THE WHOLE IS GREATER THAN THE SUM OF ITS PARTS: A HOLISTIC APPROACH TO TRIPS

*Kimberly A. Bagdis**

The onset of the COVID-19 pandemic wreaked havoc on the international community, interrupting supply chains and resulting in the unchecked spread of disease across the globe. Desperate to stop the devastating loss of life that followed, most countries took an every-country-for-itself approach to combatting the pandemic, which led to limited and fragmented access to health-saving technologies. The international community needs to ensure broader access to medical and health-related technologies, such as personal protective equipment, contact tracing software, and therapeutics, that can be used to combat a pandemic and slow the spread of a life-threatening disease. In a petition to the Council for TRIPS, South Africa and India urged adoption of a broad waiver of several articles of TRIPS, including those providing protections for copyrights, industrial designs, trade secrets, and patents. This waiver is intended to alleviate the barrier that enforcement of intellectual property rights imposes on access to medicines and other health-related technologies, particularly for least developed countries. Such a blanket waiver, however, is unnecessary because the current TRIPS flexibilities already provide countries with avenues to access protected technology in times of public health emergencies.

The WTO should take a more holistic approach to TRIPS flexibilities, particularly when countries are faced with a global health crisis. Article 31*bis* of TRIPS provides for compulsory licenses to be used during national health crises. Although Article 31*bis* is located within the section of TRIPS focused on patent protection, other articles in other sections also reference compulsory licenses. This and other flexibilities already provide countries with a legal means to access health-related technologies protected by patents, copyrights, industrial designs, and trade secrets, among other areas. Without waiving intellectual property protections in these areas, countries can use the current TRIPS flexibilities to promote access not only to medicines but also to other technologies and devices used to prevent the spread of a pandemic. By taking a holistic approach to TRIPS, countries can use to the fullest extent possible the flexibilities already written into the agreement to promote widespread access to health-related technologies in times of global or national health crises.

* J.D. Candidate, Temple University Beasley School of Law, 2022; B.A., Theatre Arts, Dickinson College, 2010. My sincere gratitude goes to my advisor, Dean Donald Harris, for his insightful guidance and support in helping me shape this comment. My appreciation goes to the diligent TICLJ team for their efforts in helping this article reach its final form. I also thank my family for their love, support, and encouragement—always.

TABLE OF CONTENTS

I. INTRODUCTION

In the wake of the COVID-19 pandemic, countries all across the world have been struggling to protect the health of their people. The infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), more commonly known as COVID-19, has taken millions of lives worldwide and inflicted substantial damage on the world's economy.[1] In the early stages of this pandemic, many countries closed their borders, ignoring global trade and turning their attention inward to prioritize the health and safety of their own citizens.[2] This approach resulted in supply chains and manufacturing capacities being pushed to—and in some cases past—their limits.[3] Many countries declared national emergencies in an

1. MARCO HAFNER ET AL., RAND EUROPE, COVID-19 AND THE COST OF VACCINE NATIONALISM 1 (2020), https://www.rand.org/content/dam/rand/pubs/research_reports/RRA700/RRA769-1/RAND_RRA769-1.pdf.

2. *See Frequently Asked Questions: The WTO and COVID-19*, WTO, https://www.wto.org/english/tratop_e/covid19_e/faqcovid19_e.htm (last visited Feb. 12, 2021) (addressing concerns over countries imposing trade restrictions and bans on medical exports in wake of COVID-19).

3. *See, e.g.*, Susan Helper & Evan Soltas, *Why the Pandemic has Disrupted Supply Chains*,

effort to stop the spread of the disease.[4] Because each country has sought to ensure the safety of its own people first, concerns for efficiency and shared resources have gone ignored.[5] The somber result has been loss of life on a massive scale in every country across the globe.[6]

Global trade foundered on this initial isolationism and persistent nationalism. The COVID-19 pandemic "fragmented global supply chains, torpedoed world travel and sparked international arguments over exports of medical equipment."[7] The first half of 2020 alone saw a fourteen percent decline in world trade from the previous year.[8] Yet, even as global trade declined,[9] demand skyrocketed for medical products and health-related goods, especially those "considered critical in the COVID-19 pandemic, such as disinfectants, face masks, gloves, hand sanitizer, pulse oximeters, syringes, thermometers and ventilators."[10] Most of these products, like vaccines, are protected by patents, copyrights, or other intellectual property rights.

Intellectual property has played a pivotal role in efforts to combat COVID-19.[11] The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) is one of the major treaties of the World Trade Organization (WTO).[12] As a major WTO treaty, all WTO members states are required to follow its provisions as part of their membership in the WTO.[13] As such, TRIPS sets the international standard for protection and enforcement of intellectual property rights. TRIPS can provide the

---

WHITE HOUSE (June 17, 2021), https://www.whitehouse.gov/cea/blog/2021/06/17/why-the-pandemic-has-disrupted-supply-chains/ (describing disruptive effects of COVID-19 pandemic on supply chains in automobile, construction, and manufacturing industries).

4. *See* Council for Trade-Related Aspects of Intell. Prop. Rts., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669, at 1 (Oct. 2, 2020) [hereinafter Communication from India and South Africa] (describing impact of COVID-19 on WTO members).

5. See *Frequently Asked Questions: The WTO and COVID-19*, *supra* note 2 (describing interdependency of countries on each other and on international trade for medical products and medicines).

6. *See WHO Coronavirus Disease (COVID-19) Dashboard*, WHO, https://covid19.who.int (last updated Mar. 29, 2021, 10:32 AM) (showing global count of COVID-19 cases and deaths).

7. Alexander Smith, *Wave of "Vaccine Nationalism" Hinders Global Efforts to Halt Coronavirus*, NBC (May 16, 2020), https://www.nbcnews.com/news/world/wave-vaccine-nationalism-hinders-global-efforts-halt-coronavirus-n1207846 [hereinafter Smith, *Vaccine Nationalism*].

8. *WTO Updates Report on Trade in Medical Goods in the Context of COVID-19*, WTO (Dec. 22, 2020), https://www.wto.org/english/news_e/news20_e/covid_22dec20_e.htm.

9. *See, e.g.*, *Least Developed Countries Hit Hard by Trade Downturn Triggered by COVID-19 Pandemic*, WTO (Nov. 11, 2020), https://www.wto.org/english/news_e/news20_e/devel_11nov20_e.htm (describing decline of exports from least developed countries).

10. *WTO Updates Report on Trade in Medical Goods in the Context of COVID-19*, *supra* note 8.

11. *See New WTO Report Looks at the Global Intellectual Property System and COVID-19*, WTO (Oct. 15, 2020), https://www.wto.org/english/news_e/news20_e/trip_15oct20_e.htm (describing role of intellectual property in efforts to curb COVID-19).

12. DANIEL C.K. CHOW & THOMAS J. SCHOENBAUM, INTERNATIONAL BUSINESS TRANSACTIONS: PROBLEMS, CASES, AND MATERIALS 553 (3d ed. 2015).

13. *Id.*

"framework in which much-needed innovation in relation to COVID-19 can be encouraged, shared and disseminated."[14] This framework, however, will be most effective if its provisions are viewed as a whole. Such a view can better keep an eye toward ensuring the promotion of global health and international cooperation. Conversely, viewing the articles of TRIPS in a piecemeal fashion focuses too much on protecting the rigid enforcement of intellectual property rights and encourages national isolationism.

In the pandemic's early stages, increased demand for health-related technologies—such as personal protective equipment—caused shortages and hampered countries' efforts to combat the spread of COVID-19.[15] As the pandemic continued, trade in these health-related goods slowly increased in an attempt to meet the surging demand.[16] Yet, as COVID-19 continues to cross borders "without regard for national boundaries or identities," the global response still remains mired in a "tide of nationalism."[17] From the early stages of the hunt for a viable vaccine, to ongoing efforts to distribute those vaccines worldwide, attempts to promote cross-border cooperation have struggled in the face of "vaccine nationalism."[18] The World Health Organization (WHO) has repeatedly called on developed countries to hold off on giving booster shots to their people who have already been vaccinated, as many developing countries remain without access to sufficient supplies to even partially vaccinate a fraction of their own people.[19] Because of this disparate access, developing countries tend to be disproportionately impacted by global pandemics.[20]

Even with countries' persistent nationalism, the resulting loss of life from this global pandemic might have been avoided, or at least mitigated, had the scope of TRIPS flexibilities been better defined and widely understood.[21] Due to pressure from developed countries and multinational enterprises, TRIPS flexibilities—like those that allow for compulsory licensing of patents for drugs and medicines—have not been applied to their fullest extent.[22] If these flexibilities were applied broadly, developing and least developed countries could more readily access the protected intellectual property that would enable them to better combat global crises, like

14. *New WTO Report Looks at the Global Intellectual Property System and COVID-19*, *supra* note 11.

15. *See* Communication from India and South Africa, *supra* note 4, at 1 (describing effect of shortages of medical products in wake of increased demand).

16. *See WTO Updates Report on Trade in Medical Goods in the Context of COVID-19*, *supra* note 8 (noting global trade in health-related products grew 29% trying to meet skyrocketing demand for goods critical to fight COVID-19 pandemic).

17. Smith, *Vaccine Nationalism*, *supra* note 7.

18. *Id.*

19. Robert Towey, *Giving Covid Booster Shots to Healthy People is 'Not Right,' WHO Says in Plea to Wealthy Nations*, NBC (Sept. 14, 2021), https://www.cnbc.com/2021/09/14/giving-covid-booster-shots-to-healthy-people-is-not-right-who-says.html.

20. Communication from India and South Africa, *supra* note 4, at 1; *see also WHO Coronavirus Disease (COVID-19) Dashboard*, *supra* note 6 (showing disparate impact of COVID-19 across globe).

21. See *infra* Part III for a discussion of how expanded use of TRIPS flexibilities may have mitigated effects of COVID-19 pandemic.

22. Communication from India and South Africa, *supra* note 4, at 2.

COVID-19.

The WTO should take a more holistic approach to TRIPS flexibilities, particularly when countries are faced with a global health crisis. A holistic approach views the whole of an entity, treating its parts as intrinsically linked with the whole, rather than treating each part separately.[23] Further, "[i]nternational cooperation and coordination are crucial" if the world is to "leave this devastating pandemic behind"[24] and if countries are to learn from past mistakes.

In light of the twin aims of interpreting TRIPS holistically and of recognizing the need for international cooperation—especially in the wake of COVID-19—TRIPS flexibilities should be reexamined in this spirit of international cooperation. Interpretation of TRIPS flexibilities should be expanded beyond compulsory licenses of patents for access to medicines. A broader interpretation would allow countries to access other health-related areas of intellectual property, such as copyrights and industrial designs for medical and health-related technology like contact tracing software and diagnostic kits. Because intellectual property has taken on such a key role at the forefront of efforts to combat the COVID-19 pandemic,[25] such expansive interpretation is not only necessary but also justified by pressing public health needs.

This Comment examines whether the current pandemic necessitates adopting a broader interpretation of TRIPS flexibilities that encompasses areas of intellectual property other than its most common use—patents for medicines—to provide for a more comprehensive application that extends these flexibilities to other health-related technologies.[26] This Comment will begin by examining the creation of TRIPS and its evolution over the years as well as the purposes behind the agreement. This Comment will consider reasons against expanding TRIPS, such as the contention that relaxing protections of intellectual property rights will severely disincentivize innovation.[27] This Comment will also address arguments for expanding TRIPS, such as the contention that keeping stringent protections of intellectual property rights hampers access to medical technologies needed to combat public health crises. Finally, this Comment will combine elements from arguments on both sides of the debate to advocate a blended approach that works

---

23. "Holistic" is defined as "[c]haracterized by comprehension of the parts of something as intimately interconnected and explicable only by reference to the whole." *Holistic*, OXFORD, https://www.lexico.com/en/definition/holistic (last visited Mar. 10, 2021).

24. *WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines*, WTO (Dec. 9, 2020), https://www.wto.org/english/news_e/news20_e/trip_09dec20_e.htm.

25. *See, e.g.*, *WTO Members Stress Role of IP System in Fighting COVID-19*, WTO (July 30, 2020), https://www.wto.org/english/news_e/news20_e/trip_30jul20_e.htm (describing importance of intellectual property in wake of COVID-19).

26. *See, e.g.*, Council for Trade-Related Aspects of Intell. Prop. Rts., *Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to TRIPS Flexibilities*, WTO Doc. IP/C/W/666 at 1 (July 17, 2020) [hereinafter Communication from South Africa] (advocating for an "integrated approach" to using TRIPS flexibilities in light of COVID-19 pandemic).

27. *See, e.g.*, *WTO Members Stress Role of IP System in Fighting COVID-19*, *supra* note 25 (describing arguments against expanding TRIPS flexibilities).

within the current framework of existing TRIPS flexibilities. This blended approach will apply a holistic view to TRIPS that promotes public health goals without needlessly sacrificing incentives for innovation.

II. EVOLUTION OF TRIPS OVER THE YEARS

Since TRIPS was first enacted in 1995, it has been the subject of intense and ongoing debate.[28] One of the most contentious issues is the effect of TRIPS on access to medicines and medical technologies.[29] This issue came to a head during the 2001 round of WTO negotiations held in Doha, Qatar.[30] The resulting Declaration on TRIPS and Public Health (Doha Declaration) clarified some issues surrounding TRIPS regarding access to medicines.[31] The Doha Declaration laid the framework for interpreting TRIPS "in the context of making a positive contribution to addressing public health problems."[32] It also clarified the scope of countries' discretion to determine what constitutes a national health crisis and what latitude countries have within TRIPS to implement relief measures without consent from intellectual property rights holders.[33] Following the Doha Declaration, TRIPS was eventually amended to make it easier for countries—particularly least developed countries—to apply certain TRIPS flexibilities, such as compulsory licensing, to override requisite patent protections in cases of national emergencies or to protect public health.[34]

In the early 2000s, the outbreak of SARS (another coronavirus)[35] brought a renewed focus to the debate surrounding TRIPS.[36] Competing perspectives ranged from biotech companies' entrepreneurialism to research institutions' pragmatism to academics' reformism.[37] Other perspectives included those desiring to abolish the

28. *See* CHOW & SCHOENBAUM, *supra* note 12, at 560 (noting how controversy regarding TRIPS and its effect on access to medicines ignited in the 1990s due to several well-publicized events).

29. *See, e.g.*, *WTO Members Stress Role of IP System in Fighting COVID-19*, *supra* note 25 (stressing importance of roles that WTO and Council for TRIPS play in combating COVID-19).

30. *See* CHOW & SCHOENBAUM, *supra* note 12, at 560-61 (describing conflict over access to medicines between the United States and Brazil in 2001).

31. World Trade Organization, Ministerial Declaration of 14 November 2001, at ¶ 5, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration]. For additional discussion of the Doha Declaration, see *infra* Section II.C.

32. *WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines*, *supra* note 24.

33. Doha Declaration, *supra* note 31, at ¶ 5(c).

34. *See* SHAYERAH ILIAS AKHTAR ET AL., CONG. RSCH. SERV., RL34292, INTELLECTUAL PROPERTY RIGHTS AND INTERNATIONAL TRADE 19 (2020) (describing Doha Declaration's effect on interpreting TRIPS to encourage access to medicines and promote public health).

35. *See* Matthew Rimmer, *The Race to Patent the SARS Virus: The* TRIPS Agreement *and Access to Essential Medicines*, 5 MELB. J. INT'L L. 335, 336 (2004) (footnotes omitted) (describing SARS, or Severe Acute Respiratory Syndrome, as new coronavirus-caused pneumonia first reported in 2002 in southern China).

36. *Id.* at 337.

37. *Id.*

patent system altogether, and critics with moral and ethical objections.[38] Even with the 2017 Amendment to TRIPS that formalized the advantages and essence of the Doha Declaration,[39] the debate between protecting intellectual property versus promoting public health remains unfinished.[40]

A. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights

TRIPS is considered a "major triumph"[41] for its role in establishing, for the first time, protection of intellectual property rights as part of the multilateral trading system.[42] The United Nations' negotiation of TRIPS in the 1990s was a major step toward creating both an international protection standard and an effective mechanism for enforcing those protections.[43] Building off protection standards set by previous international treaties, TRIPS set both minimum standards for protecting intellectual property rights and obligations for enforcing those rights.[44] Furthermore, by entering into force at the same time as the establishment of the WTO, TRIPS played a key role in reinforcing the link between intellectual property and trade.[45] Including TRIPS as one of the WTO's major treaties was the first main introduction of "[intellectual property] rules into the multilateral trading system."[46] Twenty-five years later, TRIPS is still celebrated for its lasting impact as "the most comprehensive multilateral treaty on intellectual property protection and enforcement."[47]

---

38. *Id.*

39. See *infra* Section II.D for an expanded discussion of the TRIPS Amendment.

40. *See* Ashley E. Sperbeck, *A Mathematical Solution to the Sine of Madness that is Pharmaceutical Compulsory Licensing Under the Trips Agreement and the Doha Declaration*, 23 MARQ. INTELL. PROP. L. REV. 21, 36–38 (2019) (describing effects of amendment to TRIPS and use of Article 31*bis*).

41. *See* CHOW & SCHOENBAUM, *supra* note 12, at 553 (describing inclusion through TRIPS of intellectual property rights in WTO's global trade regime as a triumph of Uruguay Round).

42. *See* AKHTAR ET AL., *supra* note 34, at 16 (noting role of TRIPS as the first incorporation of intellectual property protections in the international trading regime).

43. *See* CHOW & SCHOENBAUM, *supra* note 12, at 553 (describing origin of TRIPS); AKHTAR ET AL., *supra* note 34, at 16 (discussing same).

44. CHOW & SCHOENBAUM, *supra* note 12, at 553–54; *see also* AKHTAR ET AL., *supra* note 34, at 16 (noting TRIPS set minimum standards for intellectual property protection and enforcement with which all WTO members must comply); Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 1, 1869 U.N.T.S. 299 [hereinafter TRIPS] ("Members shall give effect to the provisions of [TRIPS]. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.").

45. *See WIPO and WTO Launch Enhanced Access to the Colloquium Research Papers Collection*, WTO (Jan. 11, 2021), https://www.wto.org/english/news_e/news21_e/trip_11jan21_e.htm (noting inclusion of TRIPS in WTO's establishing agreement as strong link between international trade and intellectual property).

46. *Id.*

47. *Virtual Symposium to Mark 25 Years of the TRIPS Agreement*, WTO (Nov. 20, 2020), https://www.wto.org/english/news_e/news20_e/trip_20nov20_e.htm.

1. Improvement over Past Efforts

Because membership in the WTO requires adherence to its major treaties, including TRIPS, WTO members and prospective members must ensure that their own laws meet TRIPS' minimum standards of protection and enforcement.[48] TRIPS itself is a non-self-executing treaty and, as such, requires WTO members to enact domestic legislation to give its provisions force.[49] TRIPS was a significant improvement over the previous General Agreement on Tariffs and Trade (GATT) system[50] that had allowed members to pick and choose which provisions to follow and which to ignore.[51] TRIPS also provides for dispute resolution using the WTO's binding settlement mechanism, which "sets this agreement apart from previous [intellectual property rights] treaties that did not have effective dispute settlement mechanisms."[52]

Like GATT before it, TRIPS includes both a national treatment requirement and most-favored-nation provision.[53] The national treatment requirement ensures that a WTO member affords the same treatment of intellectual property rights to nationals of other member states that the member affords to its own nationals.[54] Similarly, the most-favored-nation treatment requires that "any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members."[55]

When TRIPS first took effect, WTO members were given different deadlines—based on their level of development—before which to implement domestic legislation to give force to TRIPS.[56] Developed countries were given one year to ensure their legislation was compliant.[57] Developing countries and least developed

48. CHOW & SCHOENBAUM, *supra* note 12, at 553.

49. *Id.*; *see also* TRIPS, *supra* note 44, art. 1 ("Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.").

50. *See* CHOW & SCHOENBAUM, *supra* note 12, at 554 (describing TRIPS as both major triumph over GATT for industrial nations and major shift in how intellectual property is viewed within international commerce).

51. *See id.* at 553 ("Some called this system 'GATT a la carte,' [because it permitted] contracting states [to] enjoy[] GATT trading benefits even though they refused to enact intellectual property laws that met international standards.").

52. AKHTAR ET AL., *supra* note 34, at 16.

53. TRIPS, *supra* note 44, art. 3–4.

54. *See id.* art. 1 ("Members shall accord the treatment provided for in [TRIPS] to the nationals of other Members."); *id.* art. 3 (footnote omitted) ("Each Member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection of intellectual property [absent exceptions already allowed in certain other international treaties].").

55. *Id.* art. 4.

56. *See* CHOW & SCHOENBAUM, *supra* note 12, at 553 (noting different timelines for enacting compliant legislation based on a country's level of development); *see also* TRIPS, *supra* note 44, art. 65 (describing transitional arrangements for implementing TRIPS in member states).

57. CHOW & SCHOENBAUM, *supra* note 12, at 553; *see also* TRIPS, *supra* note 44, art. 65 (describing developed countries' one-year obligation for implementing TRIPS).

countries were given additional time (ranging from five years to ten or more years) to bring their own legislation into compliance.[58] Indeed, many least developed countries were given further extensions of time in which to enact such legislation, particularly with regard to patent protections for pharmaceuticals.[59] Because developing and least developed countries often face greater challenges to bringing their laws and enforcement processes into agreement with TRIPS, they were given additional time to affect compliance.[60] Most recently, in recognition of least developed countries' special requirements, including "economic, financial and administrative constraints," they were given further extensions until July 1, 2021 to bring their domestic laws into compliance with TRIPS.[61] Although global implementation has yet to be achieved, TRIPS in its amended form[62] has been accepted by 132 WTO members, which is a significant step toward ensuring countries have "a legal pathway to access affordable medicines under WTO rules."[63]

2. Purpose and Principles Behind TRIPS

TRIPS attempted to balance intellectual property rights and trade.[64] More specifically, TRIPS was enacted to "promote effective and adequate protection of intellectual property rights" while ensuring that measures and procedures for enforcement of those rights would not become barriers to trade.[65] TRIPS recognized the need to account for differences in countries' national legal systems.[66] TRIPS also acknowledged the need for procedures that would effectively and expeditiously resolve disputes between different national governments (i.e., between different WTO member states).[67] Additionally, TRIPS noted the important public policy considerations underlying national legal systems' protection of intellectual property.[68] TRIPS also acknowledged that least developed countries' national legal systems would require special consideration and flexibility in order to enable those countries to balance enacting domestic laws for protection and enforcement of intellectual property rights with creating a "viable technological base."[69] Another consideration behind TRIPS was the desire for a "mutually supportive relationship"

58. CHOW & SCHOENBAUM, *supra* note 12, at 553; *see also* AKHTAR ET AL., *supra* note 34, at 16 (noting delayed compliance periods granted to developing countries as factor in their agreement to include TRIPS in WTO agreements).

59. *See* CHOW & SCHOENBAUM, *supra* note 12, at 553 (describing various deadlines and extensions for developing and least developed countries to enact compliant legislation).

60. AKHTAR ET AL., *supra* note 34, at 17–18.

61. *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, WTO (Mar. 11, 2021), https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm.

62. See *infra* Section II.D for further discussion of the amendment to TRIPS.

63. *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, *supra* note 61.

64. TRIPS, *supra* note 44, pmbl.

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

between the newly-created WTO and the already existent World Intellectual Property Organization (WIPO), an international organization that administers the previously enacted international intellectual property treaties.[70]

The principles and purposes behind TRIPS are spelled out in Article 8.[71] These principles allow WTO members to construct their domestic laws and regulations in such a way as "to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."[72] This ability to promote the public interest is narrowly confined—WTO members have the discretion to protect public health and promote public interest only so long as those measures are consistent with other TRIPS obligations, such as providing effective protection to intellectual property rights.[73] The purpose of such measures is to "prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."[74] At the same time, TRIPS also provides considerable flexibilities for countries to use to balance the twin aims of protecting intellectual property and ensuring public health.[75]

3. Minimum Standards of Protection

Countries have the flexibility to determine how their laws will effectuate the minimum standards set by TRIPS for determining and protecting different types of intellectual property rights.[76] These standards serve as a guiding framework within which countries try to balance concerns like access for public health needs with protection of intellectual property holders' rights.[77] The minimum standards of protection that TRIPS requires member states to enact varies depending on the type of intellectual property right to be protected.

TRIPS affords copyright protection to an author's original work, provided that the work is fixed in a tangible medium.[78] Copyright protection extends to expressions but not to "ideas, procedures, methods of operation or mathematical concepts as such."[79] It extends to computer programs and compilations of data or

70. *Id.*

71. *Id.* art. 8.

72. *Id.* art. 8(1).

73. *Id.* art. 8.

74. *Id.* art. 8(2).

75. See *infra* Section II.B for a discussion of selected TRIPS flexibilities.

76. *See* AKHTAR ET AL., *supra* note 34, at 16 (noting that TRIPS only sets minimum standards for compliance); TRIPS, *supra* note 44, art. 1 ("Members shall give effect to the provisions of [TRIPS]. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.").

77. *See* AKHTAR ET AL., *supra* note 34, at 47 (explaining that debates regarding trade policy as a vehicle for advancing enforcement of intellectual property rights have focused on balancing protection and enforcement of those rights with other policy objectives, such as access to medicines and free flow of information).

78. *See* TRIPS, *supra* note 44, art. 14 (enumerating protections of performers, producers of phonograms, and broadcasting organizations).

79. *Id.* art. 9(2).

other materials, although not to the data or materials themselves.[80] The right to protection lasts for an author's lifetime or not less than fifty years when the term is not based on the lifespan of a natural person.[81] TRIPS provides for fair use exceptions to an author's exclusive rights provided that such uses "do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder."[82]

TRIPS also provides protection criteria for industrial designs.[83] Industrial designs, like copyrighted works, need to be original and independently created in order to be protectable.[84] Member states have the option of extending protection to textiles either as industrial designs or through copyright protection.[85] TRIPS provides exceptions to the protection of industrial designs, "provided [those] exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design."[86] Protection for industrial designs lasts for a minimum of ten years.[87]

Further, TRIPS relates the conditions for determining and granting trademarks[88] as well as protections afforded to them and to indications of the geographical origins of products.[89] Member states have a great deal of latitude in determining whether to grant or deny a trademark, "provided that they do not derogate from the provisions of the Paris Convention (1967)."[90] TRIPS provides a fair use exception to trademark protection.[91] Trademark protection must last for a minimum of seven years and can be renewed indefinitely.[92] TRIPS also outlines other requirements, such as termination for non-use and trade usage.[93] TRIPS specifically prohibits the compulsory licensing of trademarks.[94]

TRIPS also addresses terms for the protection of topographies and other layout-designs.[95] TRIPS incorporates protections for the topography of integrated circuits from provisions in the Treaty of Intellectual Property in Respect of Integrated Circuits.[96] TRIPS describes the scope of such protection and spells out certain

80. *Id.* art. 10.
81. *Id.* art. 12.
82. *Id.* art. 13.
83. *Id.* art. 25–26.
84. *Id.* art. 25(1).
85. *Id.* art. 25(2).
86. *Id.* art. 26(2).
87. *Id.* art. 26(3).
88. *Id.* art. 15.
89. *Id.* art 15–24.
90. *Id.* art. 15(2); *see also id.* art. 16 (describing rights conferred on trademarks and specifically including parts of Paris Convention into TRIPS).
91. *Id.* art. 17.
92. *Id.* art. 18.
93. *Id.* art. 19–20.
94. *Id.* art. 21.
95. *Id.* art. 35–38.
96. *Id.* art. 35.

actions that cannot be legally taken without permission from the right holder.[97] Such actions include "importing, selling, or otherwise distributing" the integrated circuit's layout-design when the action is done for a commercial purpose.[98] TRIPS does provide a safe-harbor for actions otherwise illegal under the article, if those actions are done without knowledge or reason to know the protected layout-design or if the use conforms with conditions in subparagraphs (a) through (k) of Article 31.[99] The term of protection for topographies and layout-designs is set at a minimum of ten years.[100]

Protection for undisclosed information, such as trade secrets and technical know-how, is described in TRIPS to prevent such information from being disclosed without consent from the lawful controller of the information.[101] Conditions for this protection require that the information not be "generally known among or readily accessible to" people who normally deal with such information, that the information have commercial value, and that there have been reasonable steps taken to keep the information secret.[102] Information that can fit within this protection includes testing data from the development of pharmaceutical and chemical products, unless disclosure of such information is "necessary to protect the public."[103]

TRIPS also covers the protection, scope, and limitations of patents.[104] With a few exceptions, TRIPS provides for patent protection for "any inventions, whether products or processes, in all fields of technology, provided that they are new, [non-obvious, or] involve an inventive step and are [useful or] capable of industrial application."[105] The rights covered by a patent include the exclusive right to make, use, sell, or import either a patented product or the product of a patented process.[106] TRIPS sets out minimum conditions for obtaining a patent, such as disclosure of the invention in such a way that is "sufficiently clear and complete" so as to allow a "person skilled in the art" to make the invention.[107] Patent protection is available for a minimum of twenty years after the patent is filed,[108] although TRIPS provides some limited exceptions to a patent holder's exclusive rights.[109]

Article 31 specifically addresses terms for the use of patented subject matter

---

97. *Id.* art. 36.

98. *Id.*

99. *Id.* art. 37; See *infra* notes 110–20 and accompanying text for a description of the provisions in Article 31.

100. *Id.* art. 38.

101. *Id.* art. 39.

102. *Id.* art. 39(2).

103. *Id.* art. 39(3).

104. *Id.* art. 27.

105. *Id.* art. 27(1).

106. *Id.* art. 28(1).

107. *See id.* art. 29(1) ("Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best [known] mode for carrying out the invention . . . .").

108. *Id.* art. 33.

109. *Id.* art. 30.

absent consent from the intellectual property right holder.[110] Key limitations include the requirement that the user make reasonable efforts to obtain the right holder's permission before use,[111] that there be a limited scope and duration of the use,[112] that the use be primarily for supply in the user's domestic market,[113] and that the right holder be adequately remunerated for the use of the protected intellectual property.[114] The requirement for prior reasonable efforts to obtain permission may be waived "in the case of a national emergency or other circumstances of extreme urgency" as well as "in cases of public non-commercial use."[115] However, even in times of national emergency, the right holder must be notified of the use "as soon as reasonably practicable."[116]

Within this framework of protection standards, there are explicit and implicit flexibilities that provide countries with a fair amount of latitude for balancing protection of intellectual property rights with other purposes, like promoting public health in times of national emergency. Copyright protection recognizes a fair use exception.[117] Industrial design protection provides for certain exceptions, provided they "do not unreasonably prejudice" the right holder's legitimate interests.[118] Protection for undisclosed information, such as trade secrets, can be waived if disclosure of such information is "necessary to protect the public."[119] Exceptions to patent protections can be made in cases of national emergency and extreme urgency, provided the right holder is notified "as soon as reasonably practicable" under the circumstances.[120]

B. TRIPS Flexibilities

While TRIPS flexibilities are most commonly thought of with regard to patents,[121] TRIPS allows countries to adapt protection for a range of intellectual property rights to address important situations concerning public health.[122] TRIPS flexibilities allow for such measures including determining criteria for protection, issuing compulsory licenses, authorizing parallel imports, and determining how to limit or remedy abuse of intellectual property rights.[123] Even with such varied

110. *Id.* art. 31.
111. *Id.* art. 31(b).
112. *Id.* art. 31(c).
113. *Id.* art. 31(f).
114. *Id.* art. 31(h).
115. *Id.* art. 31(b).
116. *Id.*
117. *Id.* art. 13.
118. *Id.* art. 26(2).
119. *Id.* art. 39(3).
120. *Id.* art. 31(b).
121. *See, e.g.*, Communication from South Africa, *supra* note 26, at 1 (noting that use of TRIPS flexibilities for public health concerns is usually seen as a matter only concerning patents).
122. *See id.* (explaining how WTO members are able to use flexibilities within TRIPS to adapt their intellectual property laws to meet human rights and public health objectives).
123. *See id.* (describing TRIPS flexibilities available to countries including enacting domestic legislation, such as general exceptions and competition laws, to limit and remedy intellectual

measures available, many countries still are unable to take full advantage of these flexibilities.[124]

1. Compulsory Licenses

Within certain limitations, TRIPS allows countries to use compulsory licensing to promote access to medicines.[125] When permission of the rights holder is absent, "[a] compulsory license is an authorization by a government for third parties (such as a company or the government itself) to manufacture or use a product" otherwise protected by intellectual property law.[126] For example, compulsory licenses can be used by countries without the capacity to manufacture generic substitutes for patented pharmaceuticals.[127] These countries can then import those generic substitutes from countries that have the capacity to make them, without the risk of interference from the patent holders.[128] Countries without adequate manufacturing capabilities (usually least developed countries) can use compulsory licenses to obtain needed products from a country that can produce the products, subject to certain requirements and restrictions:

> [First,] countries without sufficient manufacturing capacity . . . issue a compulsory license to a company in a country that can produce such a product. After a matching compulsory license is issued by the producer country, the drug can be manufactured and exported subject to various notification requirements, as well as quantity and safeguard restrictions.[129]

Although the actual use of compulsory licenses has been rare,[130] a number of countries have successfully used the threat of compulsory licensing as a negotiating strategy to obtain more favorable prices from manufacturers.[131] Recently, some countries have taken steps toward revisiting whether to issue compulsory licenses, particularly in the context of COVID-19.[132] Israel was the first country to issue a compulsory license in response to the COVID-19 pandemic.[133] Chile and Ecuador's National Assemblies also called for the use of compulsory licenses to combat the

---

property rights abuse).

124. *Id.*; *see also* AKHTAR ET AL., *supra* note 34, at 19–20 (describing use of free trade agreements to limit some countries' ability to use TRIPS flexibilities including compulsory licenses).

125. AKHTAR ET AL., *supra* note 34, at 19.

126. *Id.*

127. Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 386 (2011).

128. *Id.*

129. AKHTAR ET AL., *supra* note 34, at 19.

130. Harris, *supra* note 127, at 387; *see also* Communication from South Africa, *supra* note 26, at 1 (noting that use of compulsory licenses, even in context of access to medicines, remains under-utilized).

131. *See* AKHTAR ET AL., *supra* note 34, at 19 (noting that it is more common for countries to use compulsory licenses as leverage in negotiations rather than to use actual licenses).

132. *See id.* at 20 (reporting certain governments' preliminary steps toward revisiting use of compulsory licenses in wake of COVID-19).

133. *Id.*

pandemic.[134] Some countries, such as Canada and Germany, have even gone so far as to pass legislation to make it easier to issue compulsory licenses in those countries.[135]

While compulsory licenses are typically thought of only with regard to patents, other provisions of TRIPS refer to their use. The section on protection of layout-designs references Article 31, which relates to compulsory licenses,[136] and the section on protection of trademarks specifically prohibits the use of compulsory licenses for trademarks.[137] These internal references imply that compulsory licenses are not a flexibility that merely relates to patents, but rather are one that can be used for other areas of intellectual property rights, unless specifically prohibited. If TRIPS is viewed using this holistic approach, it already provides significant flexibilities for countries to access protected health-related technologies necessary to combat public health crises.

2. Parallel Imports

Under TRIPS, in addition to the use of compulsory licenses, countries have the freedom to allow parallel imports to augment their domestic manufacturing capacities to increase the availability of products in the domestic market.[138] Parallel imports, a type of gray-market goods, include products with protected intellectual property rights that are brought to a specific market through an import channel other than the one used by the right holders.[139] For example, a U.S. company may license a manufacturer in Mexico to produce its goods and allow it to sell them in Mexico.[140] The U.S. company imports the goods into the United States for sale (the authorized channel).[141] If another company buys the same goods in Mexico from the manufacturer then imports them into the United States for sale, this creates a second or parallel channel.[142] Because the goods were legally bought from the manufacturer, they are not black market goods.[143]

Gray-market goods are products "with genuine trademarks that are intended for

---

134. *Id.*

135. *Id.*

136. TRIPS, *supra* note 44, art. 31, 37.

137. *Id.* art. 21.

138. *See generally* Eric W. Bond & Kamal Saggi, *Compulsory Licensing, Price Controls, and Access to Patented Foreign Products*, 109 J. Dev. Econ. 217 (2014) (describing use of compulsory licenses for patents); *see also* Priscila Santos, *Health, Technology, & International Law—Health Technologies and International Intellectual Property: A Precautionary Approach*, 14 J. HEALTH & BIOMEDICAL L. 407, 409 n.15 (2018) (describing same).

139. *See* CHOW & SCHOENBAUM, *supra* note 12, at 567 (describing gray-market goods including parallel imports).

140. *See id.* (describing how a country can license a foreign manufacturer to produce their goods for local sale at lower prices).

141. *See id.* (noting how foreign-made goods are imported back into the domestic country for sale).

142. See *id.* (illustrating how a parallel channel is created when a different company imports the same goods back into the country for sale).

143. *See id.* (explaining that goods legally bought from foreign manufacturers and sold in the initial country are not black market goods but rather are "gray-market goods").

sale and use in [non-domestic] markets" that are nevertheless imported into and sold in the domestic market without the consent of the intellectual property right holder.[144] Right holders generally dislike gray-market goods because gray-market goods tend to be cheaper, and their presence often leads to price erosion in the domestic market, which harms the right holders' profit margins.[145]

Gray-market goods are also disfavored by right holders because these products, unlike authorized products sold in the domestic market, typically lack intangible product features like a manufacturer's warranty, notification of recall information, or entitlement to software updates.[146] When unknowing consumers discover these differences, the resulting dissatisfaction may harm the goodwill consumers associate with the product's rights holders and could result in boycotts and further loss of sales of the right holders' products within the domestic market.[147] Regardless of the rights holders' feelings, however, gray-market goods—unlike counterfeit or pirated goods—are genuine products.[148] As such, these products, often obtained through parallel import channels, can be sold through legal marketing channels in the domestic market without infringing intellectual property rights.[149]

Parallel imports arise when two separate channels are used to import goods into the same market.[150] One situation involving parallel imports occurs when goods are made abroad by a licensed manufacturer who is also an authorized distributor in a market that is non-domestic to the rights holder.[151] The licensing intellectual property right holder imports the products made by the foreign manufacturer into its domestic market, thereby creating an authorized channel of importation.[152] A separate, unauthorized channel is created when a second distributor purchases the products from the licensed manufacturer/distributor in the foreign market, taking advantage of that market's low prices, and then the second distributor subsequently imports those products for sale in the same domestic market as the intellectual property right holder.[153]

Although this second channel means that the right holder's authorized distributor will face competition from the second distributor/importer in the right holder's domestic market, the imported products from the second channel allow

144. Paul Tanck & Neal McLaughlin, *Combating Gray Market Goods: Using the ITC to Solve the Gray Market*, A.B.A: BUS. L. TODAY (July 2, 2019), https://businesslawtoday.org/2019/07/combating-gray-market-goods-using-itc-solve-gray-market/.

145. *Id.*

146. *Id.*

147. *See id.* (noting dilemma rights holders face between accepting unhappy customers, hoping they do not leave for competitors, and granting expensive exceptions and support costs).

148. CHOW & SCHOENBAUM, *supra* note 12, at 568.

149. *See id.* (explaining that unlike counterfeit or pirated goods, gray-market goods are genuine, and their market is lawful).

150. *See id.* at 567–68 (explaining that one channel is authorized and the other, for grey-market goods, is not).

151. *Id.* at 567.

152. *Id.*

153. *Id.*

consumers in the domestic market to purchase the same products at reduced prices.[154] These reduced prices are possible because the second distributor/important purchased the products at cheaper sale prices in the foreign market.[155] The second channel can also increase the availability of the products in the domestic market.[156] By using parallel imports, countries can increase the availability of health-related technology, such as personal protective equipment, within their domestic markets to further their efforts to combat public health crises like the COVID-19 pandemic.[157]

C. The Doha Declaration on TRIPS and Public Health

Historically, the WTO has always had a main focus on "how to facilitate access to medicines in the context of the Doha Declaration on TRIPS and Public Health."[158] Prior to TRIPS, there had always been a longstanding tension between developing countries and pharmaceutical companies regarding patent protection for medicines and other pharmaceutical products.[159] Certain developing countries refused to afford patent protection for pharmaceuticals, arguing that public health and safety concerns outweighed the need for protective restrictions on access to essential drugs and medicines.[160] Because TRIPS requires all WTO members to enact protections for intellectual property, including protections for patents on pharmaceuticals,[161] the agreement quickly faced heated criticism for the restrictions these protections placed on access to critically needed medicines.[162] Critics of the protections on intellectual property rights required under TRIPS vehemently argue that:

> (1) increased patent protection leads to higher drug prices, which will cause drugs to be out of reach for many developing countries; (2) enforcement of TRIPs will restrict local manufacturing capacity and remove a source of drugs on which many in the developing world depend; [and] (3) widespread patent protection will further discourage drug companies from undertaking research and development on diseases such as malaria and tuberculosis, widespread in developing countries, because drugs developed to treat these diseases will not earn high profits . . . .[163]

---

154. *See id.* (noting that reduced prices are typically due to less expensive labor costs abroad).

155. *Id.*

156. Duncan Matthews & Viviana Munoz-Tellez, *Parallel Trade: A User's Guide*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 1429, 1430 (Anatole Krattiger et al. eds., 2007).

157. *See id.* (describing how parallel imports can lead to greater availability of medicines at lower prices in developing countries).

158. Communication from South Africa, *supra* note 26, at 1.

159. *See* CHOW & SCHOENBAUM, *supra* note 12, at 558–59 (describing how prior to TRIPS, some developing countries, such as Thailand and India, refused to offer patent protection for pharmaceuticals).

160. *Id.*; *see also* AKHTAR ET AL., *supra* note 34, at 19 ("[S]everal countries did not provide for patenting pharmaceutical products prior to TRIPS, or, as in the case of India, provided process patents that covered the manufacturing process but not [the] product itself.").

161. *See* CHOW & SCHOENBAUM, *supra* note 12, at 559 (describing effect of TRIPS on WTO members resulting in their need to enact domestic intellectual property laws that meet minimum substantive standards of TRIPS).

162. *Id.*

163. *Id.*

These critics also object to TRIPS because compliance with TRIPS merely sets a threshold for minimum protections, with the result that "many developed countries are putting pressure on developing countries to provide 'TRIPS-plus' protection by extending patent protection beyond the required 20-year period."[164]

During the Doha Round of negotiations in 2001, the WTO adopted the Doha Declaration,[165] which sought to alleviate some of the dissatisfaction with certain aspects of TRIPS, especially regarding the implementation of patent protections for pharmaceuticals.[166] In its first paragraph, the Doha Declaration acknowledges the serious nature of certain public health problems that affect developing countries and least developed countries, including a number of specific epidemics, like HIV/AIDS.[167] The Doha Declaration stresses the need for TRIPS to be included as part of national and international efforts to deal with such public health problems.[168] It also recognizes the concerns that many countries, particularly least developed countries, have expressed regarding the effect of intellectual property rights on the prices of various products, many of which are essential, life-saving medicines.[169]

Additionally, the Doha Declaration balances the concern for public interest with the recognition that protections of intellectual property rights are important, particularly regarding the costs of developing new medicines and their market prices.[170] Nevertheless, the Doha Declaration boldly acknowledges that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health."[171]

The Doha Declaration, moreover, reaffirms member states' commitment to interpreting and implementing TRIPS in ways that support both the rights of WTO members to protect public health and their need "to promote access to medicines for all."[172] Accordingly, it reiterates the WTO members' right to use the TRIPS flexibilities to the fullest extent of the purposes underlying those flexibilities.[173]

The Doha Declaration even sets forth certain recognized flexibilities within TRIPS.[174] Among those specific flexibilities is the requirement that any interpretation of TRIPS should be mindful of "the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."[175] The Doha Declaration also clarifies that each member has the discretion to determine the

164. *Id.*; *see also* Harris, *supra* note 127, at 374 (describing developed countries' use of free trade agreements as means to leverage developing countries into providing "TRIPS-plus commitments" like restricted use of compulsory licensing and increased protection of data).

165. Doha Declaration, *supra* note 31.

166. AKHTAR ET AL., *supra* note 34, at 18.

167. Doha Declaration, *supra* note 31, ¶ 1.

168. *Id.* ¶ 2.

169. *Id.* ¶¶ 1, 2.

170. *Id.* ¶ 3.

171. *Id.* ¶ 4.c.

172. *Id.*

173. *Id.*

174. *Id.* ¶ 5.

175. *Id.* ¶ 5(a).

grounds upon which it would use and grant compulsory licenses.[176] In addition to specifically recognized public health emergencies like HIV/AIDS, the Doha Declaration highlights that each member state has the discretion "to determine what constitutes a national emergency or other circumstances of extreme urgency."[177] The Doha Declaration further clarifies that as long as members abide by the national treatment and most-favored-nation provisions of TRIPS, each member state has the freedom to establish its own intellectual property rights regime.[178]

Furthermore, the Doha Declaration acknowledges that some countries, in particular least developed countries, that have either insufficient—or a complete lack of—manufacturing capabilities face additional difficulties in effectively using the compulsory licenses available under TRIPS.[179] Accordingly, the Doha Declaration instructs the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS)[180] to develop an "expeditious solution" to this problem.[181] In its final paragraph, the Doha Declaration reaffirms the commitment of developed countries to encourage their domestic "enterprises and institutions to promote and encourage technology transfer to [least developed member states]."[182] Additionally, least developed member states were given an extension until 2016 before they would be required to enforce rights provided under certain provisions of TRIPS.[183]

The Doha Declaration commits WTO members "to interpret and implement the agreement to support public health and to promote access to medicines for all."[184] TRIPS is supposed to provide countries with "public-health-protecting flexibilities to mitigate the negative externalities of diminished medicines access from cross-country harmonization of patent protection."[185] The Doha Declaration highlights certain flexibilities in TRIPS to allow, among other things, for countries to grant compulsory licenses for pharmaceuticals.[186] It also clarifies that individual countries have the discretion to determine what constitutes a national emergency[187] and expressly includes examples of public health emergencies such as "those relating to

176. *Id.* ¶ 5(b).

177. *Id.* ¶ 5(c).

178. *Id.* ¶ 5(d).

179. *Id.* ¶ 6.

180. The WTO established the Council for TRIPS "to monitor implementation of the agreement and transitional arrangements [that] were devised for developing countries." AKHTAR ET AL., *supra* note 34, at 16; *see also* TRIPS, *supra* note 44, art. 68 (describing role of Council for TRIPS).

181. Doha Declaration, *supra* note 31, ¶ 6.

182. *Id.* ¶ 7.

183. *Id.*

184. AKHTAR ET AL., *supra* note 34, at 18; *see also* CHOW & SCHOENBAUM, *supra* note 12, at 561 (noting the Doha Declaration recognized that least developed countries have increased difficulties regarding access to medicines).

185. Ebenezer K. Tetteh, *Pharmaceutical Innovation, Fair Following and the Constrained Value of TRIPS Flexibilities*, 14 J. WORLD INTELL. PROP. 202, 202 (2011).

186. *See* AKHTAR ET AL., *supra* note 34, at 18 (noting to Doha Declaration directed WTO members to find a solution that would enable countries with insufficient or inadequate manufacturing capabilities to use compulsory licensing).

187. *Id.*

HIV/AIDS, tuberculosis, malaria and other epidemics."[188] In 2005, TRIPS was amended to reflect the changes highlighted by the Doha Declaration;[189] however, this amendment did not enter into force until 2017.[190] Currently, 132 WTO member states have accepted the amendment to TRIPS, leaving 32 member states with a current deadline of December 31, 2021 to add their acceptance of the amendment.[191]

D. Amendment to TRIPS: Article 31bis

Amending TRIPS was a significant step forward, but this amendment has not been applied broadly enough to ensure access to health-related technologies—other than certain medicines—that are needed to help countries facing public health crises.[192] On January 23, 2017, the TRIPS amendment was finally ratified by a sufficient number of WTO member states to enter into force.[193] The amendment to TRIPS—including Article 31*bis*, as well as an Annex and Appendix—codifies much of the Doha Declaration as part of TRIPS.[194] The Annex and Appendix add further clarification to the provisions of Article 31*bis*.[195] In addition to formalizing the Doha Declaration, Article 31*bis* effectively makes permanent the waiver that allows least developed countries facing a public health crisis, but lacking domestic manufacturing facilities for necessary pharmaceuticals, to use compulsory licenses in order to obtain those pharmaceuticals from other countries that have the requisite manufacturing capabilities.[196]

Article 31*bis* elucidates the conditions under which compulsory licenses may be granted and used under TRIPS.[197] The first provision of Article 31*bis* clarifies the

---

188. Doha Declaration, *supra* note 31, ¶ 1.1

189. *See id.* (explaining that the Doha Declaration was incorporated into TRIP in December 2005 at the Hong Kong Ministerial); *see also* Harris, *supra* note 127, at 386 (noting that WTO members adopted the amendment to TRIPS on December 6, 2005).

190. *See* AKHTAR ET AL., *supra* note 34, at 19 (noting that the ratification deadline was extended five times before the amendment finally entered into force on January 23, 2017); *see also Agreement on Trade-Related Aspects of Intellectual Property Rights (as Amended on 23 January 2017)*, WTO, https://www.wto.org/english/docs_e/legal_e/31bis_trips_e.pdf (showing date of amendment to TRIPS).

191. *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, *supra* note 61.

192. Communication from South Africa, *supra* note 26 (explaining that many countries still do not make full use of TRIPS flexibilities, particularly in relation to health-related technologies in the fight against COVID-19).

193. *See* AKHTAR ET AL., *supra* note 34, at 19 (explaining that because amendment to TRIPS required ratification by two-thirds of WTO members, it took until January 23, 2017 before enough members ratified for the amendment to enter into force); *see also Agreement on Trade-Related Aspects of Intellectual Property Rights*, *supra* note 190 (showing date TRIPS was amended).

194. *See* Sperbeck, *supra* note 40, at 36 (explaining that the amendment to TRIPS included Article 31*bis* and a corresponding Annex and Appendix to provide further clarity to the new article); *see also Agreement on Trade-Related Aspects of Intellectual Property Rights*, *supra* note 190 (showing amended version of TRIPS).

195. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, *supra* note 190; Sperbeck, *supra* note 40, at 36.

196. Sperbeck, *supra* note 40, at 36.

197. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, *supra* note 190;

obligations under Article 31(f).[198] Article 31(f) prevents countries from manufacturing pharmaceutical products and exporting a majority of those products to other countries.[199] This exclusion from exports effectively prevented countries without manufacturing capabilities from using compulsory licenses.[200] Not only were such countries unable to manufacture the products themselves, but they were also effectively prevented both from licensing foreign manufactures to make the products and from importing the pharmaceutical products from those countries with manufacturing capabilities.[201] However, Article 31*bis* excludes some exporting member states from the export restrictions in Article 31(f), provided that certain conditions are met.[202] These conditions include the requirement that Article 31(f) does not apply to a grant of compulsory license "to the extent necessary for the purposes of production of a pharmaceutical product(s)" as well as to the export of those products to eligible member states.[203]

Specifically, "eligible exporting Member(s)" are defined in the Annex as either a least developed country with little or no manufacturing facilities or as any member state that had applied to the Council for TRIPS with the intention to act as an importer under Article 31*bis*.[204] Such an application process requires that the member state specify the type of medication sought to be licensed, the quantity of medication to be licensed, and the designation of a member state that intends to issue the compulsory license.[205] Accordingly, the exporting member state would then issue a compulsory license to satisfy the needs of the importing member state or states. [206]

Additionally, Article 31*bis* requires that "adequate remuneration" must be paid in accordance with Article 31(h) when the compulsory license is granted.[207] At the same time, as a factor determining what constitutes adequate remuneration, the Article allows countries—and dispute settlement bodies—to consider "the economic value to the importing Member" for the use of the license to the exporting member state.[208]

Article 31*bis* affirms that its application is "without prejudice to the rights,

---

Sperbeck, *supra* note 40, at 37.

198. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, *supra* note 190; Sperbeck, *supra* note 40, at 37.

199. TRIPS, *supra* note 44, art. 31(f).

200. Sperbeck, *supra* note 40, at 37.

201. *See id.* at 30–31 (describing the challenges imposed by Article 31(f) on least-developed countries).

202. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, *supra* note 190.

203. *Id.*

204. *See* Sperbeck, *supra* note 40, at 37 ("[Paragraph 2 to the Annex sets out] an 'eligible importing Member(s)' is defined as (a) a LDC Member having little to no manufacturing capacity or (b) any Member that has submitted an application to the TRIPS Council with the intention of utilizing the Article 31*bis* system as an importing Member.").

205. *See id.* (noting requirements a member state must specify when applying to import using a compulsory license).

206. *Id.*

207. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, *supra* note 190.

208. *Id.*

obligations and flexibilities that Members have under the provisions of [TRIPS] other than paragraphs (f) and (h) of Article 31."[209] Accordingly, Article 31*bis* should not limit countries' abilities to use TRIPS flexibilities to combat public health crises.[210] Further, the affirmation of Article 31*bis* regarding its application specifically includes "those reaffirmed by the [Doha Declaration] and to their interpretation."[211] The Doha Declaration states that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health."[212] The Doha Declaration also "reaffirm[s] the right of WTO Members to use, *to the full*, the provisions in the TRIPS Agreement, which provide flexibilities" for the purpose of protecting public health.[213] Accordingly, the amendment to TRIPS including Article 31*bis* should not interfere with countries using TRIPS flexibilities to the fullest extent possible in their efforts to combat public health crises like COVID-19.[214]

III. IN THE WAKE OF COVID-19: REEXAMINING THE INTERSECTION OF INTELLECTUAL PROPERTY AND PUBLIC INTEREST

Not surprisingly, developed countries, developing countries, and least developed countries each present different—though not necessarily opposing—views on the best way in which to interpret and implement TRIPS flexibilities.[215] It is unlikely that a singular panacea will be found to appease every viewpoint, and as a result, scholars have cautioned against seeking a "one-size-fits-all solution" when examining TRIPS and use of its flexibilities.[216] In the following Sections, this Comment will examine each argument in turn. It will then present a middle ground that blends elements from both approaches to proffer a more holistic approach to international intellectual property protection in light of global health crises like the COVID-19 pandemic.

A. The Cost of Innovation: Arguments Against Expanding TRIPS Flexibilities

Even with the amendment to TRIPS, tension still exists between developed countries and pharmaceutical companies seeking greater protection for intellectual property and least developed countries and developing countries with limited domestic resources seeking increased access and assistance to combat threats to public health.[217] Many developed countries have major domestic pharmaceutical

209. *Id.*

210. *Id.*

211. *Id.*

212. Doha Declaration, *supra* note 31, ¶ 4.

213. *Id.* (emphasis added).

214. *See id.* (reaffirming WTO members' right to use the provisions in TRIPS with their accompanying flexibilities).

215. *See, e.g.*, Tetteh, *supra* note 185.

216. *See id.* at 222–23 (cautioning medicine-access advocates from recommending a singular solution using TRIPS flexibilities, especially to low-income countries facing disparate socio-economic and political situations).

217. *See* Sperbeck, *supra* note 40, at 22–26 (describing ambiguity created by TRIPS amendment regarding remuneration costs imposed on least-developed countries when exporting

companies and are primarily concerned with ensuring the protection of intellectual property rights to promote innovation and commerce within their own territories.[218] During the negotiations that led to the creation of TRIPS, developed countries generally sought to obtain stronger enforcement and protection measures, especially for patented technology.[219] In addition to developed countries, pharmaceutical manufacturers and other commercial companies have consistently argued that "a strong patent system [is] essential to promote private investment and research into diagnostics, vaccines and pharmaceutical drugs."[220] They continually contend that protection of intellectual property rights is necessary to "foster innovation" and incentivize investment in "risky research and development."[221]

Because developed countries possess greater financial resources than developing countries or least developed countries, developed countries have a stronger position from which to prepare to deal with the risk of an impending public health crisis.[222] Developed countries, with greater wealth and influence, tend to also have significantly greater bargaining power.[223] This power allows them to more readily obtain favorable prices for needed medicines patented by pharmaceutical companies.[224] Consequently, these countries tend to focus on seeking "to protect intellectual property rights to prevent misuse of compulsory licenses" rather than on the need to overcome financial barriers to obtain patented medicines.[225]

Even as this debate continues today, developed countries remain at the forefront of the opposition to expanding TRIPS flexibilities.[226] This opposition to current proposals for expanding TRIPS even includes a number of developing countries.[227] Those countries claim that intellectual property rights are "only one aspect of many" affecting the manufacture and distribution of COVID-19 vaccines,[228] despite most of the current vaccines being earmarked for the world's wealthiest countries.[229] As of December 2020, these wealthier, developed countries with "just 14% of the world's population, had secured 53% of the world's supply of the best-performing

---

generic pharmaceuticals under compulsory licenses).

218. *See* Santos, *supra* note 138, at 411–12 (noting greater presence of pharmaceutical companies in developed countries and tendency of those countries to favor protecting intellectual property and encouraging innovation).

219. Harris, *supra* note 127, at 383.

220. Rimmer, *supra* note 35, at 337.

221. Junaid Subhan, *Scrutinized: The TRIPS Agreement and Public Health*, 9 MCGILL J. MED. 152, 153 (2006).

222. Santos, *supra* note 138, at 411–12; Sperbeck, *supra* note 40, at 22.

223. Santos, *supra* note 138, at 411.

224. *Id.*

225. *Id.* at 411–12.

226. *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19,* WTO (Dec. 10, 2020), https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

227. *Id.*

228. *Id.*

229. *Share the Vaccine with the World!*, AVAAZ, (Nov. 17, 2020), https://avaaz.org/campaign/en/share_the_covid_vaccine/?slideshow.

coronavirus vaccines."[230] More than half of the 107 million COVID-19 vaccine doses administered by February 2021 were given in the United States, the European Union, and the United Kingdom.[231] Even so, developed countries still focus their arguments on the lack of a "concrete indication that intellectual property rights . . . have been a genuine barrier to accessing COVID-19 related medicines and technologies."[232] They contend that intellectual property is "only one aspect of many" affecting access to the health-related technologies needed to combat COVID-19.[233]

B. The Importance of Public Interest: Arguments for Expanding TRIPS to Better Meet Public Health Needs

Developing countries and least developed countries focus primarily on the financial barriers that hinder their abilities to protect the health of their citizens, particularly in the event of an emergent public health crisis.[234] Such countries face numerous challenges in combating and minimizing the spread of disease among their citizens.[235] One such factor is a lack of basic infrastructure, like reliable transportation and safe road systems to provide access to hospitals.[236] Problems with sanitation, particularly for rural populations, also contribute to the ready spread of disease.[237] Other factors such as corruption and political instability further challenge efforts to combat public health crises in these countries.[238] Still, arguably, intellectual property rights are the most glaring impediment these countries face in meeting public health demands.[239] Normally, it can take decades from the time a vaccine is "developed and used for the first time in rich countries and [its] getting to the poorest people in the world."[240] In short, the argument is "that stringent intellectual property legislation keeps drug prices too high and as a result makes them less accessible to those who need them the most."[241]

Pharmaceutical companies, as commercial entities, are primarily driven by profit motives.[242] Consequently, they tend to focus their research and development efforts where they are likely to generate the most profit, such as on diseases that are

230. Natasha Turak, *First COVAX Vaccine Shipment Arrives in Ghana as Developing World Hopes to Catch Up*, CNBC (Feb. 24. 2021, 2:57 PM), https://www.cnbc.com/2021/02/24/first-covax-vaccine-shipment-arrives-in-ghana-as-developing-world-hopes-to-catch-up.html.

231. Alia Chughtai & Mohammed Haddad, *The Coronavirus Vaccine Divide: In Maps and Charts*, AL JAZEERA (Feb. 4, 2021), https://www.aljazeera.com/news/2021/2/4/the-vaccine-divide-in-maps-and-charts.

232. *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19*, *supra* note 226.

233. *Id.*

234. Santos, *supra* note 138, at 412.

235. Subhan, *supra* note 221, at 152.

236. *Id.*

237. *Id.*

238. *Id.*

239. *Id.* at 153.

240. Turak, *supra* note 230.

241. Subhan, *supra* note 221, at 153.

242. *Id.* at 152.

mainly prevalent in richer, more developed countries.[243] In particular, least developed countries lack the bargaining power to induce—typically foreign—pharmaceutical companies to enter into agreements that would provide affordably priced medicines to the people of those countries.[244] Developing countries, with more limited resources and capacities than developed countries, typically seek to expand TRIPS in order "to provide easier access to patented technology, primarily through compulsory licenses."[245] In a growing number of cases, some countries have been able to use the threat of compulsory licenses as a bargaining tool to negotiate more favorable prices from pharmaceutical companies.[246] Even so, developing and least developed countries continue to struggle with "institutional and legal difficulties when using TRIPS flexibilities."[247] These countries advocate for relief from stringent intellectual property rights that impede the local production, manufacture, and procurement of health-related technologies, particularly in the face of the current global pandemic.[248]

C. Intellectual Property Measures and the Public Interest in the Context of COVID-19

In light of the ongoing COVID-19 pandemic, the international community should adopt a holistic approach to TRIPS that allows countries to use current TRIPS flexibilities "to the full" [249] in augmenting global efforts to promote public health. This approach would promote public health goals without needlessly sacrificing incentives for innovation. As a preliminary step toward this end, on July 17, 2020, South Africa submitted a proposal to the Council for TRIPS.[250] South Africa posed a number of questions regarding the scope of TRIPS flexibilities in relation to areas other than patents, expressing concerns over whether countries are implementing these flexibilities effectively, particularly when faced with an international health crisis like COVID-19.[251] Most notably, South Africa argued that because the TRIPS flexibilities are rarely used outside of the context of patents for medicines, they are less well-understood at the national level, especially by countries that have never before used compulsory licensing.[252]

Considering the events stemming from the COVID-19 pandemic, South Africa urged the WTO to adopt a "more integrated approach to TRIPS flexibilities" to encompass other types of intellectual property beyond patents, such as copyrights,

243. *Id.* at 153.

244. Santos, *supra* note 138, at 412.

245. Harris, *supra* note 127, at 383.

246. *See, e.g.*, *id.* at 386–90 (describing various countries' use of compulsory licenses including as negotiation tools).

247. *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19*, *supra* note 226.

248. *Id.*

249. Doha Declaration, *supra* note 31, ¶ 4.

250. Communication from South Africa, *supra* note 26, at 1.

251. *Id.* at 3–4.

252. *Id.* at 1.

trade secrets, and industrial designs.[253] Similarly, scholars have considered the importance of copyrights in response to COVID-19.[254] To support the argument for applying TRIPS flexibilities beyond patents, South Africa provided some specific examples of other intellectual property areas that could be more broadly applied in efforts to combat the pandemic, such as data collection to assist with contact tracing and the use of 3D printing to facilitate the increased demand for health-related equipment.[255] South Africa also stressed the pivotal effect that trade secrets, such as information about unsuccessful attempts at developing vaccines, can have on efforts to save lives across the globe.[256] In July of 2020, the Council for TRIPS discussed various intellectual property measures involved in combating COVID-19, including some debate regarding South Africa's proposal.[257] This discussion highlighted the continued divergence in prevailing views on the relationship between TRIPS flexibilities and public health concerns.[258]

Developed countries maintain that TRIPS continues to be "the right tool to strike the right balance between innovation and safeguarding public health."[259] In their view, during this pandemic, the current intellectual property system is already adapted to boost scientific and international cooperation while also encouraging further medical research and innovation.[260] To highlight this position, developed countries point to voluntary measures, such as the COVID-19 Technology Access Pool (C-TAP) maintained by the World Health Organization (WHO).[261] C-TAP is a compilation of voluntarily shared knowledge of health-related technology, intellectual property, and data intended to be part of global efforts to provide access

253. *Id.*

254. *See, e.g.*, Caroline Ncube, *The Musings of a Copyright Scholar Working in South Africa: Is Copyright Law Supportive of Emergency Remote Teaching?*, AFRONOMICSLAW (May 13, 2020), https://www.afronomicslaw.org/2020/05/13/the-musings-of-a-copyright-scholar-working-in-south-africa-is-copyright-law-supportive-of-emergency-remote-teaching/ (questioning whether copyright supports the right to education within the context of emergency remote teaching in South Africa); Michael Birnhack, *Who Controls COVID-Related Medical Data? Copyright And Personal Data*, INT'L REV. INTELL. PROP. AND COMPETITION L. (forthcoming 2021) (unpacking the relationship between data protection and copyright law in the context of COVID-19 vaccine data); Carys J. Craig & Bob Tarantino, *"An Hundred Stories in Ten Days": COVID-19 Lessons for Culture, Learning, and Copyright Law*, 57 OSGOODE HALL L. J. 567 (2020) (reflecting on the impact of copyright on creativity and learning during COVID-19 pandemic).

255. Communication from South Africa, *supra* note 26, at 2–3.

256. *See id.* at 3–4 (stating that a public health crisis as widespread as COVID-19 presents a compelling reason for reexamining the dominance of trade secrecy, as it poses a critical obstacle to combating the pandemic).

257. *WTO Members Stress Role of IP System in Fighting COVID-19*, *supra* note 25.

258. *See id.* (discussing divergent views on TRIPS flexibilities expressed by different WTO member states at WTO meeting).

259. *Id.*

260. *See id*. (stating that cooperation would involve respect for intellectual property rights as well as industry-led collaboration and sharing knowledge voluntarily).

261. *See id.* (indicating developed countries' assertion that voluntary rights pooling and other licensing arrangements provide for safe and effective diagnostics, medicines, and vaccines to help with COVID-19 response).

to life-saving technologies to combat the pandemic.[262] Further, developed countries reiterate that a hasty reexamination of TRIPS flexibilities could negatively impact investment in, research into, and development of new treatments.[263]

Conversely, developing countries and least developed countries stress that the current pandemic presents specific challenges regarding access to medicine, vaccines, and health-related technologies.[264] These countries argue that the current system presents barriers to access vaccines and new medical technologies based on a country's economic situation.[265] Further, these countries highlight that they face additional "legal, technical and institutional challenges" even with the current TRIPS flexibilities because of their limited—or lack of—domestic manufacturing capabilities.[266] These countries urge that the current situation "calls for the removal of complexities in the TRIPS Agreement" in order to improve the effectiveness of the Doha Declaration by balancing the tension between intellectual property rights and public health needs.[267] They further stress that essential goods and services needed in efforts to combat the COVID-19 pandemic—including personal protective equipment—remain in critically short supply in many developing and least developed countries.[268]

Adopting a holistic approach to TRIPS flexibilities could work within the existing framework of protection to allow countries to use those flexibilities to the fullest extent. Countries could then provide access to health-related technologies other than medicines, such as masks, sanitizers, and contact tracing software, that would aid their efforts to promote public health. By viewing TRIPS as a whole rather than as a segmented series of parts, countries could apply compulsory licensing to other areas of intellectual property rights beyond patents to increase the global production of health-related technologies needed to combat COVID-19.

D. Integrated Workshop Combining Health, Intellectual Property, and Trade Views

The holistic approach need not be limited to TRIPS and the international intellectual property system but could also be applied to other international law systems. Preliminary steps have already been taken to explore this type of integrated

262. *See id.* (describing how C-TAP works to fast-track product development and mobilize manufacturing capabilities efficiently by promoting equitable global access).

263. *See id.* (noting that incentivizing to development, testing, and production of safe and effective vaccines, therapeutics, and other relevant products for COVID-19 response is best way to effectively fight pandemic).

264. *See id.* (urging for removal of complexities in TRIPS to improve the Doha Declaration's effectiveness and ensure equitable access for members without pharmaceutical manufacturing capacity).

265. *See id.* (noting these countries advocate for the Council for TRIPS to ensure access and availability of vaccines and new medical technologies regardless of a country's economic development and that intellectual property rights are not a barrier to such access).

266. *Id.*

267. *Id.*

268. *See id.* (explaining that goods and services needed to combat COVID-19, such as masks, face shields, and hand sanitizers, remain in critical shortage for many countries).

interaction in the context of international intellectual property, trade, and health regimes.[269] On October 21, 2020, the WTO held the first round of an integrated technical workshop called "An Integrated Health, Trade and Intellectual Property Approach to Address the COVID-19 Pandemic" to explore ways health, trade, and intellectual property regimes could intersect to benefit public health response.[270] Policymakers were invited to explore ways to build capacity for accessing domestic health systems, intellectual property systems, and trade policy settings in order to develop tools for effectively responding to the COVID-19 pandemic.[271] This meeting represented the first edition of a workshop intended to assist the WTO secretariat with devising and implementing technical assistance for WTO members and observers.[272] Those present "represented expertise from many distinct policy dimensions which emphasized the need for an integrated approach" to combat the current global health crisis.[273]

At the workshop, the WTO secretariat as well as the WHO and WIPO secretariats presented overviews of the aspects of key trade policies, regulatory and health challenges, and features of the international intellectual property systems that can be used to facilitate access to health technologies involved in combating COVID-19.[274] These presentations included considerations that each organization (WTO, WHO, and WIPO) has made to determine how best to use flexibilities within their respective international framework to meet member states' development needs and domestic policy objectives.[275] The presentation also introduced the joint study that had been launched on July 29, 2020, by the WHO, WIPO, and WTO on "Promoting Access to Medical Technologies and Innovation."[276] Efforts like the integrated workshop and the joint study show that taking a holistic approach on an international level is not only possible but also beneficial.

E. Efforts to Ensure Global Access to and Affordability of COVID-19 Vaccines

> *"The scarcity of [access to] COVID-19 vaccine supplies [has] led to a situation in which around 75 countries are able to move ahead with vaccination while 115 countries wait as people die."*[277]

---

269. *WTO Workshop on Health, Trade and Intellectual Property: An Integrated Approach to COVID-19*, WTO (Oct. 21, 2020), https://www.wto.org/english/news_e/news20_e/heal_21oct20_e.htm.

270. *Id.*

271. *See id.* (describing workshop's attendees, which included experts from forty different WTO members and observers, as well as officials from various ministries and intellectual property offices).

272. *Id.*

273. *Id.*

274. *Id.*

275. *Id.*

276. *Id.*; *see also* WORLD TRADE ORG., WORLD HEALTH ORG., & WORLD INTELL. PROP. ORG., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE (2d ed. 2020), https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf (detailing findings of joint study).

277. *DG Calls on COVID-19 Vaccine Manufacturers to Increase Production in Developing*

On December 9, 2020, the WTO received a petition seeking to ensure that COVID-19 vaccines would be both accessible and affordable across the globe.[278] This petition was delivered virtually by Avaaz, a nonprofit organization promoting global activism online, and signed by over 930,000 people around the world as of December 2020.[279] Addressing the petition to all governments, the WTO, and pharmaceutical companies, the petitioners seek to "ensure access to lifesaving Covid-19 vaccines, treatments and equipment for everyone in the world."[280] They urge global cooperation and seek more equitable sharing of resources.[281] The petition ends with the chilling declaration that "[t]he pandemic will not be over, until [it is] over everywhere."[282] The WTO received this petition just before the Council for TRIPS met on December 10, 2020.[283]

In response to the rising tide of "vaccine nationalism" in 2020, the WHO, the Coalition for Epidemic Preparedness Innovations, and Gavi, the Vaccine Alliance, formed a partnership called COVAX, which seeks to "fairly distribute vaccines between rich countries and the developing world."[284] COVAX's main goal is to supply COVID-19 vaccines to "20 percent of people in 92 low- and middle-income countries, whose populations total some 3.6 billion."[285] However, COVAX's efforts have been constrained by a lack of supply, with the vast majority of COVID-19 vaccine doses going to rich countries.[286] Although their efforts were initially slow, COVAX delivered its first shipment of six hundred thousand vaccines to Ghana by late February 2021.[287] Delivering vaccines to poor countries only twelve months after the COVID-19 outbreak was declared a pandemic seems like "lightspeed" in comparison to previous global immunization programs.[288] Nevertheless, developing and least developed countries are still "deeply marked by the memory of unaffordable HIV/AIDS drugs."[289] Similarly, during the swine flu pandemic, developing countries were "left at the back of the queue" as richer, developed

---

Countries, WTO (Mar. 9, 2021), https://www.wto.org/english/news_e/news21_e/dgno_09mar21_e.htm.

278. *WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines*, *supra* note 24.

279. *See Share the Vaccine with the World!*, *supra* note 229 (showing current signature total is now over 2.77 million).

280. *WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines*, *supra* note 24; *Share the Vaccine with the World!*, *supra* note 229.

281. *Share the Vaccine with the World!*, *supra* note 229.

282. *Id.*

283. *WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines*, *supra* note 24.

284. Alexander Smith, *COVAX: Why Biden's Billions Won't Fix Covid Vaccine Inequality Worldwide*, NBC NEWS (Feb. 26, 2021, 4:04 PM), https://www.nbcnews.com/news/world/covax-why-biden-s-billions-won-t-fix-covid-vaccine-n1258816 [hereinafter Smith, *COVAX*].

285. *Id.*

286. *Id.*

287. *Id.*

288. *Id.*

289. *DG Calls on COVID-19 Vaccine Manufacturers to Increase Production in Developing Countries*, *supra* note 277.

countries bought up most of the available H1N1 vaccines, which ultimately went unused.[290]

Currently, distributions of the COVID-19 vaccines are following a similar trend.[291] While more than a hundred of the poorest countries have not administered a single vaccine, the United States alone has managed about twenty vaccinations per one hundred people as of late February 2021.[292] If the past trend of vaccine nationalism continues and wealthy countries persist in buying up the initial supplies of vaccines, widespread immunization prior to 2023 is highly unlikely for some countries in Africa, South America, and Asia.[293] Even if some countries achieve widespread immunization, their people could remain at risk from inevitable mutations of new variants that develop in countries waiting to begin their vaccination efforts due to lack of supplies.[294]

Scholars have warned that by delaying widespread control of COVID-19, global economic demands will remain impaired and supply chains will remain interrupted.[295] Conversely, if developed countries shared the limited supply of vaccines equitably with developing countries, it could prevent a "$119 billion hole in the global economy."[296] Additionally, scholars caution that countries might resort to "desperate measures" if they believe access to vaccines could prevent their economic collapse.[297] In such cases, countries might completely ignore protections for intellectual property rights in TRIPS and simply manufacture the vaccines and therapies without consent from the rights holders.[298] In March of 2021, the WTO Director-General expressed hope that manufacturers from both developed and developing countries could collaborate with civil society groups, international organizations, and business associations to simultaneously increase vaccine production and search for a solution to the ongoing TRIPS debate.[299] By taking a more holistic view of TRIPS flexibilities, the international community can militate the need for drastic measures and, at the same time, find ways to increase production of health-related technologies and vaccines to combat COVID-19.

F. Proposed Waiver of TRIPS Provisions to Facilitate Efforts to Combat COVID-19

In response to developing and least developed countries' current struggles with

---

290. *Id.*; *see also* Smith, *Vaccine Nationalism*, *supra* note 7 (describing how wealthy countries' advance orders for vaccines essentially blocked poorer countries' access).

291. *See* Smith, *COVAX*, *supra* note 284 (finding that rich countries, such as the United States, are not willing to donate stockpiled vaccines to poorer countries).

292. *Id.*

293. *Id.*

294. *Id.*

295. HAFNER, *supra* note 1, at iv.

296. Smith, *COVAX*, *supra* note 284; *see also* HAFNER, *supra* note 1, at v–vi (describing economic incentives for providing widespread access to vaccines as soon as possible).

297. Smith, *Vaccine Nationalism*, *supra* note 7.

298. *Id.*

299. *DG Calls on COVID-19 Vaccine Manufacturers to Increase Production in Developing Countries*, *supra* note 277.

limited access to much-needed health-related technologies, India and South Africa submitted a proposal to the Council for TRIPS on October 2, 2020.[300] This proposal asked for a waiver of obligations[301] under Part II of TRIPS.[302] Specifically, the waiver would apply to Sections 1, 4, 5, and 7, which govern protections for copyrights and related rights, industrial designs, patents, and undisclosed information, respectively.[303] If accepted, the proposal would waive all obligations under those sections[304] "in relation to prevention, containment or treatment of COVID-19," for a set number of years,[305] until the majority of the world's population had been vaccinated or become immune.[306] Delegations from Kenya, Pakistan, Eswatini, Mozambique, and Bolivia joined India and South Africa as co-sponsors of the proposal.[307] As of March 11, 2021, Venezuela, Mongolia, Zimbabwe, Egypt, the African Group, and the Least Developed Countries Group (LDC Group) have also joined as co-sponsors of the proposed waiver.[308]

The requested waiver highlights the importance of the international community working together to overcome barriers that intellectual property rights can create, which barriers hinder countries' abilities to combat this global pandemic.[309] India and South Africa claim that developing and least developed countries are disproportionally impacted by COVID-19.[310] In light of past shortages in health-related products, they reiterate significant concern for the ready availability of therapeutics and vaccines and advocate for a rapid increase in the manufacturing of critically needed medical supplies across the globe.[311] These countries call for "global solidarity" through the sharing of technology and know-how to facilitate efforts to combat COVID-19.[312] The Council for TRIPS discussed this proposed waiver during its meeting on December 10, 2020.[313]

In the weeks between the proposal made on October 2, 2020 and the Council

---

300. *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, *supra* note 61.

301. *Id.*

302. Communication from India and South Africa, *supra* note 4, ¶ 12.

303. *Id.*

304. Although extremely broad in scope, the waiver does make a narrow exception for "protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14" of TRIPS. *Id.*

305. *Id.* ¶ 12–13.

306. *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, *supra* note 61.

307. *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19*, *supra* note 226.

308. *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, *supra* note 61.

309. *See* Communication from India and South Africa, *supra* note 4, ¶ 13 (advocating waiver of TRIPS obligations in order to further efforts to combat COVID-19 pandemic).

310. *Id.* ¶ 4.

311. *Id.* ¶¶ 7–10.

312. *Id.* ¶ 11.

313. *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19*, *supra* note 226.

for TRIPS meeting held on December 10, 2020, there were a number of comprehensive discussions and informal meetings during which WTO members were able to share their views on the proposal, voice concerns, and seek clarification on aspects of the proposed waiver.[314] Despite these discussions, a consensus was not reached in December 2020, and the matter was left unresolved for renewed consideration when the Council for TRIPS next met in March 2021.[315]

On March 10, the Council for TRIPS continued its discussions of the proposed waiver to TRIPS to assist countries with the "'prevention, containment, [and] treatment' of COVID-19."[316] Proponents advocated for the waiver as a means "to avoid barriers to the timely access to affordable medical products, including vaccines and medicines, and to the scaling-up of manufacturing and supply of essential medical products."[317] These countries argued that barriers caused by intellectual property rights cause "existing vaccine manufacturing capacities in the developing world [to] remain[] unutilized."[318]

Other countries sought a discussion based on evidence of specific examples where intellectual property rights have proven to be "a barrier to manufacturing and access to vaccines that could not be addressed by existing TRIPS flexibilities."[319] These countries focused their argument on the role intellectual property protection has "as an incentive for innovation to fight the current and future pandemics."[320] Once again, the matter went unresolved, pending additional meetings leading up to renewed consideration at the June 2021 meeting.[321] In June 2021, the Council for TRIPS yet again left the matter unresolved, pending future assessment.[322]

Although proponents of the waiver raise important concerns over underutilizing resources in developing countries, the waiver is an overly broad means of addressing the need to increase global efforts to combat COVID-19. By embracing a holistic approach to the current TRIPS flexibilities, countries can use the means they already have at their disposal to increase access to the health-related technologies needed to augment global efforts to combat the pandemic. More importantly, without prolonged abandonment of protections for intellectual property rights, countries can use the current TRIPS flexibilities to promote public health and further global efforts to combat the pandemic.

---

314. *Id.*

315. *Id.*

316. *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, *supra* note 61.

317. *Id.*

318. *Id.*

319. *Id.*

320. *Id.*

321. *See id.* (concluding that additional meetings before the formal TRIPS Council meeting may be necessary to assess progress on the IP waiver discussion).

322. *TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19*, WTO (July 20, 2021), https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm.

IV. LIGHTING THE PATH AHEAD: A HOLISTIC APPROACH

> *"A full response to the COVID-19 crisis requires wide access to an extensive array of medical products and other technologies, ranging from protective equipment to contact tracing software, medicines and diagnostics, as well as vaccines and treatments that are yet to be developed."*[323]

Although the debate over whether TRIPS offers too much or not enough protection for intellectual property rights is an ongoing process, the widespread impact of the current global health crisis has cast this debate into a more personal light for many people across the globe. The tension between access to medicines and other health-related technology has become an ever-present discussion topic for many citizens around the world.[324] As laboratories and drug companies race to develop and distribute a viable vaccine,[325] the need for global access to medicine and health-related technology has become a very palpable part of people's lives.[326]

For years, scholars have advocated that greater incentives are required to encourage institutions to cooperate and share research.[327] These scholars have highlighted a need to reform intellectual property protections "to better reflect the large scale and collaborative nature of scientific projects" such as research into viruses and vaccines.[328] Other scholars have supported a more precautionary approach that would allow the need to prevent impending harm to take precedence over other concerns such as financial incentives for innovation, and they urge that such precedence is especially important during public health crises.[329]

On the other hand, the need to protect the financial incentives that make it viable to invest in the cost of research and development and that promote future innovation is likewise an important concern. From a business perspective, any weakening of the protections for intellectual property rights runs the risk of

---

323. *New WTO Report Looks at the Global Intellectual Property System and COVID-19*, *supra* note 11.

324. *See, e.g.*, *WHO Coronavirus Disease (COVID-19) Dashboard*, *supra* note 6 (showing global extent of COVID-19 impact); *WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines*, *supra* note 24 (describing global community's petition for a universally accessible and affordable COVID-19 vaccine).

325. *See* Philip Ball, *What the Lightning-Fast Quest for Covid Vaccines Means for Other Diseases: The Speedy Approach Used to Tackle SARS-CoV-2 Could Change the Future of Vaccine Science*, 589 NATURE 16 (2021) (describing efforts to develop COVID-19 vaccine).

326. *See Share the Vaccine with the World!*, *supra* note 229, (outlining terms of global community's petition for a universally accessible and affordable COVID-19 vaccine); *see also WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines*, *supra* note 24 (describing global community's petition for COVID-19 vaccine).

327. Rimmer, *supra* note 35, at 338.

328. *Id.*; *see also id.* at 339 (underscoring need to ensure patent system is flexible enough to allow for international research efforts on infectious diseases).

329. *See generally* PHOEBE LI, HEALTH TECHNOLOGIES AND INTERNATIONAL INTELLECTUAL PROPERTY: A PRECAUTIONARY APPROACH (2014) (advocating for precautionary approach in treatment of intellectual property rights during times of public health crises); Santos, *supra* note 138 (discussing same).

disincentivizing the development of new technologies.[330] Without sufficient incentives for the cost of innovation, there would likely be a severe decline in the pursuit and development of new medicines, life-saving devices, and other health-related technologies.[331] Such a loss of innovation would assuredly be more detrimental to public health than the current limits on TRIPS flexibilities for access to medicines and medical technology.[332]

At the same time, the use of TRIPS flexibilities in areas of intellectual property rights other than patents needs to be explored and further developed. Many countries, particularly least developed countries that would benefit most from such use of flexibilities, do not understand how to effectively implement tools like compulsory licenses; consequently, little success has been made in efforts to use these flexibilities in other areas of intellectual property.[333] Further, without a clear understanding of how to effectively use TRIPS flexibilities in areas other than patents, it is unlikely that countries will feel emboldened enough to try using these flexibilities even while faced with a serious health crisis.

Accordingly, the use of TRIPS flexibilities to increase access to health-related technologies protected by other areas of intellectual property rights that are not specifically precluded from such flexibilities (e.g., the prohibition on compulsory licensing of trademarks[334]) needs to be encouraged. Ensuring that COVID-19 vaccines and therapies are universally accessible and affordable is "a human rights duty that requires political commitment and international cooperation."[335] Encouraged use of TRIPS flexibilities will facilitate global efforts to combat this pandemic as well as subsequent serious health crises. Health-related technologies such as contact tracing software, diagnostic tools, and protective equipment are key components of the international community's efforts to combat COVID-19.[336] Countries without the resources or capabilities to manufacture these technologies should be able to use compulsory licenses to import them from other countries to assist in their domestic efforts to minimize and mitigate the damage done by the spread of this disease.

---

330. *See, e.g.*, Subhan, *supra* note 221, at 153 (highlighting financial motive behind investment in research and development efforts).

331. *See, e.g.*, *id.* at 152–53 (recommending measures to ensure preservation of incentives considered necessary for innovation).

332. *See, e.g.*, Subhan, *supra* note 221, at 156 (explaining that development of medications requires its producers to be financially compensated for their efforts by those who use those medications, despite many users being unable to afford to do so).

333. *See WTO Members Stress Role of IP System in Fighting COVID-19*, *supra* note 25 (noting that many countries do not effectively use TRIPS flexibilities).

334. TRIPS, *supra* note 44, art. 21.

335. Katrina Perehudoff & Jennifer Sellin, *COVID-19 Technology Access Pool (C-TAP): A Promising Human Rights Approach*, MEDICINES LAW & POLICY (June 18, 2020), https://medicineslawandpolicy.org/2020/06/covid-19-technology-access-pool-c-tap-a-promising-human-rights-approach/.

336. *See, e.g.*, *WTO Updates Report on Trade in Medical Goods in the Context of COVID-19*, *supra* note 8 (describing increased demand for international trade in medical goods); *see also New WTO Report Looks at the Global Intellectual Property System and COVID-19*, *supra* note 11 (describing health-related technologies fundamental to COVID-19 response).

Additionally, relaxing the rigid enforcement and protection of trade secrets, particularly when such information regards unsuccessful trial data, would further facilitate efforts to combat global health crises. Voluntary knowledge-sharing efforts, like C-TAP,[337] need to be encouraged and expanded to ensure that global resources are not wasted in pursuit of known-to-be fruitless paths to developing effective vaccines and treatment methods. By default, "[p]andemics epitomize the need for scientific and technical international assistance and cooperation," which cooperation can ensure that no country is left alone without the resources to combat the health crisis.[338] When the WHO launched C-TAP on May 29, 2020, it was "an encouraging and important step towards equitable access" to medicines to combat COVID-19.[339] Such efforts to voluntarily pool resources[340] should be encouraged and incentivized, particularly as they have been shown to be effective in the past in other contexts.[341]

Further, these types of knowledge-sharing pools are not adverse to the financial concerns of technology developers and intellectual property rights holders, as the pools allow for some financial remuneration to be paid to the developers whose technology is shared in the pool.[342] This sharing of scientific knowledge is "crucial to mitigat[ing] the impact of [a global pandemic], and to expedit[ing] the discovery of effective treatments and vaccines" as well as other health-related technologies.[343] The equitable sharing of resources like vaccines is critical to avoid "devastating and prolonged consequences . . . [,] dramatically widening inequalities, hampering social and economic development, and leaving scores of countries in significantly [worse economic shape]."[344]

Effective and efficient use of intellectual property systems by the international community can also facilitate greater access to those health-related technologies needed to combat a global pandemic.[345] Current efforts by the WHO, WTO, and WIPO to explore avenues for making the intersection of health, trade, and intellectual property regimes more accessible for global health initiatives[346] should

337. *See* Perehudoff & Sellin, *supra* note 335 (explaining C-TAP).

338. *Id.*

339. *Id.*

340. For examples of voluntary pooling efforts, see *WTO Members Stress Role of IP System in Fighting COVID-19*, *supra* note 25.

341. *See* Perehudoff & Sellin**,** *supra* note 335 (noting that systems which voluntarily pool resources have been successful in aviation and the pharmaceutical industry).

342. *See id.* (describing pools as effective and efficient means for bringing together new technologies for use at fair prices, while offering some compensation to developers of those technologies).

343. *Id.*

344. Turak, *supra* note 230.

345. *See New WTO Report Looks at the Global Intellectual Property System and COVID-19*, *supra* note 11 (describing significance of TRIPS in supporting creation and dissemination of health-related technologies).

346. *E.g.*, *WTO Workshop on Health, Trade and Intellectual Property: An Integrated Approach to COVID-19*, *supra* note 269; WORLD TRADE ORG., WORLD HEALTH ORG., & WORLD INTELL. PROP. ORG., *supra* note 276.

also be encouraged and expanded.[347] Applying this holistic view to international law regimes would allow for a more comprehensive and effective means not only of combating the current global pandemic but also of preparing to alleviate future global health crises and other emergencies. Taking the holistic approach with respect to TRIPS and its flexibilities will benefit the international community as a whole by ensuring that everyone has the ability to access the knowledge and technologies needed to combat a global health crisis and promote public health.

V. CONCLUSION

There is no one right answer—no simple panacea—to fix every concern or perceived deficiency with the current international intellectual property rights regime embodied in TRIPS. In light of the COVID-19 pandemic, however, a more holistic approach to TRIPS, particularly with respect to the use of its flexibilities to improve access to all types of health-related technologies, is required. Viewing TRIPS holistically would allow the flexibilities available in one part of TRIPS—such as compulsory licensing under Article 31*bis*—to apply (unless explicitly prohibited in a specific section) to the agreement as a whole. This holistic approach would ensure that countries have broad discretion to take steps to combat national—and global—public health crises without unnecessarily eroding protections for intellectual property rights. The international community should adopt a holistic approach to TRIPS that promotes public health goals without needlessly sacrificing incentives for innovation and that supports international cooperation. This holistic approach would balance needs for innovation in and access to health-related technologies integral to combating widespread emergencies and global pandemics.

347. International law regimes could also be incorporated in key ways to shape an effective global response to serious health crises. *See* Perehudoff & Sellin, *supra* note 335 (describing importance of human rights law acting as a guide to governments and businesses for navigating out of global health crises).