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Immuno-Imperialism: TRIPS and the Third World's Disadvantaged Access to the COVID-19 Vaccine

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Abstract

Between October 2020 and June 2022, the WTO's TRIPS Council was the location of a sustained challenge brought by the Third World to the TRIPS Agreement on account of the Agreement's effect on the global response to the COVID-19 pandemic. A key element of the Third World's challenge related to the barriers that TRIPS allegedly raised to vaccine access. This article considers that aspect of the Third World's challenge by analysing how Third World vaccine production and procurement has been impacted by intellectual property rights universalised in TRIPS, focusing on patents. Alongside this analysis, the article reviews the TRIPS 'waiver' which resulted from the TRIPS Council discussions in June 2022. The article identifies a 'cascade of disadvantage' faced by the Third World, whereby TRIPS limits the potential for Third World pharmaceutical production, directly and indirectly increases procurement costs through its cultivation of the anti-commons, and has, combined with the effects of the WTO's Dispute Settlement Understanding, channelled Third World advocacy in the identified period into a 'waiver' whose provisions do not meet the Third World's original demands.

Key words

TRIPS, WTO, vaccines, patents, intellectual property

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1. Introduction

On 11 March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak to be a pandemic.[1] Several months later, in October 2020, a group of Third World states[2] submitted a proposal to the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) at the World Trade Organization (WTO) for the temporary waiver of sections of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) concerning copyrights, industrial designs, patents, and the protection of undisclosed information. Although the waiver proposal was justified differently by the supporting states – some focused on promoting global collaboration,[3] others on securing greater domestic policy discretion[4] – their core allegation was the same: TRIPS was disadvantaging the Third World's response to the COVID-19 pandemic, including its access to vaccines.[5] Eventually, in June 2022, the WTO's Ministerial Conference agreed to a TRIPS waiver,[6] albeit one which only partially met the requests formulated by the Third World twenty months prior.

This article will interrogate the Third World's vaccine access challenge embodied in the TRIPS waiver discussions between October 2020 and June 2022. Applying a TWAIL critique, it breaks down the West's interaction with the Third World in the interrelated context of intellectual property rights (IPRs), TRIPS, and vaccine accessibility. Section 2 considers the barriers raised by the most relevant IPR, patent rights; with Sections 3 and 4 providing brief considerations regarding the effect of the protection of undisclosed information and copyright.[7] These sections analyse

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[1] BBC News, 'Coronavirus confirmed as pandemic by World Health Organization' (March 2020) www.bbc.co.uk/news/world-51839944 (accessed 20 September 2022).

[2] 'Third World' is understood in the orthodox sense: a shared and non-exclusive identity constituted with the descriptive aim to recognise the disadvantages non-European nations face in international law and the normative intent to spur resistance against those disadvantages: B.S. Chimni, 'Third World Approaches to International Law: A Manifesto' (2006) 8 *International Community Law Review* 3, at 5-6 and Karin Mickelson, 'Rhetoric and Rage: Third World Voices in International Legal Discourse' (1998) 16:2 *Wisconsin International Law Journal* 353, at 360. It may also refer to the 'Other' against which the West defines itself and enforces its universalised norms: Sundhya Pahuja, *Decolonising International Law* (CUP, 2011) 28-30.

[3] For example, by South Africa and India: TRIPS Council, 'Minutes of Meeting Held in the Centre William Rappard on 15-16 October 2020 and 10 December 2020' (February 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M96A1.pdf&Open=True (accessed 29 September 2022) (hereafter 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020') paras 861 and 865.

[4] For example, by Nepal and Sri Lanka: ibid, paras 896 and 928.

[5] Ibid, paras 853-874.

[6] WTO Ministerial Conference, 'Ministerial Decision on the TRIPS Agreement' (June 2022) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True (accessed 29 September 2022) (hereafter 'TRIPS Waiver').

[7] Regarding industrial designs, no link has been made between their protection and vaccine access problems, although links have been made between their protection and accessibility to essential materiel, such as personal protection equipment : TRIPS Council, 'Minutes of Meeting Held in the Centre William Rappard on 30 July

how IPRs were integrated into the multilateral trading system by the West; how TRIPS has generally impeded Third World access to vaccines by obstructing their production outside of the West; and how TRIPS, combined with Western policymaking, has impacted the Third World's ability to procure sufficient COVID-19 vaccine supplies during the pandemic's acute stage. Section 5 examines the role that the WTO's systems and norms play in stopping the Third World from circumventing the disadvantageous TRIPS framework, focusing on the Dispute Settlement Mechanism (DSM), the WTO's general law of waivers, and the aforementioned TRIPS waiver. Section 6 offers some concluding remarks.

2. TRIPS as a Barrier to Vaccine Access: Patents

2.1. Development of the TRIPS Regime

Patents are private rights conferred by the state that allow the patent-holder to exclude competition with the patented product. TRIPS outlines both the scope and substance of patents for WTO Members. Patentable subject-matter is delimited by Article 27.1: states must provide patents for novel, inventive and industrially applicable products or processes without discrimination as to their place of invention or their field of technology, subject to some limited exclusions under Articles 27.2 and 27.3. The substance of the patent is regulated in Article 28.1(a): product patent-holders are allowed to prevent third parties from making, using, offering for sale, or selling the protected product, or importing the protected product for those purposes,[8] subject to limited exceptions under Article 30. Per Article 33, the Article 28 rights are to be enjoyed for a period of at least twenty years from the patent's date of filing.

The basic justification for the patent is that society receives a net benefit from the innovation which is spurred by the improved likelihood of the patent-holder recouping their investment in the patented product. This outweighs the social deficit caused by the artificially higher prices the patent-holder can charge the consumer thanks to their monopoly.[9] This rationale was accepted in the TRIPS context by the Panel in *Canada – Patent Protection of Pharmaceutical Products*[10] and was consistently affirmed by leading Western states throughout the waiver proposal discussions.[11] By

2020' (October 2022) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M95A1.pdf&Open=True (accessed 29 September 2022) (hereafter 'Minutes of Meeting on 30 July 2020') para. 65.

[8] Similar coverage is afforded under Art. 28.1(b) for process patents.

[9] Robert Merges, *Justifying Intellectual Property* (Harvard University Press, 2011) 2.

[10] *Canada – Patent Protection of Pharmaceutical Products,* 17 March 2000, para. 7.55, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/114R.pdf&Open=True (accessed 20 September 2022).

[11] E.g., by the USA and UK: TRIPS Council, 'Minutes of Meeting on 30 July 2020', paras 118 and 511-512; and TRIPS Council, 'Minutes of Meeting on 15-16 October and 10 December 2020', paras 1044 and 1082.

the West's account, the TRIPS patent norms are settled, universal, and reasonable standards of international law. If such a view is accepted, the patent appears to be a useful tool to incentivise the development of new but costly pharmaceutical products, such as vaccines. However, the West's account is contestable. As this contribution aims to demonstrate, the patent's claim to universality is undermined by both the way in which TRIPS was created, and the differential treatment that TRIPS demands of the Third World compared with the West's engagement with patent rights during its own industrialisation. Furthermore, the basic justification for patent protection espoused by the West – that patents promote innovation – is far from self-evident in the Third World as shall be discussed below.

The patent is a norm of European stock, first emerging in its modern form in fifteenth century Venice before eventually spreading across the industrialising West in the 1800s.[12] Following the US adoption of a reformed patent system, which considered the expansion of the patent-holder's rights to be intertwined with the patent's social benefit,[13] domestic patent regimes proliferated. By the 1880s, patents were the leading means of incentivising innovation in the industrialised world.[14] Predictably, the Euro-American patent regime did not confine itself to Europe and North America. During the original colonial encounter, imperial powers exported their patent norms to subjugated colonial territories. For example, imperial Portuguese and British legislators enacted and enforced the first Brazilian and Indian patent laws in 1809 and 1856 respectively.[15] Such law-making ignored the fact that the colonised peoples may have held differing, often more communitarian, notions of property and ownership which clashed irreconcilably with the colonisers' capitalistic ideology.[16] The battle over which knowledge or resources may properly be considered 'property', and therefore subject to regulation through IPRs, continues today, as seen in the discourse surrounding the status and regulation of Indigenous knowledge and plant genetic resources.[17]

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[12] B. Zorina Khan and Kenneth L. Sokoloff, 'Historical Perspectives on Patent Systems in Economic Development' in Neil Weinstock Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (OUP, 2009) 215, at 218-224; and John N. Adams, 'History of the patent system' in Toshiko Takenaka (ed.), *Research Handbook on Patent Law and Theory* (Edward Elgar, 2019) 2ff.

[13] Zorina Khan and Sokoloff (2009) 226-229.

[14] Ibid, 216 and 231.

[15] Amaka Vanni, *Patent Games in the Global South: Pharmaceutical Patent Law Making in Brazil, India and Nigeria* (Hart Publishing, 2019) 68 and 109.

[16] Natsu Taylor Saito, 'From Slavery and Seminoles to AIDS in South Africa: An Essay on Race and Property in International Law' (2000) 45:5 *Villanova Law Review* 1135, at 1179-1181; and Zorina Khan and Sokoloff (2009) 241.

[17] Both areas are classic examples of 'regime shifting' to combat perceived failures in TRIPS, see Laurence R. Helfer, 'Regime Shifting: The TRIPs Agreement and the New Dynamics of International Intellectual Property Lawmaking' (2004) 29:1 *The Yale Journal of International Law* 1, at 28-40.

Following formal decolonisation, many postcolonial states deliberately reformed their imperial-era patent regimes to further their self-determined socio-economic and political interests. One notable policy undertaken by some states, including Brazil and India, was the elimination of patent protection for pharmaceuticals to encourage the growth of a domestic medicines industry.[18] The rejection of comprehensive and strict IPR protection was not a novel policy choice. As summarised by Chang, during the nineteenth century, the general Western approach to IPRs was to offer patchy local protection and to ignore the widespread infringement of foreign IPRs.[19] Even as domestic and international IPR regulation tightened during the twentieth century, until relatively recently many Western states shared the Third World's rejection of pharmaceutical patenting. Switzerland, famed as a hub for pharmaceutical development, did not allow such patents until 1977. Canada, one of the most vociferous opponents to the TRIPS waiver, has only recognised pharmaceutical patents since 1983.[20] With the adoption of TRIPS, however, the ability of the Third World to follow a similar policy as the West with regard to the (non-)patentability of pharmaceuticals would evaporate.

Before TRIPS, IPRs were regulated internationally through the Paris and Berne Conventions by the World Intellectual Property Organization (WIPO).[21] The Conventions were not intended to be instruments of comprehensive, substantive regulation, rather they focused on the way in which domestic IPRs could be applied.[22] However, not all states were satisfied with the WIPO. Moved by concerns including competition from Third World economies and corporate dissatisfaction with the WIPO's lack of anti-piracy action, the US, in cooperation with private enterprise, began lobbying to ensure that states enacted comprehensive domestic IPR regimes, and that these regimes were enforced.[23] Originally, the US adopted a bilateral strategy of putting states with 'weak' IPR regimes under diplomatic and economic pressure with the threat of 'Section 301' trade sanctions.[24] This strategy was soon swapped in

[18] Vanni (2019) 71 and 116.

[19] Ha-Joon Chang, 'Intellectual Property Rights and Economic Development: Historical lessons and emerging issues' (2001) 2:2 *Journal of Human Development* 287, at 290-293.

[20] Francesco Laforgia, Fabio Montobbio and Luigi Orsenigo, 'IPRs and Technological Development in Pharmaceuticals: Who is Patenting What in Brazil After TRIPS?' in Neil Weinstock Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (OUP, 2009) 293, at 300.

[21] Art. 4(ii) Convention Establishing the World Intellectual Property Organization.

[22] UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP, 2005) 19. However, even this lighter-touch regulation could be disadvantageous to the Third World: Vanni (2019) 15-16.

[23] Peter Drahos, 'Global Property Rights in Information: The Story of TRIPS at the GATT' (1995) 13:1 *Prometheus* 6, at 7-8.

[24] Under Section 301 of the US Trade Act of 1974, 19 U.S.C. §2411, the US Trade Representative is authorised to act against States violating US rights under trade agreements.

favour of lobbying for 'improved' IPR protection under the General Agreement on Tariffs and Trade (GATT) system, which offered a more diplomatically palatable forum for its campaign, replete with its own enforcement mechanism.[25] Following US 'consensus-building' efforts, IPR protection was included in the Uruguay Round of GATT negotiations beginning in 1986.[26] In 1995, the result of the IPR negotiations, the TRIPS Agreement, was adopted, to be administered by the newly created WTO. Some commentators from within the WTO, such as former Chair of the Appellate Body, Peter van den Bossche and former Appellate Body Secretariat Director, Werner Zdouc, describe the transposal of IPRs into the multilateral trading system as a reform to which the Third World assented after much negotiation.[27] By contrast, commentary from outside of the Organization gives a starker assessment: the Third World was coerced into accepting TRIPS,[28] or at least succumbed to the pressures of its unequal power dynamic with the West.[29] From the outset, due to their late inclusion in the Uruguay agenda, few Third World delegations were prepared to conduct negotiations on IPRs, nor would they have had the expertise to negotiate effectively if they had received more notice. Moreover, the Third World was subject to a carrot-and-stick strategy from the US; the carrot comprising trade concessions, the stick the threat of Section 301 sanctions.[30]

The West's desired policy objectives, now universalised in TRIPS legal norms, have overridden much of the Third World's postcolonial IPR reforms. Particularly illustrative (and restrictive) is Article 27.1, whose patentability requirements prevent states from excluding pharmaceuticals patents.[31] As was the case during the West's industrialisation, weak IPR protection for pharmaceuticals is not indicative of improper policymaking. In reality, such a choice demonstrates a critical appreciation of the relationship between legitimate domestic socio-economic and normative considerations, and the effects of IPR regulation.[32] Yet, despite that fact, patent norms promulgated by the West *after* its adoption of stricter IPR standards now serve as the 'proper' legal standard against which the Third World is judged during its

[25] Drahos (1995) 9-13.

[26] Ibid.

[27] See Peter Van den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (CUP, 2019) 996.

[28] Drahos (1995) 16. The imposition of alien property standards through economic coercion has direct historical parallels within the context of the colonial encounter, see Saito (2000) 1179-1186.

[29] Helfer (2004) 21-22.

[30] Drahos (1995) 15-16; and UNCTAD-ICSTD (2005) 4.

[31] Vanni (2019) 47-48.

[32] Ruth Gana, 'Prospects for Developing Countries under the TRIPS Agreement' (1996) 29:4 *Vanderbilt Journal of Transnational Law* 735, at 746-747.

development, with such differential treatment masked by TRIPS's neutral, objective vocabulary.[33]

The West's hypocrisy is not limited to history, however. This is clear from TRIPS's location in the international order. TRIPS is a WTO Agreement, but its objective and means of achieving that objective sit awkwardly within the Organization. TRIPS is the only WTO Agreement that regulates private rights,[34] with those rights explicitly *restricting* market competition. This is in sharp contrast with the WTO's mission to liberalise global trade, and its usual focus on regulating governmental trade policies.[35] The logic of TRIPS's location within the WTO is even more questionable considering that IPRs were *already* internationally regulated via the WIPO. The US-led mission to bring TRIPS within the multilateral trading system did, however, make sense for the West. By shifting global IPR regulation from the WIPO to the GATT/WTO, the West was able to take advantage of a preferable forum for the pursuit of its own interests thanks to, *inter alia*, the GATT/WTO's enforcement mechanism, and the West's greater economic and institutional clout in the multilateral trading system.[36] The Third World, led by India and Brazil, attempted to challenge this regime shift during the Uruguay Round, but was unsuccessful.[37] Thus, the West's desired control over global IPR came to pass.

2.2. Patents as a Barrier to Vaccine Production

Unsurprisingly, the ostensible objective of TRIPS is not to support Western hegemony. Instead, the 'TRIPS promise' is encapsulated in Articles 7 and 8.1: IPRs should be used instrumentally to promote technological innovation conducive to the improvement of socio-economic welfare and public health.[38] Notwithstanding the differential treatment to which it subjects the Third World, if the TRIPS patent regime *is* objectively beneficial to the development and production of vaccines, the opposition expressed in the waiver proposal would be largely neutralised. However, such a dynamic between patents and pharmaceutical manufacturing is far from apparent.

The academic commentary on the merits of patent protection as a means for promoting pharmaceutical manufacturing is vast and varied. Nevertheless, three

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[33] Vanni (2019) 40-41 and 46-47.

[34] Preamble clause 4 TRIPS; and UNCTAD-ICSTD (2005) 11.

[35] Preamble clause 3 Marrakesh Agreement; and Carlos Correa, 'The Trips Agreement and Developing Countries' in Patrick F. J. Macrory, Arthur E. Appleton and Michael G. Plummer (eds.), *The World Trade Organization: Legal, Economic and Political Analysis (Volume II)* (Springer, 2005) 419, at 428.

[36] Helfer (2004) 21.

[37] Vanni (2019) 73 and 125.

[38] Notwithstanding Correa's claim that TRIPS is liable to narrow interpretations in favour of maximum IPR protection: Correa (2005) 432.

broadly defined groups can be identified. The anti-patent camp advocates the total abolition of patents in the belief that they stifle the innovation they are supposed to promote by artificially blocking access to information and raising prices for consumers.[39] The pro-patent camp supports patent protection on the basis that IPRs appear to be essential to pharmaceutical manufacturing or, at least, do not obstruct it.[40] Occupying the sizeable, equivocal middle ground are the patent sceptics. Their common claim is that patents *can* encourage pharmaceutical production, but it is not self-evident that they *will* in the Third World. The sceptics connect the benefits of patent protection with multiple underlying socio-economic factors which are invariably absent or weak in the Third World, such as sufficient domestic market demand to support a pharmaceutical sector,[41] local infrastructure and human capital capable of supporting pharmaceutical manufacturing,[42] a 'developed' legal system capable of enforcing IPRs effectively,[43] and a pre-existing social structure amenable to IPRs in principle.[44]

A determination of the precise relationship between patents and pharmaceutical production is beyond the scope of this article. Nonetheless, following the broadly adopted 'patent sceptic' view, certain disadvantages which the Third World faces in relation to its development of pharmaceutical industries due to TRIPS's patent norms are clearly visible. First, the Third World has not had the same timeframe as the West in which to lay the foundations required to ensure the patent's effectiveness.[45] WTO Members had one year in which to implement TRIPS following its entry into

[39] Michele Boldrin and David K. Levine, 'The Case Against Patents', (2013) 27:1 *Journal of Economic Perspectives* 3, at 7-13 and Jean-Paul Gaudillière, 'How pharmaceuticals became patentable: the production and appropriation of drugs in the twentieth century' (2008) 24:2 *History and Technology* 99, at 99.

[40] Laforgia and others (2009) 293 and (qualified with doubts as to whether innovation is spurred in the Third World) 301-302; Hilde Stevens, Isabelle Huys, Koenraad Debackere and others, 'Vaccines: Accelerating Innovation and Access. Global Challenges Report' (2017) www.wipo.int/publications/en/details.jsp?id=4224 (accessed 21 September 2022) 19-22; and Merges (2011) 282.

[41] Baker and others (2017) 30; Christopher Garrison, 'Background paper for WHO workshop: Intellectual Property Rights and Vaccines in Developing countries' (April 2004) https://perma.cc/BM4J-TUPM (accessed 21 September 2022) 29-31; and Ellen 't Hoen, 'Report of the Commission on Intellectual Property Rights, Innovation and Public Health: a call to governments', (2006) 84:5 *Bulletin of the World Health Organization* 421, at 421.

[42] Baker and others (2017) 30; Laforgia and others (2009) 298-299; and Yi Qian, 'Are National Patent Laws the Blossoming Rains? Evidence from Domestic Innovation, Technology Transfers, and International Trade Post Patent Implementations in the Period 1978–2002' in Neil Weinstock Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (OUP, 2009) 191, at 208.

[43] Zorina Khan and Sokoloff (2009) 240.

[44] Gana (1996) 738.

[45] Qian (2009) 207.

force,[46] with Developing Country Members (DCMs)[47] afforded a period of four years in which to implement the TRIPS patent regime,[48] with an additional five years granted in which to make pharmaceuticals patentable.[49] Least-Developed Country Members (LDCMs)[50] were granted ten years for general implementation.[51] This period was later extended to 2021,[52] and until 2033 for obligations affecting pharmaceuticals under Part II, Sections 5 and 7.[53] However, even during the transitional periods, DCMs and LCDMs are required to ensure patent applications and exclusive marketing rights are offered, *inter alia*, for pharmaceuticals under the so-called 'mailbox' obligations.[54] These obligations are not merely aspirational: Western allegations of Third World violations of the mailbox obligations have been the subject of four of the eleven TRIPS-related disputes concerning pharmaceuticals notified to the WTO's Dispute Settlement Body (DSB).[55] Moreover, irrespective of whether the transitional periods are used, states must shoulder significant institutional burdens to ensure TRIPS compliance, for example, by establishing IP offices and enacting new IP laws.[56] By comparison, the West enjoyed more than a century-and-a-half to develop and adjust its patent norms

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[46] Art. 65.1 TRIPS.

[47] 'Developing Country Member' status is self-determined: WTO, 'Who are the developing countries in the WTO?' www.wto.org/english/tratop_e/devel_e/d1who_e.htm (accessed 21 September 2022).

[48] Art. 65.2 TRIPS.

[49] Art. 65.4 TRIPS.

[50] The status is determined with reference to the UN's list of Least Developed Countries. As of September 2022, 35 of the 46 UN's Least-Developed countries are WTO Members: WTO 'Least-developed countries' www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (accessed 22 September 2022).

[51] Art. 66.1 TRIPS.

[52] TRIPS Council, 'Extension of the Transition Period under Article 66.1 for Least Developed Country Members' (June 2003) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/88.pdf&Open=True (accessed 29 September 2022).

[53] TRIPS Council, 'Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with respect to Pharmaceutical Products' (November 2015) https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?Language=E&CatalogueIdList=228924,135697,117294,75909,77445,11737,50512,1530,12953,20730&CurrentCatalogueIdIndex=1&FullTextHash=371857150 (accessed 29 September 2022).

[54] Arts 70.8 and 70.9 TRIPS.

[55] These cases being *Pakistan – Patent Protection for Pharmaceutical and Agricultural Chemical Products,* 7 March 1997 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/D/2A1.pdf&Open=True (accessed 24 September 2022); *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products,* 19 December 1997 https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=22367&CurrentCatalogueIdIndex=0&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True (accessed 24 September 2022); *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products,* 24 August 1998 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/79R.pdf&Open=True (accessed 24 September 2022); and *Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals,* 31 May 2002 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/D/22A1.pdf&Open=True (accessed 24 September 2022).

[56] Qian (2009) 206.

and supporting legal structures to its own self-determined needs before TRIPS came into force.

Second, for the Third World states that have implemented the TRIPS patent regime, the empirical evidence of its invariable benefit to the development of domestic pharmaceutical production is, at best, mixed. For example, recent commentary which analyses the impressive capabilities of India's post-TRIPS pharmaceutical industry attributes the essential strength of the sector to its early, TRIPS-free, development.[57] Likewise, Brazil's experience of TRIPS has not been unequivocally positive: a 2015 study of the Agreement's implementation in the country surmises that, 'Brazil has been struggling to balance its interest in protecting technology mostly developed abroad with its interest in fostering local technology while at the same time assuring that social policies are implemented.'[58] Comparative law theory may suggest that this result flows from the patent's origins outside of the Third World.[59] However, some scholars have suggested that there may even be no positive causative or correlative relationship between patent protection and pharmaceutical development in the West,[60] a proposition supported by the historical absence of patent protection during the rise of Western pharmaceutical industries. Such pharmaceutical companies today insist that the availability of patents is crucial to their operations,[61] but it can hardly be surprising

[57] Atsuko Kamiike, 'The TRIPS Agreement and the Pharmaceutical Industry in India' (2020) 32:1 *Journal of Interdisciplinary Economics* 95, at 96-99; Biswajit Dhar and Reji K. Joseph, 'The Challenges, Opportunities and Performances of the Indian Pharmaceutical Industry Post-TRIPS' in Kung-chung Liu and Uday S. Racherla (eds.), *Innovation, Economic Development and Intellectual Property in India and China* (Springer Singapore, 2019) 299, at 300 and 321. See also earlier research which suggested that there was no link between the identification of new chemical entities (NCEs) and the post-TRIPS environment in India: Sudip Chaudhuri, 'Is Product Patent Protection Necessary to Spur Innovation in Developing Countries? R&D by Indian Pharmaceutical Companies After TRIPS' in Neil Weinstock Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (OUP, 2009) 265, at 288-289, cf. recent sources which suggest that research and development has generally intensified post-TRIPS, e.g., Dhar and Joseph (2019) at 316-320.

[58] Viviane Yumy Mitsuuchi Kunisawa, *The TRIPS Agreement Implementation in Brazil* (Nomos, 2015) 180. Note also that, from 2001 to 2004, foreign pharmaceutical firms were eight of the ten most prolific patentors in Brazil: Laforgia and others (2009), cf. McCabe's view that the reformed Brazilian framework for pharmaceutical patents had neither boosted nor harmed the share of national ownership in the pharmaceutical sector and that, in fact, Brazilian companies had benefited under the framework, notwithstanding the framework's failure to meet certain goals, such as expanding access to cheap pharmaceuticals for the poor: Ariane McCabe, 'Rhetorics of Power and Development: Intellectual Property Rights and the Pharmaceutical Industry in Brazil' (2007) 6:4 *Perspectives on Global Development and Technology* 585, at 602-606. For a more positive assessment of the balance struck by Brazil, see: M. Monirul Azam, 'The Experiences of TRIPS-Compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh' (2014) 7:2 *Akron Intellectual Property Journal* 61, at 65-73.

[59] Daniel Berkowitz, Katharina Pistor, and Jean-Francois Richard, 'The Transplant Effect' (2003) 51:1 *The American Journal of Comparative Law* 163, at 189-190.

[60] Chang, (2001) 301; and Keith Maskus, 'Encouraging International Technology Transfer' (May 2004) https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.297.4284&rep=rep1&type=pdf (accessed 24 September 2022) 26. See also Gaudillière (2008) and Boldrin and Levine (2013).

[61] See, in the US, for example: Iain Cockburn and Genia Long, 'The importance of patents to innovation: updated cross-industry comparisons with biopharmaceuticals' (2015) 25:7 *Expert Opinion on Therapeutic Patents* 739. See also the conclusion drawn in Henry G. Grabowski, Joseph A. DiMasi and Genia Long, 'The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation' (2015) 34:2 *Health Affairs* 302.

that such sentiment is held by businesses operating within a capitalistic economic system. That which is egregious about the West's rhetoric, epitomised by the statements at TRIPS Council, is its inability to countenance the structural problems which follow from the adoption of patent-based incentive systems or the fact that alternative models which could otherwise support innovation are imaginable.[62]

Third, and particularly significant, the TRIPS patent regime comes with the unavoidable burden of the 'anti-commons'. The anti-commons describes the situation in which so much information has been locked away within patents that innovation within a sector becomes stifled because too little knowledge is accessible for use by non-patent-holders.[63] This siphoning of information away from the public domain is facilitated through the combined effects of Articles 27.1, 28, and 33. Whilst TRIPS includes so-called 'flexibilities' to ameliorate this problem, including the exceptions and limitations to patents allowed under Articles 27.2 and 30, practical access to these allowances is circumscribed for the Third World. Bilateral pressure against their usage,[64] a lack of knowledge surrounding their availability and application,[65] and difficulties in implementing known flexibilities due to the general institutional burdens created by TRIPS,[66] all contribute to an exacerbation of the exclusory effect of the anti-commons. Indeed, even when flexibilities have been successfully implemented domestically, their usage may be subject to extensive legal challenges lasting years which require substantial resources to defend, a famous example being the saga of *Novartis v Union of India*, concerning the refusal of Indian authorities to grant patent protection, in accordance with TRIPS Article 27, for the alleged minor modification of an anti-cancer drug, which lasted from 1998 until 2013.[67]

In addition to the flexibilities, TRIPS contains technology-sharing obligations in Articles 66.2 and 67. These should combat the anti-commons by directly facilitating

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[62] For example, the US Congressional Budget Office's assessment of the manner in which the government can support pharmaceutical research and development is essentially indirect, i.e., increasing the supply of medicinal drugs by affording exclusivity protections, mainly in the form of patent protection: Congressional Budget Office, 'Research and Development in the Pharmaceutical Industry' (April 2021) https://www.cbo.gov/publication/57126 (accessed 26 August 2023). It is surely not beyond the wit of humankind to imagine a system of medicinal drug development in which supply is affected more directly without reliance on market forces, e.g., through the public ownership of pharmaceutical companies.

[63] Garrison (2004) 38. The anti-commons is particularly visible in the context of mRNA COVID-19 vaccines: Mario Gaviria and Burcu Kilic, 'A network analysis of COVID-19 mRNA vaccine patents' (2021) 39 *Nature Biotechnology* 546, at 546.

[64] For example, the usage of compulsory licenses has drawn the threat of Section 301 sanctions: TRIPS Council, 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020', paras 1157 and 1496.

[65] For example, the use of Art. 31(k): Duncan Matthews, 'TRIPs Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements' (2005) 27:11 *European Intellectual Property Review* 420, at 422.

[66] Chang (2001) 299.

[67] Dhar and Joseph (2019) 301-304.

the transfer of knowledge to the Third World. However, in stark contrast with the Third World's burdensome TRIPS obligations, the West's duties under these Articles are minimal. Article 66.2 obliges developed states to provide incentives to private actors to promote technology transfer to LDCMs. This is a weak obligation of means[68] and one limited to a subset of states at that. Article 67 obliges developed states to provide financial and technical IPR-related assistance to LDCMs and DCMs aimed at counteracting IPR abuse, alongside strengthening IPR protection and enforcement. However, empirical evidence suggests that Article 67 assistance focuses narrowly on the latter at the expense of the former.[69] Hence TRIPS technology sharing framework is superficial, at least compared with the wholesale, direct, unconditional transfer of knowledge that the Third World requested in order to facilitate industrial development under the New International Economic Order proposals.[70]

2.3. Patents as a Barrier to COVID-19 Vaccine Procurement

Although the TRIPS patent regime causes a clear disadvantage to the Third World's independent production of vaccines, a reasonable counterpoint could be made that not every Third World state can be expected to maintain a pharmaceutical sector, let alone one capable of vaccine production. In response, two points should be made. First, existing Third World pharmaceutical sectors *have* independently manufactured the necessary doses to protect their peoples. For example, despite its relatively small population and economy, Cuba managed to fully inoculate more than 80 percent of its population with domestically developed COVID-19 vaccines by the end of 2021.[71]

Second, the TRIPS patent regime is not of neutral effect when it comes to the Third World's ability to procure vaccines on the global market: TRIPS directly and indirectly increases the cost of such procurement. The direct effect is obvious: patents increase the cost of the product which is patented. This is not accidental. As already noted, patent orthodoxy accepts that higher prices result from the patent-holder's monopoly, but that this is an acceptable price to pay for innovation. Notwithstanding

[68] See Garrison's suggestion that the obligation could be discharged with nothing more than a tax incentive for businesses to share technology, regardless of whether technology was actually shared: Garrison (2004) 41.

[69] Matthews (2005) 423. This problem is amplified, *inter alia*, by the predominance of corporate actors in the delivery of cooperation projects: Duncan Matthews and Viviana Munoz-Tellez, 'Bilateral Technical Assistance and TRIPS: The United States, Japan and the European Communities in Comparative Perspective' (2006) 9:6 *Journal of World Intellectual Property* 629, at 632-638. See also Arno Hold and Bryan Mercurio, 'Transitioning to Intellectual Property: How Can the WTO Integrate Least-Developed Countries into TRIPS?' (2012) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2169352 (accessed 26 August 2023) 9.

[70] Vanni (2019) 18.

[71] Ed Augustin, 'Cuba's vaccine success story sails past mark set by rich world's Covid efforts' (January 2022) www.theguardian.com/world/2022/jan/05/cuba-coronavirus-covid-vaccines-success-story (accessed 24 September 2022).

that claim, it is trite that higher consumer costs reduce consumer accessibility, especially when that consumer is a Third World consumer bearing the enormous socio-economic costs associated with combatting a pandemic. Indirectly, TRIPS has the consequence of stalling the entry into the market of generic competition which could undercut the patent monopoly and precipitate a price reduction[72] through its cultivation of the anti-commons. Generic competitors cannot produce drugs if the information required for their production is locked within patents. Due to Article 33, any generic manufacturers seeking to use the technology sequestered in the current generation of COVID-19 vaccine patents will have to wait years before it enters the public domain. The Third World cannot wait that long.[73] Whilst TRIPS accommodates the 'Bolar exception', which allows for generic competitors to commence applications for regulatory approval for a product before the patent has expired for the product on which it is based,[74] the exception has been undermined for some states through the inclusion of 'linkage' obligations in their bilateral trade agreements with the USA. Such obligations require that the patent-holder be granted the power to block regulatory approval for generics during the patent period.[75] Even with a utilisable Bolar exception, of course, generic manufacturers still need to wait for the expiration of the lengthy Article 33 period before their products can be sold.

In the context of the COVID-19 pandemic, this inaccessibility problem was intensified by 'vaccine nationalism', whereby the West absorbed huge volumes of vaccine supply, depriving the Third World of a fair chance at purchasing doses. By 2 January 2021, twenty-six states had arranged known 'Advance Market Commitments' (AMCs) with vaccine manufacturers. These agreements pre-emptively secured two or more COVID-19 vaccine doses per capita for their populaces prior to their production.[76] Within this group, eleven states, including Sri Lanka, the Dominican Republic, and Bahrain, had secured 2-3 doses per capita. The top five pre-purchasers

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[72] E.g., following the expiration of Merck's patents on their rDNA Hepatitis B vaccine and the entrance of generic competitors into the market, the price of the vaccine dropped from $40 to $0.60 per dose: Garrison (2004) 18-20.

[73] This problem caused by Art. 33 is not new, see Ruth Mayne and Michael Bailey, 'TRIPS and Public Health' (March 2002) https://oxfamilibrary.openrepository.com/bitstream/handle/10546/115047/bp15-trips-public-health-010302-en.pdf;jsessionid=A8B7C1404266430609A3AB0B501D8010?sequence=1 (accessed 27 September 2022) 4-5. 'Evergreening', an abusive practice in which superficial alterations to a product are used to renew patent protection can also be used to extend patent protection beyond the Art. 33 minimum: Amaka Vanni, 'On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism' (March 2021) https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/ (accessed 27 September 2022).

[74] Carlos Correa, 'Expanding Patent Rights in Pharmaceuticals: The Linkage between Patents and Drug Registration' in Neil Weinstock Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (OUP, 2009) 247, at 260.

[75] Ibid.

[76] Duke Global Health Innovation Center, 'Launch and Scale Speedometer: Vaccine Purchases' https://launchandscalefaster.org/covid-19/vaccinepurchases (accessed 27 September 2022).

– the EU, New Zealand, the UK, Australia, and Canada – had all secured at least 7 doses per capita, with Canada having procured almost 11.5 doses per capita. By comparison, Benin, Ghana, and Senegal secured only 0.01 doses per capita. The enormous global demand for vaccines, the supply shortages precipitated by the TRIPS anti-commons' obstruction of generic competition, and Western AMCs resulted in the Third World paying more for COVID-19 vaccines compared with the West. For example, it was reported at the TRIPS Council that one version of AstraZeneca's vaccine had been sold to the EU for $3.50 per dose, South Africa for $5.25, and Uganda for $8.50.[77]

The inaccessibility caused by TRIPS and exacerbated by Western purchasing practices did have an apparent solution in Article 31, TRIPS's compulsory licencing provision. A compulsory licence (CL) cuts through the anti-commons by requiring licences to be granted for patent-protected technology. This increases accessibility by allowing technology otherwise locked in patents to be utilised by generic competitors to produce their own products. However, in common with other TRIPS flexibilities, Article 31's actual effect is limited. Third World states wishing to issue CLs themselves often face a lack of the local expertise required for their implementation,[78] a problem Article 67 assistance conspicuously fails to address. Where such knowledge exists, bilateral pressure, such as the threat of Section 301 sanctions, has been utilised to discourage the use of CLs.[79] Alternatively, a Third World state may seek to rely on another state with a developed pharmaceutical sector and an effective CL regime to issue licences to stimulate the production of generic products for that Third World state to import. TRIPS, however, precludes such a strategy: Article 31(f) prohibits a CL being issued to produce pharmaceuticals predominantly for export, notwithstanding the public health needs of the importing state.

The Article 31(f) barrier has been, in theory, moderated by the WTO Ministerial Conference's Doha Declaration on the TRIPS Agreement and Public Health,[80] which was promulgated to address concerns regarding the interaction of TRIPS and public health policymaking following Western pressure placed on South Africa for its usage of TRIPS flexibilities in its HIV/AIDS response.[81] The Declaration

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[77] TRIPS Council, 'Minutes of Meeting Held in the Centre William Rappard on 10-11 March 2021' (July 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M98A1.pdf&Open=True (hereafter 'Minutes of Meeting on 10-11 March 2021') para. 284.

[78] This obviously requires the issuing state to have a pharmaceutical industrial base which can make use of a CL. This is made less likely by TRIPS's own effect vis-à-vis industrial development.

[79] TRIPS Council, 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020', paras 1157 and 1496.

[80] WTO Ministerial Conference, 'Ministerial Declaration of 14 November 2001' (November 2001) www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (hereafter 'Doha Declaration').

[81] Saito (2000) 1187-1189 and Mayne and Bailey (2002) 4.

clarified that TRIPS should be interpreted and implemented in a manner supportive of public health objectives,[82] and affirmed that a solution would be found to the difficulties faced by states lacking the pharmaceutical manufacturing capabilities to make use of CLs themselves, implicitly referring to Article 31(f). The solution took the form of the Special Compulsory Licensing System (SCLS), first formulated in the WTO General Council's Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,[83] before being incorporated into TRIPS as Article 31*bis*.

The SCLS allows a state with adequate pharmaceutical manufacturing capacity to issue a CL to produce a patented pharmaceutical product for export to an eligible importing state, bypassing Article 31(f). According to the WTO Secretariat, using the SCLS is simple.[84] First, a state must be eligible to import under the System. LDCMs are automatically eligible, whereas other WTO Members are eligible after notifying the TRIPS Council.[85] Second, a state must notify the TRIPS Council of the product which they intend to import. This notification must include the name and expected quantities of the product to be imported,[86] and confirm that the importing state will grant or has granted a CL in its territory if the product is patented there.[87] Non-LDCMs must additionally confirm that they do not possess adequate domestic pharmaceutical manufacturing capacity.[88] Third, the exporting state is required to issue a CL. This CL may only authorise production of the patented product to the extent necessary to fulfil the importing state's request, the produced products may only be used to fulfil that request,[89] and the produced products must be clearly identifiable through specific labelling or marking.[90] The licensee must publish the information regarding the produced product's quantity and identifying characteristics online itself or through the

[82] Para. 4, Doha Declaration.

[83] WTO General Council, 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (September 2003) https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?CatalogueIdList=51809,2548,53071,70701&CurrentCatalogueIdIndex=1 (accessed 29 September 2022) (hereafter 'Paragraph 6 Decision').

[84] WTO General Council, 'Annual Review of the Special Compulsory Licensing System' (November 2020) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/86.pdf&Open='True (accessed 29 September 2022) para. 9.

[85] Para. 1(b), Annex to the TRIPS Agreement and Paragraph 6 Decision.

[86] Ibid, para. 2(a)(i).

[87] Ibid, para. 2(a)(iii). Due to Art. 66.1 TRIPS, it is unlikely that such a notification will be required for LDCMs. However, where such patents do exist, it may not be easy for the importing state to issue a CL due to the Third World's expertise deficit and pressure from the West against their use.

[88] Ibid, para. 2(a)(ii).

[89] Ibid, para. 2(b)(i).

[90] Ibid, para. 2(b)(ii).

WTO.[91] Lastly, the exporting state must notify the TRIPS Council that the CL was issued and provide details on the quantity, identification, and destination of the products produced.[92]

Despite the WTO Secretariat's rosy view of the SCLS, the Third World has consistently disavowed the System due to its impracticability.[93] The System's problems are best illustrated through examples. In 2004, Rwanda, assisted by Médecins Sans Frontières (MSF), sought to use the SCLS, as implemented under the Canadian Patent Act, to license anti-retroviral HIV/AIDS drugs. In its report on the operation, MSF concluded that the SCLS was unworkable for two reasons.[94] First, the System was inordinately slow. This problem was primarily attributable to Article 31(b), which ambiguously requires negotiations on 'reasonable commercial terms' with the patent-holder to secure a voluntary licence before a CL can be issued.[95] Second, the SCLS was structurally unsuited to dealing with a dynamic public health crisis. The System's notification conditions require medicines to be procured on an inflexible basis, subject to cumbersome procedural requirements.[96] Furthermore, the SCLS does not prevent exporting states from adding *additional or stricter* conditions to their issue of a CL. For instance, the Canadian regime exceptionally required the national regulator's approval for SCLS exports, and the specification of a *maximum* (rather than *expected*) quantity of product to be delivered in the CL application.[97] So impracticable is the SCLS that the Rwandan attempt remains the *only* instance of a CL having been issued under the System so far.[98] In the COVID-19 context there have been some attempts to utilise the SCLS but these attempts show that the System's faults persist. On 11 May 2021, Bolivia notified the TRIPS Council that it intended to import 15 million doses of a generic version of the Johnson & Johnson vaccine to be produced by a Canadian

[91] Ibid, para. 2(b)(iii).

[92] Ibid, para. 2(c).

[93] For example, by South Africa and India, TRIPS Council, 'Annual Review of the Special Compulsory Licensing System', paras 41 and 47-48; and Sri Lanka and Mozambique, TRIPS Council, 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020', paras 908-909 and 1399.

[94] Médecins Sans Frontières, 'Neither Expeditious, Nor a Solution: The WTO Decision of 30th August is Unworkable' (August 2006) https://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_NeitherExpeditiousNorSolution_WTO_ENG_2006.pdf (accessed 27 September 2022).

[95] Ibid, 2-3. Although Art. 31(b)'s negotiation requirement can be waived in the context of a 'national emergency or other circumstances of extreme urgency', the focus on the issuing nation suggests that a vaccine access problem *in another country* may be insufficient.

[96] Ibid, 4.

[97] Ibid, 5-6.

[98] Eduardo Urias and Shyama V. Ranami, 'Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence' (2020) 3 *Journal of International Business Policy* 367, at 377.

generic manufacturer, Biolyse, under Canada's SCLS regime.[99] As reported by Biolyse's executive vice-president, John Fulton, the task was hamstrung by serious obstacles, such as the vaccine's absence from a required schedule of the Patent Act. According to Fulton, Biolyse's attempt to use the SCLS was akin to 'triggering a fire alarm and finding that the water wasn't connected to the sprinklers'.[100]

Despite these experienced difficulties, the West maintains unwavering support for the SCLS. Ironically, a chief advocate is Canada, which has claimed that the System 'on the basis of concrete experience ... worked as intended' and that the System's rare invocation shows how TRIPS effectively accommodates public health policymaking.[101] Such conclusions indicate a blatant disregard of the Third World's own experiences by a state that has never used the SCLS in the vulnerable position of an importer,[102] and whose SCLS implementation manifestly failed. In reality, of course, if the Third World *could* procure vaccines to combat COVID-19 under TRIPS, it would have. Our conclusion must be that it could not.

3. TRIPS as a Barrier to Vaccine Access: Protection of Undisclosed Information

TRIPS is the first international convention to substantively regulate the protection of undisclosed information (PUDI),[103] an unusual IPR which protects the *de facto* possession of information between private economic actors under Article 39.2, and between pharmaceutical producers and the state under Article 39.3. Focusing on the latter, PUDI under TRIPS provides that, where states require the submission of undisclosed test or other data which involved considerable effort to originate as a condition for the approval of the marketing of a pharmaceutical product that utilises a new chemical entity, the state will protect such data against unfair commercial use. In addition, Members will protect such data against disclosure, except where necessary

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[99] TRIPS Council, 'Notification of Need to Import Pharmaceutical Products under the Special Compulsory Licensing System' (May 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/N/9BOL1.pdf&Open=True (accessed 29 September 2022), and WTO-WIPO-WHO, 'Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade. Updated extract: integrated health, trade and IP approach to respond to the COVID-19 pandemic' (August 2021) www.wto.org/english/res_e/booksp_e/who-wipo-wto_2021_e.pdf (accessed 27 September 2022) 9.

[100] Francesca Bruce, 'Canadian Firm Scathing on Obstacles to Compulsory Licensing' (May 2021) https://pink.pharmaintelligence.informa.com/PS144384/Canadian-Firm-Scathing-On-Obstacles-To-Compulsory-Licensing (accessed 27 September 2022).

[101] TRIPS Council, 'Minutes of Meeting Held in the Centre William Rappard on 15-16 October 2020 and 10 December 2020', para. 1187.

[102] More precisely, Canada *cannot* use the SCLS as an importer, as it excluded itself from eligibility under Art. 31*bis*: para. 1(b), Annex to the TRIPS Agreement.

[103] UNCTAD ICTSD (2005) 522; Correa (2020) 351.

to protect the public, or unless steps are taken to ensure that the data is protected against unfair commercial use.

The potential barriers raised by PUDI regarding Third World vaccine access are, in substance, repetitions of problems already identified. The first is the institutional burden which is placed on Third World states regarding the inclusion, for the first time, of PUDI within their domestic legal systems. Unlike patents, the concept of which at least *existed* in Third World states prior to its expansion into novel areas by TRIPS, PUDI is a recent development in IP law, originating in the United States and the EU in the 1970s and 1980s respectively.[104] Few other states followed the Euro-American model.[105] Indeed, a degree of conceptual uncertainty lingers around the right, with Correa remarking that TRIPS Article 39 does not actually give rise to a proprietary right, rather it regulates unfair competition as a 'discipline of industrial property'.[106] Yet, despite its novelty and despite the protestations of the Third World that PUDI should not be incorporated into TRIPS,[107] Article 39.3 now obliges *all* states, subject to TRIPS Articles 65 and 66, to generally protect test data submitted to national health regulators.

The second unsurprising barrier is that Article 39.3 contributes, as all IPRs necessarily do, to the expansion of the anti-commons. As with the patent, this is justified with reference to the benefit which flows from allowing companies to recoup costs and to make a profit as a *quid pro quo* of the investment required for, in this case, the testing of new chemical entities.[108] As Carvalho summarises, the purpose of PUDI is to prevent 'parasitism, which is not only socially reproachable but also leads to economic inefficiency'.[109] Expectedly, the cost of this protection is borne by society-at-large; specifically by generic competitors who would otherwise rely on the approval of a patented medication to speed up their own generic product's regulatory approval

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[104] Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (Kluwer Law International, 5 edn 2018), 520-523. See also Solovy and Raju's view that PUDI is 'traditionally' rooted in principles of property law, against a broader Euro-American backdrop of the protection of trade secrets from the nineteenth century onwards: Eric M. Solovy and Deepak Raju, 'Compulsory Licensing of Trade Secrets: Illegality under International and Domestic Laws' (2022) 55:2 *International Lawyer* 221, at 224-225.

[105] Correa (2020) 361.

[106] Ibid 351-353. Carvalho also refers to the right, cryptically, as 'a *sui generis* quasi-proprietary mechanism': Carvalho (2018) 546. PUDI, in the context of the TRIPS waiver's introduction to the TRIPS Council was also conflated with 'trade secrets' by some delegations which used the term instead of 'PUDI' in their contributions, or was characterised as *encompassing* trade secrets by others, e.g., by the USA: 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020', paras 871 (India), 878 (Kenya), 881 (Nigeria), 895 (Sri Lanka), 1138 (WHO) and 1331 (USA).

[107] Correa (2020) 360.The Third World's opposition to PUDI's inclusion resulted in Art. 39 being 'essentially formulated' by the US, EC, and Switzerland: Carvalho (2018) 491-492, 537, cf. the dissenting voice of Mexico at 494.

[108] Carvalho (2018) 538. See also Correa (2020) 360.

[109] Carvalho (2018) 538.

process.[110] This is especially so in the context of vaccine production in which data protected by PUDI, such as the efficacy of different vaccine formulations, has been simultaneously recognised as critical to the manufacturing process such that CLs are rendered useless without it,[111] and fiendishly difficult to identify through reverse engineering.[112] By contrast, allowing reliance on existing test data benefits economic efficiency by reducing resource waste (as otherwise generic competitors would have to produce their own test data which would be substantially the same as the patented product's) and prevents unnecessary human and animal suffering which could result from repeated tests.[113] This is alongside the broader social benefit conferred by reducing the delay between the creation of cheaper, more accessible generic products and their availability on the national and international market. Moreover, PUDI's subject-matter scope may also expand the anti-commons by acting as a surrogate for patent protection in Third World states that hitherto have not accepted the patentability of pharmaceutical products.[114] Such concerns subsist alongside more basic difficulties surrounding the definition of Article 39.3's terms, such as the scope of 'pharmaceutical' and 'new',[115] whose broad interpretation may further stretch the anti-commons' borders.

The obstacles caused by Article 39.3 should not be overstated; proponents of the provision could point to several facts which indicate that the protection required by TRIPS is flexible enough to be inoffensive to the Third World. For example, Article 39.3 protection is contingent on certain facts, such as the national health regulator *requiring* that test or other data be submitted as a condition of approval,[116] and in any case evaporates if or when the company releases the information into the public domain.[117] Furthermore, the state is able to utilise the exception baked into Article 39.3 by disclosing information where necessary to protect the public interest. Commentators have noted the need to interpret the provision broadly in favour of protecting the 'public interest'.[118] However, it would also be wrong to overlook

[110] An approach allowed by 'most countries' according to Correa, with some (such as Argentina, Taiwan, and Singapore) even allowing the approval of a patent product by a *foreign* regulator to suffice: Correa (2020) 361.

[111] Garrison (2004) 26.

[112] Durrell (2016) 801-802.

[113] Carvalho (2018) 539-540.

[114] Correa (2020) 361.

[115] Justin Malbon, Charles Lawson, and Mark Davison, *Commentary on the Provisions of the TRIPS Agreement* (Edward Elgar, 2014) 582-584.

[116] Correa (2020) 361; although it would be surprising for any national health regulator to be uninterested in receiving test data proving that a medication was safe before approving it for public use.

[117] Carvalho (2018) 578; this would be a surprisingly charitable move for a pharmaceutical business to make.

[118] Malbon, Lawson and Davison (2014) 592-593 (also citing the Doha Declaration); Carvalho (2018) 541.

continued legal and factual causes for concern for the Third World. As a matter of law, notwithstanding the aforementioned institutional burden that inescapably flows from the adoption of novel IP norms, there remains uncertainty regarding the scope of terms which affect the utility of the in-built exception,[119] and conflicting commentary on the possibility that test data can be compulsorily licenced to breach the anti-commons.[120] As a matter of fact, the utility of the Article 39.3 exception is limited for the Third World as it assumes that the state *has* test data which can be shared for the public interest; the concentration of pharmaceutical production in the West places agency to crack open the anti-commons squarely in the hands of the same governments that steadfastly support the logic of IPR protection.[121] Moreover, some Western states wrongly, but persistently, use Article 39.3 to justify keeping test data unavailable to *national regulatory authorities*.[122]

4. TRIPS as a Barrier to Vaccine Access: Copyright

Compared with patents, the relationship between copyright and vaccine accessibility has been relatively unexplored in academic commentary.[123] However, some important observations can still be made about their effect regarding access to the bodies of essential scientific, design and explanatory literature connected with the production of vaccines.[124]

The TRIPS copyright regime incorporates and expands the Berne Convention's copyright norms.[125] These, *inter alia*, require that copyright-holders be

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[119] E.g., the term 'public': Malbon, Lawson and Davison (2014) 592.

[120] See the opposing perspectives of Carvalho (in support of potential CLs, subject to reasonable remuneration), and Solovy and Raju (against CLs): Carvalho (2020) 595 and 600-601; Solovy and Raju (2022) 229-235. That utilising compulsory licensing would be novel (and therefore challenging) in the context of PUDI was noted by South Africa in its introduction of the waiver proposal: 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020', para. 1156.

[121] Should the in-built exception not be used, states may only have recourse to the national security exception under Art. 73 TRIPS, cf. the existence of general exceptions under Art. XX GATT: Solovy and Raju (2022) 229.

[122] Carvalho (2018) 542-543.

[123] Even recent academic commentary on the relationship between IPRs and COVID-19 omits or only lightly touches upon copyrights: see, e.g., Olasupo Owoeye, 'Intellectual property and equitable access to COVID-19 vaccines and therapeutics' (2020) 48:9 *European Intellectual Property Law Review* 584; Germán Velásquez, *Vaccines, Medicines and COVID-19: How Can WHO Be Given a Stronger Voice* (Springer Cham, 2022) 73-92; Brigitte Tenni, Hazel V. J. Moir, Belinda Townsend and others, 'What is the impact of intellectual property rules on access to medicines? A systematic review' (2022) 18 *Global Health* 40; Siva Thambisetty, Aisling McMahon, Luke McDonagh and others, 'Addressing Vaccine Inequality During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond' (2022) 81:2 *The Cambridge Law Journal* 384; Ton Zuijdwijk, 'TRIPS and COVID-19 Vaccines: The New WTO TRIPS COVID-19 Waiver' (2022) 17:11-12 *Global Trade and Customs Journal* 452.

[124] Hilde Stevens, Koenraad Debackere, Michel Goldman and others, 'Vaccines: Accelerating Innovation and Access. Global Challenges Report' (2017) www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_16.pdf (accessed 27 September 2022) 19.

[125] Art. 9.1 TRIPS.

accorded exclusive rights of reproduction,[126] that a copyright-holder can bring infringement proceedings,[127] and that copyright-infringing material can be subject to seizure.[128] Under Article 2(1) of the Berne Convention, scientific publications must be copyrightable. Where the publication has been produced by a natural person, the minimum required copyright duration is the length of the life of the author plus fifty years.[129] Where the duration of the copyright cannot be calculated with reference to the lifespan of a natural person, the minimum duration of protection is fifty years from authorised publication, or production.[130]

The difficulties raised by copyright norms are less obvious and more limited than its patent and PUDI counterparts,[131] but this is not to say that they are imaginary. As regards information traditionally protected under copyright, TRIPS copyright protections cultivate the anti-commons by artificially keeping critical information related to vaccine development and production out of the public domain. Such information typically includes details of the efficacy or safety of a particular vaccine formulation, or industrial information regarding a vaccine's component materials.[132] A newer question, which looms large for the future, concerns the extent to which TRIPS Article 10, which extends the Berne Convention's copyright protections to computer programmes[133] and compilations of data,[134] will be used to keep machine learning tools and their datasets out of the public domain.[135] Machine learning systems have already been utilised in COVID-19 vaccine production, with positive results seen regarding

126 Art. 9(1) Berne Convention.

127 Art. 15(1) Berne Convention.

128 Art. 16 Berne Convention.

129 Art. 7(1) Berne Convention.

130 Art. 12 TRIPS.

131 As much is clear from the contributions of states during the introduction of the waiver proposal in which references to the substantive barriers raised by copyright were fleeting: see 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020', paras 895 (broad point made by Sri Lanka), 1068 (recognition by Japan that copyrighted works are useful to share for the combatting of COVID-19), and 1138 (WHO notes that copyrighted works are being shared via the WHO COVID-19 Technology Access Pool to expand the development and production of existing and new technologies to fight the pandemic).

132 Karen Durrell, 'Vaccines and IP Rights: A Multifaceted Relationship' in Sunil Thomas (ed.), *Vaccine Design* (Humana, 2016) 791, at 800.

133 Art. 10.1 TRIPS.

134 Art. 10.2 TRIPS.

135 See Doris Estelle Long, 'The Overlooked Role of Copyright in Securing Vaccine Distribution Equity' (6 September 2021) *TradeRX Report* https://traderxreport.com/covid-19/the-overlooked-role-of-copyright-in-securing-vaccine-distribution-equity/ (accessed 21 September 2023). See also views regarding the copyrightability of data mined databases, and algorithms in Daniel J. Gervais, 'TRIPS Meets Big Data' in Mira Buri (ed.), *Big Data and Global Trade Law* (2021, CUP) 170, and Katarina Foss-Solbrekk, 'Three routes to protecting AI systems and their algorithms under IP law: The good, the bad and the ugly' (2021) 16:3 *Journal of Intellectual Property Law & Practice* 247, at 249-250.

their ability to filter information.[136] Indeed, the copyrightability of machine learning systems may soon impact *patenting* practices, as the first cases come before municipal courts seeking the recognition of 'AI' inventors on patent applications, for example in the multi-jurisdictional *Thaler* litigation.[137] Furthermore, it is already recognised by commentators that the datasets produced out of machine learning and algorithms are subject to TRIPS Article 39.3 protection,[138] engaging the cavalcade of PUDI anti-commons problems irrespective of how they may be overcome with reference to copyright-oriented flexibilities.

As with its patent and PUDI regimes, TRIPS copyright standards are subject to an exception in the form of Article 13, which allows for exemptions or limitations from copyright in 'certain special cases' if there is no conflict with the normal exploitation of the copyright, nor unreasonable prejudice caused to the legitimate interests of the copyright-holder. It is imaginable that the provision could be used to require the publication of scientific works related to vaccine production, formulations, efficacy, and so on for the benefit of generic competitors – a kind of compulsory licence for research. However, as with the other exceptions discussed, there are reasons to doubt the utility of Article 13 for ensuring access to copyrighted works for the Third World. The current authoritative interpretation of Article 13 was made by the Panel in *US – Section 110(5) of the US Copyright Act*.[139] The tenor of the Panel's interpretation was that Article 13 should be interpreted strictly due to its exceptional nature.[140] The Panel specifically determined that a limitation or exception under the provision must meet three cumulative conditions: (i) confinement to certain special cases, (ii) no conflict with the normal exploitation of the work, and (iii) the legitimate interests of the right-holder are not unreasonably prejudiced.[141] Although a global

[136] See Ashwani Sharma, Tarun Virmani, Vipluv Pathak and others, 'Artificial Intelligence-Based Data-Driven Strategy to Accelerate Research, Development, and Clinical Trials of COVID Vaccine' (2022) *Biomedical Research International* www.ncbi.nlm.nih.gov/pmc/articles/PMC9279074/ (accessed 21 September 2023).

[137] See, for an overview of this litigation: Alex Dunlop, Grant Fisher, David Fixler and others, 'High Court denies special leave in AI inventorship case' (17 November 2022) *Corrs Chambers Westgarth* www.corrs.com.au/insights/high-court-denies-special-leave-in-ai-inventorship-case (accessed 21 September 2023). Dr Thaler's case is under deliberation at the UK Supreme Court as of September 2023. Note that in South Africa, however, DABUS, the machine learning system created by Dr Thaler, was successfully registered as the inventor of a food container: Long (2021).

[138] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights (2nd Edition): A Commentary on the TRIPS Agreement* (OUP, 2020) 125 (in the form of a computer programme); Foss-Solbrekk (2021) 257.

[139] S. 110(5) US Copyright Act, 15 June 2000, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/160R-00.pdf&Open=True (accessed 27 September 2022).

[140] Ibid, para. 6.97. See also Correa (2020) 155.

[141] S. 110(5) of the US Copyright Act, para. 6.97.

pandemic would likely fall under (i),[142] problems may be caused by (ii), which cannot be satisfied where uses of the right which are subject to the exception or limitation enter into economic competition with the ways that right-holders would normally extract economic value from the right, thereby depriving them of significant or tangible economic gains.[143] Additionally, (iii), despite the apparent acceptance of the Panel that exceptions implemented via a CL system could be conferred,[144] is especially broad in its personal and material scope, covering the interests of rights-holders *outside* of the Complainant Member.[145] Furthermore, the Panel interpreted 'interests' as encompassing 'concern about a potential detriment or advantage' and 'something that is of some importance to a natural or legal person' beyond mere economic considerations,[146] and determined that 'prejudice' is unreasonable where it has or has the potential to cause an unreasonable loss of income to the copyright owner.[147] In light of this restrictive jurisprudence, which has been characterised as 'disregarding' the TRIPS Article 7 promise,[148] and the overall uncertainty regarding its exact scope,[149] Article 13 does not offer a good foundation for states wishing to take sure-footed steps to release scientific knowledge from the anti-commons.

5. Circumventing TRIPS

At this juncture, it is necessary to ask how the Third World could circumvent its norms and afford itself essential room for policymaking. Two options were available: the national security exception in TRIPS Article 73 and the Marrakesh Agreement's waiver mechanism.

5.1. TRIPS Article 73 and the Dispute Settlement Mechanism

Under Article 73, a state is not prevented from taking action 'which it considers necessary for the protection of its essential security interests' where those measures are taken in specific circumstances. Relevant is Article 73(b)(iii), which allows such

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[142] Insofar as the exemptions or limitations of copyright in a pandemic could be certainly defined in national legislation, relates to something a specific and exceptional, and relates to an event: ibid, paras 6.108-110.

[143] Ibid, para. 6.183.

[144] Correa (2020) 155.

[145] S. 110(5) of the US Copyright Act, para. 6.231.

[146] Ibid, para. 6.223. See also the determination that 'legitimacy' has connotations of normative legitimacy, i.e., whether the exception or limitation is justifiable in light of the objectives which underlie the protection of intellectual property: ibid, para. 6.224.

[147] Ibid, para. 6.229.

[148] Correa (2005) 442.

[149] Correa (2020) 135.

action to be taken 'in time of war or international emergency'. Academic commentary is split as to whether the exception is available in the COVID-19 context. Ruse-Khan suggests that the Doha Declaration's determination that epidemics are national emergencies means a WHO-declared pandemic satisfies Article 73(b)(iii) *ipso facto*.[150] Regardless, Oke questions the extent to which a reduction in patent protection in State A for the purpose of enabling vaccine production for the benefit of State B evidences a sufficient connection with the protection of State A's essential security interests.[151] Ultimately, however, this discussion may be moot considering that the exception's invocation (or, indeed, the invocation of *any* TRIPS flexibility) opens the door for potential litigation through the WTO's Dispute Settlement Mechanism,[152] a threat which is by no means illusory, as shown by the US and EU's complaints against India, Pakistan, and Argentina regarding TRIPS's mailbox obligations. In such litigation, the Third World is at a clear structural disadvantage compared with the West.

The clearest disadvantage the Third World faces in the DSM is a relative lack of resources, which reduces its ability to effectively participate in litigation. The DSM's legalised approach to dispute settlement requires states to navigate various procedures and complex substantive principles. Western states have access to in-house legal teams and well-trained private legal sectors to assist them. The Third World generally cannot rely on such resources,[153] but must instead utilise *ad hoc* legal services or invest heavily in building legal capacity. Accordingly, the Third World's DSM litigation costs tend to be greater than the West's in absolute terms.[154] This imbalance of resources has been recently exacerbated by the DSM's remote meetings during the pandemic: technological problems such as poor internet connections have effectively excluded some states from DSM participation altogether.[155] The Third World's participatory

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[150] Henning Grosse Ruse-Khan, 'Access to Covid-19 Treatment and International Intellectual Property Protection – Part II: National security exceptions and test data protection' (April 2021) https://www.ejiltalk.org/access-to-covid19-treatment-and-international-intellectual-property-protection-part-i-patent-protection-voluntary-access-and-compulsory-licensing/ (accessed 27 September 2022).

[151] Emmanuel Kolawole Oke, 'Is the National Security Exception in the TRIPS Agreement a Realistic Option in Confronting COVID-19?' (August 2020) www.ejiltalk.org/is-the-national-security-exception-in-the-trips-agreement-a-realistic-option-in-confronting-covid-19/ (accessed 27 September 2022). For the 'sufficient connection' requirement, see 'Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights' (16 June 2020) www.wto.org/english/tratop_e/dispu_e/567r_e.pdf (accessed 27 September 2022) paras 7.241-242.

[152] This is, of course, additional to the domestic legal challenges which can beset the attempted use of flexibilities, such as the aforementioned *Novartis* litigation.

[153] Amrita Bahri, *Public Private Partnership for WTO Dispute Settlement* (Edward Elgar, 2018), 19-20 and 24.

[154] Niall Meagher, 'Representing Developing Countries in WTO Dispute Settlement Proceedings' in George A. Bermann and Petros C. Mavroidis (eds.), *WTO Law and Developing Countries* (CUP, 2011) 213, at 218-219.

[155] Dispute Settlement Body, 'Minutes of Meeting Held in the Centre William Rappard on 18 December 2020' (February 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/DSB/M447.pdf&Open='True (accessed 29 September 2022) paras 6.5 and 6.11.

disadvantage is intensified by the fact that the WTO's dispute resolution model has been moulded by Anglo-American common law, rendering its processes relatively inaccessible to lawyers from non-common law traditions.[156] Whilst the Third World has access to flexibilities intended to assist its participation,[157] these are rarely invoked out of concern their usage may undermine the legitimacy of any Third World victories.[158]

If, against this unbalanced institutional backdrop, the DSB determines that a state has violated a WTO Agreement, that state may be subject to retaliatory measures as a 'last resort' to ensure compliance with the DSB's conclusions.[159] Such measures must first be implemented in the same area as the obligation violated,[160] but they may be extended to other WTO Agreements if required to make the retaliation practicable and effective.[161] Self-evidently, such retaliatory measures have a disproportionate effect on relatively undiversified Third World economies compared with their Western counterparts. Such is the imbalance that Third World states have deliberately refrained from using retaliatory measures when they are seeking to *enforce* DSB reports against the West due to the disproportionate harm that would be caused to their own economies.[162]

It is, of course, true to say that the usage of TRIPS flexibilities in the context of the pandemic has not given rise to litigation before the DSM – although this is unsurprising considering the Appellate Body's current abeyance.[163] However, it would be remiss to overlook the dispute settlement barrier which is baked into TRIPS, especially because the DSM cannot be evaded: the DSB's jurisdiction is compulsory[164] and exclusionary.[165] Even if the chilling effect is only theoretical,[166] the risk of litigation

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156 Joost Pauwelyn, 'The Limits of Litigation: "Americanization" and Negotiation in the Settlement of WTO Disputes' (2003) 19:1 *Ohio State Journal on Dispute Resolution* 121, at 121, 126 and 130.

157 For example, the possibility of extending the consultation period prior to the request for a panel report: Art. 12.10 Annex 2 Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement (hereafter 'DSU').

158 Meagher (2011) 224-225.

159 Art. 3.7 DSU.

160 Art. 22.3(a) DSU.

161 Arts 22.3(b) and 22.3(c) DSU.

162 Van den Bossche and Zdouc (2019) 206-207.

163 See generally Henry Gao, 'Finding a Rule-Based Solution to the Appellate Body Crisis: Looking Beyond the Multiparty Interim Appeal Arbitration Arrangement' (2021) 24:3 *Journal of International Economic Law* 354.

164 Art. 6.1 DSU.

165 Art. 23.1 DSU.

166 A position which could be doubted in the specific context of pharmaceutical patenting, considering the apparent strength of Western feeling regarding the veracity of its pro-patent mantra and the diplomatic and economic action taken, especially by the US, on a bilateral basis to challenge the usages of TRIPS flexibilities.

under the DSM in which the Third World cannot participate as effectively as the West, which, if lost, may result in trade-destructive retaliatory measures being deployed unless the state returns to TRIPS compliance, further illustrates how the cards are stacked against the Third World when it comes to utilising TRIPS flexibilities.

5.2. The TRIPS Waiver

Without a secure pre-existing legal mechanism through which TRIPS could be circumvented, the Third World was left with only one course of action: seeking a waiver from its obligations. Article XI:3 of the Marrakesh Agreement provides that the WTO's biannual Ministerial Conference can waive obligations of WTO Agreements by a three-quarters majority. In practice, it is the WTO's plenary body, the General Council, which approves waiver proposals by consensus.[167]

From October 2020 onward, the Third World pressed for the waiver of a swathe of TRIPS obligations. The campaign can be seen as the continuation of other occasions during which the Third World has successfully lobbied to alter TRIPS for the benefit of its collective interests, with both Article 66.1 and the SCLS being examples of previous waiver-based alterations to TRIPS.[168] Moreover, the normative undercurrent of those waivers, identified by Feichtner as the protection of the WTO from allegations of illegitimacy caused by the untampered application of its obligations,[169] was clearly applicable to the COVID-19 waiver discussion.

Belatedly, the Ministerial Conference agreed to a five-year long[170] TRIPS waiver in June 2022. This outcome followed a bitter and protracted countercampaign of prevarication and obstruction by the West. According to South Africa, progress at the TRIPS Council was repeatedly stalled by ideological debates surrounding the general value of IPR protection raised by Western representatives, and by the bad faith decisions of some states to renege on their agreement to enter written negotiations.[171] Whilst the latter accusation is tricky to verify, there is ample evidence of the persistent deployment of an ideological refrain by the West to oppose the waiver by claiming, *inter alia*, that IPRs support innovation, and that TRIPS, thanks to its flexibilities, causes no systemic problems for vaccine accessibility.[172] In response, the Third World

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167 Isabel Feichtner, *The Law and Politics of WTO Waivers* (CUP, 2011) 61.

168 Ibid, 124-132 and 139-143.

169 Ibid, 276-277.

170 Para. 6, TRIPS Waiver.

171 WTO General Council, 'Minutes of Meeting Held in Virtual Format on 7-8 October 2021' (22 November 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/M193.pdf&Open=True (accessed 19 November 2023) para. 4.18.

172 See the statements of the EU and Switzerland at TRIPS Council in July 2020, 'Minutes of Meeting on 30 July 2020', paras 530 and 558-560; and the EU, US, Switzerland, the UK and Canada in October 2020, 'Minutes of

directly confronted the questions posed by the West as to the value of a waiver,[173] revising the waiver proposal to encourage further substantial discussion.[174] Even after some Western states, including the US, came around to supporting a TRIPS waiver in principle,[175] other Western states maintained trenchant opposition. Due to WTO practice requiring consensus before a waiver is adopted, this was enough to keep the waiver out of reach. This opposition eventually coalesced around the EU's counterproposal to the waiver: a proposed draft declaration to aid the pro-public health interpretation of Articles 31(b) and 31(h) and streamline an exporting state's notification requirements under the SCLS[176] – a plaster offered by the West when the Third World was seeking an amputation.

That months of opposition were eventually overcome and a TRIPS waiver adopted appears to be a victory for the Third World in a regime otherwise imbalanced against its interests. Unfortunately, the TRIPS waiver failed to live up to the demands made in 2020. First, whereas the Third World sought a broad waiver of specific sections of TRIPS in relation to the production of multiple health products and technologies,[177] the adopted waiver is significantly narrower: its subject-matter is limited to patents and PUDI, while its provisions may only be invoked in the context of vaccine production.[178]

Second, in substance, the waiver appears only to waive *one* TRIPS provision, that being Article 31(f), by allowing COVID-19 vaccines to be compulsorily licenced for export without limitation.[179] Otherwise, the TRIPS 'waiver' appears to act more like the EU's proposed declaration by offering broadly generous interpretations of select TRIPS provisions. Thus, as regards TRIPS's patent rules, the 'waiver' clarifies

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Meeting on 15-16 October 2020 and 10 December 2020', paras 1027-1029, 1044-1048, 1053-1055, 1081-1084 and 1186.

173 TRIPS Council, 'Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document IP/C/W/671' (January 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W673.pdf&Open=True (accessed 29 September 2022).

174 TRIPS Council, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19' (May 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True (accessed 29 September 2022).

175 Office of the United States Trade Representative, 'Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver' (May 2021) https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver (accessed 27 September 2022).

176 TRIPS Council, 'Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic' (June 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W681.pdf&Open=True (accessed 29 September 2022).

177 Para. 1, TRIPS Waiver.

178 Para. 8 of the revised Waiver clarifies that the matter of extending the provisions to COVID-19-related therapeutics and diagnostics will be discussed no later than six months after the waiver's adoption.

179 Ibid, para. 3(b). This is confirmed in para. 9, which states that the waiver is without prejudice to the rights and obligations of TRIPS, subject to para. 3(b).

that Article 31 allows CLs to be authorised by non-legislative instruments;[180] Article 31(b) does not require the proposed user of a CL to negotiate for a voluntary licence with the patent-holder;[181] and that Article 31(h)'s requirement that 'adequate remuneration' be provided for the patent-holder takes into account the CL's humanitarian and non-profit purpose.[182] The waiver's impact on TRIPS PUDI regime is even more slight: the waiver recognises that, 'Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision.'[183]

The TRIPS waiver only masquerades as such; rather than freeing the Third World from the rigours of TRIPS, the waiver merely reconfigures its requirements. At face value, the Article 31(f) reform is not insubstantial, insofar as it slices away the need to use the obstructive SCLS. Unfortunately, the waiver *itself* creates new obligations for states making use of its provisions comparable to Article 31*bis*. States issuing a CL under the terms of the waiver must provide the TRIPS Council with the name and address of the CL user, the products authorised for licence, the duration of the licence, the quantity of vaccines authorised, and the country of supply.[184] These notification obligations exist alongside additional new institution-burdening obligations for states to take 'all reasonable efforts' to prevent the re-exportation of vaccines imported under the waiver.

Third, the waiver restricts access to its provisions to DCMs only.[185] Hence, the West cannot have recourse to the waiver, protecting their well-developed pharmaceutical sectors from being deployed at the state's behest to manufacture and export COVID-19 vaccines to the Third World without recourse to the SCLS. Furthermore, the waiver appears reticent for even the eligible DCMs to make use of its provisions at all; the waiver 'encourages' DCMs with sufficient capacity to manufacture COVID-19 vaccines to make binding declarations that they will not avail themselves of its provisions. Ultimately, it is difficult not to view the waiver as an insult to the Third World: a declaration of little substance, covering a narrow field, accessible only to a few.

Even more concerning than the ineffective waiver is the domination of the West over the Third World symbolised by the negotiation at the TRIPS Council, a

[180] Ibid, para. 2.

[181] Ibid, para. 3(a).

[182] Ibid, para. 3(d).

[183] Ibid, para. 4.

[184] Ibid, para. 5.

[185] Ibid, para. 1.

domination that stretches far beyond the immediate context of COVID-19. As Pahuja describes, a key means of suppressing the Third World's perception of international law's radical potential is the capture and translation of the Third World's transformative proposals into systems that benefit a global order weighed in favour of the West.[186] In the context of vaccine access, such a capture is apparent. Rather than arguing for radical, transformative changes to a systemically disadvantageous system, the Third World's efforts were channelled into advocacy in favour of temporary waiver justified by references to the 'extraordinary' nature of the pandemic, and a self-declared intention not to generally undermine the TRIPS framework.[187] Ironically, in their most significant challenge to TRIPS since the Uruguay Round, the Third World has only cemented the triumph of the West's fundamental (and flawed) IPR logic.

6. Conclusion

As the delegation from Mozambique reminded the TRIPS Council in February 2021, 'behind the figure of 2.4 million deceased, there are health workers, care givers, teachers, fathers and mothers, a long list of professionals who left an empty hole in their communities'.[188] Despite this poignant warning, at time of writing, the WHO has recorded approximately 6.5 million deaths from COVID-19.[189] To protect against the growth of this catastrophic toll, the world now has effective and safe vaccines at its disposal, but only for some. Whilst countries such as Australia and Canada have fully vaccinated more than 80 percent of their populations, less than 5 percent of the citizens of the Democratic Republic of the Congo, Haiti and Papua New Guinea have the same protection.[190] The inequity in the distribution of the COVID-19 vaccine has not been an unfortunate accident. TRIPS and the WTO have caused a cascade of disadvantages that have precluded the Third World from making its own vaccines, buying vaccines cheaply on the global market, and circumventing the very framework that has given rise to those disadvantages. Chimni reminds us that critique without

[186] Pahuja (2011) 95-96.

[187] See South Africa and India's various statements at TRIPS Council, 'Minutes of Meeting on 15-16 October 2020 and 10 December 2020', para. 1151; and TRIPS Council, 'Minutes of Meeting Held in the Centre William Rappard on 30 April 2021' (July 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M99A1.pdf&Open=True (accessed 29 September 2022) paras 12, 15, and 35. See also South Africa at the WTO General Council, 'Minutes of Meeting on 7-8 October 2021', para. 4.12.

[188] TRIPS Council, 'Minutes Held in the Centre William Rappard on 30 August 2021' (7 April 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M97A1.pdf&Open=True (accessed 29 September 2022) para. 61.

[189] WHO, 'WHO Coronavirus (COVID-19 Dashboard)' https://covid19.who.int (accessed 27 September 2022).

[190] Ibid.

construction is an empty gesture.[191] Although a detailed proposal for reform is outside the practical scope of this study, one thing is clear: only structural, regime-level change can overcome the obstacles baked into the TRIPS and WTO, which have prevented the Third World's access to the COVID-19 vaccine. Anything less will only ensure that more empty holes are left across the world's communities come future pandemics.

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[191] Chimni (2006) 26.

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