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Historic Tensions Involving International Intellectual Property Protection of Medical Technology with Disastrous Public Health Consequences

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Historical tensions have pervaded the alliance of the ill-fated accord between intellectual property (IP) and trade. The intersections of the alliance have impacted access to medical technologies resulting in plaguing public health with disastrous consequences in select parts of the globe, the first of which was perhaps most notably seen during the HIV/AIDS crisis at the turn of the century. At this time, the sacrosanct norms of the World Trade Organization (WTO) from the accord between trade and IP rights essentially forced African countries to choose between international trade sanctions and saving thousands of lives by allowing exceptions to patent rights. While much has been written about global public health, especially post-COVID, not enough has been said about the consequences arising from the ill-fitting accommodation of IP rights into the trade regime and its impact on medical technology. Even less has been written about the history of the alliance and how it was fated to affect global public health right from conception, leading to a loss of access to medical innovations globally.

This Article's focus examines the historic accord to learn lessons from the past. The research is distinctive in that two authors from different corners of the globe examine the historic alliance between IP and trade and make the case to reinforce the need for appropriate protection regimes to foster innovation but not compromise public health. This Article starts with the rationales generally offered for the initial shift from viewing IP as a matter of domestic sovereignty to its inclusion as a cornerstone within the larger international trade regime. It then delves into an examination of how it resulted in reframing global norms,

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which in turn contributed towards a top-down assertion of increasingly expansive IP norms in the name of global harmonization leading to more patents and less innovation impacting global public health. Such a reframing, this Article asserts, has resulted in two distinct consequences. The first is an outsourcing of policy positions with scant regard to the ability of local realities to accommodate the outsourced position; the second is the limiting of IP norm discourses to the boundaries imposed by the trade lens. In both instances, this Article argues, true innovation that can positively affect public health is a significant casualty by virtue of the simultaneous perception of health care by international trade norms both as an "exception" as well as a "priority" dictated by the power dynamics that drive international trade. In other words, although public health is impacted by IP norms, the reframing through a trade lens by and large sidelines the issues leaving them underappreciated in the limited contexts when it does arise. The ultimate result are IP policies completely divorced from the local realities of member states. The Inflation Reduction Act of the United States, the Article asserts, is a great example of why we need a reframing of IP issues to better fit the needs of public health. An examination of the genesis of the historical alliance, the Article asserts, does not support the needs of public health especially in the context of being governed by the trade and IP accord of the WTO.

This Article concludes by outlining the need for an alternative framework that posits public health in the front and center with a view to create a workable mechanism to result in global health care equity.

INTRODUCTION

History has but one constant, and that is change.[1] The descent of the year 2020 brought several changes, some predictable, such as climate studies and race relations.[2] But one of the most unpredicted and yet impactful changes would unleash a level of global destruction that remains alien to the modern world. By March 2020, it was clear that the globe was being powered by a historical, albeit dark, phenomenon.[3] Much like how the dementors circled Hogwarts in *Harry Potter*, the onset of 2020 felt as if the Voldemort of viruses was circling the globe.[4] It felt like the Dark Lord, who perhaps disappeared after the Spanish flu and influenza pandemics, had reappeared after years of hibernation, only more potent and powerful in the form of another virus.[5]

History is also characterized by another feature, accords. As the real impact of a pandemic wrecked global supply chains emerged, it begged the question of whether the global public health disaster was history's condemnation of a tense and uncomfortable alliance between trade and intellectual property (IP) rights. In gist, public health was and remains a significant casualty of the alliance of trade with IP rights. As this Article will further showcase, this alliance and its resulting tensions can be traced to the creation of the World Trade Organization (WTO) and its trade-related IP accord in the form of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which for the first time fused together trade with IP.[6]

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[1] SRIVIDHYA RAGAVAN, PATENT AND TRADE DISPARITIES IN DEVELOPING COUNTRIES 1 (2012) [hereinafter RAGAVAN, PATENT AND TRADE DISPARITIES], https://doi.org/10.1093/acprof:oso/9780199840670.003.0001.

[2] *See, e.g.*, WORLD METEOROLOGICAL ORG., STATE OF THE GLOBAL CLIMATE 2020, at 3 (2021), https://library.wmo.int/doc_num.php?explnum_id=10618; BLACK LIVES MATTER, BLACK LIVES MATTER: 2020 IMPACT REPORT 4–5 (2020), https://blacklivesmatter.com/wp-content/uploads/2021/02/blm-2020-impact-report.pdf.

[3] Ivan Pereira & Arielle Mitropoulos, *A Year of COVID-19: What Was Going on in the US in March 2020*, ABC NEWS (Mar. 6, 2021, 10:06 AM), https://abcnews.go.com/Health/year-covid-19-us-march-2020/story?id=76204691.

[4] J.K. ROWLING, HARRY POTTER AND THE PRISONER OF AZKABAN 74–75 (1999).

[5] *See* J.K. ROWLING, HARRY POTTER AND THE DEATHLY HALLOWS 9 (2007).

[6] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter WTO Agreement]; *see also* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

WTO had a significant flaw. That is, it was based on a per se theory of juridical equality and equal bargaining powers among the signatory nations. In reality, however, the juridical equality was indifferent to the presence of highly unequally posited parties.[7] Academics decried the (mis)conceptualized juridical equality.[8] Richard Steinberg, for instance, asserted that WTO exacerbated the power disparities between states, often to the detriment of local realities and showcased the dent from reality caused from blind ideological affinity.[9] Others, like Professor Olufunmilayo Arewa, termed the global IP regimes' "top-down approach" as catering to the interests and needs of IP-rich states.[10] Similarly, Professor Jerome Reichman decried the establishment of the WTO system as "efforts to rig a regime for short-term advantages" and predicted how it could "boomerang against those who pressed hardest for its adoption."[11] Yet others, like Margaret Chon, asserted that the approach of WTO failed to generate the full range of policy choices for both developed and developing countries to maximize global social welfare with respect to human development

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[7] Pascal Lamy, *The Place of the WTO and its Law in the International Legal Order*, 17 EUR. J. INT'L. L. 969, 972 (2006), https://doi.org/10.1093/ejil/chl035 ("[T]he WTO legal order respects, inter alia, the sovereign equality of states, good faith, international cooperation, and the obligation to settle disputes peacefully, not to mention the rules of interpretation of conventions which the Appellate Body, for example, applies without hesitation.").

[8] Srividhya Ragavan, *World Trade Organization: A Barrier to Global Public Health?*, *in* INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES: TRIPS AGREEMENT, HEALTH, AND PHARMACEUTICALS 25, 27 (Srividhya Ragavan & Amaka Vanni eds., 2021) [hereinafter Ragavan, *A Barrier to Global Public Health*], https://doi.org/10.4324/9781003176602.

[9] Richard H. Steinberg, *In the Shadow of Law or Power? Consensus-Based Bargaining and Outcomes in the GATT/WTO*, 52 INT'L ORG. 339, 341 (2002), https://doi.org/10.1162/002081802320005504 (asserting that trade rounds have been closed through power-based bargaining and "[have] been dominated by powerful states"); *see also* Chios Carmody, Fairness in WTO Law 11 (Nov. 2013) (unpublished manuscript) (on file with the University of Western Ontario), http://dx.doi.org/10.2139/ssrn.2161623; Adam S. Chilton & Ryan W. Davis, *Equality, Procedural Justice, and the World Trade Organization*, 7 INTERCULTURAL HUM. RTS. L. REV. 277, 280 (2012).

[10] Olufunmilayo B. Arewa, *Piracy, Biopiracy and Borrowing: Culture, Cultural Heritage and the Globalization of Intellectual Property* 79 (Case W. Rsrv. Univ. Sch. of L., Working Paper No. 1114, 2006), https://law.bepress.com/expresso/eps/1114.

[11] Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?*, 46 HOUS. L. REV. 1115, 1119 (2009).

needs such as education.[12] Criticisms notwithstanding, with a singular objective of facilitating global trade by reducing barriers that affect trade, WTO created sovereign international obligations packaged as negotiated agreements.[13] In turn, these agreements generated sovereign commitments covering a wide range of subjects affecting trade.[14] But, the historical tension between trade and IP rights only increased as the scope of all intangible properties—especially patents—expanded, in turn, altering the structure of international trade permanently.

Notably, as part of linking IP with trade in an internationally significant manner, WTO required members to sign the TRIPS Agreement, along with the General Agreement on Trade and Tariffs (GATT)[15] and General Agreement on Trade and Services (GATS)[16] to gain membership.[17] Naturally, the wide membership of WTO caused the TRIPS Agreement to soon become the dominant international framework for IP norms in trade. Thus, the mid-1990s were characterized by countries attempting to ally trade with IP laws causing the latter to be substantively harmonized. In turn, the TRIPS Agreement[18] was embroiled in a controversy owing to tensions caused on account of its inability to balance IP rights in a manner facilitating sovereign members to preserve and protect national public health.[19] In fact, during the pre-COVID-19 (COVID) era, trade dictated public

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[12] Margaret Chon, Intellectual Property "from Below": Copyright and Capability for Education, 40 U.C. DAVIS L. REV. 803, 810–12 (2007).

[13] *See* Chon, *supra* note 12, at 828–829.

[14] WORLD TRADE ORGANIZATION, THE WTO AGREEMENTS: THE MARRAKESH AGREEMENT ESTABLISHING THE WORLD TRADE ORGANIZATION AND ITS ANNEXES, at vii (Cambridge Univ. Press, 2017), https://doi.org/10.1017/9781108529471.

[15] General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187 [hereinafter GATT 1994].

[16] General Agreement on Trade in Services, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B, 1869 U.N.T.S. 183 [hereinafter GATS].

[17] *See* RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 67.

[18] TRIPS Agreement, *supra* note 6.

[19] *Id.* It is one of several agreements established as an annex of the agreement that established WTO. The purpose of TRIPS is to provide effective and adequate protection of IP rights to encourage global competition and reduce barriers to international trade. When WTO was established, the signing of the TRIPS agreement marked a distinguished effort to control worldwide deterrence of IP in international trade. *Id.* art. 1; *see also* RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 63–64.

health such that efforts to protect public health were considered a barrier to trade.[20]

As the tense coexistence of trade with IP rights resulted in an era of indiscriminate expansion of the scope of private property rights,[21] in the realm of health-related innovations, such expansion created public health barriers.[22] Scholars, such as Carlos Correa, asserted that global patent mechanisms, when working alongside trade flexibilities such as the Declaration on TRIPS and Public Health ("Doha Declaration"), failed in creating operationally friendly mechanisms to deal with a public health crisis.[23] Similarly, Brook Baker found it unacceptable that even amidst public health crises, whether global or local, patent ideologues continue to support very limited exceptions to a patent owner's rights, while hesitating to impose mandatory obligations to differentially price or license the patent, voluntarily or compulsorily.[24]

While textbooks define the goal of the patent system as a public benefit, a patent owner's ability to reap profits has been disconnected from the deprivation to life-saving medication that the patent system enables. In fact, abject failings of the trade regime to preserve global public health had long been rationalized based on the utilitarian

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[20] *See generally* Ragavan, *A Barrier to Global Public Health*, *supra* note 8, at 26.

[21] *See, e.g.*, Michael Palmedo & Srividhya Ragavan, *The U.S. Posture on Global Access To Medication & the Case for Change*, 11 INDIAN J. INTELL. PROP. L. 76, 80 (2020), https://doi.org/10.2139/ssrn.3838856.

[22] *See* Ragavan, *A Barrier to Global Public Health*, *supra* note 8, at 26.

[23] *See* Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines*, *in* ROUTLEDGE HANDBOOK ON THE POLITICS OF GLOBAL HEALTH 321, 321 (Richard G. Parker & Jonathan Garcia eds., 2019); World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration], https://doi.org/10.1017/S0020782900012055.

[24] Brook K. Baker, *The Cynical Connectedness of Gilead's Hepatitis C Pricing and Anti-Diversion Policies*, THEBODYPRO (Jan. 16, 2015), https://www.thebodypro.com/article/the-cynical-connectedness-of-gileads-hepatitis-c-p; *see also* BROOK BAKER, UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES, BACKGROUND PAPER: EXISTING AND PRIOR WORK, INITIATIVES AND PROPOSALS TO IMPROVE INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 7 (2016), https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56da11782b8dde9c3d5865b4/1457132156145. Eminent domain has always been an exception to the acquisition of private property, although the extension of the same principles in patent law has been much more controversial. *See generally* U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation.").

theory of "greatest happiness of the greatest number."[25] Often times, it is seen through the lens of "free market," where it is assumed preferences will make themselves heard. Increasingly though, the theory-practice gap has been getting harder to ignore. In the context of public health, the greatest number benefitting from the trade regime is increasingly becoming a smaller number, as more countries and people are steadily excluded because of their inability to afford life-saving medication protected by patents.[26] Over time, it turns out that states and institutions promoting free market policies, rather than being the bearers of preferences of societal needs, have instead worked to *protect the market* against democratic contestations including those relevant to public health.[27]

It is perhaps a good time now to recollect that historically, IP rights have been present in various forms from as early as the 1400s, but the alliance between trade and IP regimes is a recent historical development.[28] England's Statute of Monopolies in 1623 laid the foundation for patent law in the commonwealth region, slowly diffusing to other European countries. Nevertheless, it was only at the time of the Industrial Revolution that it became clear that the increase in international trade and commerce necessitated an international agreement to handle the coordination of IP rights protection across countries.[29] The Paris Convention for the Protection of Industrial Property ("Paris Convention") of 1883 and the Berne Convention for the Protection of Literary and Artistic Works ("Berne Convention") of 1886 were the first international instruments directed toward creating the first semblance of international harmonization by requiring common administrative frameworks and common principles for

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[25] JEREMY BENTHAM, A FRAGMENT ON GOVERNMENT; BEING AN EXAMINATION OF WHAT IS DELIVERED ON THE SUBJECT OF GOVERNMENT IN GENERAL IN THE INTRODUCTION TO SIR WILLIAM BLACKSTONE'S COMMENTARIES, at i (1776) ("[I]t is the greatest happiness of the greatest number that is the measure of right and wrong").

[26] *See* Carlos M. Correa, *TRIPS and Access to Drugs: Toward a Solution for Developing Countries Without Manufacturing Capacity*, 17 EMORY INT'L L. REV. 389, 393 (2003); Carlos M. Correa, *TRIPS Agreement and Access to Drugs in Developing Countries*, 3 SUR INT'L J. ON HUM. RTS. 25, 27–28 (2005).

[27] *See* QUINN SLOBODIAN, GLOBALISTS: THE END OF EMPIRE AND THE BIRTH OF NEOLIBERALISM 2–6 (2018).

[28] *See* Giulio Mandich, *Venetian Patents (1450–1550)*, 30 J. PAT. OFF. SOC'Y 166, 171 (1948).

[29] *See WIPO—A Brief History*, WIPO, https://www.wipo.int/about-wipo/en/history.html (last visited Oct. 5, 2023) ("[F]oreign exhibitors refused to attend the International Exhibition of Inventions in Vienna, Austria in 1873 . . . ."); RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 12.

patents and copyrights.[30] Although there were proposals for more "substantive" harmonization, these did not gain traction at that time due to differences in how IP rights were granted and regulated across different countries.[31]

Historically, the alliance between trade and IP is a contemporary beast. The significance of the onset of COVID represents the convergence of the trade regime's disadvantages with that of the patent regime's failings, begging, nay, forcing us to examine the ill-fated historic and yet contemporary alliance of trade and IP rights. In that, contemporary IP laws are independently embroiled in a struggle to define the limits of the involved exclusivities, especially in the context of addressing the system's ability to deliver its purported objective. [32] More often, the seemingly indiscriminate expansion of private rights has come at the cost of "marginalization of other interests at the heart of the IP system," eventually leaving both the source and the recipient bereft of benefits that the system intended.[33] In this background, the significance of the onset of COVID represents the convergence of trade regime's disadvantages with that of the patent regime's failings, in turn, forcing a re-examination of the ill-fated historic, and yet, contemporary alliance of trade and IP rights.

This Article's goal is to examine the historical tension that has prevailed between IP and trade and its consequences on public health. Importantly, this examination of history is timely and is required to confront the contemporary challenges to global health. This Article is distinguished in examining the nuts and bolts of the alliance between trade and IP rights and how, in turn, it came about to affect public health. This Article, in examining these tensions from the inception of the ill-fated alliance between IP and trade, is unique in making a case to reconsider the place of public health in this alliance.

Thus, Part I outlines the general rationale behind including IP within the larger trade regime. It examines the historical reasons and effects that caused IP issues to become a part of the international trade

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[30] When the World Intellectual Property Office (WIPO) was created in 1967, the administration of these two treaties was transferred to the WIPO. *See* WIPO, *supra* note 29.

[31] FREDERICK M. ABBOTT ET AL., INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY 3 (4th ed. 2019).

[32] *See, e.g.*, Carlos M. Correa, *Interpreting the Flexibilities Under the TRIPS Agreement*, *in* ACCESS TO MEDICINES AND VACCINES: IMPLEMENTING FLEXIBILITIES UNDER INTELLECTUAL PROPERTY LAW 1, 18 (Carlos M. Correa & Reto M. Hilty eds., 2022).

[33] Eva Hillberg, *The Terra Nullius of Intellectual Property*, 36 ETHICS & INT'L AFFS. 125, 128 (2022), https://doi.org/10.1017/S0892679422000144.

framework and explains the impact of the historic arrangement on global public health. Part II discusses how the historic inclusion of IP into the trade regime caused a further expansion of property rights leading to an eventual reframing of IP. The reframing resulted in enunciating a rearrangement of global norm-setting for IP. Part III examines how the power dynamics paradigm has resulted in outsourcing policy positions and limiting discourses on IP norms to the boundaries imposed by a trade lens, thus completely divorcing policies from the local realities of member states. Part IV outlines that the historical narrative does not support IP and health being governed by TRIPS. It asserts that there is a need for an alternative framework that will create a workable mechanism to result in global health care equity. This Article concludes by discussing how the public health black swan events have provided the rare effective counter to an otherwise robust IP-trade linkage.

I. THE RATIONALE BEHIND INCLUDING IP IN WORLD TRADE

This Part outlines the contrasting approaches and positions that "developed" and "developing" countries had towards IP norms prior to and during the negotiations that led to the creation of WTO, where the IP-trade nexus was first solidified in an enforceable manner. In particular, this Part highlights the contrasting positions developed nations took on IP norms when they were still developing their technological capabilities, vis-à-vis the positions they advocated for other countries that are now in those positions, using trade as a vehicle.

After failed attempts at creating an International Trade Organization[34] post-World War II, the legal principles in the provisional General Agreement on Tariffs and Trade (GATT) effectively served as the only multilateral governing instrument for international trade from 1948 to 1995.[35] During this period, historians assert that "a series of multilateral negotiations" ("trade rounds") were convened with a view to improve this system.[36] The eighth trade round, also known as the Uruguay Round, held from 1986 to 1994, created WTO and its constituent agreements, including the TRIPS Agreement.[37] This ill-fated round represents the first significant

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[34] *The GATT Years: From Havana to Marrakesh*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm (last visited Oct. 5, 2023).

[35] *Id.*

[36] *Id.*

[37] *See id.*

substantive harmonization of IP norms internationally, as well as the first time that international trade was linked with the international IP regime.[38] This combination of harmonization of substantive IP norms with trade linkage would mean that the TRIPS Agreement would go much further than the IP-trade linkage of its predecessors, such as the North American Free Trade Agreement (NAFTA),[39] or the "Special 301" process from the US Trade Representative (USTR), in its ability to affect IP norms.[40]

Prior to TRIPS, IP norms varied greatly between countries, usually based on the prevailing state of technological development they were in. Indeed, developing countries generally preferred flexible IP regimes calibrated to account for their development needs, including balancing trade with welfare such as by ensuring that any economic development is commensurate with social development and poverty alleviation.[41] In the century prior to this, countries like the United States, Switzerland, Germany, and Japan, which were in their own developing phases, embraced very flexible patent regimes based on industry developments taking place at the time.[42]

For instance, the period from 1400 to 1550 represents the peak of Venetian economic prosperity.[43] The fall of Constantinople to the Turks in 1453 resulted in artisans moving to the Roman Empire.[44] Hence, Venice adopted several measures to establish and maintain

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[38] *See id.*

[39] North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 289; *see also* U.S. CUSTOMS & BORDER PROT., NAFTA: A GUIDE TO CUSTOMS PROCEDURES (1998), https://www.cbp.gov/trade/nafta/a-guide-to-customs-procedures (providing a guide to NAFTA); 48 C.F.R. § 25.405 (2022).

[40] Section 182 of the Omnibus Trade Act of 1974 is commonly referred to as "Special 301" for the enforcement of IP rights. Trade Act of 1974, Pub. L. No. 93-618, § 182, 88 Stat. 1978, 2041 (codified as amended at 19 U.S.C. § 2242).

[41] Graham Dutfield, *TRIPS and Its Impact on Developing Countries*, SCIDEVNET (Jan. 10, 2001), https://web.archive.org/web/20201019224909/https://www.scidev.net/global/policy-brief/trips-and-its-impact-on-developing-countries.html.

[42] *See id.*; GRAHAM DUTFIELD & UMA SUTHERSANEN, HARMONIZATION OR DIFFERENTIATION IN INTELLECTUAL PROPERTY PROTECTION? THE LESSONS OF HISTORY 7–14 (2004), https://quno.org/sites/default/files/resources/Harmonisation-or-Differentiation.pdf.

[43] Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 1)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 697, 710 (1994) [hereinafter Walterscheid (Part 1)].

[44] *Id.* at 703, 710.

preeminence in manufacturing.[45] These measures included enacting laws prohibiting the emigration of skilled artisans and the export of certain materials, encouraging the immigration of skilled workers from other countries by providing a tax holiday for two years after their arrival in Venice, and preserving manufacturing preeminence through similar measures.[46] Providing monopoly rights to foreign artisans to attract immigrants to encourage local industrialization was one such measure.[47]

In England, Queen Elizabeth's original efforts to grant patents were meant "to stimulate domestic production of both raw materials and a wide variety of manufactured goods previously imported from abroad."[48] England focused on acquiring superior technology to reduce imports.[49] The Crown, Sir Walterscheid wrote, wanted to "attain economic self-sufficiency, thereby gaining in power and strength not only within its own borders, but also relative to other states."[50] Patents are acknowledged as enabling Britain to achieve a level of self-sufficiency.[51] Thus, like Venice, England did not use its patent laws as a mechanism to increase trade but instead as a tool to improve local industrialization.[52] Later, "when the British wanted to compete with the United States and Germany in large-scale industrial production, the Sir Edward Fry Commission of 1901 recommended the local working requirement to industrialize Britain."[53]

Other parts of Europe were no exception. "A rule prohibiting product patents for chemicals was first introduced in the German Patent Law of 1877 to stimulate research in alternative methods of

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[45] *Id.* at 708–09; *see also A Brief History of the Patent Law of the United States*, LADAS & PERRY LLP (May 07, 2014), https://ladas.com/education-center/a-brief-history-of-the-patent-law-of-the-united-states-2; ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 12 (5th ed. 2019).

[46] *See* Walterscheid (Part 1), *supra* note 43, at 710.

[47] *See id.*

[48] *See generally* Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 2)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 849, 855 (1994) [hereinafter Walterscheid (Part 2)]; CHRISTINE MACLEOD, INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM 1660–1800 (1988); s*ee also* Walterscheid (Part 1), *supra* note 43, at 700–01.

[49] Walterscheid (Part 2), *supra* note 48, at 856.

[50] *Id.* at 855

[51] Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 278–79 (2006) [hereinafter Ragavan, *Inequals of the Uruguay Round*].

[52] RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 4.

[53] *Id.* at 39.

producing a product."[54] Within the next thirty years, Germany's process patent regime enabled the growth of the chemical industry.[55] Indeed, at the end of World War I, "a British Law Amendment Committee chaired by Lord Parker" pointed to the German patent system and favored process protection for chemicals, food, and medicine.[56] Consequently, "the UK Patent Amendment Act of 1919 passed with the amendments recommended by Lord Parker" with a view to ensure that England's policies were comparable with and along the lines in Germany.[57]

Similarly, "Sweden, Spain, and Japan did not allow product claims for articles of food or medicine, and Demark did not allow any patents on food."[58] Further, the 1957 Italian law prohibited patenting medicinal products.[59] The United Kingdom's Sargant Committee made the following recommendation to make food affordable in England:

> During the [w]ar it became apparent that Great Britain was suffering from a lack of medicine and drugs, many of which were the subject of patent rights in this country. On the other hand, it was found that in many European countries (e.g., France, Germany, Switzerland) such substances were not capable of protection under the patent laws of those countries. In this state of things it was considered expedient to modify to some extent the monopoly consequent on the existence of patent rights in regard to such substances.[60]

Particularly, England's Patents and Designs Amendment Act, 1919 in section 38, introduced process patents and imposed restrictions on patent protection for food.[61] Further, the statute, under section 38B(2),

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[54] *Id.* at 38.

[55] *Id.* Prior to 1877, Germany followed the French model. *Id.* Under the French statute of 1844, patents were granted to chemical products per se. *Id.* "German scientists and research workers attributed the failure of the French chemical industry to the [French] product patent system. The Ayyangar Committee favourably cited the German belief that grant of a product patent per se to chemical products precluded alternative processes of production." *Id.* (footnotes omitted).

[56] RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 38–39.

[57] *Id.* at 39 (alteration in original).

[58] *Id.* at 37.

[59] *Id.*

[60] *Id.* (quoting N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW ¶ 98 (1959)).

[61] *Id.*

also "introduced compulsory licensing of patents relating to food substances."[62]

Meanwhile, many countries that were considered "developing" at the time of the TRIPS Agreement were in the process of (re)molding the transplant of IP laws that were introduced as part of the outcome of empire building and colonization from key western states.[63] Indicatively, prior to TRIPS, "over [forty] countries in the world did not grant patent protection for pharmaceutical products."[64] During the TRIPS negotiations, India, Spain, Brazil, Mexico, and Peru advocated that patent terms should be left to the discretion of states.[65] Developing countries did not view TRIPS as favorable to their interests with its widening of subject matter scope, the addition of new rights to the global IP regime, and the required minimum standardization—resulting in a maximalist approach—of duration and basic features.[66]

Nonetheless, several reasons, including unilateral pressure mechanisms, such as the USTR Special 301 process,[67] experience, and expertise asymmetries,[68] lack of bargaining parties,[69] and the desire to be a part of the global trade regime, resulted in 112 countries joining

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[62] RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 38–39.

[63] Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, 5 J. WORLD INTELL. PROP. 765, 772–73 (2002), https://doi.org/10.1111/j.1747-1796.2002.tb00181.x; *see generally* Ayyangar, *supra* note 60 (forming the basis for India's much discussed 1970 Patent Law wherein patent laws of various countries were examined, along with the feasibility for such regimes in less developed countries such as India).

[64] *WTO and the TRIPS Agreement*, WORLD HEALTH ORG., https://www.who.int/medicines/areas/policy/wto_trips/en (last visited Oct. 5, 2023).

[65] Additionally, "Australia and New Zealand historically had shorter patent terms and therefore advocated patent terms of fifteen and sixteen years respectively[,]" while certain developed countries, including the United States, advocated for a duration of more than twenty years. Simon Lester & Huan Zhu, *Rethinking the Length of Patent Terms*, 34 AM. UNIV. INT'L L. REV. 787, 797 (2019), https://doi.org/10.2139/ssrn.3328596; *see also* Josh Lerner, *150 Years of Patent Protection*, 7 AM. L. & ECON. REV. 112, 221–24 (2002), https://doi.org/10.1257/000282802320189294 (discussing historical patent lengths).

[66] *See* Dutfield, *supra* note 41.

[67] *See generally* Suzanne Zhou, *Challenging the Use of Special 301 Against Measures Promoting Access to Medicines: Options Under the WTO Agreements*, 19 J. INT'L ECON. L. 51 (2016), https://doi.org/10.1093/jiel/jgw004 (examining Special 301).

[68] Peter Drahos, *Global Property Rights in Information: The Story of TRIPS at the GATT*, 13 PROMETHEUS 6, 15 (1995), https://doi.org/10.1080/08109029508629187.

[69] Ragavan, *Inequals of the Uruguay Round*, *supra* note 51, at 274.

WTO by the end of 1995.[70] The number today stands at 164 member countries.[71]

The TRIPS Agreement expanded the realm of IP to unprecedented levels. In addition to implementing minimum standards and mandating compliance with the substantive provisions of the Berne and Paris Conventions, it required compliance with select provisions of the Convention for the Protection of Performers, Producers of Phonograms, and Broadcasting Organizations ("Rome Convention") and the Treaty on Intellectual Property in Respect of Integrated Circuits.[72] More significantly, it required WTO member states to guarantee detailed enforcement procedures under national laws and submit themselves to the decisions of the Dispute Settlement Body (DSB).[73]

Even prior to the TRIPS Agreement, developing countries started raising concerns in the World Intellectual Property Organization (WIPO) diplomatic conferences between 1980 and 1984, demanding revisions to the Paris Convention to make it more favorable to their domestic interests, such as health and agriculture.[74] But developed countries, led by the United States, successfully resisted these revisions. Claiming the superiority of a maximalist IP ideology, developed nations predicted a world order where they would export knowledge capital (to countries that established a minimum level of IP protection) to prompt a trade cycle generating investments.[75] Thus,

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[70] *See* Press Release, Director-General, Overview of Developments in International Trade and the Trading System, WTO Press Release WT/TPR/OV/1 (Dec. 1, 1995), https://www.wto.org/english/news_e/pres95_e/ov11.htm.

[71] *See Members and Observers*, WORLD TRADE ORG., www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Oct. 5, 2023).

[72] J.H. Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT'L L. 363, 366 n.11 (1996); *see also* Treaty on Intellectual Property in Respect of Integrated Circuits, May 26, 1989, 28 I.L.M. 1477; International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations, Oct. 26, 1961, 496 U.N.T.S. 43.

[73] Reichman, *supra* note 72, at 366–67.

[74] Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 20 (2004); *see* Nagesh Kumar, *Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries*, 38 ECON. & POL. WKLY. 209, 210 (2003) ("The top [ten] countries account for as much as 84 percent of global resources spent on [R&D] activity annually, they control 94 percent of the technological output in terms of patents taken out in the US, and receive 91 percent of global cross-border royalties and technology license fees.").

[75] *See* RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at xii, 196.

the idea of mandatory international minimum standards of protection was floated particularly by the United States, Europe, and Japan, carefully calibrating it as beneficial for their economic interests.[76] These countries also saw the reliance on the International Court of Justice (as prescribed by the Paris Convention) as an inadequate enforcement mechanism due to its basis on voluntary cooperation.[77] Finally, a substantial part of rising gross domestic products in developed countries was owed to IP-heavy industries, even while their capacity to rival manufacturing centers in Asia's newly developing economies was declining. It was therefore in the interest of the developed economies to press this comparative advantage internationally.[78]

The one-state-one-vote rule of WIPO prevented developed countries from taking these proposals forward successfully within the system.[79] The linking of IP to trade shifted the forum to WTO, resulting in the following two institutionally derived benefits for developed countries.

The first benefit was negotiating power, which caused bargaining parities to skew towards developed nations. In linking IP with trade, the dependence of developing countries on the developed country markets helped the latter to better exert pressure over IP matters.[80] In combination with the desire to belong to the global trading regime, WTO presented both carrot and stick incentives for developing countries to accept changes to international IP norms. Further, since decisions are generally made by consensus at WTO rather than by vote, bilateral pressure mechanisms and side deals were used to prevent

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[76] *Id.* at 65–67. Generally, "stronger" IP protections refer to more expansive exclusion rights. It should be clarified though that the rhetoric value of "stronger" has no normative usage here, as it is now well established that countries require different IP norms depending on various socio-economic variables.

[77] The ICJ's jurisdiction was based on the consent of states, making the voluntary cooperation of states mandatory for effective enforcement or dispute settlement. *See* Anthony D. Sabatelli, *Impediments to Global Patent Law Harmonization*, 22 N. KY. L. REV. 579, 592–93 (1995).

[78] *See* Ruth Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. & TECH. J. 125, 128 (2003); Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 356–57 (2004).

[79] *See* PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? 93, 94, 96, 237 (2002) [hereinafter INFORMATION FEUDALISM].

[80] *See* Helfer, *supra* note 74, at 16–17 (discussing the effects of regime shifting and the benefits to powerful actors).

formal objections, thus resulting not only in a consensus but also in masking the true positions of member states. [81]

The second benefit was that the dispute settlement mechanism of WTO had more teeth than the redressal mechanisms under the Paris and Berne Conventions by including compensatory or retaliatory actions, such as trade sanctions for a state not submitting to the DSB's decisions.[82] Ruth Okediji captures the underlying sentiment behind the massive lobbying that took place:

> It is important to emphasize that the integration of intellectual property and trade in that multilateral trade context was not solely or even primarily to curtail piracy in global markets, although this was certainly an important issue. The more vital role of the trade context for intellectual property was the consolidation of a *domestic* reconditioning of the basis of comparative advantage in order to exploit both factor endowments and to adjust to the new division of labour evident in the global economy. To secure these ends, a new multilateral order was necessary to: provide coherence in the global intellectual property framework; decrease the dependence of effective protection on the vagaries of political relations; capture the static gains of the multiple bilateral agreements already in place; and legitimize the economic imperative of unilateralism.[83]

Regardless, developing and least developed nations were left with little choice but to join WTO if they wanted to partake in the new world of globalized trade that was opening out with much vaunted promises of improved economic growth for all members. Thus, with the institutionally derived benefits open to the developed nations as described above, the stage was set for them to progress in a manner most beneficial to them under the guise of a new economic world order brought about by increased interdependence, cooperation, and trade.

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[81] Consensus at WTO is obtained when no member country makes a formal objection to a proposal. *See* WTO Agreement, *supra* note 6, art. IX, ¶ 1.

[82] J.H. Reichman, *Enforcing the Enforcement Procedures of the TRIPS Agreement*, 37 VA. J. INT'L L. 335, 339 (1997) ("Taken together, the enforcement and dispute-settlement provisions of the TRIPS Agreement put teeth into the pre-existing intellectual property conventions . . . ."); *see also* Srividhya Ragavan & Brian Manning, *The Dispute Settlement Process of the WTO: A Normative Structure to Achieve Utilitarian Objectives*, 79 UMKC L. REV. 1, 27–28 (2010).

[83] Okediji, *supra* note 78, at 135.

II. CONVERTING NEGOTIATING POSITIONS INTO INTERNATIONAL NORMS

Part I outlined the rationale behind developed nations taking a more IP maximalist stance as well as the tactical utility for them in connecting it to international trade. But the converting of controversial and minority opinions into international norms involved a confluence of complex and intentional factors. This Part traces the specifics of these unique developments that led to TRIPS standards not only becoming the norm, but also becoming the floor for future norm setting.

The intriguing question is what factors are causative to link IP with trade? In that, how did what was once an idealistic goal become an international legal reality disconnected with local realities of different member states? In dealing with this question, the discussion below highlights the story of the faces behind how governments are lobbied into shifting their postures on policy issues.[84]

The US Advisory Committee on Trade Negotiations (ACTN), which was the USTR body to advise on domestic industry interests, led the effort to link trade with IP rights. Most interestingly at that time, Edmund Pratt, the then CEO and chairman of Pfizer, was also the chairman of ACTN through most of the 1980s.[85] The ACTN, as the advisory committee relaying the interests of the industry, expressed that the industries most deserving of protection were those with large IP portfolios—"[p]harmaceuticals, semiconductor chips[,] and the copyright in icons like Mickey Mouse."[86] The ACTN took two actions towards this goal. First, it created an IP task force, and second, it ensured that a special position was created within the USTR to ensure that IP remains a priority through the negotiations. John Opel, the then chairman of IBM (where coincidentally Pratt had worked for

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[84] *See* SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 8 (Thomas Biersteker et al. eds., 2003) ("State-centric accounts of the Uruguay Round are at best incomplete, and at worst misleading, as they obscure the driving forces behind the TRIPS Agreement.").

[85] INFORMATION FEUDALISM, *supra* note 79, at 72; *see also* MOHAN KUMAR, NEGOTIATION DYNAMICS OF THE WTO: AN INSIDER'S ACCOUNT 36 (2018), https://doi.org/10.1007/978-981-10-8842-1.

[86] INFORMATION FEUDALISM, *supra* note 79, at 72.

around eleven years before joining Pfizer),[87] headed ACTN's task force on IP.

As Drahos and Braithwaite note in *Informational Feudalism*, the ACTN Task Force on IP released two sets of recommendations, which included several policy positions later taken by the USTR in its international negotiations, including the "no IP, no trade round" position.[88] These were largely taken from a 1985 paper written by Jacques Gorlin, a former IBM consultant, outlining strategies for a trade-based approach for IP.[89] Notably, the paper recommended the use of "a carrot and stick approach," such as providing technical trainings to foreign IP officials on the one hand, while also strengthening section 301 processes and using the Generalized System of Preferences (GSP) to link access to the US market with "improved" IP protection.[90]

In early 1986, the then US trade representative, Clayton Yeutter, sought to include European, Japanese, and Canadian governments on the board in the Uruguay Round.[91] The USTR identified the inefficiencies of working through industry associations in each of these countries directly.[92] Consequently, the USTR seems to have worked through the industry association in the United States, which resulted in John Opel and Edmund Pratt, executives of IBM and Pfizer, constituting the Intellectual Property Committee (IPC).[93] The IPC included twelve CEOs from large corporations, including Bristol-Myers, CBS, Du Pont, General Electric, General Motors, Hewlett-

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87 *See Alumni Profile: Edmund T. Pratt Jr.*, DUKE PRATT SCH. OF ENG'G (May 3, 2013), https://web.archive.org/web/20210128095256/https:/pratt.duke.edu/about/news/edmund-t-pratt-jr.

88 *See* INFORMATION FEUDALISM, *supra* note 79, at 72.

89 SELL, *supra* note 84, at 101.

90 *Id.* at 103.

91 *See* Scott Burris et al., *Nodal Governance*, 30 AUSTL. J. LEGAL PHIL. 30, 44–46 (2005); *see also U.S. Trade Representative Clayton Yeutter Today Urged Japan to. . .*, UPI (Apr. 20, 1987), https://www.upi.com/Archives/1987/04/20/US-trade-representative-Clayton-Yeutter-today-urged-Japan-to/3444545889600 (noting that the USTR went to Tokyo to brief on US positions in the new round of trade liberalization talks under the GATT); FIONA HAYES-RENSHAW & HELEN WALLACE, THE COUNCIL OF MINISTERS 206 (Neil Nugent et al. eds., 2d ed. 2006); *see generally* INFORMATION FEUDALISM, *supra* note 79.

92 *See generally* INFORMATION FEUDALISM, *supra* note 79.

93 *See* SELL, *supra* note 84, at 2 n.1, 48–89 (discussing Fritz Attaway, John Opel, and Edmund Pratt, executives at Motion Picture Association, Pfizer, and IBM, launched the committee); Burris et al., *supra* note 91, 45.

Packard, IBM, Johnson & Johnson, Merck, Monsanto, and Pfizer.[94] The IPC members, along with their peers from Europe and Japan, stressed that IP issues required robust industry involvement with the government considering the effect of piracy on profit margins.[95] The IPC, in turn, lobbied their respective governments leading to the eventual adoption of these ideas by the Europeans and Japanese at the Uruguay Round in September 1986.[96] In June 1988, this group released its "Basic Framework of GATT Provisions on Intellectual Property," which borrowed heavily from the substantive proposals of Gorlin's 1985 paper.[97] This proposal, which advocated minimum standards, national enforcement mechanisms, and dispute settlement mechanisms, among other things, eventually formed the basis of the TRIPS Agreement.[98]

The successful framing of the harmonization of IP as a trade issue coincided with a dramatic expansion of IP rights in the last three decades.[99] Indeed, this represents the largest expansion of property rights to include a swathe of intangible properties within its realm. Indeed, the TRIPS Agreement converged copyrights, patents, trademarks, geographical indications, designs, plant variety protection, etc. (previously existing as separate legal instruments) under a common umbrella of "IPR."[100] These expansions have notably included the requirement of patent protection for inventions in all fields of technology, with patents requiring a minimum twenty-year duration,[101] protection for micro-organisms and plant varieties,[102] expansions in copyright-protectable subject matter, a minimum

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[94] SELL, *supra* note 84, at 1–2 & 2 n.1.

[95] *Id.*

[96] *See* INFORMATION FEUDALISM, *supra* note 79, at 96–102, 212; SELL, *supra* note 84, at 1–20, 103.

[97] SELL, *supra* note 84, at 107.

[98] Compromises, such as Compulsory Licenses, for preferential treatment for developing countries and transition provisions were included so as to make a document that could reach consensus. *See id.*

[99] *See* RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 67–69.

[100] *See* Amy Kapcyznski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 821–24 (2008), https://doi.org/10.2307/20455812; TRIPS Agreement, *supra* note 6, art. 1.2.

[101] *See* Bryan Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends*, *in* REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM 215, 229 (Lorand Bartels & Federico Ortino eds., 2006), https://doi.org/10.1093/acprof:oso/9780199206995.003.0010; TRIPS Agreement, *supra* note 6, art. 27.1.

[102] TRIPS Agreement, *supra* note 6, art. 27.3(b).

copyright duration of fifty years,[103] criminal penalties for trademark and copyright infringement,[104] and more.[105]

Although the TRIPS Agreement serves as the most important international framework for IP norms, it is relevant to note that by mandating minimum standards, in practice, it has more often than not served as a floor.[106] That is, while the TRIPS Agreement embodies several flexibilities, very few of them have actually been used in reality.[107] This is true despite the oft repeated touting of flexibilities by the developed nations. After twenty-five years of TRIPS, the fact remains that the claims by developing countries—namely that the international IP regime has failed to take into consideration their needs, interests, and local realities—are more factual.[108]

Indeed, while the upward harmonization of IP norms due to TRIPS is well noted, it is also true that the United States and other developed countries could not achieve all of their goals via the TRIPS Agreement. Moreover, the final agreement of TRIPS was based on consensus, which naturally involved compromises. Unfortunately, the compromises and the lack of flexibility merely caused WTO to normatively enforce the TRIPS Agreement and aggressively pursue its goals. In turn, it has arguably led to the collapse of WTO as a favorable venue to negotiate, pursue other negotiations, or deal with issues relating to trade and IP rights. For instance, at the Third Ministerial Conference of WTO held at Seattle in 1999, the efforts of the United

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[103] *Id.* art. 12, 14.5.

[104] *Id.* art. 61 ("Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale.").

[105] *See generally* Mercurio, *supra* note 101, at 215–37.

[106] *See* Yu, *supra* note 78, at 364, 381; *see also* Henning Grosse Ruse-Khan, *Time for a Paradigm Shift—Exploring Maximum Standards in International Intellectual Property Protection*, 1 TRADE L. & DEV. 56, 62 (2009) (exploring the possibilities of reversing this equation by identifying and examining rationales for a ceiling or maximum standards in international IP protection).

[107] *See* SISULE F. MUSUNGU & CECILIA OH, S. CTR., THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES?, at xiii–xv (2006).

[108] *See* MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL PROPERTY MONOPOLY 247–48 (Scott Parris ed., 2008), https://doi.org/10.1017/CBO9780511510854. These claims are borne out by history as well. For instance, several developed countries, which now advocate for strong patent protection, did not provide for product patent protection for chemicals/pharmaceuticals until very late in their own technological development trajectories, such as Japan (1976), Germany (1967), Switzerland (1977), and Sweden (1978). *See, e.g.*, Ragavan, *Inequals of the Uruguay Round*, *supra* note 51, at 284–86.

States and Europe to introduce new areas of the agreement under WTO, "such as investment, competition, government procurement, and labour and environmental standards," backfired.[109] Nevertheless, the exclusion of developing countries in crucial negotiations when the United States and Europe held secretive "green room" meetings[110] as an effort to manipulate the WTO process led to developing countries preemptively denying consensus to any declaration made at the Conference.[111] The collapse of that Ministerial Round signified the invigoration of developing countries as a group and brought their goals to the forefront of the multilateral process.

Simultaneously, the HIV/AIDS crisis was unfolding around the world as a public health issue on a scale that was not known or seen before. Soon the epidemic affected millions of people, especially in developing countries, because of the lack of access to the patent-protected medications. By this time, within developing countries, academics and civil society groups had coalesced energies around common concerns, especially regarding the effect of the TRIPS Agreement on public health. It was highly unusual, at that time, for nontrade bodies to add their input to trade-related concerns.[112] Remarkably, these coalitions led to other international institutions—such as the World Health Organization (WHO), Joint United Nations Programme on HIV/AIDS (UNAIDS), and various regional organizations—adding their voice to the debate on TRIPS and public health.[113] In 2001, WHO adopted two resolutions addressing TRIPS-related concerns—resolutions that brought these issues within the larger mandate.[114] The next WTO Ministerial Conference, held in

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[109] *See* Martin Khor, *The Revolt of Developing Nations*, TWN THIRD WORLD NETWORK BERHAD, https://twn.my/title/deb1-cn.htm (last visited Oct. 5, 2023).

[110] *See* KENT JONES, GREEN ROOM POLITICS AND THE WTO'S CRISIS OF REPRESENTATION 2–3 (2004), https://edisciplinas.usp.br/pluginfile.php/161151/mod_resource/content/1/Jones%202004.pdf.

[111] *See Africa, Caribbean and Latin America Protest No Democracy in WTO Available*, TWN THIRD WORLD NETWORK BERHAD, https://twn.my/title/deb5-cn.htm (last visited Oct. 5, 2023).

[112] *See* Kapcyznski, *supra* note 100, at 832; Ellen t'Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3 CHI. J. INT'L L. 27, 38 (2002).

[113] *See* t'Hoen, *supra* note 112, at 38.

[114] *See* World Health Organization [WHO], Assembly Res. WHA54.10, *Scaling up the Response to HIV/AIDS*, WHO Doc. A54/VR/8, at 2 (May 21, 2001), https://apps.who.int/iris/bitstream/handle/10665/78785/ea54r10.pdf; World Health Organization [WHO], Assembly Res. WHA54.11, *WHO Medicines Strategy*, WHO

Doha in 2001, acknowledged these concerns, causing the adoption of a Declaration on TRIPS and Public Health.[115] The Doha Declaration noted that the TRIPS Agreement could and should be interpreted in a manner supportive of WTO members' right to protect public health, including the promotion of access to medicines for all.[116]

This relative recapture of the multilateral process by developing countries, however, led to developed countries modifying their own approach. In order to sidestep the multilateral impediments, they started focusing more on bilateral and regional agreements with the more willing or susceptible countries as a method of spreading norms they desired. The next chapter of this saga resulted in the TRIPS Agreement being considered the mere threshold or "floor" of international IP norm setting. Soon, various free trade agreements (FTAs), bilateral agreements, and unilateral pressure mechanisms denied the effective exercise of TRIPS flexibilities due to further upward harmonization through "TRIPS-Plus" provisions.[117] As Ruth Okediji notes, "rather than signal an end to the aggressive unilateralism that characterised pre-Uruguay Round intellectual property strategies, the new bilateralism is rightly viewed as a means to roll back both substantive and strategic gains of the TRIPS Agreement for developing countries."[118]

III. TRIPS AND TRIPS-PLUS

The "flexibilities" in the TRIPS Agreement notwithstanding, purportedly drafted to give room to developing countries to implement without compromising their national interests, there was a proliferation of TRIPS-Plus provisions in bilateral trade agreements

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Doc. A54/VR/8, at 1 (May 21, 2001), https://apps.who.int/iris/bitstream/handle/10665/78786/ea54r11.pdf?sequence=1&isAllowed=y.

[115] Doha Declaration, *supra* note 23, ¶¶ 17–19; *see also* t'Hoen, *supra* note 112, at 28; discussion *infra* Part III.

[116] Doha Declaration, *supra* note 23, ¶ 17.

[117] Yu, *supra* note 78, at 429; *see also* Mercurio, *supra* note 101, at 215; *see generally* Peter Drahos, *BITS and BIPS: Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791 (2001); Rosemary J. Coombe, *Fear, Hope, and Longing for the Future of Authorship and a Revitalized Public Domain in Global Regimes of Intellectual Property*, 52 DEPAUL L. REV. 1171, 1177 (2003) (describing the "growing tendency" of US and Europe to press developing countries to accede to bilateral treaties with higher IP protection, termed as TRIPS-Plus, which were norms that exceeded the minimum standards in the TRIPS agreement).

[118] *See* Okediji, *supra* note 78, at 129.

(BTAs) and FTAs. This Part reviews key provisions of the TRIPS Agreement, particularly focusing on the issues that arise therefrom. Thus, Section A addresses the general provisions and basic principles, while Sections B to D outline the TRIPS-Plus provisions including enforcement and the resulting post-TRIPS FTAs. Section E concludes by outlining the impact of TRIPS-Plus provisions during the pandemic.

A. *General Provisions and Basic Principles*

The TRIPS Agreement opens with general provisions and basic principles that are applicable to all forms of IP contemplated by the agreement. This Part covers the most important principles of the TRIPS Agreement.

Nature and Scope: The TRIPS Agreement requires all members to establish the minimum standards set forth in it, while specifying that members are free to implement more extensive protection than is required by the TRIPS Agreement.[119] It incorporates, by reference, substantive portions of the Paris and Berne Conventions, requiring WTO members to adopt these provisions.[120] This resulted in a Paris-plus and a Berne-plus approach, which forced members to comply with these referenced provisions even if they are not a party to either of those conventions. In turn, members had to face the WTO dispute resolution mechanism if they violated these provisions.

National Treatment and Most Favored Nation Clauses: Articles 3 to 5 of the TRIPS Agreement lay out the requirement of uniformity of treatment of nationals of all member states with regard to IP covered by TRIPS.[121] Article 3, the "national treatment" clause, requires each member to treat "nationals of other [m]embers no less favourably than it [treats] . . . its own [nationals]."[122] Although both the Paris and Berne Conventions also have national treatment clauses, they are applied in the context of equal treatment of imported and domestic products. The context of Article 3 in the TRIPS Agreement forces countries to establish minimum standards (one of the TRIPS required standards) for IP not covered in Paris and Berne Conventions, as well as for the enforcement provisions of IP rights.[123] Article 4, entitled the "most favoured nation" (MFN) clause, forbids discrimination by a

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[119] TRIPS Agreement, *supra* note 6, art. 1.

[120] *Id.* arts. 1–3, 16, 39, 63. It does, however, exclude Article 6*bis* of the Berne Convention, dealing with "moral rights." *Id.* art. 9.

[121] *Id.* arts. 3–5.

[122] *Id.* art. 3.1.

[123] *Id.*

member when trading between different nationals of other member states.[124] The TRIPS Agreement retained the preexisting exceptions to the national treatment clause and MFN, such as material reciprocity, which were originally allowed under the WIPO IP Conventions.[125] But, the TRIPS Agreement is silent on whether agreements entered into *after* the TRIPS Agreement, such as BTAs and FTAs, would be exempt as well, leaving open the question of whether the BTA signatories should implement TRIPS-Plus provisions in such agreements with respect to all other WTO members. While this is still being used to impose soft-power pressure, commentators note that such an interpretation would be incongruous with the TRIPS Agreement taken as a whole.[126]

Exhaustion of Rights: Exhaustion of IP rights refers to the limits of IP rights. At the first sale of an IP-protected product, the IP owner's rights to commercially exploit the product exhaust within a specified territory (national, regional, or international), depending on the law of the country in question. In the context of international trade, this first sale can take place in a country or region other than the place of final sale, leading to what is called parallel importation.[127] Considering that TRIPS negotiations were not conclusive on the issue of exhaustion of rights, allegations of TRIPS violations based on exhaustion could not lead to WTO dispute resolution unless fundamental principles of nondiscrimination (national treatment and MFN) were involved. Later, the Doha Declaration in paragraph 5(d) clarified that members were free to choose their own exhaustion regime without challenge.[128] This intended to allow countries to take advantage of differential pharmaceutical pricing policies.[129] Nonetheless, TRIPS-Plus provisions

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[124] *Id.* art. 4.

[125] TRIPS Agreement, *supra* note 6, art. 3.1, art. 4.

[126] *See* Drahos, *supra* note 117, at 801; Prabhash Ranjan, *Bilateralism, MFN and TRIPS: Exploring the Possibilities of Alternative Interpretation*, 13 INT'L TRADE L. & REGUL. 67, 70 (2007).

[127] *See generally* Frederick M. Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, 1 J. INT'L ECON. L. 607, 607–36 (1998), https://doi.org/10.1093/jiel/1.4.607.

[128] *See* Doha Declaration, *supra* note 23, ¶ 5(d).

[129] The exhaustion policies were critical to allow sovereign nations the ability to choose when IP rights exhaust. That is, it determines whether a patent holder's rights are "exhausted" after the first sale of a drug. National exhaustion exhausts rights domestically after the first sale and allows price setting based on each country's income level. Lower prices can be charged in poorer markets, but it creates differential pricing

in various FTAs have violated this freedom in spirit, even if perhaps not in form, by authorizing patent owners to prevent parallel imports through the use of contracts or other means.[130]

Objectives and Principles: The preamble of the TRIPS Agreement outlines the objectives, which include a reduction of international trade distortions and promotion of adequate protection of IP rights, while also "recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives."[131] Article 7, entitled "objectives," promotes both sides of the oft contested IP paradigm, those being "promotion of technological innovation" and "producers" as well as "the transfer and dissemination of technology" and "users."[132] Such promotion should be done "in a manner conducive to social and economic welfare."[133] Notwithstanding these seemingly contrasting positions, the TRIPS Agreement asserts that international obligations of protection and enforcement of IP rights should contribute to the national, social, and economic welfare of members.[134] This perhaps echoes the first and second recitals to the Agreement Establishing the World Trade Organization,[135] which expresses a concern for increasing

across different markets. But, international regime exhausts IP rights globally at the instance of first sale and allows for parallel importation while preventing differential pricing. Thus, by carefully crafting a proper regime of exhaustion of IP, member states could promote access to medication. *See generally* World Intellectual Property Organization [WIPO], Standing Comm. on the L. of Patents, *Exceptions and Limitations to Patent Rights: Exhaustion of Patent Rights*, WIPO Doc. SCP/21/7 (Oct. 6, 2014), https://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_7.pdf (describing various policy objectives for exhaustion as reported by Member States); JEROME H. REICHMAN ET AL., THE WTO COMPATIBILITY OF A DIFFERENTIATED INTERNATIONAL EXHAUSTION REGIME (2014), http://www.eurasiancommission.org/ru/act/finpol/dobd/intelsobs/Documents/WTO%20Compartibility%20of%20Exhaustion%20Regimes_EEC_SkHSereport.pdf (discussing problem sounding on various approaches to exhaustion regimes).

[130] Examples include the United States' FTAs with Australia, Morocco, and Singapore. *See* Pedro Roffe & Christoph Spennemann, *The Impact of FTAs on Public Health Policies and TRIPS Flexibilities*, 1 INT'L J. INTELL. PROP. MGMT. 75, 81 (2006), https://doi.org/10.1504/IJIPM.2006.011023.

[131] TRIPS Agreement, *supra* note 6, pmbl.

[132] *Id.* art. 7.

[133] *Id.*; *see also* RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 69.

[134] TRIPS Agreement, *supra* note 6, art. 7.

[135] Alison Slade, *The Objectives and Principles of the WTO TRIPS Agreement: A Detailed Anatomy*, 53 Osgoode Hall L.J. 948, 978–79 (2016) [hereinafter Slade, *The Objectives and Principles*], https://doi.org/10.60082/2817-5069.3042 (analyzing Articles 7 and 8

global welfare and perhaps demonstrates a particular concern for developing countries that presumably would benefit the most from a welfare paradigm.[136] This simultaneous emphasis on contrasting positions, however, has been criticized for not providing interpretative clarity.

Article 8, entitled "principles," recognizes members' rights to "adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their . . . development, provided the measures are consistent with the [TRIPS] Agreement."[137] The usage of the word "necessary" has been pointed to as curtailing potential policy space of members.[138] Alison Slade notes, "[t]he use of the term 'necessary' within Article 8.1 mirrors the wording within other WTO texts, where, as the 'necessity test,' it functions to control the autonomy State Parties have to ensure non-trade objectives."[139] But unlike the GATT provisions, Article 8 is not an exception provision but merely constrained by the requirement to be consistent with the provisions of the TRIPS Agreement, thus likely emphasizing the policy flexibility that members have in their interpretation of the TRIPS Agreement. The Doha Declaration reaffirms an interpretation that is supportive of WTO members' right to protect public health and to use the provisions in the TRIPS Agreement to provide flexibility for this purpose.[140]

While the DSB has acknowledged Articles 7 and 8,[141] it has not provided an interpretation of these clauses. Thus, while Articles 7 and

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of the TRIPS Agreement, arguing they affirm national regulatory autonomy in applying TRIPS).

136 Michael Spence, *Which Intellectual Property Rights Are Trade-Related?*, *in* ENVIRONMENT, HUMAN RIGHTS AND INTERNATIONAL TRADE 264, 265 (Francesco Francioni ed., 2001).

137 TRIPS Agreement, *supra* note 6, art. 8.1.

138 Slade, *The Objectives and Principles*, *supra* note 135, at 978–79.

139 *Id.* at 978–79, 979 n.140 ("Key WTO provisions that contain a necessity requirement include Articles XX and XI of the GATT; General Agreement on Trade in Services ('GATS') Articles XIV and VI:4, paragraph 2(d) of Article XII and paragraph 5(e) of the Annex on Telecommunications; Articles 2.2 and 2.5 of the Agreement on Technical Barriers to Trade ('TBT'); Articles 2.2 and 5.6 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); Articles 3.2, 8.1[,] and 27.2 of the TRIPS Agreement; and Article 23.2 of the Agreement on Government Procurement.").

140 Doha Declaration, *supra* note 23, ¶ 17.

141 Panel Report, *Canada–Term of Patent Protection*, ¶ 101, WTO Doc. WT/DS170/AB/R (adopted Sept. 18, 2000); Appellate Body Report, *United States–Section 211 Omnibus Appropriations Act of 1998*, ¶ 161 n.101, WTO Doc.

8 provide context, object, and purpose to the interpretation of the TRIPS Agreement, the clauses themselves are still open to interpretation, making their use currently questionable.[142] Significantly, later agreement negotiations have seen language from Articles 7 and 8 used, such as in the text of the Trans-Pacific Partnership Act (TPP), the proposed Anti-Counterfeiting Trade Agreement (ACTA), the WIPO Development Agenda, and the Indian Patents Act.[143] Their growing usage highlights the importance of a more detailed understanding and interpretation going forward.

B. *Copyright and Patent: Standards, Scope, and Use*

The TRIPS Agreement lays down substantive standards for copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits, protection of undisclosed information, and control of anticompetitive practices in contractual licenses. But the effects of expanded patent and copyright norms in these subject areas constitute the bulk of negotiations, disagreements, and protests. Aggressive harmonization has resulted in inadequate flexibility for members with different socioeconomic realities to balance between the incentives and access paradigm in ways that account for their diversity.[144]

Copyright: Article 9 of the TRIPS Agreement incorporates copyright norms through reference to Articles 1 to 21 of the Berne Convention, with the exception of Article 6*bis*, which relates to moral rights of authors.[145] The TRIPS Agreement further expands protection by including computer programs and compilations of data, rental rights for computer programs, cinematographic works, producers of

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WT/DS176/AB/R (adopted Jan. 2, 2002)*; see* Slade, *The Objectives and Principles*, *supra* note 135, at 952; *see, e.g.*, Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, ¶¶ 4.12, 4.37, WTO Doc. WT/DS114/R (adopted Mar. 17, 2000).

142 *See* Peter K. Yu, *The Objectives and Principles of the Trips Agreement*, 46 HOUS. L. REV. 979, 1019–20 (2009) (detailing five ways in which the provisions could be put into effective use).

143 *See* Slade, *The Objectives and Principles*, *supra* note 135, at 954–955.

144 *See generally* Ruth Gana Okediji, *Copyright and Public Welfare in Global Perspective*, 7 IND. J. GLOB. LEGAL STUD. 117 (1999) (asserting that harmonized IP are unlikely to produce the type of net welfare gains domestically or globally). The process of globalization perversely requires more government intervention due to a multitude of factors, which goes against the tenet of free trade. *Id.* at 133. Taking away government flexibility to work within local constraints, the author argues, will result in domestic constituencies having less access to the significant resources of this era. *See id.* at 121.

145 TRIPS Agreement, supra note 6, art. 9.1 (excluding moral rights from the scope of TRIPS).

phonograms, and any other right holders in phonograms[146] within the scope of copyright eligibility.[147] It also ties term duration to legal personhood[148] and incorporates protection to related rights.[149] Much like most other agreements, limitations and exceptions to these rights are arguably general and imprecise.[150]

Patents: Perhaps the most important change was the expansion in the field of patents. Under the TRIPS Agreement, product and process inventions in all fields of technology are patentable, "provided that they are new, involve an inventive step and are capable of industrial application."[151] The minimum duration of protection was set at twenty years.[152] This expanded scope was counter to the patent laws of several countries at the time, which made exceptions or limitations based on their domestic interests, especially with regard to pharmaceutical and agriculture industries.

Members were also required to protect plant varieties either by patents, an effective sui generis system, or any combination thereof, thereby expanding the role of private exclusion rights in the field of agriculture.[153] Developed nations, particularly the United States, have argued that the effective sui generis system refers to the system outlined in the International Convention for the Protection of New Varieties of Plants ("UPOV").[154] But developing countries have pushed back for alternate models of sui generis systems.[155]

Exclusions from patentability were allowed on the basis of *ordre public* or morality, with the provision "that such exclusion is not made

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146 *Id.* arts. 10–11, 14.

147 *Id.* art. 9.2.

148 *Id.* art. 12.

149 *Id.* arts. 9–11, 14.

150 *Id.* art. 13.

151 TRIPS Agreement, *supra* note 6, art. 27.1.

152 *Id.* art. 33.

153 Susan K. Sell, *What Role for Humanitarian Intellectual Property? The Globalization of Intellectual Property Rights*, 6 MINN. J.L. SCI. & TECH. 191, 203 (2004).

154 *See id.* (detailing that plant breeders in the United States have been pushing UPOV as the model *sui generis* system).

155 *See id.* at 204–05; Robert J.L. Lettington, Small-Scale Agriculture and the Nutritional Safeguard Under Article 8(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights: Case Studies from Kenya and Peru 40 (Nov. 2003) (working paper), https://unctad.org/system/files/official-document/ictsd2003d2_en.pdf.

merely because the exploitation is prohibited by their [domestic] law."[156]

Nonvoluntary Licensing: One of the most controversial issues of the TRIPS Agreement was compulsory licensing—both during the negotiation and later while interpreting the provisions to ensure compliance. Technically, the phrase "compulsory licensing" does not appear in the TRIPS Agreement, but rather, the broader term "use without authorization of right holder" is employed in Article 31.[157] This encompasses government use as another prominent form of involuntary usage.[158] The TRIPS Agreement does not list or define the situations where a compulsory license can be granted but indicates possible grounds and sets out specific conditions for the grant. These conditions are as follows: (1) prior negotiations with the right holder, except in cases of national emergency, "other [cases] of extreme urgency or . . . public noncommercial use[,]" or when a judicial or administrative body has granted the license for anticompetitive practices, although the patent holder must be promptly notified; (2) adequate remuneration to the patent holder taking into account the economic value of the authorization; (3) revocation of the license if circumstances for the grant cease to exist; (4) limitation to authorized uses; (5) nonexclusive, nonassignable licenses granted "predominantly for the supply of the domestic market" (unless a license has been granted due to anticompetitive practices by the right holder); and (6) the grant is "subject to judicial or . . . independent review."[159]

The compulsory license provisions were first tested during the HIV/AIDS public health crisis, which tested the practical utility of these provisions. Between 1996 and 1999, in the face of South Africa's attempts to retain the right to compulsory licenses and statutorily import medicines (in limited circumstances) at a time when one in five of its citizens was infected with HIV/AIDS, the United States threatened trade sanctions.[160] Similar pressure on Thailand resulted

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156 TRIPS Agreement, *supra* note 6, art. 27.2.

157 *Id.* art. 31.

158 *Id.*

159 *Id.* art. 31(b)–(i); *see also id.* art. 31(1) (defining further conditions in cases where the license is for a dependent patent).

160 *See* Brook Baker, *U.S. Post-Doha Conditions Can Kill*, HEALTH GAP (Mar. 4, 2002), http://allafrica.com/stories/200203040443.html (noting that "it took South Africa three years and four hundred thousand lives before President Clinton issued the Executive Order validating South Africa's Medicines Act); Naomi A. Bass, Note, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 211 (2002);

in Thai patent legislation abolishing unauthorized use provisions in 1999, which, in turn, caused grave problems with access to medicines at a time when HIV/AIDS ravaged the nation.[161] By 2000, after 3 percent of the Thai population was reportedly infected with AIDS, the US Trade Office finally backed down, stating that they would not object to the use of compulsory licenses consistent with the TRIPS Agreement.[162]

Developing countries strongly urged action to address the inability to use negotiated flexibilities of the TRIPS Agreement.[163] They did not want the TRIPS Agreement to "undermine the legitimate right of WTO [m]embers to formulate their own public health policies and implement them by adopting measures to protect public health."[164] Instead, developing and least developed countries wanted the TRIPS provisions to "be read in light of the . . . objectives and principles [enshrined] in Articles 7 and 8."[165] Nonetheless, the United States and Europe continued to assert that a strong patent regime would be beneficial for all countries.[166] But shortly prior to the Fourth WTO Ministerial Conference, another significant event took place, which greatly reduced the United States' credibility on this stance: the United States responded to a domestic anthrax scare that had resulted in less than a dozen deaths by threatening to compulsorily license anthrax medication unless Bayer AG Corporation, the patent owner involved, lowered the selling price of its drug.[167]

In November 2001, the Declaration on TRIPS and Public Health, issued at the Fourth WTO Ministerial Conference at Doha,[168] clarified

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RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 6, 84 (discussing the South African AIDS crisis including the executive orders).

161 *See, e.g.,* OXFAM, THAILAND COUNTRY PROFILE: THE IMPACT OF PATENT RULES ON THE TREATMENT OF HIV/AIDS IN THAILAND 1 (2001).

162 *Id.* at 8.

163 Cecilia Oh, *Developing Countries Call for Action on TRIPS at Doha WTO Ministerial Conference*, TWN THIRD WORLD NETWORK BERHAD, https://www.twn.my/title/twr131d.htm (last visited Oct. 6, 2023).

164 *Id.*

165 *Id.*

166 *Id.*

167 Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT'L L. REV. 1299, 1315 (2002).

168 Doha Declaration, *supra* note 23.

several flexibilities in response to concerns about access to medicine.[169] In recognition of the special requirements of countries lacking local manufacturing capacity, the Doha Declaration brought about more changes. Paragraph 6 of the Doha Declaration and the August 30th decision were permanently inserted into the text of the TRIPS Agreement as Article 31*bis*.[170] This allowed countries with local manufacturing capacity to export pharmaceutical products to countries with public health requirements, nullifying the Article 31(f) requirement to predominantly supply the domestic market and the Article 31(h) requirement of adequate remuneration to the right holder.[171] But the complex procedure involved in using this provision has led some to call it impractical and unworkable.[172]

C. *Enforcement*

National Enforcement: Criticisms against the Paris Convention's lack of remedial measures led to the drafting of mandatory enforcement provisions, such as remedies and deterrents in the TRIPS Agreement.[173] This was the first time domestic enforcement provisions had been introduced in any area of international law, and their introduction into the TRIPS Agreement was a widely celebrated accomplishment of the negotiations.[174] Part III of the TRIPS Agreement articulates these provisions, including civil and administrative procedures,[175] provisional measures,[176] criminal

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169 *The Doha Declaration Explained*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm (last visited Oct. 6, 2023).

170 *See* Mike Gumbel, *Is Article 31bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 TEMP. INT'L & COMP. L.J. 161, 162 (2008).

171 TRIPS Agreement, *supra* note 6, art. 31*bis*.

172 *See* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 340–42 (2005), https://doi.org/10.2307/1562501 (noting the onerous nature of the procedure involved may defeat the Article's objective); Gumbel, *supra* note 170, at 171.

173 DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 440 (2d ed. 2008).

174 *Id.* ("The enforcement section of the TRIPS Agreement is clearly one of the major achievements of the negotiation."); *see also* Reichman, *supra* note 82, at 339 ("Taken together, the enforcement and dispute-settlement provisions of the TRIPS Agreement put teeth into the pre-existing intellectual property conventions . . . .").

175 TRIPS Agreement, *supra* note 6, arts. 42–49.

176 *Id.* art. 50.

procedures,[177] and special requirements relating to border measures.[178] Professor Reichman summarizes the "four cardinal principles" of these enforcement provisions, outlined in Article 41, as:

> (1) Enabling specific procedures under domestic law with a view to provide *effective action* against all actions that can amount to infringement;
> (2) Establishing *fair and equitable* procedures—both judicial and administrative;
> (3) Ensuring that courts and administrators render reasoned opinions, comporting with principles of natural justice based "on evidence available to all the parties"; and
> (4) Providing for hierarchical appellate review of administrative and judicial decisions.[179]

Some have criticized these enforcement provisions for being insensitive to the financial investments required for full compliance, especially for lower-income countries where IP is often not as high a priority as in others.[180] On the one hand, the crafting of enforcement provisions "as broad legal standards, rather than narrow rules" creates inherent ambiguity.[181] On the other hand, provisions mandating criminal enforcement mechanisms do not account for the varying approaches to criminal sanctions across different legal regimes and cultures.[182] Mandated criminalization of IP violations has the potential for dangerous effects outside of the trade-IP framework, such as when viewed from the perspectives of human rights and civil liberties, where

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[177] *Id.* art. 61.

[178] *Id.* arts. 51–60.

[179] Reichman, *supra* note 82, at 340.

[180] As a partial safeguard against this, Article 41.5 states that these mechanisms for IP enforcement do not need to be distinct from enforcement of law in general, nor does it create obligations on member countries with respect to the distribution of resources between IP enforcement and enforcement of law in general. *See* TRIPS Agreement, *supra* note 6, art. 41.5. Nonetheless, administrative and judicial mechanisms for IP enforcement do presume specialized infrastructure such as trained personnel, as well as an ability to effectively distribute scarce financial resources. *See* C. Joël Van Over, *Collateral Estoppel and* Markman *Rulings: The Call for Uniformity*, 45 ST. LOUIS U. L.J. 1151, 1179 (2001) ("The costs of defending a patent infringement suit can be staggering.").

[181] J.H. Reichman & David Lange, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. & INT'L L. 11, 35, 38–39 (1998).

[182] *See* Peter K. Yu, *The TRIPS Enforcement Dispute*, 89 NEB. L. REV. 1046, 1087–88 (2011).

such criminalization could be used as a tool for repression.[183] The WTO DSB has since scrutinized the effectiveness of these enforcement provisions in *United States—Section 211 Omnibus Appropriations Act of 1998*[184] and *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*.[185]

International Enforcement: Regarding disputes between members, the TRIPS Agreement incorporates the dispute settlement mechanism of WTO outlined in Article XXIII of the 1994 GATT Agreement.[186] The procedure is basically the same as for other non-TRIPS-related WTO disputes. The Dispute Settlement Understanding (DSU) process contains three main phases: (1) consultations between parties; (2) adjudication by a panel, or appellate body if on appeal from the panel opinion; and (3) adoption and implementation of the panel or appellate report, including possible countermeasures in the event of

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[183] *Id.* at 1089; *see also* Andrew C. Mertha, *Shifting Legal and Administrative Goalposts: Chinese Bureaucracies, Foreign Actors, and the Evolution of China's Anti-Counterfeiting Enforcement Regime*, *in* ENGAGING THE LAW IN CHINA: STATE, SOCIETY, AND POSSIBILITIES FOR JUSTICE 180 (Neil J. Diamant et al. eds., 2005).

[184] The Appellate Board accepted the European Communities' argument that Article 42 requires WTO members to establish fair judicial procedures concerning the enforcement of IP rights but held that the US legislation being challenged did not violate this requirement as it provided for appropriate procedural due process. *See* Appellate Body Report, *United States—Section 211 Omnibus Appropriations Act of 1998*, ¶¶ 218–30, WTO Doc. WT/DS176/AB/R (adopted Jan. 2, 2022); Robert Howse & Damien J. Neven, *United States—Section 211 Omnibus Appropriations Act of 1998 (WT/DS176/AB/R)*, *in* 4 WORLD TRADE REV. 179, 204 (2005), https://doi.org/10.1017/S1474745605001291.

[185] The Panel ruled on three claims by the US against China with regard to IP law and practice: (a) that China was failing to fulfill its obligations by not providing copyright protection to censored works; (b) that obligations under Article 59 were not exclusive, and therefore, the action of Chinese authorities in donating seized counterfeit goods to the Red Cross rather than destroying them was not in violation of Article 59 read with principles in Article 46; and (c) that it was unclear, in the absence of evidence, that China's threshold limits were violative of Article 61, which requires criminal penalties in domestic law for willful trademark counterfeiting or copyright piracy on a commercial scale. *See* Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, ¶¶ 2.1–2.4, WTO Doc. WT/DS362/R (adopted Jan. 26, 2009); Daniel Gervais, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, 103 AM. J. INT'L L. 549, 549 (2009), https://doi.org/10.1017/S0002930000019990.

[186] TRIPS Agreement, *supra* note 6, art. 64. Article 64 of the TRIPS Agreement provides for dispute settlement through Articles 22 and 23 of GATT read with the Understanding on Rules and Procedure Governing the Settlement of Disputes. *See* Understanding on Rules and Procedures Governing the Settlement of Disputes art. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S 401 [hereinafter DSU].

failure to implement.[187] This ability to impose countermeasures is considered an effective mechanism in ensuring resolution, as both retaliatory (within the violated WTO Agreement) and cross-retaliatory (within a different WTO Agreement) measures can be sanctioned.[188]

There are three grounds for complaints under the DSU: (1) a member violated a WTO obligation, (2) a member's use of a measure resulted in impairing or nullifying another member's benefits under the TRIPS Agreement, or (3) the existence of any other situation. [189] Most complaints that reach the DSU phase are for violating a WTO obligation.[190] Non-violation complaints can be based on the expected loss of benefits, even if no violation of the TRIPS Agreement has actually taken place.[191]

Although, in theory, the powers of the DSB are limited to addressing issues affecting international trade, in practice, it has addressed issues that are essentially of national interest, such as in the Appellate Body Report of the DSB titled *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products.*[192] The DSB also does not require or obligate members to be cognizant of local realities when bringing TRIPS compliance issues to them, as seen in the manner in which the United States pressured South Africa to introduce pharmaceutical patents.[193] While the DSU attempts to address the

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187 *See* GATT 1994, *supra* note 15, art. XXIII.

188 *See generally* Shamnad Basheer, *Turning TRIPS on Its Head: An "IP Cross Retaliation" Model for Developing Countries*, 3 LAW & DEV. REV. 141, 143–47 (2010), https://doi.org/10.2202/1943-3867.1063; *see also* Arvind Subramanian & Jayashree Watal, *Can TRIPS Serve as an Enforcement Device for Developing Countries in the WTO?*, 3 J. INT'L ECON. L. 403, 405–11 (2000), https://doi.org/10.1093/jiel/3.3.403.

189 *See* GATT 1994, *supra* note 15, art. XXIII, ¶ 1.

190 *'Non-violation' Complaints (Article 64.2)*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/nonviolation_e.htm (last visited Oct. 6, 2023);

191 *See id.*; *see also* TRIPS Agreement, *supra* note 6, art. 64.2 (placing a moratorium on the use of non-violation complaints for the first five years of the TRIPS Agreement, which has been extended repeatedly since then).

192 *See* Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 36, WTO Doc. WT/DS50/AB/R (adopted Dec. 19, 1997); *see generally* David K. Tomar, *A Look Into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 585–90 (1999) (discussing India's resistance to amending patent legislation).

193 Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. SCH. J. INT'L & COMPAR. L. 109, 121 (2001) (highlighting US opposition to South Africa's attempts to legislate compulsory licensing provisions).

power imbalance between different parties,[194] this remains impractical.[195] A 2017 statistical analysis by Arie Reich shows that there is a strong correlation between a country's GDP and the number of dispute settlements initiated.[196] While there is approximately an 80 percent compliance rate, 68 percent of the suspension requests filed for noncompliance were against the United States and 15.8 percent against the European Union (EU).[197]

D. *The Role of Post-TRIPS FTAs*

Post-TRIPS, various bilateral and multilateral trade agreements have taken TRIPS-Plus measures to further expand copyright and patent protection levels, such as in the TPP[198] and the newly signed Regional Comprehensive Economic Partnership (RCEP).[199] Multilateral and BTAs have become post-TRIPS target areas for

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[194] Article 27.2 of the DSU provides special legal assistance for developing nations. DSU, *supra* note 186, art. 27.2. Article 24 of the DSU urges members to refrain from using the DSU against least developed countries. *See* Carrie P. Smith, *Patenting Life: The Potential and the Pitfalls of Using the WTO to Globalize Intellectual Property Rights*, 26 N.C. J. INT'L L. & COM. REGUL. 143, 168 (2000) ("Proponents of the DSU mechanism argue that the model balances out the power differential between nations.").

[195] *See* Brian Manning & Srividhya Ragavan, *The Dispute Settlement Process of the WTO: A Normative Structure to Achieve Utilitarian Objectives*, 79 UMKC L. REV. 1, 4–5 (2010) (discussing the disadvantages of the working of the DSB).

[196] Arie Reich, *The Effectiveness of the WTO Dispute Settlement System: A Statistical Analysis* 30 (Eur. Univ. Inst. Dep't of L., Working Paper No. 2017/11), https://cadmus.eui.eu/bitstream/handle/1814/47045/LAW_2017_11.pdf?sequence=1.

[197] *Id.*

[198] The TPP was first negotiated and signed by twelve countries on February 4, 2016. *See* Jack Caporal & Jonathan Lesh, *The CPTPP: (Almost) One Year Later*, CTR. FOR STRATEGIC & INT'L STUD. (Nov. 5, 2019), https://www.csis.org/analysis/cptpp-almost-one-year-later. These countries were Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam, and the United States. *See id.* But the United States withdrew from the TPP under President Donald Trump in January 2017. *Id.* The other eleven TPP countries later revived it under the name Comprehensive and Progressive Agreement for Trans-Pacific Partnership. *Id.* This incorporated most of the provisions of the TPP and entered into force on December 30, 2018. *Id.*

[199] The RCEP is being negotiated between fifteen countries including Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, Vietnam, Australia, China, Japan, New Zealand, and South Korea; India, which had been part of it, opted out of RCEP in November 2019. *See* Nayanima Basu, *India Opts Out of RCEP for Now but to Continue Negotiating Over Differences*, The Print (Nov. 4, 2019, 10:00 PM), https://theprint.in/diplomacy/india-opts-out-rcep-now-but-continue-negotiating-over-differences/315676.

maximizing IP norms through targeted negotiations with individual countries. For example, commenters have noted that the TRIPS-Plus copyright norms under the TPP further builds upon already existing TRIPS-Plus bilateral agreements, such as the Australia-US FTA and the Singapore-US FTA.[200] The lack of transparency is a common area of concern in the negotiation of these mega-trade deals, with the only source of public deliberation often stemming from leaked drafts. This is relevant considering the massive public protests against earlier trade agreements that sought to maximize IP norms, such as the proposed ACTA and the suspended EU-India FTA.[201] As such, the Electronic Frontier Foundation speculated that the IP provisions of the RCEP would mirror the ill-fated TPP provisions.[202]

But in stark contrast, after significant pushback from developing countries, including India opting out of the agreement altogether, the final draft did not introduce TRIPS-Plus provisions which negatively impacted access to medicines.[203] Leaked drafts indicate that, unlike

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[200] Matthew Rimmer, The Trans-Pacific Partnership: Copyright Law, the Creative Industries, and Internet Freedom. Submission to the Productivity Commission, the Joint Standing Committee on Treaties, and the Senate Foreign Affairs, Defence and Trade References Committee 12 (Nov. 21, 2016) (unpublished manuscript), https://eprints.qut.edu.au/101783.

[201] *See e.g.*, Dave Lee, *Acta Protests: Thousands Take to Streets Across Europe*, BBC NEWS (Mar. 8, 2012), https://www.bbc.com/news/technology-16999497; Charles Arthur, *Acta Criticised After Thousands Protest in Europe*, THE GUARDIAN (Feb. 13, 2012, 2:37 PM), https://www.theguardian.com/technology/2012/feb/13/acta-protests-europe; *see generally World Trade Organization Protests in Seattle*, SEATTLE MUN. ARCHIVES, https://www.seattle.gov/cityarchives/exhibits-and-education/digital-document-libraries/world-trade-organization-protests-in-seattle (last visited Oct. 6, 2023); *EU Trade Relations with India. Facts, Figures and Latest Developments*, EUR. COMM'N, https://ec.europa.eu/trade/policy/countries-and-regions/countries/india/ (last visited Oct. 6, 2023); *see also* Krista L. Cox, *The Intellectual Property Chapter of the Trans-Pacific Partnership Agreement and Investment in Developing Nations*, 35 U. PA. J. INT'L L. 1045, 1045–59 (2014).

[202] *See* Anupam Chander & Madhavi Sunder, *The Battle to Define Asia's Intellectual Property Law: From TPP to RCEP*, 8 U.C. IRVINE L. REV. 331, 348–49 (2018). *But see* Prashant Reddy Thikkavarapu, *Will RCEP Redefine Norms Related to Pre-grant Opposition and Experimental Use Exceptions in International Patent Law?*, *in* THE FUTURE OF ASIAN TRADE DEALS AND IP 159, 181–82 (Kung-Chung Liu et al. eds., 2019) (commenting that the absence of the US and EU within the larger RECP group of countries could open possibilities to incorporate more scrutiny against IP maximalism).

[203] *See* Victor Ido, *TRIPS Flexibilities and TRIPS-Plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space is Retained?*, at iii (S. CTR., Rsch. Paper No. 131, 2021), https://www.econstor.eu/handle/10419/248630 ("Significantly, it does not contain substantive TRIPS-Plus provisions that undermine public health in developing countries—although it does contain such provisions in other areas such as

trade agreements where countries like the United States set the agenda, there was no single dominating power in RCEP, but rather a multitude of diverse members who demonstrated internal resistance to controversial proposals, including an extension of maximalist IP norms to areas of public health.[204] Interestingly, on the question of public participation, Kelsey notes that although actual protests were muted, "joint civil society initiatives across the participating countries, presence at negotiations and sharing of analysis based on available information clearly influenced some delegations and were reflected in the final text."[205] It seems clear that despite the lack of transparency in these negotiations, "imposed" public participation can play an influential role in bringing some balance to these trade deals that affect public health.

Despite the careful balance required for appropriate calibration of copyright and patent regimes vis-à-vis a welfare paradigm, the evolution of IP flexibilities has not taken place at the same rate or in the manner commensurate with the expansion of rightsholders. Instead, more rights have steadily been identified and strongly pushed.[206] Some examples include requiring test data exclusivity periods rather than test data protection, easing the standard of patentability, prohibitions on pregrant oppositions, and patent linkages that tie marketing approval with patent status.[207] As commentators have noted, a rights-centric approach has been encouraged in various FTAs by an interpretation of the most favored nation clause in TRIPS.[208] Consequently, TRIPS-Plus obligations have been extended to WTO members who are not members of that FTA. At the same time, relying on the exception to the nondiscrimination

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copyrights, trademarks, and IP enforcement."); Jane Kelsey, *RCEP: Nothing to See and Everything to See*, AFRONOMICSLAW (Feb. 15, 2021), https://www.afronomicslaw.org/index.php/category/analysis/rcep-nothing-see-and-everything-see.

204 *See* Kelsey, *supra* note 203.

205 *See id.*

206 Olugbenga A. Olatunji, *Historical Account of Dwindling National Flexibilities from the Paris Convention to Post TRIPS Era: What Implications for Access to Medicines in Low and Middle Income Countries?*, 25 J. WORLD INT'L INTELL. PROP. 391, 392, 396 (2022), https://onlinelibrary.wiley.com/doi/pdf/10.1111/jwip.12228, https://doi.org/10.1111/jwip.12228.

207 *See* UNITED NATIONS SECRETARY-GENERAL, REPORT OF THE UNITED NATIONS SECRETARY GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES 25–26 (2016), http://www.unsgaccessmeds.org/final-report.

208 *Id.* at 19.

rule in GATT Article XXIV (which allows discrimination in trade concessions contained in BTAs or FTAs) carefully limits the trade concessions and favorable trading terms to parties of the FTA.[209] This further nudges WTO members to join FTAs and BTAs, and more voluntarily accept trade terms that have maximalist IP norms including those that harm access to medicines.

In contrast, flexibilities have been left ambiguous and discretionary, while hard and soft pressure to limit their usage remains. For example, when Brazil implemented a law in 1996 establishing a "local working" requirement that would have allowed compulsory licensing if a patent had not been worked in the territory of Brazil, the United States initiated dispute settlement proceedings in "Brazil—Measures Affecting Patent Protection."[210] Similarly, India has been repeatedly placed on USTR's Special 301's "priority watchlist" for using TRIPS permitted flexibilities, such as utilizing its legislation to deny frivolous patents and for its single usage of the compulsory license regime, while also having referred to multilateral agreements such as the TPP as positive developments.[211]

Other forms of soft pressure include the United States and Switzerland hinting at bringing a "non-violation" complaint against India, to WTO, for the same legislative provision meant to deny frivolous patents.[212] Non-violation complaints, which have been under moratorium for some time now, would allow countries to approach the WTO dispute settlement mechanism, wherein a WTO member alleges that there has been an impairment of benefits despite no actual violation of the TRIPS Agreement.[213] Interestingly, some authors have observed that developing countries could argue that enforcing TRIPS-Plus measures has created a systemic violation of the TRIPS

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[209] Olatunji, *supra* note 206, at 400; *see also* Drahos, *supra* note 63, at 802.

[210] The case however did not see a panel resolution as it was 'mutually' settled between the countries. *See Brazil–Measures Affecting Patent Protection*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (last visited Oct. 6, 2023).

[211] *See* Swaraj Paul Barooah, *USTR's Special 301 Process 2013—India on Priority Watchlist*, SPICYIP (May 4, 2013), https://spicyip.com/2013/05/ustrs-special-301-process-2013-india-on.html.

[212] Swaraj Paul Barooah, *US, Switzerland Take Out WTO Gun for India's Sec 3(d); Point at Foot*, SPICYIP (June 17, 2015), https://spicyip.com/2015/06/us-switzerland-take-out-new-wto-gun-for-indias-sec-3d-point-at-foot.html.

[213] *Id.*

Agreement's structure and purpose.[214] Such an argument could be a segue for member-states to potentially file a complaint under the WTO dispute resolution process using the norms for a non-violation dispute, which is a complaint for violating the spirit as opposed to the letter of the agreement.[215] Nevertheless, the current state of international power dynamics is such that the question remains academic and seems unlikely to emerge into the WTO arena.

Aside from the distortion of IP norms to distract from their intended goals, the use of Investor-State Dispute Settlement (ISDS) as a resolution mechanism for IP violations raises more concerns.[216] This allows foreign companies to bypass their own governments and directly bring arbitration claims against another country for compromising the value of its IP based on TRIPS-Plus norms contained in the relevant FTA. The combination of a trade framing of IP, along with an investment framing of IP, can result in a challenge to the negotiated TRIPS flexibilities. For example, Prabhash Ranjan notes that countries may need to adopt FTAs that explicitly exclude compulsory licenses from being challenged as expropriation under ISDS provisions.[217] The various ways in which TRIPS-Plus measures can be pushed, while at the same time, limiting the use of flexibilities, once again underscores the weakness of WTO as a venue to facilitate member states' ability to accomplish national public health goals.

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[214] *See* Susy Frankel, *Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes*, 12 J. INT'L ECON. L. 1023, 1041 (2009), https://doi.org/10.1093/jiel/jgp039; Haochen Sun, TRIPS and Non-violation Complaints from a Public Health Perspective 13 (Nov. 2002) (unpublished manuscript), https://www.iprsonline.org/cidtrade/Papers/Sun-TRIPS.pdf.

[215] Sun, *supra* note 214, at 13.

[216] Major corporations have leveraged ISDS for IP disputes. It puts pressure on national governments to reconsider legislation. Eli Lilly filed a $500 million ISDS suit against Canada under NAFTA over two patents. *See* Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Final Award (Mar. 16, 2017). The company filed an ISDS claim citing Panama's Supreme Court refusal to restore Bridgestone's trademark rights after they were nullified. *See* Bridgestone Licensing Servs., Inc. & Bridgestone Ams., Inc. v. Republic of Panama, ICSID Case No. ARB/16/34, Award, ¶¶ 234, 239 (Aug. 14, 2020).

[217] *See* Prabhash Ranjan, *Issuance of Compulsory Patent Licenses and Expropriation in Asian BITs and FTA Investment Chapters*, *in* THE FUTURE OF ASIAN TRADE DEALS AND IP, *supra* note 202, at 142–43, https://doi.org/10.2139/ssrn.3275937.

E. *COVID and IP Rights*

The COVID pandemic, which struck the world in early 2020, has once again brought a spotlight on the tension between public health and IP. Even as the seriousness of the virus was making itself known, South Africa and India, in October 2020, proposed a waiver for WTO TRIPS provisions that related to COVID treatment ("TRIPS waiver") for the duration of the pandemic.[218] The TRIPS waiver was intended to temporarily freeze international IP obligations to ensure they do not morph into a barrier hindering the manufacturing or creating access to affordable vaccines, medicines, and supplies for vaccine and medical products essential to deal with COVID.[219] In addition to the TRIPS waiver, other calls for addressing IP-related barriers came to include Costa Rica's patent pooling proposal and open source approaches to research and development (R&D) for COVID.[220] Several governments of developing and least developed countries, as well as members of civil society, supported the TRIPS waiver.[221] As of the time of this writing, however, nearly a year and a half since the first introduction, the debates and negotiations are still ongoing at WTO, with the EU, United Kingdom, Switzerland, and other northern nations opposing the waiver.[222] While the initial version of the waiver intended to apply to diagnostics and therapeutics as well as medicines, the latest version does not include diagnostics and therapeutics.[223]

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[218] *See* Srividhya Ragavan, *Waive the IP Rights & Save Lives*, (S. Ctr., Working Paper No. 231, 2021) [hereinafter Ragavan, *TRIPS Waiver*]; Kalinga Seneviratne, *A Covid-19 Vaccine Patent Waiver Will Save Lives. The Rich West Must Stop Blocking It*, S. CHINA MORNING POST (Dec. 29, 2021, 6:45 AM), https://www.scmp.com/comment/opinion/article/3161245/covid-19-vaccine-patent-waiver-will-save-lives-rich-west-must-stop; *see generally* Press Release, Daniela Bagozzi, World Health Org. [WHO], WHO and Costa Rica Preview Technology Pooling Initiative to Ensure Access to COVID-19 Health Products for All (May 15, 2020), https://www.who.int/news/item/15-05-2020-who-and-costa-rica-preview-technology-pooling-initiative-to-ensure-access-to-covid-19-health-products-for-all.

[219] Ragavan, *TRIPS Waiver*, *supra* note 218, at 6.

[220] *See generally* Praharsh Gour, *Wishful Thinking? Analyzing India and South Africa's Joint Statement to Waive Key Provisions of TRIPS- Part II*, SPICYIP (Oct. 20, 2020), https://spicyip.com/2020/10/wishful-thinking-analyzing-india-and-south-africas-joint-statement-to-waive-key-provisions-of-trips-part-ii.html.

[221] *See generally id.*

[222] Roshan John, *The Quad Discussion Group's Compromise Falls Short of a Comprehensive TRIPS Waiver*, SPICYIP (Mar. 17, 2022), https://spicyip.com/2022/03/the-quad-discussion-groups-compromise-falls-short-of-a-comprehensive-trips-waiver.html.

[223] *Id.*

Further, the definition of who can use the proposed solution has been narrowed down to include a limited set of developing countries who have not exported more than 10 percent of global exports of the COVID vaccine in 2021—effectively removing (only) China from the list of countries that could have utilized the waiver.[224] Additionally, there is still strong pressure to ensure that the waiver is limited to patents alone, although the original measure sought to extend the waiver to all forms of IP rights.[225] This keeps open the possibility of reduced access due to data exclusivity barriers, even if patent barriers do not exist.[226] Nevertheless, the negotiations are ongoing at the time of this writing, and the final outcome remains to be seen. Regardless of the specificities of the waiver, the fact that WTO is yet to take action of any form, despite the intense global nature of the pandemic, demonstrates the backseat that public health has taken at this forum.

IV. NEED FOR A NEW FRAMEWORK

The debacle during COVID and the inability of WTO to make a proper decision during and after the pandemic created the need for a new or alternative framework to address global public health issues. Thus, this Part offers a treaty addressing robust global public health for consideration as an exemplar alternative framework.

Contemporary discussions of public health while implicating trade, globalization, and access to medication, have increasingly come at risk as being seen as a subset of the discourse on trade and innovation. This Article argues that the fragmentation of venues, where both the IP and public health norms are shaped and influenced, plays a large role in generating a power dynamic that favors the powerful countries at the expense of the weak.[227] Over time, health has become a matter of "diplomacy," although, in fact, health is *not* a matter of diplomacy.

Health is a right of people and an obligation of governments. The right to health finds support in a number of international instruments,

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224 *Id.*

225 *See* Ragavan, *TRIPS Waiver*, *supra* note 218, at 2 (discussing the need for waiver of all forms of IP during the pandemic); John, *supra* note 222.

226 *See, e.g.*, Srividhya Ragavan, *The Drug Debate: Data Exclusivity Is the New Way to Delay Generics*, 50 CONN. L. REV. ONLINE 1, 5 (2018).

227 Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TTP*, 18 J. INTELL. PROP. L. 447, 451 (2011); *see also* Eyal Benvenisti & George W. Downs, *The Empire's New Clothes - Political Economy and the Fragmentation of International Law*, 60 STAN. L. REV. 595, 606 (2007).

such as Article 25 of the United Declaration of Human Rights (UDHR), 1948, Articles 7, 11, and 12 of the International Covenant of Economical, Social and Cultural Rights (ICESCR), 1966, as well as the preamble of the WHO Constitution.[228] While noting the "misalignment between public health objectives and trade and [IP] protection," the *2016 Report of the United Nations High-Level Panel on Access to Medicines* goes on to recognize that access to medicines is a human right.[229]

Constitutions of several countries protect the right to life, of which health has been considered a sub-set.[230] Other countries, several of which are members of WHO and WTO, promise universal health care within their socialist structure. A study of the constitutions of several countries shows clear associations with right to life and health outcomes of citizens with a view to create a channel from health policy's benefits to the national economic productivity and well-being.[231] "More than half of the world's countries have some degree of a guaranteed, specific right to public health and medical care for their citizens written into their national constitutions."[232] Brennan et al., in a policy paper for the Global Health Justice Partnership, note that pursuing "human rights arguments in IP-related court cases at the national level" are most likely to provide "real results" for access.[233]

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[228] *See* G.A. Res. 217 (III) A, art. 25, Universal Declaration of Human Rights (Dec. 10 1948); G.A. Res. 2200A (XXI), arts. 7, 11–12, International Covenant on Economic, Social and Cultural Rights (Dec. 16, 1966); Constitution of the World Health Organization pmbl., July 22, 1946, 14 U.N.T.S. 185.

[229] UNITED NATIONS SECRETARY-GENERAL, *supra* note 207, at 21.

[230] *See* U.N., Econ. & Soc. Council, Note by the Sec'y Gen., UN Doc. CERD/C/SR.1119, https://digitallibrary.un.org/record/501357 (stating that in over fifty countries the right to health or health care is recognized as a Constitutional right and has been interpreted to be part of the right to life or an explicit part of right to health care).

[231] Hiroaki Matsuura, *Exploring the Association Between the Constitutional Right to Health and Reproductive Health Outcomes in 157 Countries*, 27 SEXUAL & REPROD. HEALTH MATTERS, 168, 175–78 (2019), https://doi.org/10.1080/26410397.2019.1599653; *see generally* Hiroaki Matsuura, *The Effect of a Constitutional Right to Health on Population Health in 157 Countries, 1970–2007: The Role of Democratic Governance* (Program on the Glob. Demography of Aging, Working Paper No. 106, 2013), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1288/2013/10/PGDA_WP_106.pdf.

[232] Mark Wheeler, *A Constitutional Right to Health Care: Many Countries Have It, but Not the U.S.*, SCIENCEDAILY (July 19, 2013), https://www.sciencedaily.com/releases/2013/07/130719104927.htm.

[233] Hannah Brennan et al., *A Human Rights Approach to Intellectual Property and Access to Medicines* 1, 11 (Glob. Health Just. P'ship, Policy Paper No. 1, 2013) (emphasis

About eighty-six countries, of which the United States is one, do not guarantee any constitutional health protection.[234] More studies may be needed to specifically show whether a constitutional right to health translates into better healthcare and, if so, by how much.

Another study of 194 countries outlined several indicators as forming constituents of the right to health.[235] These indicators included access to essential medicines or technologies statutorily recognized as a right and further concretized using a national policy on health.[236] Other indicators include price control regimes, access to health care facilities, access to health education, public per capita expenditure on medicines, availability of essential medications, and more.[237] As such, access and affordability are the two main components of healthcare. Most interestingly, a 2008 study by WHO found that constitutions conceived prior to 1948, the beginning of an international discourse on health rights, were unlikely to include the right to health.[238] Constitutions adopted within the last sixty years fared better at including more duties or entitlements to health.[239]

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omitted),
https://law.yale.edu/sites/default/files/area/center/ghjp/documents/humanrightsapproachintellectualproperty.pdf.

[234] Wheeler, s*upra* note 232.

[235] Gunilla Backman et al., *Health Systems and the Right to Health: An Assessment of 194 Countries*, 372 LANCET 2047, 2047 (2008) [hereinafter Backman et al., *Study*], https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)61781-X/fulltext; *see also* Katrina Perehudoff et al., *Access to Essential Medicines in National Constitutions*, 88 BULL WORLD HEALTH ORG. 800, 800 (2010) [*Access to Medicines*], https://doi.org/10.2471/BLT.10.078733.

[236] *Access to Medicines*, *supra* note 235, at 800.

[237] *See generally* Katrina Perehudoff et al., *Essential Medicines in National Constitutions: Progress Since 2008*, 18 HEALTH & HUM. RTS. J. 141, 141–56 (2016) [hereinafter *Progress Since 2008*], https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5070687; S. KATARINA PEREHUDOFF, HEALTH, ESSENTIIAL MEDICINES, HUMAN RIGHTS & NATIONAL CONSTITUTION 27, 29 (2008) [hereinafter PEREHUDOFF, HEALTH].

[238] *See* Hans Hogerzeil et al., *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?* 368 LANCET 305, 305 (2006), https://doi.org/10.1016/S0140-6736(06)69076-4.

[239] *Id.*; PEREHUDOFF, HEALTH, *supra* note 237, at 29.

Figure 1[240]

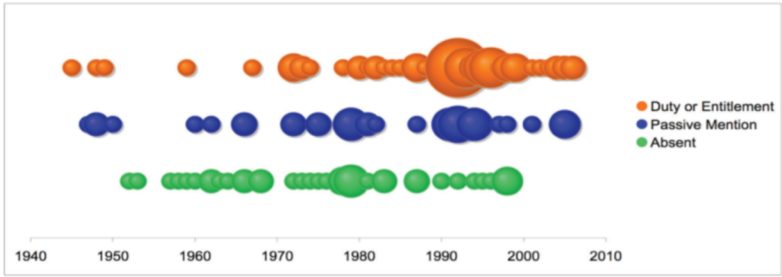

Figure 4-6.
Global level of constitutional commitment to health rights by date of constitutional adoption

Yet, important aspects showcase failures that resonate as public health issues. The gap caused by the disconnect between an ideologically posited forum and another based on realities on the ground has remained unbridged. For instance, documents on the right to health rarely discuss trade and lack of access from patent monopolies as barriers to health.

Amidst this, the inability by WTO to appreciate its own inbuilt flexibilities has been an important failure.[241] WTO eventually presided over a steady downgrading of public health as it simultaneously upgraded the role of private rights through patents.[242] Doing so, meant to encourage innovation and trade. Nevertheless, it resulted in IP rights being "transformed into an [important] barrier to" access medications on account of several factors including evergreening and/or the rapidly decreasing quality of patents.[243] WTO oversaw the transformation of a regulatory regime founded on shaky legal grounds into a powerhouse that created more private rights.[244]

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[240] PEREHUDOFF, HEALTH, *supra* note 237, at 27 fig.4-6.

[241] Srividhya Ragavan, *World Trade Organization: A Barrier to Global Public Health?* 23 (Texas A&M Univ. Sch. of L. Legal Stud. Rsch. Paper No. 20-32, 2020) [hereinafter *Barrier to Health*], https://dx.doi.org/10.2139/ssrn.3709643.

[242] *Id.* at 23–24.

[243] *Id.* at 32–33; *see also* Srividhya Ragavan, Make America Healthy: Reducing High Pharmaceutical Prices Without Reducing Innovation (Apr. 15, 2023) (unpublished manuscript) (on file at SSRN), http://dx.doi.org/10.2139/ssrn.4426658 (discussing how IP rights can create a barrier to accessing medication).

[244] *See Barrier to Health*, *supra* note 241, at 32–33.

Meanwhile, the diplomatic tango between WTO and WHO personifies the failure of both organizations. Mostly, it has manifested as the impotence of a multilateral international regime that allowed rich countries to unilaterally flex their muscles using trade as an excuse.[245] Several commentators have observed that the Special 301 process of the USTR in particular has been a principal source of concern regarding the threat of unilateral retaliation.[246] Going further, some have also argued that countries like the United States and China have weaponized the economic interdependence encouraged by WTO, causing vulnerabilities that, in the health context, have been exploited in the recent COVID pandemic to the Global South's detriment.[247]

The result of health diplomacy efforts has produced an endless stream of papers with no viable solutions presented to the globe to improve public health. Meanwhile, the world has been ravaged with a slew of issues that a diplomat, typically far removed from the electorate, never had to face—until COVID.

When the WHO director general declared COVID as a Public Health Emergency of International Concern (PHEIC) on January 30, 2020, there were 7,818 confirmed cases worldwide with only eighteen of these outside of China.[248] Within months, there were millions of confirmed cases across the world, and on March 11, 2020, WHO declared it to be a global pandemic.[249] The extremely virulent nature of the disease combined with lack of vaccines and treatment options resulted in COVID emerging as the most significant global health crisis since the 1918 influenza pandemic.[250] As it ravaged patient

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[245] *See id.* at 27.

[246] *See id.*

[247] *See, e.g.*, AMRITA NARLIKAR, HOLDING UP A MIRROR TO THE WORLD TRADE ORGANIZATION: LESSONS FROM THE COVID-19 PANDEMIC 2, 5–7, 9 (2021), https://doi.org/10.1525/gp.2021.24069; *see also* Henry Farrell & Abraham L. Newman, *Weaponized Interdependence: How Global Economic Networks Shape State Coercion*, 44 INT'L SEC. 42, 45, 57 (2019), https://doi.org/10.1162/isec_a_00351.

[248] *Archived: WHO Timeline - COVID-19*, WORLD HEALTH ORG. (Apr. 27, 2020), https://www.who.int/news/item/27-04-2020-who-timeline—covid-19.

[249] *Id.*

[250] Donald G. McNeil, Jr., *The Virus Can Be Stopped, But Only with Harsh Steps, Experts Say*, N.Y. TIMES, https://www.nytimes.com/2020/03/22/health/coronavirus-restrictions-us.html (Mar. 25, 2020); Jess McHugh, *How the 1918 Pandemic Changed America, from Women's Rights to Germaphobia*, THE WASH. POST (Nov. 13, 2022, 7:00 AM), https://www.washingtonpost.com/history/2022/11/13/1918-flu-pandemic-women-science.

populations and healthcare systems around the world, there was tremendous pressure for the creation of a vaccine as well as effective treatment options for the virus. Several countries in the world saw mass shortages of treatment-related material such as ventilators, personal protective equipment, and other crucial medical equipment.[251] With domestic as well as international trade and commerce severely disrupted by the virus, nations started seeing the rise of protectionist and hyper nationalistic politicize and politics.[252] Even as there were some calls for a more collectivist approach to tackling COVID,[253] the touted benefit of international trade (that is increased cooperation and interdependence between nations) was turned on its head as nations turned inwards instead, leaving other nations with dependencies hanging.[254] As fear and frustration grew, rich nations started stockpiling future supplies of vaccines.[255] A report by Oxfam International shows that in September 2020, wealthy nations representing just 13 percent of the world's population had struck deals for more than 51 percent of the promised doses of leading COVID vaccine candidates at the time.[256]

While there were many calls for actions and proposals for ways forward,[257] the unfolding of events at WTO are of specific interest for the purposes of this Article. In October 2020, India and South Africa issued a joint statement before WTO requesting the waiver of certain parts of the TRIPS Agreement "in relation to prevention,

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[251] *Id.*

[252] *See generally* Muhammad Zaheer Abbas, *Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19* 3, 5–6 (S. Ctr., Rsch. Paper No. 124, 2020), https://www.southcentre.int/wp-content/uploads/2020/11/RP-124.pdf.

[253] Divij Joshi, *COVID-19 Pandemic Spurs Calls for 'Openness' in IP*, SPICYIP (Mar. 31, 2020), https://spicyip.com/2020/03/covid-19-pandemic-spurs-calls-for-openness-in-ip.html.

[254] For instance, several countries started indulging in export bans of vaccine supplies and related material. *See* Praharsh Gaur, *A Recipe for Disaster: Export Bans, TRIPS Waiver and Hyper Nationalism*, SPICYIP (Apr. 25, 2021), https://spicyip.com/2021/04/a-recipe-of-disaster-export-bans-trips-waiver-and-hyper-nationalism.html.

[255] Kai Tabacek, *Small Group of Rich Nations Have Bought Up More than Half the Future Supply of Leading COVID-19 Vaccine Contenders*, OXFAM INT'L (Sept. 17, 2020), https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19.

[256] *Id.*

[257] *See, e.g.*, Sudip Chaudhuri, *Making Covid-19 Medical Products Affordable: Voluntary Patent Pool and TRIPS* Flexibilities 1–3, 6–7 (S. Ctr., Southviews No. 200, 2020).

containment[,] or treatment of COVID-19."[258] The stated purpose behind this waiver proposal was to ensure that IP rights would not be a barrier to access to affordable medicines, or research, development, manufacture, and supply of medical products essential to fighting COVID.[259] The proposal notes that several countries, especially in the developing world, are likely to face institutional barriers in utilizing the TRIPS flexibilities and that additionally, there were other related barriers such as regulatory exclusivities that prevented the efficient use of the existing flexibilities.[260] It also notes that the cumbersome processes for import and export of pharmaceutical goods under Article 31*bis* as problematic, especially for countries with limited or no local manufacturing capacity.[261]

The proposal brought about much debate and discussion across the world. While its proponents supported it as a necessary step towards ensuring equitable access to life-saving medicines and treatments, it was immediately opposed by a bloc of developed countries including the United States, Switzerland, Norway, Australia, Canada, Japan, Brazil, and the United Kingdom.[262] As the debate around the waiver intensified over the next several months, millions more continued to be claimed by the virus. Meanwhile, biopharmaceutical companies maintained a steady stance against the waiver, stating that supply constraints and technology transfer were the barriers, rather than patents, and that to weaken patents would "send[] the wrong signal."[263] Even in the arguendo that know-how and technology transfer were more important than patents and other forms of IP in tackling COVID-related issues, this form of opposition

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[258] Council for Trade-Related Aspects of Intell. Prop. Rts. [TRIPS Council], *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COIVD-19: Communication from India and South Africa*, ¶ 12, WTO Doc. IP/C/W/669 (Oct. 2, 2020).

[259] *Id.* ¶ 3.

[260] *Id.* ¶ 10.

[261] *Id.*; *see generally* TRIPS Agreement, *supra* note 6, art. 31*bis*.

[262] Thiru Balasubramaniam, *WTO TRIPS Council (October 2020): South Africa Issues Clarion Call Urging Support for TRIPS Waiver Proposal*, KNOWLEDGE ECOLOGY INT'L (Oct. 16, 2020), https://www.keionline.org/34235.

[263] Press Release, Int'l Fed'n of Pharm. Mfrs. & Ass'ns, IFPMA Statement on TRIPS Discussion Document (Mar. 16, 2022), https://www.ifpma.org/resource-centre/statement-ifpma-trips-discussion-document; *see also* Press Release, Pharm. Rsch. & Mfg. of Am., PhRMA Statement on WTO TRIPS Waiver Negotiations (Mar. 15, 2022), https://phrma.org/resource-center/Topics/Intellectual-Property/PhRMA-Statement-on-WTO-TRIPS-Waiver-Negotiations.

remained unrealistic considering that biopharmaceutical companies had the most ability to share know-how and commit to technology transfer.

In any event, the argument that it would send a "wrong signal" about weakening patents seemed a weak reason to oppose the waiver. This is especially true considering the several billions of dollars of public money received in the various vaccines' development process, the recoupment of which is generally considered the purpose of a patent.[264]

More than 1.5 years later, as of the time of writing this Article, the waiver is still being discussed and debated at WTO as well as by various proponents and opponents across the world.[265] Some also pointed out that, regardless of the waiver, nations should be pursuing the practice of various flexibilities already offered through TRIPS.[266] Though the United States has since changed its stance on the waiver (supporting the waiver to the extent of COVID vaccines),[267] other wealthy nations like the EU, the United Kingdom, and Switzerland continued to

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[264] For example, AstraZeneca's vaccine was developed at Oxford University with more than 90 percent public funding, the US government contributed $18 billion to Operation Warp Speed, and Moderna was funded by US taxpayers, etc. *See, e.g.*, Michael Safi, *Oxford/AstraZeneca Covid Vaccine Research 'Was 97% Publicly Funded,'* THE GUARDIAN (Apr. 15, 2021), https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded; *see also* Adyasha Samal, *COVID-19 Vaccines: Patent Ownership and the Barriers to Equitable Access*, SPICYIP (Dec. 2, 2020), https://spicyip.com/2020/12/covid-19-vaccines-patent-ownership-and-the-barriers-to-equitable-access.html (discussing ownership of patents, related public funding, and vaccine realities for the global south).

[265] Brook Baker, *Bad Faith from Big Pharma, Rich Countries and the WTO Poison WTO TRIPS Waiver Negotiations*, HEALTH GAP (June 14, 2022), https://healthgap.org/bad-faith-from-big-pharma-rich-countries-and-the-wto-poison-wto-trips-waiver-negotiations (demonstrating similar arguments for the waiver); *see also* Brook Baker, *TRIPS-Compliant Alternatives for Overcoming Intellectual Property Barriers to COVID-19 Countermeasures*, INFOJUSTICE (July 1, 2022), http://infojustice.org/archives/44766; James Love, *The Quad WTO Proposal on COVID 19 and TRIPS Proposal Is Tied for the 5th Best Option for Exports*, MEDIUM (Mar. 20, 2022), https://jamie-love.medium.com/the-quad-wto-proposal-on-covid-19-and-trips-proposal-is-tied-for-the-5th-best-option-for-exports-dd8f165efdee.

[266] *See* Prashant Reddy, *The Need for an IP Policy to Build a Strategic Stockpile for Pandemics*, SPICYIP (Mar. 26, 2020), https://spicyip.com/2020/03/the-need-for-an-ip-policy-to-build-a-strategic-stockpile-for-pandemics.html.

[267] *See* Press Release, Off. of the U.S. Trade Representative, Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.

oppose the waiver.[268] In the meantime, however, through various rounds of negotiations—including a closed-door quadrilateral discussion group (EU, India, South Africa, and the United States)—the proposal has morphed into a very different form from its original ask with many similarities to an alternative text presented by the EU that had been originally criticized as bringing nothing new to the table.[269] The alternative text removed medical tools, like therapeutics and diagnostics, from its scope and narrowed the waiver to merely address patent barriers on COVID vaccines.[270] At the time of writing, India alleged at the Twelfth WTO Ministerial Conference that the developed world was engaged in tactics with the waiver proposal while diluting it and simultaneously attempting to show faux concern.[271] It remains to be seen how or whether WTO will assist in providing any useful solutions to the COVID pandemic, whether it be through this waiver or any other method.

Meanwhile, the current state of global health causes this Article to assert that trade cannot be an excuse for any country, but especially lower income countries, to compromise their public health initiatives. Public health is a national objective for every member and cannot be sacrificed at the altar of selective international obligations. The trade regime represents an opportunity for the developing world to metamorphose into innovators.[272] But, encouraging research cannot be at the cost of human lives, the saving of which should be the very objective of the research. Thus, the *public health, the public good, or the public benefit doctrine* should be treated as a limitation to IP rights—

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[268] Peoples Health Dispatch, *People's Movements, Trade Unions, and Left Parties Join Hands Demanding TRIPS Waiver on COVID-19 Medical Products*, PEOPLES DISPATCH (Dec. 1, 2021), https://peoplesdispatch.org/2021/12/01/peoples-movements-trade-unions-and-left-parties-join-hands-demanding-trips-waiver-on-covid-19-medical-products.

[269] MSF ACCESS CAMPAIGN, MÉDECINS SANS FRONTIÈRES (MSF) ANALYSIS OF COMMUNICATIONS FROM THE EUROPEAN UNION TO THE COUNCIL FOR TRIPS 1–5 (2021), https://msfaccess.org/sites/default/files/2021-06/COVID19_TechnicalBrief_MSF_EU-counterproposal-analysis_WTO-TRIPS-Waiver_update_20210624_ENG.pdf.

[270] *Id.*

[271] Press Release, Press Info. Bureau Delhi, Statement by Shri Piyush Goyal During the WTO 12th Ministerial Conference at the Meeting with Co-Sponsors of TRIPS Waiver (June 14, 2022, 10:44 PM), https://pib.gov.in/PressReleasePage.aspx?PRID=1834066.

[272] *See* Abbott, *supra* note 172, at 325.

particularly patents.[273] The following discussion outlines a nonexhaustive list of solutions, which—like the trade and IP nexus—are not infallible. This Article, however, presents these options to showcase the breadth of flexibilities that countries can work and favor a public health treaty presenting some or all of these models for countries to promote innovation while protecting global public health.

In asserting that the historical structure should be revisited to create global health equity, this Article endorses the view that there is a need for a broader public health treaty. In reimagining a new global framework, any such treaty should result from an impartial and careful examination of the ongoing multilateral processes at the global level to identify the strengths and weaknesses of the various efforts to better address future pandemics and related issues of global public health. The goal should be to include policy proposals that may result in transparent, inclusive, and holistic approaches to managing public health broadly. Such an approach would require identifying and developing a greater understanding of the obstacles for competing international entities to work effectively together. The challenge to such an approach is to create cooperative and flexible frameworks for sovereign nations to institute safeguards, preserving public health locally as a means to improving global public health. Contrary to the existing rubric, this framework accounts for local realities to deal with public health and to sustain optimal productivity along with optimal innovation. Such a framework goes against the conventional wisdom and instead should seek to create a multilateral framework within which public health can and should work in a symbiotic fashion. In doing so, the hope is to create a framework for coexistential multilateralism. The underlying theme would be that robust public health in all parts of the globe is seen as a prerequisite rather than a negotiable trading chip vis-à-vis international trade. For this, examining the causes that impact local public health and its effect on global trade will help create a framework that takes into account existing literature on a public health treaty, patent pledge, and other impactful international law materials. Knowledge and expertise about local realities are critical to providing sound, practical suggestions as opposed to theoretical frameworks that are disconnected from local realities.

The concept of differential pricing allows for the pricing of pharmaceuticals at a lower price in a manner commensurate with

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[273] *See generally* Murthy, *supra* note 167, at 1327–31 (deciphering the definition of the term "public health").

either the per capita income of the nation, or alternatively, based on the affordability of the patient population.[274] It allows pharmaceutical companies to maintain a system that can be mutually beneficial to the patient and patent owner in that, while patients benefit from access to medication, the patent owner can benefit directly from an increased volume of sales.[275] The rhetoric of recouping the cost of innovation can be worked through volume sales as well as sales to different markets either directly or through a transfer of technology at a negotiated price. Other authors have asserted maintaining a higher cost in richer markets alone will help recover research expenditures.[276]

Different economic models have considered optimal differentiated pricing models. The Ramsey pricing model, for instance, requires that the minimum price should be equal to or very close to the marginal cost in elastic markets, such as those of developing nations.[277] The biggest benefit of Ramsey pricing is the notion that it is consistent with the criterion of economic efficiency and standard norms of equity while being beneficial to the trade regime.[278] Another model suggests that pricing in a developing country should account for the cost of research but discount the extent of public funding and other overheads such as marketing.[279] Typically, the cost of advertisements and marketing activities are also added into the price of pharmaceuticals although much of that is presented mostly to consumers in richer nations. Hence, discounting for such expenses will bring down the cost in developing countries.

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[274] Heinz Redwood, Presentation at World Health Organization-World Trade Organization Workshop: Advantages and Risks of Differential Pricing for Prescription Drugs 1, 3 (Apr. 9, 2001), http://www.wto.org/English/tratop_e/trips_e/hosbjor_presentations_e/14redwood_e.doc; *see also* Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 200–02 (2003) (highlighting that perhaps differential pricing is better than compulsory licensing).

[275] *See* Redwood, *supra* note 274, at 3; Danzon & Towse, *supra* note 274, at 200–02.

[276] *See* Helene Bank, *Differential Pricing and Politics of Health Development*, TWN THIRD WORLD NETWORK BERHAD (Apr. 25, 2001), https://www.twn.my/title/politics.htm.

[277] David W. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501, 531 (2005); *see also* Danzon & Towse, *supra* note 274, at 184 (asserting that drugs marketed in developed countries should be differentially priced in poorer nations to reconcile patents with affordability).

[278] Danzon & Towse, *supra* note 274, at 201 ("[Ramsey pricing] is consistent with the criterion of economic efficiency . . . [and] with standard norms of equity.").

[279] *See* Danzon & Towse, *supra* note 274, at 184.

The suggestion to differentially price medications and deal with parallel imports specifically should be considered. The video and computer industries serve as great examples to prove that the reimportation of spurious products can be curtailed without resorting to deprivation. Software companies such as IBM, Texas Instruments, Microsoft, and Intel have done well by embracing markets such as India and have benefitted from the talent capital. This has helped tap mutually beneficial synergies and competitive potentials.[280] The consequential explosion of talent helped develop the local software industry, which in turn encouraged the government to model legal norms in a manner that promoted this local capacity to innovate.[281]

One of the main objections against differentially pricing pharmaceuticals is a fear of parallel importation, which occurs when lower-priced drugs from low per-capita income markets find their way into rich-country markets where the same commodity is priced higher.[282] The fear is that exporters in markets that benefit from low-price pharmaceuticals can export to richer nations, causing the same drug to be sold at two prices which will eventually bring down the prices in rich-country markets. Arguably, the fear of parallel importation is exaggerated, considering that countries such as India and Brazil have manufactured generic versions of medications for more than a decade without exporting them to the west.[283] But, the high healthcare costs have resulted in the United States having to deal

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[280] *Piracy Still Prevalent in India*, TRIB. NEWS SERV. (July 1, 2002), https://m.tribuneindia.com/2002/20020701/login/main11.htm ("Independent Software [Vendors] (ISVs) like Microsoft, Oracle, [and] Adobe . . . fight individually as well as through industry alliances such as the BSA & NASSCOM, to combat the problem of piracy."); *see also* RAGAVAN, PATENT AND TRADE DISPARITIES, *supra* note 1, at 192 n.150 ("[I]ndependent Software Vendors (ISVs) such as Microsoft, Oracle and Adobe are fighting individually, as well as through industry alliances such as NASSCOM, to combat piracy.").

[281] *See generally Alternate Strategies to Prevent Software Piracy- Zero Piracy Without Pain*, NAAVI.ORG., (June 21, 2001), https://www.naavi.org/cl_editorial/edit_15jun_01_1.html. NASSCOM is the National Association of Software and Services Companies in India, representing the voice of the Indian software industry. *About Us*, NASSCOM, https://nasscom.in/about-us (last visited Oct. 7, 2023).

[282] *See Karnataka to Become a Zero Piracy State*, NAAVI.ORG (Jan. 8, 2001), https://www.naavi.org/cl_editorial/edit_08jan01_1.html; Lana Kraus, *Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry*, 37 VAND. J. TRANSNAT'L L. 527, 542 (2004).

[283] *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 201 (2005).

with imported medications from Mexico and Canada.[284] The idea of a separate public health treaty should be considered alongside obligations imposed on national governments to ensure that discounted pharmaceutical products stay in the market for which they are intended.[285]

Second, member nations will also benefit from creating a separate model for government-funded healthcare innovations. The fact is, many of the innovator pharmaceutical companies benefit from public government funding as it is. The decrying of investments has not traditionally accounted for nor discounted this reality. Whether public-funded research should be susceptible to private property rights is a question that the public health treaty should address or have countries address separately. After all, the basis of providing patent rights is to incentivize research and investment. If the public will invest in the research, creating rights that make the outcome privileged and inaccessible to the public makes very little sense. In the United States, the question of whether public-funded research should benefit from patent protection was raised even before COVID.

Considering that what falls within the public domain cannot be protected by IP rights, it makes limited sense to argue that what is funded essentially using public funds should be protected by private rights.

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[284] *See* Simon R. Rabinovitch, *On the Legitimacy of Cross-Border Pharmacy*, 43 ALBERTA L. REV. 327, 343, 345 (2005), https://doi.org/10.29173/alr1255.

[285] Markus Nolff, *Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health and the Decision of the WTO Regarding Its Implementation: An "Expeditious Solution"?*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 291, 307 (2004).

Figure 2: US Federal Subsidies or Contracts to COVID Vaccine Supply Chain (2020-2021)[286]

S. No	Vaccine Sponsor	Amount
1.	Johnson & Johnson	$2 billion
2.	Sanofi and GSK	$2.35 billion
3.	Merck and IAVI	$38 million
4.	Moderna	$5.35 billion
5.	Novavax	$2.1 billion
6.	Pfizer (BioNTech)	$5.95 billion
7.	AstraZeneca (Oxford)	$1.6 billion

Third, a medley of viable solutions that focus on reform of the patent system's interaction with public health have been offered by different commentators and authors. Economist Jean Lanjouw, for example, suggests an inventor of a patent from a developed nation should relinquish the right to sue for infringement in certain markets for technologies involving essential life-saving diseases.[287] This would be the same as a waiver.

Other commentators, such as David W. Opderbeck, prefer a game theory approach based on the elasticity of demand in the developing and the developed world.[288] The game theory solution asserts that demand for pharmaceuticals in the developed world is inelastic because a change in price does not affect demand.[289] But because demand for medications is highly elastic in the developing world, notwithstanding the level of patent protection, it is unlikely to stimulate research on diseases unique to such nations.[290] Consequently, decreasing the level of patent protection in developing countries is unlikely to affect the equilibrium of the innovation

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[286] Chad P. Brown & Thomas J. Bollyky, *Here's How to Get Billions of COVID-19 Vaccine Doses to the World*, PETERSON INST. FOR INT'L ECON.: TRADE & INV. POL'Y WATCH (Mar. 18, 2021, 12:00 PM), https://www.piie.com/blogs/trade-and-investment-policy-watch/heres-how-get-billions-covid-19-vaccine-doses-world#:~:text=One%20way%20to%20accomplish%20this,chain%20under%20Operation%20Warp%20Speed.

[287] Jean O. Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J.L. & TECH. 85, 93 (2002).

[288] Opderbeck, *supra* note 277, at 534.

[289] *Id.* at 502–03.

[290] *Id.*

game.[291] Basically, pharmaceutical companies will continue to derive the same amount of monopoly rents from the developed countries and thus should be in a position to continue current levels of investment for research.[292]

The idea of patent pledge originally proposed by Jorge L. Contreras et al. identify specific concerns that are likely to arise in the acquisition of IP rights.[293] This Article proposes the formation of "research commons" that will permit research institutions, both public and private, to share and act as a repository of research data.[294] The research commons would undertake and pledge any patents or trade secrets to minimize unnecessary barriers to R&D, facilitating safe and effective use of the technologies. Although the discussion has focused on solar climate engineering and FRAND licenses, such patent pledges can be easily replicated for biotechnology and biomedical research.[295] It can also form an integral and sustainable part of a public health treaty, should that be negotiated for a better global public health. Indeed, some of the benefits and issues from using such a patent pool have been analyzed in relation to the promotion of green and clean technologies called the Eco-Patent Commons (EcoPC).[296] The authors analyzed technology diffusion's impact, its advantages, and the issues that caused its demise in 2016.[297]

Other suggestions include incorporating incentives such as subsidies to stimulate research in technologies where demand is highly elastic—that is, on diseases unique to developing nations.[298] Researchers have also called for more transparency in the operations of pharmaceutical companies, as they have been notoriously opaque with regards to their R&D investments even while decrying the high

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[291] *Id.* at 553.

[292] *Id.* at 554.

[293] Jesse Reynolds et al., *Solar Climate Engineering and Intellectual Property: Toward a Research Commons*, 18 MINN. J.L. SCI. & TECH. 1, 1–2 (2017).

[294] *Id.*

[295] *See* Jorge L. Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, 2
UTAH L. REV. 479, 479 (2015).

[296] *See* Jorge L. Contreras et al., *Pledging Patents for the Public Good: Rise and Fall of the Eco-Patent Commons*, 57 HOUS. L. REV. 61, 61–62 (2019).

[297] *Id.*

[298] *See* Danzon & Towse, *supra* note 274, at 184 (asserting that external subsidies can be used to fund the research for drugs that cater to purely developing-country diseases).

costs they need to recuperate through patent protection.[299] Others have also pointed to requiring more transparency in the working of the patent in developing countries, as a method of determining whether multinational pharmaceutical companies were merely filing patents without actually servicing the patient population that required those patented medicines.[300] While scholars have also proposed a number of alternative pharmaceutical innovation mechanisms, external to the IP system,[301] this Article does not explore them as their intersections with innovation and public health go well beyond its scope.

Although patents form a part of the balance for the pharmaceutical industry's future research agenda, the perspective that, ultimately, research is meant to benefit humanity and not just richer sections of society.[302]

CONCLUSION

The ever-expanding IP norms in trade agreements without a corresponding emphasis on flexibility have left us with an imbalanced and distorted regime. Countries that may have otherwise been reluctant to incorporate TRIPS-Plus standards are being offered other trade-related trade-offs, such as preferential access to developed markets. Meanwhile, concerted efforts by various institutions, policy makers, and civil society actors have led to a change in the "framing" of IP: shifting it from "trade" to "public health," "human rights," "post colonialism," "access to knowledge," and "users rights" frameworks.[303] Countries that have incorporated flexibilities often do so using these

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[299] Nora Frazen, et al., *Affordable Prices Without Threatening the Oncological R&D Pipeline—An Economic Experiment on Transparency in Price Negotiations*, 2 CANCER RSCH. COMMC'NS. 49, 49 (2022), https://doi.org/10.1158/2767-9764.CRC-21-0031; *see also* Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 34 (2011).

[300] *See* SHAMNAD BASHEER & RUPALI SAMUEL, SPICYIP, BAYER'S NEXAVAR AND THE "WORKING" OF COMPULSORY LICENSING: MIND THE PATENT (INFORMATION) GAP! 15–16 (2015), https://spicyip.com/wp-content/uploads/2015/04/Report-on-Bayer-for-writ-Finalized.pdf.

[301] *See, e.g.*, Michael Abramowicz, *Prize and Reward Alternatives to Intellectual Property*, *in* 1 RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW 350, 351 (Ben Depoorter & Peter S. Menell eds., 2019).

[302] *See* Peggy B. Sherman & Ellwood F. Oakley III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 404 (2004), https://doi.org/10.1111/j.1744-1714.2004.04102004.x.

[303] *See* Kapcyznski, *supra* note 100, at 821–24.

frameworks and point to TRIPS compliance for legitimacy. This has turned the perception of TRIPS from being one of primarily upward harmonization to being a tool for maintaining policy space in the IP realm. While different parties have strongly advocated their diverse perspectives, there is yet to be a systematic assessment of IP in this fast-changing world.[304]

Nevertheless, the "trade" framing of IP has secured an indomitable grip through the various FTAs, while very few notable norm changes have actually taken place in the context of other frames.[305] Meanwhile, unauthorized unilateral mechanisms like the Special 301 process of the USTR, ongoing since 1989, continue to exert pressure in the form of trade sanctions or removal of subsidies against countries identified as not maintaining a domestic IP regime that does not benefit US IP rightsholders, even when it is harmful to that country's domestic needs.[306]

There does seem to be one situation that has very effectively been throwing a spanner in the works for the "trade" juggernaut—the situation which could be described as a "black swan" public health event. Indeed, such events have been able to pause and even stop the expansion of not just IP but also trade. One example is the anthrax situation, which caused the United States to focus on its own public health concerns, thereby destroying the credibility of its stance against compulsory licensing.[307] Another example is the HIV/AIDS epidemic, which, after being ignored for too long, ultimately resulted in some sense of normalization of patent flexibilities. Finally, the globe's unprecedented social and economic disruption from the COVID pandemic gives a reason to pause. Even the United States is finding that both trade and IP are ultimately subject to the mercy of public health. Public health has naturally regained its uncontested position as a priority, with several calls for open innovation, sharing of

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[304] *See* Rochelle Dreyfuss, *The Challenges Facing IP systems: Researching for the Future, in* 4 Kritika: Essays on Intellectual Property 1, 2–3 (Peter Drahos et al. eds., 2020); Mark A. Lemley, *IP in a World Without Scarcity*, 90 N.Y.U. L. Rev. 460, 460 (2015).

[305] A notable exception is the WIPO administered Marrakesh Treaty for the Print Disabled. Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled, June 27, 2013, 52 I.L.M. 1312.

[306] *See* Suzanne Zhou, *Challenging the Use of Special 301 Against Measures Promoting Access to Medicines: Options Under the WTO Agreements*, 19 J. INT'L ECON. L. 51, 51, 58, 70–71 (2016).

[307] Murthy, *supra* note 167, at 1315.

resources, and government procurements for medical treatment.[308] Both wealthy and impoverished countries alike are keeping themselves open to the possibility of sharing IP and related technologies.[309] The world will be a different one as humanity recovers from this crisis and moves forward.

The COVID pandemic will not be the last global public health crisis that the world faces, and it has already destroyed the narrative that strong IP is a must for international trade—if anything, robust public health promoted by a balanced IP regime is *the* must for trade.

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[308] *See, e.g.*, Linus Dahlander & Martin Wallin, *Why Now Is the Time for "Open Innovation,"* Harv. Bus. Rev., June 5, 2020, at 1, https://hbr.org/2020/06/why-now-is-the-time-for-open-innovation; *see also Health and Public Procurement*, OECD, https://www.oecd.org/gov/public-procurement/health (last visited Oct. 6, 2023).

[309] Swaraj Paul Barooah, *Patent Politics in the Time of Corona*, SPICYIP (Mar. 13, 2020), https://spicyip.com/2020/03/patent-politics-in-the-time-of-corona.html.