturing incompetence and the unwillingness or the lack of a pro-active approach by governments in quickly entering into licensing agreements- largely contributed to this loss of lives, but it was IP and TRIPS obligations which provoked this "need" for a negotiation, in exchange of so many lives. This is the neo-liberal leviathan which Prof. Amy Kapczynski spoke about,[111] where the "social" is completely dis-embedded from the economic sphere,[112] where the market regulates human activity,[113] case against social conscience regulating markets. To resort to such an extreme is to "subordinate the subsistence of society itself to the laws of the market, and the interest of the marketers, thus disenfranchising humans of the ability to direct the trajectories of their social institutions."[114]

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111 Amy Kapczynski, 'Intellectual Property's Leviathan' (2015) 77(4) Law and Contemporary Problems 131.

112 Karl Polanyi, *The Great Transformation: The Political and Economic Origins of Our Time,* (Farrar and Rinehart 1944, Reprinted in 1957 by Beacon in Coston) 60, 272.

113 Timothy Macneill, "*The End of Transformation? Culture as the Final Fictitious Commodity*", Problematique 12 (January 2010), 17.

114 Ibid at 20.