

BEYOND COMPULSORY LICENSING: PFIZER SHARES ITS COVID-19 MEDICINES WITH THE PATENT POOL

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On March 15, 2022, the United States, European Union, India, and South Africa reached an agreement on the waiver of intellectual property rights (IP rights) for COVID-19 vaccines.

The waiver agreement has rekindled the debate on the balance between IP rights protection and equitable access to medicines during a public health crisis. India, South Africa, and other developing countries maintain that a waiver was the only way to make vaccines affordable and accessible. Leading pharmaceutical companies argue that the waiver will stifle innovation and make lifesaving medicines less accessible.

Both sides have seemingly overlooked Pfizer’s voluntary agreement with the Medicines Patent Pool (MPP) to share the IP rights for Paxlovid, the company’s highly effective COVID-19 medicine. Based on a careful examination of Pfizer’s agreement, this Article argues that the MPP presents an effective alternative to the waiver approach and concludes that the Pfizer-MPP model has the potential to reach an equilibrium between access and innovation.

INTRODUCTION	2
I. THE WAIVER AND COMPULSORY LICENSING	3
A. The Waiver Requests	3
B. IP Rights under GATT	6
C. The Imbalanced Bargain	9
D. The TRIPS Agreement	12
i. The Balance Between Creation and Access ...	13
ii. Article 31 Compulsory Licensing	16
iii. The Doha Declaration	19
iv. Article 31bis	20
v. The Rwanda-Canada Case	23

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II. THE MEDICINES PATENT POOL (MPP) 24

 A. The Pfizer-MPP Agreement..... 26

 i. Coverage and Royalty 27

 ii. Outside the Territory 28

 iii. Improvements 29

 iv. Anti-Corrupt Practices 30

 v. Trademarks 32

 vi. Licensees and MPP Supervision 33

 vii. Quality Control and No Diversion 34

 B. Activist Shareholders’ Pressure 35

III. COMPULSORY LICENSING V. VOLUNTARY LICENSING ... 38

CONCLUSION..... 40

INTRODUCTION

On March 15, 2022, the United States, European Union, India, and South Africa reached an agreement on the waiver of IP rights for COVID-19 vaccines.¹ The waiver agreement has rekindled the debate on the balance between IP rights protection and equitable access to medicines during a public health crisis. India, South Africa, and other developing countries maintained that a waiver was the only way to make vaccines affordable and accessible. In contrast, leading pharmaceutical companies argued that waivers stifle innovation and make lifesaving medicines less accessible.

However, both sides seemingly have overlooked Pfizer’s voluntary agreement with the Medicines Patent Pool (MPP) to share the IP rights for its highly effective COVID-19 medicine—Paxlovid.² This Article will carefully examine the Pfizer-MPP Agreement and analyze its impact on the compulsory licensing system.

Part I of this Article explores the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the compulsory licensing system. Part II examines the MPP structure, particularly the

1. *TRIPS COVID-19 solution (the outcome of the quadrilateral discussions at the end of last week, to be presented to WTO Members)*, FREEPDFHOSTING, https://freepdfhosting.com/4d79fc6c70.pdf?mkt_tok=ndkwLUVIWwi05OTkAAAGDS8CxT-gaggGcJhS5E_DWFmBSdpRvDgfAa9gZpMKFuk4TaLcxVf1xdh9uQDnaODpvVBWMOnc_M7HFWqgP-QS5YYzSwsPm4qf2vZQOmpPt7K45G [https://perma.cc/TH2W-DXKY] (published initially by Ed Silverman, *A compromise is reached on an intellectual property waiver for Covid-19 vaccines, but does it go far enough?*, STAT (Mar. 15, 2022)).

2. Pfizer uses numerous names for the compound (C23H32F3N5O4)—Paxlovid, Nirmatrelvir, PF-07321332, PF07321332, 2628280-40-8, UNII-7R9A5P7H32, and others. For a full list of Paxlovid’s synonyms, see NAT’L LIBR. OF MED., NIRMATRELVIR (2021), <https://pubchem.ncbi.nlm.nih.gov/compound/Nirmatrelvir>.

Pfizer-MPP Agreement, and the pressure exerted by Pfizer's activist shareholders. After comparing the compulsory licensing and voluntary licensing in Part III, the Article argues that the MPP presents an efficient alternative to the waiver approach and that the Pfizer-MPP model has the potential to reach an equilibrium between access and innovation without coercive means.

The Article warns, however, that voluntary licensing through the MPP alone cannot meet the demand for COVID-19 vaccines and treatments in low- and middle-income countries. The threat of compulsory licensing makes rights-holders more likely to share their cutting-edge technologies with the MPP on a not-for-profit basis. In addition, pressure from activist shareholders may also play a role in persuading rights-holders to take a more active role in promoting global health. Only the combined forces of TRIPS, MPP, and socially responsible pharmaceutical companies will provide the global community with a solution to widespread health problems while also preserving the delicate balance between innovation and equitable access.

I.

THE WAIVER AND COMPULSORY LICENSING

A. *The Waiver Requests*

On October 2, 2020, India and South Africa petitioned the TRIPS Council of the World Trade Organization (WTO) to waive certain provisions of the TRIPS Agreement.³ The two countries stressed that IP rights should not become barriers for developing countries to have access to vaccines and other medical products urgently needed for combating the COVID-19 pandemic.⁴ Shortages of these products would not only cause more illnesses and deaths but also threaten to prolong the pandemic.⁵ Thus, the countries argued it is imperative that developing countries have prompt, adequate, and affordable access to these medical products.⁶ Specifically, the two countries pointed out that the compulsory licensing mechanism in Article 31bis of the TRIPS Agreement was cumbersome for the developing countries to

3. World Trade Organization, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid 19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter WTO Waiver Proposal], <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=CQ:/IP/C/W669.pdf&Open=true>, [https://perma.cc/TZF3-6SHD].

4. *Id.* at para. 3.

5. *Id.* at para. 6.

6. *Id.* at para. 7.

utilize.⁷ Therefore, they requested that the WTO waive their obligations to enforce the TRIPS Agreement, (Part II, Section 1 Copyright and Related Rights, Section 4 Industrial Designs, Section 5 Patents, and Section 7 Protection of Undisclosed Information).⁸ On May 25, 2021, India and South Africa coordinated with other developing countries and submitted a revised proposal, that widened the coverage of the waiver to include Part III Enforcement of IP rights.⁹ In addition, the revised version demanded a three-year waiver.¹⁰

The waiver requests were met with mixed responses. On May 5, 2021, United States Trade Representative, Katherine Tai, released a statement supporting the request for waiving the IP rights for COVID-19 vaccines.¹¹ The World Health Organization (WHO) Director-General hailed the United States' change of stance on IP waivers as a "monumental moment in the fight against COVID-19."¹² After the outgoing German Chancellor Angela Merkel opposed the waiver request,¹³ more than 140 former heads of state and Nobel laureates issued an open letter urging candidates for Chancellor to support the proposal.¹⁴ On March 28, 2022, German Chancellor Olaf Scholz expressed objections to the proposal because he believed that patent pro-

7. *Id.* at para. 10. *See also* Article 31bis, Section D of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS Agreement] for how the compulsory licensing mechanism works.

8. WTO Waiver Proposal, *supra* note 3, at para. 12. *See also*, Section D of the TRIPS Agreement, *supra* note 7, for the obligations that the TRIPS Agreement imposes on member countries.

9. World Trade Organization, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid 19*, Revised Decision Text, at WTO Doc. IP/C/W/669/Rev.1, at Annex, para. 1 (May 25, 2021) [hereinafter Revised Waiver Proposal], <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W669.pdf&Open=true> [<https://perma.cc/5JPQ-DUYV>]; *see also* TRIPS Agreement, *supra* note 7.

10. Revised Waiver Proposal, *supra* note 9, at Annex, para. 2.

11. Press Release, Off. U.S. Trade Rep., *Statement from Ambassador Katherine Tai on the COVID-19 Trips Waiver* (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> [<https://perma.cc/4Y35-738H>].

12. Talha Khan Burki, *Ensuring Fair Distribution of COVID-19 Vaccines: Is an Intellectual Waiver the Answer?* 9 *THE LANCET* e64 (May 21, 2021), [https://doi.org/10.1016/S2213-2600\(21\)00241-1](https://doi.org/10.1016/S2213-2600(21)00241-1).

13. Arne Delfs & Eric Martin, *Merkel Pushes Back on Vaccine Patent Waiver in Row with U.S.*, *BLOOMBERG NEWS* (May 6, 2021), <https://www.bloomberg.com/news/articles/2021-05-06/merkel-pushes-back-on-vaccine-patent-waiver-in-clash-with-biden> [<https://perma.cc/QUM4-7LBJ>].

14. *More than 140 former heads of state and Nobel laureates call on candidates for German chancellor to waive intellectual property rules for COVID vaccines*, UNAIDS (Sept. 14, 2021), <https://www.unaids.org/en/resources/presscentre/feature>

tection was essential for pharmaceutical companies to pursue new research.¹⁵ To make COVID-19 vaccines more accessible, the Chancellor suggested moving vaccine manufacturing facilities to undeveloped countries, rather than waiving IP rights.¹⁶ Pfizer CEO Dr. Albert Bourla issued an open letter against the waiver proposal, reasoning that the waiver would “disincentivize anyone else from taking a big risk.”¹⁷ He said the waiver would “unleash a scramble for the critical inputs” needed for making safe and effective vaccines. He also cautioned that entities with little or no experience in manufacturing vaccines could put vaccine safety and security at risk.¹⁸

Under the WTO Agreement, the WTO generally makes decisions on a consensus basis. If no consensus is reached, the Ministerial Conference or General Council makes the decision by a majority vote unless otherwise provided in the Agreement.¹⁹ The Ministerial Conference has the right to waive certain obligations imposed by the WTO Agreement or the Multilateral Trade Agreements in exceptional circumstances.²⁰ To waive obligations of the TRIPS Agreement, one of the Multilateral Trade Agreements annexed to the WTO Agreement specified that three-fourths of the members must vote in favor of the waiver request in the absence of consensus.²¹ A member seeking a waiver from obligations imposed by the TRIPS Agreement must submit its request to the Council for TRIPS, which makes a decision within ninety days of receiving the request.²² At the end of the deliberation period, the Council for TRIPS submits a report to the Ministerial

stories/2021/september/20210914_waive-intellectual-property-rules-for-covid-vaccines [https://perma.cc/3UDQ-YJTW].

15. Zuzanna Szymanska & Jane Merriman, *Germany speaks out against COVID-19 vaccine patent waiver*, REUTERS (Mar. 28, 2022, 1:25 PM), <https://www.reuters.com/world/europe/germany-speaks-out-against-covid-19-vaccine-patent-waiver-2022-03-28/> [https://perma.cc/2ZQX-CSGS].

16. *Id.*

17. Albert Bourla, *An Open Letter from Pfizer Chairman and CEO to Colleagues*, PFIZER (May 7, 2021), https://www.pfizer.com/news/articles/an_open_letter_from_pfizer_chairman_and_ceo_albert_bourla.

18. *Id.*

19. Marrakesh Agreement Establishing the World Trade Organization, art. IX, ¶ 1, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter Marrakesh Agreement].

20. Marrakesh Agreement art. IX, ¶ 3.

21. *Id.* See also, ANTONY TAUBMAN, HANNU WAGER, & JAYASHREE WATAL, A HANDBOOK ON THE WTO TRIPS AGREEMENT (2nd ed.), 30 (2020) (“Paragraph 3 and 4 of Article IX of the WTO Agreement provide the Ministerial Conference/General Council with authority to waive an obligation imposed on a member by the WTO Agreement or any of the Multilateral Trade Agreements, including TRIPS Agreement.”).

22. Marrakesh Agreement art. IX, ¶ 3.

Conference.²³ If the Ministerial Conference grants the waiver request, it must explain the exceptional circumstances that justify the decision, the terms and conditions of the waiver, and the duration of the waiver.²⁴ If the duration of the granted waiver exceeds one year, the Ministerial Conference must conduct an annual review until the waiver terminates.²⁵ In the review, the Ministerial Conference ensures that the necessity for the waiver still exists and the terms and conditions attached to the waiver are satisfied.²⁶ Based on the review, the Ministerial Conference makes a decision as to whether it will “extend, modify or terminate the waiver.”²⁷

B. IP Rights under GATT

In 1947, twenty-three nations signed the General Agreement on Tariffs and Trade (GATT),²⁸ which laid out the basic framework for the international trade in the post-World War II era.²⁹ The objectives of GATT were to raise living standards, ensure full employment, and develop “the full use of the resources of the world and expand[] the production and exchange of goods.”³⁰ To achieve these objectives, GATT called for “substantial reduction of tariffs and other barriers to trade [and] elimination of discriminatory treatment in international commerce.”³¹ While GATT’s primary goal was to break down trade barriers, it also allowed contracting parties to impose restrictions on trade under certain circumstances. For example, GATT Art. XX(b) allows contracting parties to take necessary restrictive measures “to protect human, animal or plant life or *health*,” on the condition that such measures are not arbitrary or discriminatory and do not constitute a disguised restriction on international trade.³² In addition, GATT Art. XX(d) permits contracting parties to take necessary measures to protect “patents, trademarks and copyrights, and the prevention of decep-

23. *Id.*

24. *Id.* at art. IX, ¶ 4.

25. *Id.*

26. *Id.*

27. *Id.*

28. WTO Press Release, Fiftieth Anniversary of the Multilateral Trading System, https://www.wto.org/english/thewto_e/minist_e/min96_e/chrono.htm#:~:text=ON%2030%20October%201947%2C%20the,Palais%20des%20Nations%20in%20Geneva;General%20Agreement%20on%20Tariffs%20and%20Trade,Oct.30,1947,61Stat.A-11,55U.N.T.S.194 [hereinafter GATT].

29. Douglas A. Irwin, Petros C. Maraoidis, & Alan O. Sykes, *The Genesis of the GATT*, 8 *WORLD TRADE REV.* 351, 351 (2009).

30. GATT pmbl.

31. *Id.*

32. *Id.* at art. XX.

tive practices” if these measures are “not inconsistent with the provisions of this Agreement.”³³ The Agreement did not, however, offer clear guidance for resolving conflicts between the protection of health in XX(b) and the protection of IP rights in XX(d).

During the early GATT multilateral trade negotiation rounds, contracting parties did not address the potential tension between IP rights and public health. As a result, there were no minimum standards for IP protection at the international level. In addition, the trade volume of patented pharmaceutical products was substantially lower in the first four decades of GATT compared with the period after 1990.³⁴

With services and knowledge-based products making up a greater share of global trade,³⁵ counterfeit goods became a major source of friction between developed countries and developing countries.³⁶ It is estimated that the U.S. industry lost between \$43 billion and \$61 billion, accounting for one percent of its GDP in 1986 due to lack of intellectual property protection in multilateral trade.³⁷ To confront this problem, the United States increasingly relied on Section 301 of the U.S. Trade Act of 1974.³⁸ In 1988, the U.S. Congress passed the Omnibus Trade and Competitiveness Act, which is known for “Special 301.”³⁹ The purpose of Special 301 was to “use credible threat of unilateral retaliation by the United States to ‘persuade’ trading partners to reform currently deficient intellectual property practices.”⁴⁰ In signing

33. *Id.*

34. Kenneth C. Shadlen, Bhaven N. Sampat & Amy Kapczynski, *Patents, Trade and Medicines: Past, Present and Future*, 27 *REV. OF INT’L POL. ECON.* 75, 79 (2019), www.columbia.edu/~bns3/data/ptm.pdf.

35. ANTONY TAUBMAN, HANNU WAGER & JAYASHREE WATAL, *A Handbook on the WTO TRIPS Agreement* 5 (Cambridge Univ. Press ed., 2nd ed. 2020).

36. Doris E. Long, *Copyright and the Uruguay Round Agreements: A New Era of Protection or An Illusory Promise?*, 22 *AIPLA Q. J.* 531, 536 nn.5-6 (1994).

37. World Bank, *GDP (Current US\$) - United States*, <https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?end=1986&locations=US&start=1986&view=bar> (last visited Oct. 5, 2022); see also Michael G. Harvey, *What MNC Managers Should Know About GATT?*, *INDEX ARTICLES* (1996), <https://indexarticles.com/reference/multinational-business-review/what-mnc-managers-should-know-about-gatt/>.

38. BERNARD M. HOEKMAN & MICHEL M. KOSTECKI, *The Political Economy of the World Trading System* 373–74 (Oxford Univ. Press 3rd ed., 2010).

39. Judith H. Bello & Alan F. Holmer, “Special 301”: *Its Requirements, Implementation, and Significance*, 13 *FORDHAM INT’L L.J.* 259, 259 (1989); see also Vicki Allums, *Special 301. TRIPS Plus - Alive and Kicking*, 5 *J. MARSHALL REV. INTELL. PROP. L.* 651 (2006); Hembadon I. Oguanobi, *Broadening the Conversation on the TRIPS Agreement: Access to Medicines Includes Addressing Access to Medical Devices*, 21 *J. WORLD INTELL. PROP.* 70 (2018); Michelle M. Nerozzi, Note, *The Battle over Life-saving Pharmaceuticals: Are Developing Countries Being ‘Tripped’ by Developed Countries?*, 47 *VILL. L. REV.* 605 (2002).

40. Bello & Holmer, *supra* note 39, at 259.

the Act, President Reagan claimed that Special 301 would “strengthen the ability of U.S. firms to protect their patented, copyrighted, or trademarked goods and ideas from international *thievery*.”⁴¹

Under Special 301, the U.S. Trade Representative (the “USTR”) issues an annual report identifying priority foreign countries that “deny adequate and effective protection of IP rights”⁴² or “deny fair and equitable market access” to American companies.⁴³ In deciding its priority list, the USTR consults other government offices⁴⁴ and considers the information submitted by interested persons⁴⁵ as well as from representatives of relevant domestic industries.⁴⁶ The factors that the USTR considers include the foreign countries’ egregious conduct, the adverse impact on the American products, and the failures to engage in good faith negotiations with the U.S. government.⁴⁷ Within ninety days of releasing the list of priority countries, the USTR puts forward an action plan, which prescribes benchmarks for the identified country. If the country fails to meet the benchmarks within one year, the president may take appropriate actions against the country.⁴⁸

41. *Id.* at 261 (emphasis added).

42. 19 U.S.C. § 2242(a)(1)(A).

43. § 2242(a)(1)(B).

44. § 2242(b)(2)(A) and (B).

45. § 2242(b)(2)(B).

46. § 2242(f)(2)(A).

47. § 2242(b)(1)(A)–(C).

48. § 2242(g)(2). For comments about the impact of “Special 301” on the protection of intellectual property rights in foreign countries, see generally Seemantani Sharma, *A Survey of Intellectual Property Issues between the United States and India under the Special 301 Report*, 44 N.C. J. INT’L L. 1 (2018); Jennifer Fan, *The Dilemma of China’s Intellectual Property Piracy*, 4 UCLA J. INT’L L. & FOREIGN AFF. 207 (1999); Keshia B. Haskins, Jason D. Ferrone, *Compulsory Licensing During Public Health Crises: Bioterrorism’s Mark on Global Pharmaceutical Patent Protection*, 26 SUFFOLK TRANSNAT’L L. REV. 385 (2003); Stephen K. Shiu, *Motion Picture Piracy: Controlling the Seemingly Endless Supply of Counterfeit Optical Discs in Taiwan*, 39 VAND. J. TRANSNAT’L L. 607 (2006); Allums, *supra* note 39; Christine T. Phan, *Can the Intellectual Property-Human Rights Framework Bridge the Gap between Vietnam’s Legal Reality and Rhetoric?*, 22 COLUM. J. ASIAN L. 143 (2008); Lina M. Montem, *The Inconsistency between Section 301 and TRIPS: Counterproductive with Respect to the Future of International Protection of Intellectual Property Rights?*, 9 MARQ. INTELL. PROP. L. REV. 387 (2005); Michael W. Smith, *Bringing Developing Countries’ Intellectual Property Laws to TRIPS Standards: Hurdles and Pitfalls Facing Vietnam’s Efforts to Normalize an Intellectual Property Regime*, 31 CASE W. RESV. J. INT’L L. 211 (1999); Susan Sell, *The Rise and Rule of a Trade-based Strategy: Historical Institutionalism and the International Regulation of Intellectual Property*, 17 REV. INT’L POL. ECON. 762 (2010); Suzanne Zhou, *Challenging the Use of Special 301 against Measures Promoting Access to Medicines: Options under the WTO Agreements*, 19 J. INT’L ECON. L. 51, 86 (2016); Paul McDonald, *Pirate-states: Imagining the Geography of Media Piracy*, 24 INT’L J. CULTURAL STUD. 72 (2020), <https://journals.sagepub.com/doi/pdf/10.1177/1367877919850828>;

C. *The Imbalanced Bargain*

At the international level, the United States worked closely with the European Community (EC)⁴⁹ and took retaliatory actions against foreign countries for violation of IP rights.⁵⁰ At the end of the Tokyo Round of Multilateral Trade Negotiations (1973–1979),⁵¹ the United States and the EC proposed an Agreement on Measures to Discourage the Importation of Counterfeit Goods.⁵² Even though the agreement did not come to pass for lack of consensus, the efforts advocating the protection of IP rights gained momentum.⁵³

In preparation for the Uruguay Round Negotiation (1986–1994), twelve U.S.-based multilateral corporations, including Pfizer, Merck, and Johnson & Johnson,⁵⁴ formed the Intellectual Property Committee (IPC).⁵⁵ The IPC served as a platform through which the American leading industries collaborated with their counterparts in Europe and Japan to promote IP rights protection across the world.⁵⁶ Based on developed countries' intellectual property laws, the IPC proposed a detailed set of rules directly to the GATT, which became a blueprint of the TRIPS Agreement.⁵⁷

India and other developing countries maintained that IP issues should fall under the auspices of the World Intellectual Property Organization (WIPO).⁵⁸ WIPO administers two major international con-

Suzanne Zhou, *Challenging the Use of Special 301 against Measures Promoting Access to Medicines: Options under the WTO Agreements*, 19 J. INT'L. ECON. L. 51, 86 (2016).

49. Benedicte Callan, *The Potential for Transatlantic Cooperation on Intellectual Property in Asia* (U.C. Berkeley, Working Paper No. 116, 1998), <https://escholarship.org/content/qt7fd8j3k6/qt7fd8j3k6.pdf>.

50. A. D. Demiray, *Intellectual Property and the External Power of the European Community: The New Extension*, 16 MICH. J. INT'L. L. 187, 190 (1994), <https://repository.law.umich.edu/mjil/vol16/iss1/3> (“the EC also has begun to retaliate against nations that do not protect Community producers' intellectual property and has required recognition as well as acceptance of intellectual property standards in its trade treaties.”).

51. *Pre-WTO Legal Texts*, WORLD TRADE ORG., https://www.wto.org/english/docs_e/legal_e/prewto_legal_e.htm [<https://perma.cc/YPW7-VZ2E>].

52. *Agreement on Measures to Discourage the Importation of Counterfeit Goods*, GATT Doc. L/4817 (July 31, 1979), <https://docs.wto.org/gattdocs/q/GG/L4999/4817.PDF>.

53. Daniel Gervais, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 8 (2nd ed. 2003) (“The Group of Experts on Trade in Counterfeit Goods met on six occasions in 1985.”).

54. SELL, *supra* note 37, at 107.

55. *Id.* at 96.

56. *Id.*

57. *Id.*

58. See Marshall A. Leaffer, *Protecting United States Intellectual Property Abroad: Toward a New Multilateralism*, 76 IOWA L. REV. 273, note 166 (1991). “On

ventions:⁵⁹ the Paris Convention of 1883; which covers patents, trademarks, and other industrial rights;⁶⁰ and the Berne Convention of 1886, which governs the protection of literary and artistic works.⁶¹ The developed countries opposed India's proposition and insisted that the new international intellectual property framework be established with the GATT system because the two international conventions lacked enforcement mechanisms.⁶²

In the negotiation process, the committee labeled developed countries' proposals as the "A Approach" and those tabled by the developing countries as the "B Approach."⁶³

In broad terms Approach A envisages a single TRIPS [A]greement, encompassing all the areas of negotiation and dealing with all seven categories of intellectual property [. . .]. Approach B provides for two parts, one on trade in counterfeit and pirated goods [. . .] and the other on standards and principles concerning availability, scope, and use of [Intellectual property rights].⁶⁴

September 12, 1989, India declared that it had accepted the principle of policing TRIPS within the framework of the Uruguay Round multilateral trade negotiations. Until then, India had systematically refused to accept that the GATT had this responsibility rather than the WIPO." Michael L. Doane, *TRIPS and International Intellectual Property Protection in an Age of Advancing Technology*, 9 AM. U. J. INT'L L. & POL'Y 465,473(1994). See also, Daniel Gervais, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* (2nd ed.) 16 (2003). During the negotiation, Chile supported India's proposition: "With regard to Part II of the draft [of the TRIPS Agreement], on standards relating to the protection of intellectual property, it is Chile's intention that it should in no case be incorporated in the structure of the GATT, but rather that, if it is adopted, it shall be the subject of an agreement to be administered by WIPO or another organization other than GATT."

59. *Convention Establishing the World Intellectual Property Organization*, 21 UST 1749, TIAS 6932, art. 3 (July 14, 1967), <https://wipolex.wipo.int/en/treaties/textdetails/12412>.

60. World Intellectual Property Organization, *The Paris Convention for the Protection of Industrial Property* (1883), https://www.wipo.int/treaties/en/ip/paris/summary_paris.html.

61. World Intellectual Property Organization, *Berne Convention for the Protection of Literary and Artistic Works*, art. 1 (Sept. 28, 1979), <https://wipolex.wipo.int/en/text/283693>.

62. Lina M. Montén, *The Inconsistency Between Section 301 and TRIPS: Counterproductive with Respect to the Future of International Protection of Intellectual Property Rights?*, 9 MARQ. INTELL. PROP. L. REV. 387, 392-93 (2005); Marney L. Cheek, *The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime*, 33 GEO. WASH. INT'L L. REV. 277, 287 (2001).

63. Gervais, *supra* note 53, at 25.

64. *Id.* at 25 (citing Multilateral Trade Negotiations the Uruguay Round, *Status of Work in the Negotiation Group*, GATT Doc. No. MTN.GNG/NG11/W76, at 1 (July 23, 1990), <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W76.PDF>).

The United States and other developed countries took a multifaceted approach to pressure developing countries into signing the TRIPS Agreement. The United States continued to take unilateral retaliatory actions by invoking Special 301 investigations against countries that did not respect IP rights. While the developed countries did not indicate they would drop unilateral actions completely in the future, they did promise to create a dispute resolution mechanism within the TRIPS Agreement. The developing countries, especially those facing constant threats of unilateral actions, found it appealing to have future disputes resolved through a multilateral framework. In addition, the developed countries promoted the notion that countries with robust IP protection systems would win foreign direct investments, talents, and technology transfers from the West.⁶⁵ Furthermore, the developed countries promised to open their markets to the textile and agricultural products from the developing countries.⁶⁶

Since the formation of GATT, the developing countries long sought access to the textile and agricultural markets in the United States and other developed countries, but to no avail. In exchange for market access to the agriculture and textile products, the developing countries reluctantly agreed to grant IP protection for goods and services imported from the developed countries. To further ensure that the developing countries would respect IP rights, the United States and other developed countries transformed GATT into the WTO.⁶⁷ By annexing the TRIPS Agreement with the WTO Agreement, the United States and others made signing TRIPS a prerequisite to joining the new international trade regime.⁶⁸ In other words, by joining the WTO, the developing countries automatically would accept the TRIPS Agreement, which set the minimum standard for IP protection.⁶⁹ For the developing countries, it was a take-it-or-leave-it deal because they

65. Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 *Hous. L. Rev.* 979, 1027 (2009).

66. Peter K. Yu, *TRIPS and Its Discontents*, 10 *Marq. Intell. Prop. L. Rev.* 369, 371 (2006); Daya Shanker, *Fault Lines in the World Trade Organization: An Analysis of the TRIPS Agreement and Developing Countries* (2005) (Ph.D. dissertation, Univ. of Wollongong) (on file with Univ. of Wollongong Thesis Collection), <https://ro.uow.edu.au/cgi/viewcontent.cgi?referer=&httpsredir=1&filename=0&article=1497&context=theses&type=additional>.

67. For a brief historical account of the transition from GATT to WTO, see World Trade Organization, *History of the Multilateral Trading System*, https://www.wto.org/english/thewto_e/history_e/history_e.htm (last visited Oct. 7, 2022).

68. Rachel Brewster, *The Surprising Benefits to Developing Countries of Linking International Trade and Intellectual Property*, 12 *Chi. J. Int'l L.* 1, 5 (2011), https://scholarship.law.duke.edu/faculty_scholarship/2635.

69. *Id.* at 12–13 (“The shift from the GATT to the WTO at the conclusion of the Uruguay Round was a “single undertaking”—that is, states that wish to become mem-

would lose access to the global market if they failed to join the WTO.⁷⁰

Scholars criticized the United States and others for coercing developing countries to pay for IP rights of developed countries' goods and services in exchange for market access to agricultural and textile markets in the West.⁷¹ Jagdish Bhagwati lamented that the TRIPS Agreement essentially turned the WTO into a "royalty collection agency."⁷² Peter Yu called TRIPS a "coercive" and "imperialistic" agreement, which did not reflect "the goals and interests of less developed countries."⁷³ Because of the power imbalance in the negotiation process, Donald Harris called it a "treaty of adhesion" and urged the WTO judicial body to interpret the ambiguous terms of the agreement in favor of developing countries.⁷⁴

D. The TRIPS Agreement

The preamble of the TRIPS Agreement captures the consensus reached by members during the negotiation: IP rights are private rights that warrant legal protection. The lack of such protection will lead to distortions and impediments to international trade; however, excessive protection may also hinder trade.⁷⁵ Thus, the purpose of the TRIPS Agreement is to establish proper rules and disciplines to protect IP rights by following the core principles of GATT 1994—national treat-

bers of the WTO would have to agree to all of the new agreements under the WTO umbrella.").

70. *Id.*

71. See SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 173 (Cambridge Univ. Press 2003) ("Facing United States' retaliatory action, the developing countries was left no good choices but to accept the TRIPS Agreement."); Eyal Benvenisti and George W. Downs, *Distributive Politics and International Institutions: The Case of Drugs*, 36 CASE W. RES. J. INT'L L. 21, 48-49 (2004); Donald P. Harris, *Carrying A Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 685-686 (2006) (arguing that the TRIPS Agreement is a treaty of adhesion and should be reformed); José E. Alvarez and Jagdish Bhagwati, *Afterword: The Question of Linkage*, 96 AM. J. INT'L L. 126, 127 (2002); Peter M. Gerhart, *The Tragedy of TRIPS*, 2007 MICH. ST. L. REV. 143, 167-69 (2007); Jerome H. Reichman and Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L. J. 85, 94-98 (2007); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L. J. 827, 871 (2007).

72. Susan K. Sell, *The Rise and Rule of A Trade-Based Strategy: Historical Institutionalism and the International Regulation of Intellectual Property*, 17 R. OF INT'L POL. ECON. 762,764 (2010), <https://www.jstor.org/stable/25746515>.

73. Yu, *supra* note 66 at 373.

74. Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 755 (2006).

75. TRIPS Agreement, *supra* note 7, at pmbl.

ment, most-favored nation, and transparency.⁷⁶ The Agreement provides standards and basic principles for IP rights protection and “effective and appropriate means for enforcement” of these rights, while “taking into account differences in national legal systems.”⁷⁷ In addition, it provides “effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments.”⁷⁸ The Agreement also emphasizes the importance of resolving disputes on intellectual protection through multilateral procedures. As international intellectual property scholar Daniel Gervais observed, one of the most important objectives of some participants during the negotiation was to “make it illegal to use unilateral measures in the field of intellectual property.”⁷⁹ During the negotiation, many developing countries became receptive to a multilateral approach for resolving intellectual property disputes because they faced constant threats posed by the Special 301 actions under the United States Trade Act and similar actions from the EC. In fact, it was a strategic move for the United States to pressure developing countries to sign the TRIPS Agreement.⁸⁰

The TRIPS Agreement also lays ground rules concerning its relationship with the existing international conventions on IP rights.⁸¹ Rather than replacing the WIPO, the TRIPS Agreement establishes a mutually supportive relationship between the WTO and the WIPO.⁸²

i. The Balance Between Creation and Access

During the drafting process, the negotiators realized that while failing to protect IP rights could cause distortions and impediments to international trade, overly protective measures could also become barriers to legitimate trade. It was important to strike a balance between IP rights protection and access to medicine in low- and middle-income

76. *Id.*

77. *Id.*

78. *Id.*

79. Gervais, *supra* note 53, at 171; *see also*, A.V. Ganesan, *Negotiating for India, in* WTO, THE MAKING OF THE TRIPS AGREEMENT, 211, 227 (Jayashree Watal & Antony Taubman eds., 2015), https://www.wto.org/english/res_e/booksp_e/trips_agree_e/chapter_11_e.pdf.

80. *See* Sean Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicine*, 7 J. OF GENERIC ACCESS TO MEDS. 309, 311 (2010); Ganesan, *supra* note 79, at 219 (“Retaliatory action against Indian garment and other exports to the United States was looming large over India like a Damocles’ sword, especially in the last few years of the Uruguay Round.”)

81. TRIPS Agreement, *supra* note 7.

82. *Id.*

countries.⁸³ Thus, the developing countries should be able to exclude “certain products and processes from patentability on grounds of public interest, health or nutrition.”⁸⁴ Taking advantage of the growing support from negotiators, delegates from developing countries submitted the drafts of Article 7 and Article 8. The two articles reflected the desire of developing countries to maintain certain exceptions to the obligations demanded by the developed countries. As a result of the compromise, the negotiators agreed to incorporate the two articles in the main text of the TRIPS Agreement:

Article 7 (Objectives)

The protection and enforcement of intellectual property rights *should contribute to* the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 (Principles)

1. Members *may*, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.⁸⁵

The incorporation of the two articles was a rare victory for the developing countries. However, the use of “should” in Article 7 and “may” in Article 8 generated heated debates about the applicability of the two articles.⁸⁶ Some argued that the use of the precatory words rendered

83. Gervais, *supra* note 53, at 27 (citing Negotiating Group on Trade Related Aspects of Intellectual Property Rights Including Counterfeit Goods, *Note by the Secretariat: Meeting of the Negotiating Group of 1 November 1990* MTN.GNG/NG11/27, at 3 (Nov. 14, 1990) http://www.tripsagreement.net/trips_files/documents/1_November_1990_E.pdf).

84. *Id.*

85. TRIPS Agreement, *supra* note 7, at arts. 7, 8 (emphasis added); *see also id.* (“Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”).

86. *See generally*, Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1 (2001); David Weissbrodt and Kell Schoff, *Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7*, 5 MINN. INTELL. PROP. REV. 1 (2003); Susy Frankel, *WTO Application of the Customary Rules of Interpretation of Public International Law to Intellectual Property*, 46 VA. J. INT’L L. 365, 397 (2006); Alison Slade, *The Objectives and Principles of the WTO TRIPS Agreement: A Detailed Anatomy*, 53 OSGOODE HALL L. J. 948, 951 (2016).

the two articles only symbolic provisions carrying less weight than the rest of the text with “shall.”⁸⁷ Others dismissed the importance of the distinction.⁸⁸ In the communication with the TRIPS Council, the European Union stated, “Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the Agreement, including where measures are taken by members to meet health objectives.”⁸⁹ Gervais observed that the Appellate Body of the WTO cited Article 7 in various contexts to add “‘color, texture and shading’ to the interpretation of the agreements annexed to the WTO Agreement.”⁹⁰ In the Canada-Pharmaceutical Patents case,⁹¹ the European Community alleged that the Canada Patent Act did not protect pharmaceutical patents for the entire duration of the term required by the TRIPS Agreement.⁹² On the issue of whether Article 30 should be liberally interpreted, the Panel stated: “Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.”⁹³

While Article 7 may justify flexibility based on public health and other concerns, Article 8 ensures a flexible measure is commensurate with the public interests threatened by the crisis. In the cases of Korea-Beef⁹⁴ and US-Gambling,⁹⁵ the Panel created a necessity test based on Article 8. Gervais summarized the elements of the test as follows:

- “1) The relative importance of the protected public interest(s) pursued by such inconsistent measure.
- 2) The contested measure’s contribution to the achievement of objective pursued.

87. CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 93 (Oxford Univ. Press, 2007).

88. *Id.*

89. World Trade Organization, *EU’s Paper*, WTO Doc. IP/C/W/280 (June 12, 2001) https://www.wto.org/english/tratop_e/trips_e/paper_eu_w280_e.htm.

90. Gervais, *supra* note 53, at 240 (citing World Trade Organization, *United States-Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc. WT/DS58/AB/R, ¶ 153 (Oct. 12, 1998), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?file name=Q:/WT/DS/58ABR.pdf&Open=true>).

91. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (adopted Mar. 17, 2000) [hereinafter *Canada-Pharmaceutical Patents*].

92. *Id.* at para. 3.1.

93. *Id.* at para. 7.26.

94. Appellate Body Report, *Korea- Measures Affecting Imports of Fresh Chilled and Frozen Beef*, WTO Doc. WT/DS161/AB/R (adopted Dec. 11, 2000).

95. Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WTO Doc. WT/DS285/AB/R (adopted Apr. 7, 2005).

- 3) The trade restrictiveness of the measure.
- 4) A determination of whether, in the light of importance of the interests at issue, a less trade restrictive is “reasonably available.”⁹⁶

Based on the test, whether an exception to the TRIPS obligations is justified depends on the gravity of the harm posed to public health or other public interests.⁹⁷ The greater the public interests are, the better chance that the contested restrictive measure is justified, even if the implementation of the measure could create barriers to trade. If the first prong is in favor of the applicant, the next step is to ensure that the restricted measure is rationally related to the task to be accomplished. To ensure that the measure is rationally related, the applicant needs to show that no reasonable alternatives are available. In other words, the proposed measure must be less costly not only than the potential harm threatened but also than any other available means. Article 7 and Article 8 have set the stage for the establishment of the compulsory licensing system under Article 31 and Article 31bis of the TRIPS Agreement.

ii. Article 31 Compulsory Licensing

The idea of compulsory licensing is not new. Article 5A(2) of the Paris Convention of 1883 provides: “Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.”⁹⁸ Article 31 of TRIPS Agreement is often known as the Compulsory Licensing Clause,⁹⁹ even though it is entitled as “Other Use Without Authorization of the Right-holder.”¹⁰⁰ By exercising the right of compulsory licensing, the government or its contractor can use a patent without the authorization from the right-holder under certain circumstances.¹⁰¹ Article 31 requires that the proposed user make reasonable efforts to seek authorization from the right-holder on reasonable commercial terms.¹⁰² If these efforts have not

96. Gervais, *supra* note 53, at 252.

97. *Id.*

98. Paris Convention for the Protection of Industrial Property, art. 5(A)(2), Mar. 20, 1883, 188321 U.S.T. 1583, 828 U.N.T.S. 303.

99. Johanna Kehl, *Trips Article 31(b) and the HIV/AIDS Epidemic*, 10 J. INTELL. PROP. L. 143, 143 (2002), <https://digitalcommons.law.uga.edu/jipl/vol10/iss1/6>. “TRIPS Article 31 covers compulsory licenses which, when used, remove a WTO Member from its general obligation to recognize exclusive patent rights before a patent period has expired.”

100. TAUBMAN, WAGER & WATAL, *supra* note 35, at 121.

101. TRIPS Agreement, *supra* note 7, at art. 31.

102. *Id.* at art. 31(b).

been successful within a reasonable period of time, the government can invoke the right of compulsory licensing.¹⁰³ In the case of a national emergency or other circumstances of extreme urgency, however, the government or its contractor is not obligated to make efforts to seek authorization from the right-holder before it uses the patent.¹⁰⁴ In doing so, the government must notify the right-holder promptly.¹⁰⁵ The government is free to determine what constitutes a national emergency.¹⁰⁶ To prevent the government from making an arbitrary decision, the right-holder has the right to challenge the decision that unjustifiably declared an emergency for the purpose of granting a compulsory license.¹⁰⁷

In the case of public non-commercial use, the government is required to inform the right-holder promptly when it has reasonable grounds to know the owner of the patent.¹⁰⁸ The government, however, is not obligated to conduct a patent search to ascertain what it has condemned is indeed a patent that belongs to the right-holder.¹⁰⁹

Under Article 31, licenses acquired through government compulsion are non-exclusive and non-assignable.¹¹⁰ As a result, the grant to a compulsory license does not prevent the patent owner from continuing to use the patent. Such requirements also prevent governments from misusing the patent.¹¹¹

To protect the right-holder's interests, compulsory licenses are limited both in scope and duration. The government must limit the scope of a compulsory license to serve the purpose for which it is granted. In addition, the government must terminate the compulsory license when the purpose for which it is granted is no longer justifiable for the license, for example, the national emergency or urgency passes and is unlikely to recur.¹¹² Furthermore, Article 31(g) requires the competent authority under domestic law to heed the right-holder's

103. *Id.*

104. *Id.*

105. *Id.*

106. Gervais, *supra* note 53, at 251.

107. PETER VAN DEN BOSSCHE, *THE LAW AND POLICY OF THE WORLD TRADE ORGANIZATION: TEXT, CASES AND MATERIALS* 790 (2d ed. 2008).

108. TRIPS Agreement, *supra* note 7.

109. *Id.*

110. *Id.* at art. 31(d), (e).

111. Srividhya Ragavan, Brendan Murphy, & Raj Davé, *Frاند v. Compulsory Licensing: The Lesser of The Two Evils*, 1 *DUKE L. TECH. REV.* 83, 115 (2015).

112. TRIPS Agreement, *supra* note 7, at art. 31(g).

concerns¹¹³ and review whether the continued existence of the circumstances still warrants a compulsory measure.¹¹⁴

The government is required to pay adequate remuneration to the right-holder based on the “economic value of the authorization.”¹¹⁵ Unfortunately, Article 31 does not provide detailed guidance for how the evaluation should be calculated. Professor Gervais laid out two ways to determine the value of the condemned patent. First, the value should be the normal costs to patent holders if such data are available. If there is no record for the normal costs to the patent holder, the value should be based on “the practices in relevant [neighbor] territories and world market.” Second, the value for the remuneration could also be based on “the revenues that may have been generated for the user by the compulsory license.”¹¹⁶ This proposal is difficult to implement because there is no way to calculate possible revenue. If the government grants a compulsory license for the purpose of correcting anti-competitive practices, the remuneration could be reduced.¹¹⁷

More importantly, a WTO member country must first incorporate the TRIPS Agreement in its domestic legal systems before authorizing a compulsory license.¹¹⁸ A mere recognition of the legal effect of the flexibilities set forth in Article 31 of the TRIPS Agreement is not sufficient for the government to safeguard the right-holder’s legitimate interests in its decision process to grant a compulsory license.¹¹⁹ Thus, Article 31(i) specifically requires a member country to provide the right-holder with the legal rights to seek a judicial review of the government’s decision by a distinct higher authority.¹²⁰

Article 31(f) provides that the use of a compulsory license is “authorized predominantly for the supply of the domestic market of the Member authorizing such use.”¹²¹ The purpose of the provision is to prevent diversion of the products produced under compulsory licens-

113. Gervais, *supra* note 53, at 251.

114. TRIPS Agreement, *supra* note 7.

115. Gervais, *supra* note 53, at 252.

116. *Id.* at 252.

117. *Id.* at 252.

118. TAUBMAN, WAGER & WATAL, *supra* note 35, at 199.

119. *Id.*

120. Article 31(i) appears to presume that every government operates within the confines of a domestic legal system and the supremacy of the law is unquestionably respected. Such a presumption is largely misplaced because it ignores that fact that many of the low-income countries do not have an independent judiciary. For further discussion about judicial independence, *see generally*, Omar E. García-Bolívar, *Lack of Judicial Independence and Its Impact on Transnational and International Litigation*, 18 L. & BUS. REV. AM. 29 (2012); Philip C. Aka, *Judicial Independence Under Nigeria’s Fourth Republic: Problems and Prospects*, 45 CAL. W. INT’L L.J. 1 (2014).

121. TRIPS Agreement, *supra* note 7, at art. 31(f).

ing to other countries.¹²² This well-intended provision creates “a serious disadvantage” for countries that have insufficient or no capacity to manufacture medicines domestically and must rely on imports.¹²³

iii. *The Doha Declaration*

At the Doha Ministerial Conference in 2001, the delegates recognized the grave public health issues resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics in the developing and least developed countries.¹²⁴ While protecting IP rights was important for developing new medicines, it could also increase prices, making medicines less accessible.¹²⁵ The delegates pledged that the TRIPS Agreement should not prevent members from taking actions to combat public health crises.¹²⁶ Thus, the Doha Declaration called for the TRIPS Agreement to be interpreted “in a manner supportive of WTO members’ right to protect public health, in particular, to promote access to medicine for all.”¹²⁷ Specifically, the Declaration urged members to apply the customary rules of interpretation of public international law and read the provisions of the TRIPS Agreement in light of Article 7 (Objectives) and Article 8 (Principles).¹²⁸ As a result, members were encouraged to take a balanced approach when faced with a conflict between IP rights protection and public health. One concrete measure that a member can take is to issue compulsory licenses. The member then has “freedom to determine the grounds upon which such licenses are granted.”¹²⁹ Each member should have the authority to “determine what constitutes a national emergency or

122. Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1336-1337 (2002).

123. Prof. Brook K. Baker, *A Full Description of WTO Trips Flexibilities Available to ARIPO Member States and a Critique of ARIPO’s Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities*, 30 (May 3, 2019), <https://www.bu.edu/gdp/files/2020/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf>. [https://perma.cc/AQP4-3EB2]; see also, Ann Marie Effingham, *Trips Agreement Article 31(B): The Need for Revision*, 46 SETON HALL L. REV. 883, 891 (2016).

124. World Trade Organization, *Ministerial Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2, ¶1 (2002) [hereinafter Doha Declaration], https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

125. *Id.* at para. 3.

126. *Id.* at para. 4.

127. *Id.*

128. *Id.* at para. 5.

129. *Id.* at para. 5(b).

other circumstances of extreme urgency” that justifies issuing a compulsory license.¹³⁰

In paragraph 6, the Declaration directly addressed the complaints from the developing countries who could not take advantage of compulsory licenses due to the lack of manufacturing capacity to produce the needed medicines. Under TRIPS Agreement Art. 31, these countries could not import from countries that produced the medicines under a compulsory license. The Declaration instructed the Council for TRIPS to “find an expeditious solution to this problem and report to the General Council before the end of 2002.”¹³¹ Paragraph 6 was the most consequential part of the Declaration because it led to the first amendment to the TRIPS Agreement.

iv. Article 31bis

In response to the Doha Declaration, the Council for TRIPS granted temporary waivers from the obligations imposed by Article 31(f) and (h) of the TRIPS Agreement regarding pharmaceutical products in 2003.¹³² Two years later, the General Council formally amended the TRIPS Agreement by adding Article 31bis to the text, which made the temporary waivers permanent.¹³³

The scope of Article 31bis is narrowly tailored. It only covers patented products, products manufactured through a patented process, and active ingredients of pharmaceutical products for addressing the public health problems including HIV/AIDS, tuberculosis, malaria, and other epidemics.¹³⁴ However, Article 31bis does not address the administrative costs for countries that apply for the waivers.¹³⁵

130. *Id.* at para. 5(c).

131. *Id.* at para. 6.

132. World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement And Public Health Decision of August 30, 2003*, WTO Doc. WT/L/540 (Sept. 2, 2003), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/L/540.pdf>.

133. World Trade Organization, *Article 31bis of the Agreement on Trade-Related Aspects of Intellectual Property Rights*, WTO ANALYTICAL INDEX, 5 (updated July 2022), https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

134. TRIPS Agreement, *supra* note 7, at Annex, para. 1(a).

135. Nicholas G. Vincent, *TRIP-ing Up: The Failure of TRIPS Article 31bis*, 24 GONZ. J. INT'L L. 1, 1 (2020).

The least developed countries, as designated by the UN,¹³⁶ are automatically deemed as countries without manufacturing capacity.¹³⁷ Any other country can also become an eligible importing country¹³⁸ on the condition that it either establishes that it has no manufacturing capacity, or that it has insufficient capacity to meet its needs.¹³⁹ An importing country must notify the TRIPS Council of its intention to use the compulsory licensing system as an importer. The notification, however, does not mean that the country needs to seek WTO's approval.¹⁴⁰ An importing country can use the compulsory licensing system "in whole or in a limited way."¹⁴¹ For example, countries may choose to use the system only in the case of national emergency or extreme urgency.¹⁴² The United States and other developed countries have indicated that they will not use the system as importing countries.¹⁴³

To prevent products under compulsory license from spilling over to unauthorized markets, Article 31bis lays out detailed requirements for both exporting and importing countries. First, the exporting country can only produce the amount necessary to meet the needs of eligible importing countries.¹⁴⁴ It must ensure that all the products go to the importing countries, who have notified their needs to the TRIPS Council. To distinguish from other products, the exporter is required to identify the products with specific labeling or marking, special packaging, and coloring schemes to the extent not to exert a significant impact on price. In addition, the exporter must post on its own website or on WTO's website the quantities being supplied to each destination and the distinct features of the products.¹⁴⁵

The exporting country must notify the TRIPS Council of the grant of license, name and address of the licensee, the products for

136. *UN list of least developed countries*, U.N. CONF. ON TRADE AND DEV., <https://unctad.org/topic/least-developed-countries/list> (last visited Oct. 20, 2022). For how the United Nations determines a country as a Least Developed Country (LDC), see *LDC Identification Criteria & Indicators*, U.N. Dep't Econ. & Soc. Affs., <https://www.un.org/development/desa/dpad/least-developed-country-category/ldc-criteria.html> (last visited Oct. 20, 2022).

137. TRIPS Agreement, *supra* note 7, at app. to the Annex.

138. *Id.*

139. *Id.*

140. *Id.* at Annex, para. 1(b) n.2.

141. *Id.* at Annex, para. 1(b).

142. *Id.*

143. *Id.* at Annex, para. 1(b) n.3 ("Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.").

144. *Id.* at Art. 31bis.

145. *Id.*

which the license has been granted, the quantities, importing countries, and the duration of the license.¹⁴⁶ In addition, importing countries must take reasonable measures to prevent re-exportation of the products imported to their territories.¹⁴⁷ If an importing country is incapable of implementing those measures, it may request necessary assistance from developed countries to meet the statutory requirements based on mutually agreed terms and conditions.¹⁴⁸

All member countries must have legal means to prevent importation of the products produced under compulsory licensing from entering their territories. If a country is unable to implement the preventative measures, it may request a review from the TRIPS Council.¹⁴⁹ If a country intends to become an exporting country, it must notify the Council of “the grant of the license, including the condition attached to it.”¹⁵⁰ In the notification, the exporting country must provide the information.

The exporting country that grants a compulsory license is obligated to pay adequate remuneration based on the economic value to the importing country.¹⁵¹ Once the exporting country has made the payment to adequately compensate the right-holder, the importing country is relieved of the obligation to pay the right-holder again.¹⁵²

The TRIPS Council also plays an important role in maintaining the compulsory licensing system’s credibility and efficacy. The TRIPS Council is required to review the system and issue an annual report about its findings.¹⁵³ The TRIPS Council reports to the General Council annually on its operation.¹⁵⁴ According to the latest report, Bolivia, Antigua, and Barbuda notified the TRIPS Council of their respective intentions to use the compulsory licensing system as for the importation of COVID-19 vaccines.¹⁵⁵ While Bolivia reached out to Biolyse, a Canadian pharmaceutical manufacturer, for producing the vaccines under the compulsory system, there is no indication that the Canadian

146. *Id.*

147. *Id.* at Annex, para. 3.

148. *Id.*

149. *Id.* at para 4.

150. *Id.* at para. 2(c).

151. *Id.* at art. 31bis 2.

152. *Id.*

153. *Id.* at para. 7.

154. *Id.*

155. World Trade Organization, *COVID-19: Measures regarding trade-related intellectual property rights* (updated Apr. 20, 2022), https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

government would grant a compulsory license.¹⁵⁶ The Council Report shows that it has received no notifications by exporting countries.¹⁵⁷

v. *The Rwanda-Canada Case*¹⁵⁸

In 2004, Doctors Without Borders/Médecins Sans Frontières (MSF)¹⁵⁹ requested Canadian pharmaceutical company, Apotex, produce “a fixed-dose combination of the three HIV/AIDS drugs zidovudine, lamivudine, nevirapine, later to be known as TriAvir.”¹⁶⁰ Before making the request, MSF could not find a country that was willing to identify itself as a recipient for the drugs under compulsory licensing. The reason was that Thailand and Brazil had been threatened by pharmaceutical companies and developed countries for making such requests. However, under the Canadian Patent Act, Apotex could not receive a compulsory license without identifying a user. It was not until May 2007 that Rwanda expressed willingness to receive the drugs obtained through compulsory licensing in Canada. On September 19, 2007, the Canadian government finally issued a compulsory license to Apotex after it made efforts to negotiate with patent holders. Canada notified the Council for TRIPS of its decision on compulsory license for a two-year period on October 4, 2007.¹⁶¹ Rwanda received the drug at US\$ 0.195 per tablet.¹⁶²

156. Helen Lock, *Bolivia Could Unlock New Access to Life-Saving COVID-19 Vaccines — But Needs Canada to Grant a License*, GLOBAL CITIZEN (Aug. 2, 2021), <https://www.globalcitizen.org/en/content/bolivia-canada-patents-covid-19-vaccines-trips/>.

157. Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS), *Report to the General Council: Annual Review of the Special Compulsory Licensing System*, WTO Doc. IP/C/90 (Oct. 26, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/90.pdf&Open=true>.

158. World Trade Organization, *Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm.

159. *Who We Are*, MEDECINS SANS FRONTIERS DOCTORS WITHOUT BORDERS, <https://www.doctorswithoutborders.org/who-we-are>.

160. Holger P. Hestermeyer, *Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, ASIL INSIGHTS (Dec. 10, 2007), https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and#_ednref8 [<https://perma.cc/33AQ-ZERV>].

161. Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/N/10/CAN/1 (Oct. 8, 2007), https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=44973&CurrentCatalogueIdIndex=0&FullTextSearch=&.

162. WTO, WIPO, WHO, EXTRACT FROM THE WHO-WIPO-WTO TRILATERAL STUDY THE PARAGRAPH 6 SYSTEM: SPECIAL EXPORT LICENSES FOR MEDICINES, box

II.

THE MEDICINES PATENT POOL (MPP)

In 2006, Brazil, Chile, France, Norway, and the United Kingdom created Unitaid, an international drug purchasing facility financed by a levy on air tickets.¹⁶³ In 2010, Unitaid created the Medicines Patent Pool (MPP),¹⁶⁴ an independent, non-profit foundation registered under the law of Switzerland, with a principal place of business in Geneva, Switzerland.¹⁶⁵ MPP's mission is to improve the health of people in low- and middle-income countries by increasing "access to quality, safe, efficacious, more appropriate and more affordable health products, including through a voluntary patent pool mechanism."¹⁶⁶ MPP's initial focus is to provide "antiretroviral pharmaceutical products, pediatric antiretroviral products and new fixed dose combinations."¹⁶⁷ On March 31, 2020, MPP's Board expanded its coverage to include "any health technology that could contribute to the global response to COVID-19 and where licensing could facilitate innovation and accelerate access."¹⁶⁸ To achieve its objective, MPP pursues various activities including:

- a. Negotiating terms and conditions of license agreements;
- b. Entering into license agreements with patent holders;
- c. Enforcing the terms and conditions of the license agreements;
- d. Assisting in dispute resolution procedures;
- e. Ensuring products produced by licensees through MPP obtain approval from regulatory authorities;
- f. Ensuring the traceability of the licensed products and preventing the products from being diverted to unauthorized markets;

4.15 (2013), https://www.wto.org/english/tratop_e/trips_e/who-wipo-wto2013_par6_extract_e.pdf .

163. About Us, UNITAID, <https://unitaid.org/about-us/#en> [<https://perma.cc/JX5R-W2S5>]; see also, *Secretary-General's remarks at official launch of UNITAID, the International Drug Purchase Facility*, UNITED NATIONS (Sept. 19, 2006), <https://www.un.org/sg/en/content/sg/statement/2006-09-19/secretary-generals-remarks-official-launch-unitaid-international>.

164. UNITAID, *IMPACT STORY—MEDICINES PATENT POOL: VOLUNTARY LICENCES CAN MAKE MEDICINES MORE ACCESSIBLE* (Dec. 2007), https://unitaid.org/assets/impact-story_medicines-patent-pool.pdf.

165. Medicines Patent Pool Foundation, *Statutes of 8 July 2010*, at art. 2 (Nov. 23, 2020) [hereinafter MPP Statute], <https://medicinespatentpool.org/who-we-are/statutes-by-laws-policies>.

166. *Id.* at art. 3.

167. *Id.*

168. *MPP's contribution to the global response to COVID-19*, MEDICINES PATENT POOL, <https://medicinespatentpool.org/covid-19> [<https://perma.cc/L2KX-GC4X>].

- g. Collaborating with stakeholders to advocate for MPP activities.¹⁶⁹

On September 30, 2010, the U.S. National Institute of Health (NIH) became the first patent-holder to share its intellectual property on HIV/AIDS medicines with MPP.¹⁷⁰ Experts hailed the NIH's generous offer to the MPP as a critical step towards achieving equitable access to lifesaving medicines. NIH Director Francis S. Collins stated that "the license underlines the U.S. government's commitment to the Medicines Patent Pool and its goal to increase the availability of HIV medicines in developing countries."¹⁷¹ However, the NIH's offer to share multiple patents covering medicines for HIV/AIDS did not make the drugs instantly available for developing countries because other joint holders refused to share their patents.¹⁷² Tido von Schoen-Angerer of Medecins sans Frontier pointed out that the NIH's offer to license its patents "isn't enough to allow a cheaper version of the medicine to be produced. We need to build on this—the onus is on the drug companies that own patents on this and other key AIDS medicines to put their patents in the Pool."¹⁷³

On July 12, 2011, Gilead Sciences entered into an agreement with the MPP to share its patents on several key HIV/AIDS medicines.¹⁷⁴ Unlike the agreement with the NIH, which still needed joint holders to step up, this agreement with Gilead directly authorized the production of several critical HIV medicines. Ellen 't Hoen, executive director of the MPP, characterized the agreement as a milestone because it would make the lifesaving medicines available at lower costs to developing countries without delay.¹⁷⁵ Currently, sixteen patent holders have signed agreements with MPP, covering agreements

169. MPP Statute, *supra* note 165, at art. 4(a)–(g).

170. Press Release, MEDICINES PATENT POOL, *US National Institutes of Health (NIH) First to Share Patents with Medicines Patent Pool As It Opens for Business* (Sept. 30, 2010), <https://medicinespatentpool.org/news-publications-post/us-national-institutes-of-health-nih-first-to-share-patents-with-medicines-patent-pool-as-it-opens-for-business>.

171. *Id.*

172. *Id.*

173. Sarah Boseley, *Time for the Drug Companies to Hand over Their Patents*, *GUARDIAN* (Sept. 30, 2010), <https://www.theguardian.com/society/sarah-boseley-global-health/2010/sep/30/aids-drugs>.

174. Krista L. Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses*, 4 *HASTINGS SCI. & TECH. L.J.* 291, 302 (2012); Press Release, MEDICINES PATENT POOL, *Medicines Patent Pool Announces First Licensing Agreement with a Pharmaceutical Company* (June 12, 2011), <https://medicinespatentpool.org/news-publications-post/medicines-patent-pool-announces-first-licensing-agreement-with-a-pharmaceutical-company>.

175. Press Release, MEDICINES PATENT POOL (June 12, 2011), *supra* note 170.

for “13 HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, four long-acting technologies, two experimental oral antiviral treatments for COVID-19 and 12 COVID-19 technologies.”¹⁷⁶ Through the licensing agreements with the pharmaceutical companies, MPP has brought out tremendous positive social and economic impact, especially to the developing countries. “[T]he direct savings generated by the MPP are estimated to be USD 2.3 billion (net present value) by 2028, representing an estimated cost-benefit ratio of 1:43, which means for every USD 1 spent on MPP, the global public health community saves USD 43.”¹⁷⁷

On March 3, 2022, the NIH announced that it would share several technologies with the WHO’s COVID-19 Technology Access Pool (C-TAP) and sublicensed to the MPP.¹⁷⁸ WHO Director-General Dr. Tedros Adhanom Ghebreyesus was grateful to the NIH for its timely commitment to the fight against the COVID-19 pandemic. He commented, “[v]oluntary sharing of technologies through non-exclusive agreements will not only help us put the pandemic behind us; it will also empower low- and middle-income countries to produce their own medical products and achieve equitable access.”¹⁷⁹

A. *The Pfizer-MPP Agreement*

On November 15, 2021, Pfizer signed a voluntary agreement with MPP (Pfizer-MPP Agreement) to allow its COVID-19 oral antiviral treatment candidate PF-07321332 to be made and sold inexpensively in ninety-five countries.¹⁸⁰ A study showed that candidate PF-07321332, also known as Paxlovid, “reduced risk of hospitalization or

176. *Licenses*, MEDICINES PATENT POOL, <https://medicinespatentpool.org/progress-achievements/licences> (last visited Sept. 30, 2022).

177. Sandeep Juneja et al., *Projected Savings Through Public Health Voluntary Licenses of HIV Drugs Negotiated by the Medicines Patent Pool (MPP)*, PLOS ONE, May 25, 2017, 1, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5444652/>.

178. *The US NIH will Share Technology with WHO to Fight the Pandemic*, MEDS. L. & POL’Y (Mar. 3, 2022), <https://medicineslawandpolicy.org/2022/03/the-us-nih-will-share-technology-with-who-to-fight-the-pandemic/>.

179. Press Release, WORLD HEALTH ORG., *WHO and MPP welcome NIH’s offer of COVID-19 health technologies to C-TAP*, (Mar. 2, 2022), <https://www.who.int/news/item/03-03-2022-who-and-mpp-welcome-nih-s-offer-of-covid-19-health-technologies-to-c-tap>.

180. PFIZER AND MEDICINES PATENT POOL NIRMATRELVIR LICENSE AGREEMENT (2021), <https://medicinespatentpool.org/licence-post/pf-07321332> [hereinafter PFIZER-MPP AGREEMENT]; see also Stephanie Nolen & Rebecca Robbins, *Pfizer Will Allow Its Covid Pill to Be Made and Sold Cheaply in Poor Countries*, N.Y. TIMES (Nov. 16, 2021), <https://www.nytimes.com/2021/11/16/health/covid-pill-pfizer.html>.

death by 89%.”¹⁸¹ On December 22, 2021, the U.S. Food and Drug Administration (FDA) granted Paxlovid an Emergency Use Authorization (EUA) for the treatment of mild-to-moderate COVID-19 in certain adults and pediatric patients.¹⁸² There are two major parts in the Pfizer-MPP Agreement: the first part lays out the rights and obligations for Pfizer and MPP; the second part in Exhibit D provides a sample agreement between MPP and a licensee.¹⁸³

i. Coverage and Royalty

The license agreement between Pfizer and MPP covers “the treatment and/or prevention of COVID-19 caused by SARS-Cov-2.”¹⁸⁴ If a new use of the medicine is discovered in the future, the agreement does not apply. This limitation is consistent with similar license agreements that MPP signed with other pharmaceutical companies in the past.¹⁸⁵ The license that Pfizer grants to MPP is non-exclusive, which means that Pfizer expressly reserves all its rights under the patents.¹⁸⁶ Therefore, Pfizer is free to grant additional licenses or distribute the products to a third party and “make, use, import, offer for sale and/or donate” the products on its own behalf.¹⁸⁷ Licensees must refrain from infringing or misappropriating Pfizer’s patents, know-how, confidential information, and other IP rights.¹⁸⁸ In addition, the license is non-transferrable but sublicensable.¹⁸⁹ Thus, MPP does not have a right to transfer the ownership to a third party. MPP has limited the regranting of the right to a licensee by one tier.¹⁹⁰ In other words, a licensee is not permitted to re-sublicense the right to another party.¹⁹¹ Once receiving the grant of license from MPP, a licensee has the right to manufacture the licensed product at a facility within the territory

181. Press Release, PFIZER, *Pfizer’s Novel COVID-19 Oral Antiviral Treatment Candidate Reduced Risk of Hospitalization or Death by 89% in Interim Analysis of Phase 2/3 EPIC-HR Study* (Nov. 5, 2021, 6:45AM), <https://www.pfizer.com/news/press-release/press-release-detail/pfizers-novel-covid-19-oral-antiviral-treatment-candidate>.

182. Press Release, *Coronavirus (COVID-19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID-19*, FOOD & DRUG ADMIN. (Dec. 2021), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19>.

183. See generally PFIZER-MPP AGREEMENT, *supra* note 180.

184. *Id.* at §1.10.

185. Cox, *supra* note 174, at 304.

186. PFIZER-MPP AGREEMENT, *supra* note 180, at §2.1.

187. *Id.* §2.5.

188. *Id.* §2.4.

189. *Id.* §2.1(a)-(f).

190. *Id.*

191. *Id.* §2.3.

authorized in this agreement.¹⁹² In addition, licensees have the right to commercialize, retail, register, sell, or import/export the licensed product by itself or through its affiliates for the defined use and within the authorized territory.¹⁹³

The territory that Pfizer agrees to grant licenses in consists of ninety-five countries, twenty-nine of which are low-income countries based on the World Bank's classification.¹⁹⁴ The rest are low- middle-income countries and upper-middle-income countries. Pfizer does not charge royalties for any sale of the licensed products in the low-income countries.¹⁹⁵ If the sale takes place in a territory other than low-income countries, Pfizer charges five percent of aggregate net sales of the licensed product sold to a government authority or public purchaser under either of the two conditions: (1) a valid patent claim exists in the country of manufacture and/or sale of the licensed product, or (2) regulatory exclusivity¹⁹⁶ exists for a such licensed product in the country.¹⁹⁷ Subject to the same conditions stated above, Pfizer charges ten percent of aggregate net sales of the licensed products sold to a commercial entity.¹⁹⁸ However, Pfizer does not charge a royalty during the public health emergency of international concern for the COVID-19 pandemic, as declared by the WHO.¹⁹⁹

ii. Outside the Territory

While Pfizer designated ninety-five countries as covered by the agreement, it allows a licensee to export the licensed products outside the territory under limited circumstances. A licensee can export the products into a country, where the government has lawfully granted a compulsory license for the same products covered in this agreement. In doing so, the licensees must confine the marketing of the products exclusively restricted within the said country and refrain from infringing or misappropriating Pfizer's IP rights.²⁰⁰ The licensees are not permitted to donate the licensed product outside the designated territory.

192. *Id.* §2.1 (a)-(f).

193. *Id.*

194. *Id.* at Exhibit C.

195. *Id.* at Exhibit D, §7.1.

196. Daniel J. Nam, *Patent & Regulatory Exclusivities: The Two Keys Driving Generic and Follow-on Market Availability*, U.S. PHARMACIST (June. 16, 2016), <https://www.uspharmacist.com/article/patent-and-regulatory-exclusivities-the-two-keys-driving-generic-and-followon-market-availability>.

197. PFIZER-MPP AGREEMENT, *supra* note 180, at Exhibit D, §7.1-7.2(a).

198. *Id.* at Exhibit D, §7.2(b).

199. *Id.* at Exhibit D, §7.3.

200. *Id.* §2.4.

Nothing in this Agreement or any Sublicense shall provide a right to [v]end,²⁰¹ donate, distribute, offer for sale or otherwise sell the Compound, Product or Licensed Product outside the Territory for further offer for sale, sale, donation or distribution of the Compound, Product or Licensed Product outside or for use outside the Territory.²⁰²

In this regard, the Pfizer Agreement is comparable with other licensing agreements that the MPP signed with other pharmaceutical companies.²⁰³ For example, the agreement between Gilead Sciences and MPP, the first voluntary licensing agreement between a private pharmaceutical company and MPP, permitted licensees to export the licensed products outside the designated territory under either of the two circumstances: (1) if the government of the importing country issued a compulsory license; or (2) the government of India, where the licensed manufacturers are solely designated in the agreement, issued a compulsory license under Art. 92A of the India Patents Act.²⁰⁴

iii. *Improvements*

If a licensee has made improvements on the licensed product,²⁰⁵ it must promptly notify Pfizer in English and without charge.²⁰⁶ The licensee acquires the sole ownership of the improvements, but it must grant to Pfizer, its affiliates, as well as MPP “a perpetual, irrevocable,

201. *Id.* §1.33.

202. *Id.* §2.4.

203. For example, the agreement between Gilead Sciences and MPP had a similar clause. An excellent discussion about the linkage between private license agreement and TRIPS Agreement, Art. 31bis can be found in Cox, *supra* note 174, at 312. For a useful comparison, see a portion of the Gilead-MPP agreement regarding export outside the territory: “For further clarity, and notwithstanding anything to the contrary in this Agreement, it shall not be deemed to be a breach of the Agreement for Licensee to supply an API or Product outside the Territory into a country where (i) the government of such country has issued a compulsory license relating to such API or Product allowing for the importation of such API or Product into such country, provided Licensee’s supply of Product or API into such country is solely within the scope and geographic range of such compulsory license and only for the duration that such compulsory license is in effect and/or (ii) the Government of India has issued a compulsory license allowing for the export of any API or Product from India and into such country, provided that (Y) there are no patents controlled by Gilead that contain a valid claim covering the use, import offer for sale or sale of such API or such Product issued in such country or a compulsory license has also been issued by the relevant authorities of such country and (Z) Licensee’s supply of Product or API into such country is solely within the scope and geographic range of the compulsory license issued by the Government of India and only for the duration that such compulsory license is in effect.”

204. *Id.* at 313.

205. PFIZER-MPP AGREEMENT, *supra* note 180, §1.13.

206. *Id.* §4.5.

worldwide, non-exclusive, transferable, and fully paid license.”²⁰⁷ Pfizer and other grantees are free to grant their licensees the right to use, manufacture, commercialize, sell, or donate the improved products for the treatment and prevention of diseases caused by COVID-19.²⁰⁸ Without the consent of both Pfizer and the owner of the improvements, MPP has no right to grant the improvements to any third party or other licensees.²⁰⁹ Again, this “grant back” provision can also be found in previous agreements between pharmaceuticals and MPP.²¹⁰ This clause is important both for the pharmaceutical company’s interests in the improvements and for consumers’ interests because the non-exclusive right to the improvements promotes competition.²¹¹

iv. Anti-Corrupt Practices

The license agreement obligates MPP to conduct business based on applicable law and good business ethics.²¹² MPP officials or affiliates must refrain from holding official positions in the government, which have the authority to purchase the licensed Pfizer products.²¹³ In addition, MPP must refrain from making payments to government officials or business representatives, where such payments violate any applicable law.²¹⁴ Even if not in violation of the law, MPP must not make payments to government officials “for the purpose of influencing decisions or actions with regard to the subject matter of this agreement or any other aspect of MPP’s or Pfizer’s business.”²¹⁵

The agreement defines “bribes” as:

Offering, promising, or giving a financial or other advantage to another person where (a) it is intended to bring about the improper performance of a relevant function or activity, or to reward such “improper performance” (as that term is used in the [Federal Corrupt Practices Act (FCPA)]; or (b) acceptance of the advantage offered promised or given in itself constitutes improper performance of a relevant function or activity.²¹⁶

207. *Id.*

208. *Id.* §§ 4.5, 1.20.

209. *Id.*

210. Cox, *supra* note 174, at 314.

211. *Id.* at 315.

212. PFIZER-MPP AGREEMENT, *supra* note 180, §4.9.

213. *Id.*

214. *Id.*

215. *Id.*

216. *Id.*

MPP is obligated to maintain proper and accurate accounts to record all payments and expenses.²¹⁷ It must also maintain an internal control mechanism to prevent, detect, report, and deter violation of the accounting rules.²¹⁸ Pfizer has the right to hire an independent accounting firm to audit the MPP's accounts once in any twelve-month period. If there is evidence of irregularities, Pfizer may conduct the audit more frequently. In doing so, Pfizer needs to give MPP a reasonable notice, and MPP must assist with Pfizer's auditing process.²¹⁹ If the audit reveals that MPP has breached any provision in Section 4.9, Pfizer may provide MPP with a written notice of its intent to terminate the agreement.²²⁰ In the event that Pfizer and MPP cannot reach consensus to resolve irregularities, Pfizer has the sole right to terminate the agreement.²²¹ MPP must indemnify Pfizer of any loss as a result of MPP's breach of Section 4.9 of the agreement and hold Pfizer and its affiliates "harmless from and against any and all liabilities."²²²

The TRIPS Agreement does not address any issues of corrupt practices in the process of technical transactions.²²³ However, the omission in the TRIPS Agreement does not mean that the issue of corruption can be ignored. Section 4.9 of the Pfizer and MPP license agreement shows how the pharmaceutical giant was concerned about corrupt practices in the developing countries. These concerns are warranted because other multinational pharmaceutical companies have been subject to substantial fines for corrupt practices in developing countries.²²⁴ Several prominent pharmaceutical companies that are currently taking the leading role in fighting the COVID-19 pandemic have a history of facing charges under the FCPA for bribing health officials and health providers to gain market access in other countries.²²⁵ For example, on August 7, 2012, the Securities and Exchange

217. *Id.*

218. *Id.*

219. *Id.*

220. *Id.*

221. *Id.*

222. *Id.*

223. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (2017) (there is no mention of "corrupt" or "bribes" in the agreement).

224. Joel Androphy & Ashley Gargour, *The Intersection of the Dodd-Frank Act and the Foreign Corrupt Practices Act: What All Practitioners, Whistleblowers, Defendants, and Corporations Need to Know*, 45 TEX. J. BUS. L. 129 (2013).

225. For a list of multinational companies charged under the Foreign Corrupt Practices Act, see the Securities and Exchange Commission's press releases at: Press Release, *SEC Enforcement Actions: FCPA Cases*, U.S. SECS. AND EXCH. COMM'N (Sept. 26, 2022), <https://www.sec.gov/enforce/sec-enforcement-actions-fcpa-cases>.

Commission (SEC) alleged that Pfizer's subsidiaries bribed officials in Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia to obtain regulatory and formulary approvals. In settling with the SEC, Pfizer agreed to pay a total of \$26.3 million in disgorgement and prejudgment interests.²²⁶

v. *Trademarks*

Under the agreement, Pfizer prohibits MPP or its licensees from using Pfizer's trademarks in connection with any sale, distribution, promotion, or marketing of the licensed products.²²⁷ A licensee must send a complete description of the trademark it proposes to use to MPP, which resubmits it to Pfizer for approval.²²⁸ Pfizer will not approve a proposed trademark if it is "identical or confusingly similar to any of Pfizer[s] trademark[s]."²²⁹ MPP must ensure licensees do not use trade dress, packaging, or labeling that is the same as or similar to that of Pfizer's in marking the licensed products.²³⁰ In addition, licensees must not give the impression that the licensed products are manufactured by Pfizer or in any way connected with Pfizer.²³¹ Pfizer has the sole discretion to approve the proposed trademark, trade dress,

226. Press Release, U.S. SECS. AND EXCH. COMM'N, *SEC Charges Pfizer with FCPA Violations*, (Aug. 7, 2012), <https://www.sec.gov/news/press-release/2012-2012-152htm>. Other multinational pharmaceutical companies have been faced similar charges: On April 7, 2011, the Johnson & Johnson (J&J) agreed to pay more than \$70 million to settle the charges that it bribed health officials and providers in Greece, Romania, and Iraq in exchange for obtaining market access for its products. See Press Release, U.S. SECS. AND EXCH. COMM'N, *SEC Charges Johnson & Johnson With Foreign Bribery* (Apr. 7, 2011), <https://www.sec.gov/news/press/2011/2011-87.htm>. On August 30, 2016, AstraZeneca PLC agreed to pay more than \$5 million to settle charges for paying health officials in China and Russia with cash and gifts as incentives to purchase or prescribe its products. See Admin. Proceeding File N. 3-17517, U.S. SECS. AND EXCH. COMM'N, *AstraZeneca Charged with FCPA Violations* (Aug. 30, 2016), <https://www.sec.gov/litigation/admin/2016/34-78730-s.pdf>. On December 22, 2016, Teva Pharmaceutical Industries Ltd. agreed to pay \$519 million to settle charges that it bribed foreign government officials in Russia, Ukraine, and Mexico. See Press Release, U.S. SECS. AND EXCH. COMM'N, *Teva Pharmaceutical Paying \$519 Million to Settle FCPA Charges* (Dec. 22, 2016), <https://www.sec.gov/news/pressrelease/2016-277.html>. On June 25, 2020, the Novartis AG, a global pharmaceutical and health care company agreed to pay over \$112 million to settle charges that it bribed "public and private health care providers in South Korea, Vietnam, and Greece in exchange for prescribing or using" its products. See Press Release, U.S. SECS. AND EXCH. COMM'N, *SEC Charges Novartis AG With FCPA Violations* (June 25, 2020), <https://www.sec.gov/news/press-release/2020-144>.

227. PFIZER-MPP AGREEMENT, *supra* note 180, §2.8.

228. *Id.*

229. *Id.*

230. *Id.*

231. *Id.*

packaging, and labeling and then make a decision within thirty days.²³² However, Pfizer has no liability if the proposed trademarks are the same or similar to those used by other licensees.²³³

vi. Licensees and MPP Supervision

Pfizer and MPP jointly administer the licensee application process, but Pfizer has the final say.²³⁴ A qualified licensee must possess the ability and readiness to develop, produce, and market the licensed products and meet all other requirements of the agreement.²³⁵ To obtain a license, an applicant must enter a license agreement with MPP based on Exhibit D, annexed in the Pfizer-MPP Agreement. MPP cannot unilaterally “amend, modify, supplement or otherwise alter the terms and conditions of the terms” in Exhibit D without Pfizer’s consent.²³⁶ Any deviation from the form in Exhibit D will make the sublicense “null and void and of no effect.”²³⁷ This requirement is to ensure that MPP will not grant a sublicense without going through the agreed process defined in the Pfizer-MPP Agreement. Furthermore, Pfizer has the ultimate right to approve each proposed licensee.²³⁸ Pfizer must make the final decision within thirty days after receiving the application. In certain circumstances, it may take forty-five days to make the decision. If Pfizer refuses to approve the sublicense, Pfizer and MPP must keep the reasons for the denial confidential.²³⁹

One of the most important functions of MPP is to ensure that each licensee complies with the license agreement.²⁴⁰ Licensees are required to file reports with MPP every three months.²⁴¹ MPP must review the reports with reasonable skill and care, and then decide whether the supplies of the licensed products comply with the terms of the sublicense. MPP notifies Pfizer of any discrepancies it found during the review.²⁴² If MPP finds that a licensee has breached the licensing agreement, it must immediately notify Pfizer.²⁴³ If the breach is

232. *Id.*

233. *Id.*

234. *See generally* PFIZER-MPP AGREEMENT, *supra* note 180, §3.

235. *Id.* §3.3.

236. *Id.* §3.2.

237. *Id.* §3.1.

238. *Id.* § 3.4.

239. *Id.*

240. *Id.* § 4.1.

241. *Id.* §§ 4.1, 1.6 (“Calendar Quarter shall mean any period of three (3) months ending on the last day of March or June or September or December.”).

242. *Id.* §4.1(a)-(b).

243. *Id.* §4.6.

incurable, either MPP or Pfizer can terminate the sublicense agreement.²⁴⁴

In addition, MPP is obligated to submit to Pfizer a quarterly progress report documenting the development and testing of the licensed products, regulatory filing plans, anticipated market introduction dates, and other key information.²⁴⁵ In addition, MPP must ensure that licensees will assist Pfizer to meet any pharmacovigilance reporting responsibilities that Pfizer has under the applicable laws as a holder of EUA (Emergency Use Authorization). If MPP or the licensee finds any adverse reaction to the licensed products, MPP or the licensee is obligated to notify Pfizer within twenty-four hours and cooperate with Pfizer in meeting its legal duties under the applicable law.²⁴⁶

vii. Quality Control and No Diversion

Once the sublicense agreement becomes effective, the licensees take full control of the development, registration, importation, manufacturing, and marketing of the licensed products.²⁴⁷ Therefore, Pfizer only plays a limited supporting role at this stage. Upon the licensee's request through MPP, Pfizer provides a discrete data package related to the licensed products on a confidential basis. It has the discretion to limit the contents of the package.²⁴⁸ The agreement does not require Pfizer to provide any technical support or assistance to the licensees.²⁴⁹

During the development process, the licensee may also conduct clinical trials or other studies with the licensed products.²⁵⁰ Pfizer retains the right to review the licensee's "study design, specifications, protocol and related materials of any proposed studies."²⁵¹ Even if Pfizer approves the studies proposed by the licensee, it will not become a sponsor or hold regulatory responsibility unless otherwise specified in the agreement.²⁵² Pfizer is not responsible for any liabilities incurred during the studies or trials conducted by the licensee. However, Pfizer may request to use the data free of charge in the same manner that it uses any improvements made by licensees.²⁵³

244. *Id.*

245. *Id.* §4.2.

246. *Id.* §4.4.

247. *Id.* at Exhibit D, §3.1.

248. *Id.* at Exhibit D, §3.2.

249. *Id.*

250. *Id.* at Exhibit D, §3.3.

251. *Id.*

252. *Id.*

253. *Id.* at Exhibit D, §3.4.

In the manufacturing process, the licensee must comply either with the WHO prequalification standards or with the standards of the country where the manufacture is located. The licensee must observe all the laws and regulations in the jurisdiction, as well as standard manufacturing practices in the industry.²⁵⁴

Without either WHO prequalification or the government approval, the licensee is prohibited from marketing the licensed products.²⁵⁵ While the licensee is solely responsible for seeking regulatory approvals, Pfizer will facilitate the application process to the extent necessary.²⁵⁶

Like the TRIPS Agreement Article 31bis, the Pfizer-MPP Agreement sets forth measures to prevent market diversion.²⁵⁷ Licensees are not permitted to market, distribute, or donate the licensed products outside the authorized territory except as expressly permitted in the agreement.²⁵⁸ The prohibition includes when a licensee “knows, believes or ought reasonably to suspect” the licensed products will enter unauthorized territory where a non-territory patent exists.²⁵⁹ To prevent licensees from facilitating infringement of Pfizer’s patent outside the authorized countries, licensees must expressly label the licensed products that they are made under a license from MPP and are prohibited from marketing in unauthorized territories. Licensees also need to make best efforts to ensure that the recipients of the licensed products will abide by the restrictions.²⁶⁰

B. Activist Shareholders’ Pressure

Pfizer faced pressure from a group of health activists in the company’s shareholder meeting in 2022 to broaden access to COVID-19 vaccines.²⁶¹ Rule 14a-8, promulgated under the Securities Exchange

254. *Id.* at Exhibit D, §1.7 (“cGMP shall mean all applicable standard relating to current good manufacturing practices for fine chemical, intermediates, bulk products and/or finished pharmaceutical drugs, including (a) all applicable requirements detailed in the FDA’s current Good Manufacturing Practices regulations, 21 C.F.R. pts. 210, 211, (b) all applicable requirements detailed in the EMA’s “EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use,” and (c) all applicable laws promulgated by any Agency having jurisdiction over the manufacture of the applicable compound or pharmaceutical drug product, as applicable.”).

255. *Id.* at Exhibit D, §3.6.

256. *Id.*

257. *Id.* at Exhibit D, § 5.

258. *Id.* at Exhibit D, § 5.1.

259. *Id.*

260. *Id.* at Exhibit D, § 5.2-5.3.

261. Peter Loftus, *Pfizer, Moderna and J&J Face Shareholder Pressure to Broaden COVID-19 Vaccine Access*, WALL ST. J. (Mar. 27, 2022), <https://www.wsj.com/arti->

Act of 1934, permits shareholders who have continuously held at least \$2,000 in market value of the company's securities for at least three years to submit a proposal to be included in the company's proxy card.²⁶² The proposal must be 500 words or fewer.²⁶³ The company can only exclude the shareholder's proposal after consent from the Securities Exchange Commission (SEC).²⁶⁴ By taking advantage of Rule 14a-8, Oxfam and other global health activists successfully placed their non-binding proposal on the proxy materials for Pfizer's 2022 annual meeting of shareholders.²⁶⁵ Regardless of the legal effects, the ramifications from the appearance of the proposal in the meeting's minutes substantially increased the internal pressure from within Pfizer forcing it to act.²⁶⁶

RESOLVED that shareholders of Pfizer ask the Board of Directors to commission a third-party report to shareholders, at reasonable expense and omitting confidential and proprietary information, analyzing the feasibility of promptly transferring intellectual property and technical knowledge ("know-how") to facilitate the production of COVID-19 vaccine doses by additional qualified manufacturers located in low- and middle-income countries, as defined by the World Bank.²⁶⁷

Oxfam's supporting statement emphasized that herd immunity through vaccination was the key to end the COVID-19 pandemic. However, the inequitable distribution and access to effective vaccines remained as a hurdle. The vaccine inequity could incur a two-trillion-dollar loss to the global economy and potentially cause social instabil-

cles/pfizer-moderna-and-j-j-face-shareholder-pressure-to-broaden-covid-19-vaccine-access-11648373402.

262. 17 C.F.R. § 240.14a-8, pmbl. (2021). For eligibility, *see* section 240.14a-8(b)(1)(i)(A)-(D) (requiring that an eligible shareholder must have continuously held at least \$2,000 in market value of the company's security, or \$15,000 for two years, or \$25,000 for one year).

263. § 240.14a-8(d).

264. § 240.14a-8, at pmbl; *see also*, SEC Response, *infra* note 267.

265. 2021 Annual Report on Form 10-K, *Breakthrough that Change Patient's Lives: Proxy Statement for 2022 Annual Meeting of Shareholders*, PFIZER (Mar. 17, 2022), https://s28.q4cdn.com/781576035/files/doc_financials/2021/sr/Pfizer-Proxy-2022.pdf.

266. Loftus, *supra* note 261.

267. Letter from Rule 14a-8 Review Team, U.S. Secs. and Exch. Comm'n, to Margaret M. Madden, Sr. Vice Pres. And Corp. Sec'y, Chief Governance Couns., Pfizer (Feb. 23, 2022) [hereinafter SEC Response], <https://www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2022/oxfampfizer022322-14a8.pdf>; *see also*, Kobi Kastiel, Yaron Nilia, *In Search of the "Absent" Shareholders: A New Solution to Retail Investor's Apathy*, 41 DEL. J. CORP. L. 55, 73 (2016) ("While shareholder proposals are usually submitted in a non-binding form, they have become an important mechanism to drive governance reforms in the past decade.").

ity.²⁶⁸ Pfizer's efforts to contribute to COVAX at a "not-for-profit" price was insufficient to meet the global demand.²⁶⁹ The ultimate solution was to transfer the IP rights to low- and middle-income countries.²⁷⁰ In response to Pfizer's argument that it was not efficient nor effective to transfer vaccine technology to low- and middle-income countries, Oxfam cited Moderna's transfer of its technology to Swiss manufacturer Lonza, which began producing Moderna's mRNA vaccine within six months.²⁷¹ It also cited the support from various government officials and prominent scholars throughout the world for pressuring Pfizer and other pharmaceutical companies to share their IP rights for COVID-19 vaccines.²⁷²

Pfizer requested that the SEC exclude the proposal from the company's proxy materials for the upcoming annual meeting of security holders.²⁷³ Departing from its long-held deferential approach,²⁷⁴ the SEC denied Pfizer's request without explanation.²⁷⁵ As a result, Oxfam's proposal appeared in item number six in Pfizer's Proxy Statement.²⁷⁶ Pfizer's Board of Directors recommended a vote against the proposal.²⁷⁷ Regardless of the results, Oxfam has succeeded in commanding the attention of the public. Had Pfizer not realized the impact of Oxfam's activism, it would not have petitioned the SEC to

268. SEC Response, *supra* note 267, Exhibit A.

269. *Id.*

270. *Id.*

271. *Id.*

272. *Id.*

273. Letter from Margaret M. Madden, Sr. Vice Pres. and Corp. Sec'y, Chief Governance Couns., Pfizer, to Off. of Chief Couns., U.S. Secs. and Exch. Comm'n (Dec. 22, 2021) [hereinafter Pfizer's Petition] <https://www.sec.gov/divisions/corpfin/cf-no-action/14a-8/2022/oxfampfizer022322-14a8.pdf>.

274. In 2016, SEC permitted Pfizer's request to exclude a proposal which asked the company to prevent the sale of medicines used in executions to prisons. It agreed that the proposal was related to the sale or distribution of the Pfizer's products, an essential part of the management. Similarly, the SEC permitted Verizon Communications Inc. to remove shareholder proposals that were related to the company's the products and services. In another case, the SEC allowed Walt Disney Co. to remove a proposal that requested the company's board to approve the release of a specific film on Blu-ray. The SEC agreed that the proposal was related to the products and services offered for sale by the company. Likewise, the SEC agreed with Abbott Laboratories that "a proposal requesting a review of the economic effects of the HIV/AIDS, tuberculosis and malaria pandemics on the company's business and initiatives" was related to ordinary business under 14a-8(i)(7). Thus, it permitted *Abbott* to exclude the proposal from the proxy materials. *See* Pfizer's Petition, *supra* note 273.

275. SEC Response, *supra* note 267.

276. 2021 Annual Report on Form 10-K, *Breakthrough that Change Patient's Lives: Proxy Statement for 2022 Annual Meeting of Shareholders*, PFIZER (Mar. 17, 2022), https://s28.q4cdn.com/781576035/files/doc_financials/2021/sr/Pfizer-Proxy-2022.pdf.

277. *Id.* at 82.

exclude it from the proxy materials for the annual meeting of shareholders.

Before signing the agreement with MPP, Pfizer was under pressure from various fronts: India and South Africa had requested to waive IP rights on COVID-19 vaccines, which was a position supported by the Biden Administration. Public health experts were frustrated over the lack of COVID vaccines and treatments in low-income countries. Bolivia and other countries threatened to initiate the compulsory licensing process over the patents on COVID-19 vaccines and drugs.²⁷⁸ Oxfam's activism during Pfizer's shareholder meeting may have been the crucial force that nudged the pharmaceutical giant to overcome its reluctance to share its patents—the last straw that broke the camel's back. Between compulsory methods and voluntary agreement, Pfizer chose the latter. The Pfizer-MPP Agreement offers the right balance between low-income countries' access to critical medicines for fighting the pandemic and the pharmaceutical's desire to protect its IP rights. Without either external or internal forces, the Pfizer-MPP agreement would not have been possible.

III.

COMPULSORY LICENSING V. VOLUNTARY LICENSING

To achieve equitable global access to COVID-19 vaccines and therapeutics, there are at least two means to the end: (1) compulsory licensing based on Article 31 and Article 31bis of the TRIPS Agreement or (2) voluntary licensing through MPP on a not-for-profit basis.²⁷⁹ Which type of licensing is more conducive to innovation and equitable access to lifesaving medicines in low- and middle-income countries?

First, voluntary licensing through MPP offers stronger protection of the right-holder's incentive to innovate because the holder has a choice to determine the coverage and terms of the license agreement. Despite the moderate economic return, the right-holder obtains intangible social benefits, such as being perceived as a responsible corporate citizen. Compulsory licensing, however, is akin to takings in property law, where a condemnee is often perceived as a selfish hold-out. In addition, the right-holder has no bargaining power over the

278. World Trade Organization, *Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic* (May 12, 2021), https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm.

279. For the sake of simplicity, waivers are regarded as compulsory licensing here.

value of compensation in the context of compulsory licensing.²⁸⁰ Despite Article 31 of the TRIPS Agreement ensuring the right to judicial review for the right-holder, not every low-income country has an independent judiciary. In fact, in a country where judges are beholden to the government, ruling against the government is nearly impossible.

Second, voluntary licensing promotes compliance with the quality and safety of licensed products. Even though MPP appoints licensees, the right-holder makes the final decision to approve or reject the candidates. Through the review process, the right-holder can evaluate the candidates' manufacturing capacity, past experiences, reputation in the field, and other vital information. Even though the licensees market the products under their own trademarks, the public can still look to the right-holder's reputation and expertise when choosing the licensed products. The quality and safety of licensed products will eventually affect the right-holder's reputation and goodwill in the pharmaceutical industry. More importantly, the quality and safety of the licensed products are of direct concern to public health. Therefore, it is vital for the right-holder to collaborate with competent and reliable licensees. Under Article 31 of the TRIPS Agreement, however, the right-holder has no comparable capacity to have control over the government-appointed licensees.

Third, under a voluntary license, MPP requires licensees to notify the right-holder immediately if any improvements are made. MPP also requires that the licensees grant to the right-holder "a perpetual, irrevocable, worldwide, non-exclusive, transferable and fully paid-up license" to the improvements. Even though the licensees retain ownership over the improvements, the right-holder has unfettered authority to use the improvements. Under Article 31 of the TRIPS Agreement, there is no requirement for the government-appointed licensees to grant the right-holder license to utilize the improvements. The law does not even require licensees to notify the right-holder of any improvements made in the manufacturing process. Without the grant-back provision, the right-holder may face existential threats from the improvers within the term that the right-holder is entitled to the legal monopoly over its invention.²⁸¹

Fourth, voluntary licensing through MPP provides the right-holder greater power to prevent the diversion of licensed products.

280. See generally Thomas W. Merrill, *The Economics of Public Use*, 72 *CORNELL L. REV.* 61 (1986).

281. See John M. Murraya, *Antitrust and Patent License Agreements: A New Look at The Grantback Clause in High Technology Markets*, 3 *CASE W. RESV. J.L. TECH. & INTERNET* 299, 306 (2012).

The commercial relationship with the licensees makes it possible for the right to demand how the licensed products are trademarked, labeled, and distributed. Through quarterly royalty reports, the holder can gain first-hand information about where the products are marketed and the likelihood of whether the licensed products could spill into unlicensed territories. In addition, MPP also monitors whether the licensees distribute the licensed products according to the agreement. Under Article 31 of the TRIPS Agreement, however, it is the government's responsibility to prevent diversion. Like the judicial review provision, the right-holder must rely on a foreign government alone to safeguard the holder's economic interests. Without close ties to the government-appointed licensees, the right-holder has no direct information about whether the products would be in direct competition with the holder's products.

Fifth, in terms of access, voluntary licensing through MPP is no less capable of providing pharmaceutical products to the developing world than compulsory licensing. As a non-profit foundation, MPP's mission is to provide access to more affordable medicines to low- and middle-income countries. It is against the MPP's mission if the licensing agreement is substantially limited in scope. The Pfizer-MPP Agreement covered ninety-five countries, of which twenty-nine low-income countries could receive the licensed products royalty-free. Similarly, the Gilead-MPP Agreement also had wide coverage. Under Article 31 and 31bis of the TRIPS Agreement, it is up to an individual country to grant compulsory licenses. If the country has no manufacturing capacity, it needs to rely on manufacturing in the exporting country. The administrative complexity at the national level could be "bureaucratic, uncertain and/or time consuming."²⁸² In the Rwanda-Canada compulsory licensing case, it took fifteen months for Rwanda to receive the licensed products.²⁸³

CONCLUSION

Despite its numerous advantages, voluntary licensing through the MPP alone cannot meet the demand for COVID-19 vaccines and treatments in low- and middle-income countries. The threat of compulsory licensing makes rights-holders more likely to share their cutting-edge technologies with the MPP on a not-for-profit basis. In addition, pres-

282. Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang & Graham Dutfield, *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic* (London Sch. of Econ. Pol. Sci., Working Paper No. 06/2021).

283. *Id.* at 28.

2022] *BEYOND COMPULSORY LICENSING* 41

sure from activist shareholders may also play a part in persuading rights-holders to take a more active role in safeguarding world health. Only the combined forces of TRIPS, MPP, and socially responsible pharmaceutical companies will provide the world with a solution to widespread health problems while preserving the delicate balance between innovation and equitable access.

