

## ARTICLES

### ACCESS TO MEDICINES AND PHARMACEUTICAL PATENTS: FULFILLING THE PROMISE OF TRIPS ARTICLE 31BIS

*Ezinne Mirian Igbokwe\* & Andrea Tosato\*\**

*The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has long stood accused of reducing access to medicines for the poorest and most vulnerable nations. Enacted in 1994 as one of the founding pillars of the World Trade Organization, TRIPS has enabled pharmaceutical companies to enforce their patent rights in almost every country, precluding cheaper generics from being distributed, save for very limited exceptions.*

*But in 2001, TRIPS was amended expressly to address this issue, allowing countries with limited resources to lodge a formal request to obtain patented medicines at a sustainable cost. Generics manufacturers worldwide can answer this call, operating under the protection of a special export compulsory license that shields them from claims by the patent holder. And yet, this mechanism has been successfully utilized only once.*

*In this Article, we explain why export compulsory licenses have failed and suggest reforms that would help fulfill their promise. First, we identify and analyze the factors that deter countries from making recourse to export compulsory licenses. Second, we argue that the only way for nations to use the current legal framework effectively is to act jointly through pooled procurement initiatives. Finally, we advance the view that TRIPS reform is necessary to unlock the potential of export compulsory licenses, proposing targeted amendments and explaining how these revisions would bolster the flow of patented pharmaceuticals from the Global North to the Global South.*

INTRODUCTION..... 1792

I. ACCESS TO MEDICINES, PHARMACEUTICAL PATENTS, AND  
COMPULSORY LICENSING ..... 1798

---

\* Lecturer, Nottingham Law School.

\*\* Visiting Associate Professor, University of Pennsylvania Carey Law School; Associate Professor, University of Nottingham, School of Law. The authors thank Professors Brook K. Baker, Anupam Chander, Daniel J. Gervais, Lawrence Gostin, David Hoffman, Ronald Labonté, Christopher K. Odinet, Carla Reyes, Madhavi Sunder, Paul Torremans, Christopher S. Yoo, Polk Wagner, and Lindsay Wilde for their suggestions and observations.

A. <i>Access to Medicines</i> .....	1798
B. <i>Patents and Pharmaceutical Inventions</i> .....	1802
C. <i>Compulsory Licensing</i> .....	1806
II. TRIPS, PHARMACEUTICAL PATENTS, AND EXPORT	
COMPULSORY LICENSES .....	1809
A. <i>From the General Agreement on Tariffs to the</i> <i>World Trade Organization</i> .....	1809
B. <i>The TRIPS Framework</i> .....	1812
C. <i>The TRIPS Patent Regime</i> .....	1813
D. <i>The TRIPS Compulsory Licensing Regime:</i> <i>Article 31</i> .....	1815
E. <i>The Impact of TRIPS on WTO Members Lacking</i> <i>Pharmaceutical Manufacturing Capabilities</i> .....	1817
F. <i>The Doha Declaration and Export Compulsory</i> <i>Licenses: Article 31bis</i> .....	1819
III. FACTORS HINDERING EXPORT COMPULSORY LICENSES .....	1823
A. <i>Governmental and Corporate Interferences</i> .....	1824
B. <i>Domestic Law and Free Trade Agreements</i> <i>Obtrusions</i> .....	1828
C. <i>Procedural Complexities</i> .....	1832
D. <i>Economic Challenges</i> .....	1834
IV. FULFILLING THE PROMISE OF EXPORT	
COMPULSORY LICENSES .....	1838
A. <i>The Unique Potential of Export Compulsory</i> <i>Licenses</i> .....	1838
B. <i>Pooled Procurement Strategies</i> .....	1840
C. <i>Law Reform</i> .....	1843
CONCLUSION.....	1846

#### INTRODUCTION

There is great inequality in access to medicines worldwide.<sup>1</sup> In wealthy countries, those covered by well-funded health-care systems benefit from an ever-expanding range of treatments for diseases deemed fatal just a few years ago. In poorer nations, even basic drugs, such as penicillin and other antibiotics, are scarce and often unavailable in rural areas. As witnessed

---

1. See generally ACCESS TO MEDS. FOUND., ACCESS TO MEDICINES INDEX 2021 (2021), [https://accessmedicinefoundation.org/medialibrary/resources/613f5fb390319\\_Access\\_to\\_Medicine\\_Index\\_2021.pdf](https://accessmedicinefoundation.org/medialibrary/resources/613f5fb390319_Access_to_Medicine_Index_2021.pdf) [<https://perma.cc/2KQG-XLF5>]; WORLD HEALTH ORG., GLOBAL EXPENDITURE ON HEALTH: PUBLIC SPENDING ON THE RISE (2022), <https://apps.who.int/iris/bitstream/handle/10665/350560/9789240041219-eng.pdf> [<https://perma.cc/E4P8-6FMZ>]; WORLD HEALTH ORG., ACCESS TO MEDICINES AND HEALTH PRODUCTS PROGRAMME: ANNUAL REPORT 2020 (2021), <https://apps.who.int/iris/bitstream/handle/10665/342314/WHO-EURO-2021-2104-35776-47442-eng.pdf> [<https://perma.cc/LY28-6AYL>].

during the SARS-CoV-2 (COVID-19) pandemic,<sup>2</sup> this disparity is especially acute regarding advanced pharmaceuticals, such as mRNA vaccines, monoclonal antibodies, and antivirals.<sup>3</sup> These medicines are only available in countries with highly advanced manufacturing capabilities and to the most affluent, often self-paying, patients.<sup>4</sup>

There is no single root cause of this situation, but fingers have long pointed at the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>5</sup> TRIPS is critiqued for creating an international legal regime in which pharmaceutical companies enjoy worldwide patent protection, enabling them to charge exorbitant prices while precluding the production of inexpensive generics, even to supply the neediest nations.<sup>6</sup> But how did we get to this point? And is the current system irredeemably flawed?

During the twentieth century, each country found its own balance between stimulating the development of medical inventions through the patent system

---

2. See Alexander E. Gorbalenya, Susan C. Baker, Ralph S. Baric, Raoul J. de Groot, Christian Drosten, Anastasia A. Gulyaeva, Bart L. Haagmans, Chris Lauber, Andrey M. Leontovich, Benjamin W. Neuman, Dmitry Penzar, Stanley Perlman, Leo L.M. Poon, Dmitry V. Samborskiy, Igor A. Sidorov, Isabel Sola & John Ziebuhr, *The Species Severe Acute Respiratory Syndrome-Related Coronavirus: Classifying 2019-nCoV and Naming It SARS-CoV-2*, 5 NATURE MICROBIOLOGY 536 (2020).

3. See generally Amaka Vanni, *Lessons from COVID-19 for Medicines Access*, in INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES 484 (Srividhya Ragavan & Amaka Vanni eds., 2021); Maya Tannoury & Zouhair Attieh, *The Influence of Emerging Markets on the Pharmaceutical Industry*, 86 CURRENT THERAPEUTIC RSCH., 2017, at 19; ALEXANDER VON SCHWERINET, HEIKO STOFF & BETTINA WAHRIG, BIOLOGICS, A HISTORY OF AGENTS MADE FROM LIVING ORGANISMS IN THE TWENTIETH CENTURY (2016).

4. See generally Erwin A. Blackstone & Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH DRUG BENEFITS 469 (2013); Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, in ROUTLEDGE HANDBOOK ON THE POLITICS OF GLOBAL HEALTH 321 (Richard Parker & Jonathan Garcia eds., 1st ed. 2019).

5. See Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter Marrakesh Agreement]; 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 ILM 1197 (1994) [hereinafter TRIPS].

6. See generally ELLEN F.M. 'T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR ACCESS TO MEDICINES 19–49 (2016); VALBONA MUZAKA, THE POLITICS OF INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES 60–84 (2011); Andreas Rahmatian, *Neo-Colonial Aspects of Global Intellectual Property Protection*, 12 J. WORLD INTELL. PROP. 40 (2009); Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369 (2006); F.M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 WORLD ECON. 1127 (2004); CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 1–17 (2d ed. 2020); Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819 (2003); SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003); J. Michael Finger & Philip Schuler, *Implementation of Uruguay Round Commitments: The Development Challenge*, 23 WORLD ECON. 511 (2000); PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? (2002); Marci A. Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective American Association of Law Schools' Intellectual Property Section's Symposium on Compliance with the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 613 (1996).

and assuring affordable access to life-enhancing treatments.<sup>7</sup> At one extreme, countries like the United States preferred privatized health-care systems and unrestricted patentability for pharmaceuticals.<sup>8</sup> At the other, countries such as Brazil and Ecuador favored universal public health care, coupled with a complete bar on medical patents.<sup>9</sup> In between lay a huge spectrum of intermediate positions, most commonly blending partially subsidized health-care systems with narrow protections for pharmaceutical patents.<sup>10</sup>

At the heart of many such national regimes were compulsory licenses,<sup>11</sup> a form of permission that governments grant to public or private entities allowing them to manufacture and sell a patented invention without the patent holder's consent.<sup>12</sup> Compulsory licenses constitute a meaningful exception to the proprietary nature of patents, weakening the monopoly held by patent holders over the commercial exploitation of the protected invention.<sup>13</sup> Many governments used this legal tool against pharmaceutical companies that either charged excessive prices for patented medicines or kept production artificially low.<sup>14</sup> Some went further, liberally granting compulsory licenses for pharmaceutical patents to any producer that committed to manufacturing locally and pricing reasonably.<sup>15</sup>

Against this international backdrop, even nations with limited resources and no domestic biochemical industries had options to obtain expensive patented drugs. These countries would typically procure supplies from countries such as India and Brazil, where pharmaceuticals were cheaply

---

7. See *infra* Part I.B.

8. See generally Graham Dutfield, *The Pharmaceutical Industry, the Evolution of Patent Law and the Public Interest: A Brief History*, in EMERGING ISSUES IN INTELLECTUAL PROPERTY 109, 122–24, 135–46 (Guido Westkamp ed., 2007) (providing an extensive historical account of pharmaceutical patents in the United States).

9. See generally Carolyn S. Corn, Note, *Pharmaceutical Patents in Brazil: Is Compulsory Licensing the Solution?*, 9 B.U. INT'L L.J. 71 (1991) (documenting Brazil's pharmaceutical patents history); Kenneth C. Shadlen, *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies*, 42 COMPAR. POL. 41 (2009); Kumariah Balasubramaniam, *Pharmaceutical Patents in Developing Countries: Policy Options*, 22 ECON. & POL. WKLY. 103, 113–15, 117 (1987) (documenting Ecuador's pharmaceutical patents history).

10. See *infra* notes 77–82 and accompanying text.

11. In this Article, we abbreviate the phrases “compulsory licensing of patents” and “patent compulsory licenses” as “compulsory licensing” and “compulsory licenses,” respectively.

12. See *infra* Part I.C.

13. See *infra* Part I.C.

14. See, e.g., Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT'L LAW. 835 (1996).

15. See Judy Slinn, *Patents and the UK Pharmaceutical Industry Between 1945 and the 1970s*, 24 HIST. & TECH. 191 (2008) (charting the history of the United Kingdom's legislation on pharmaceuticals compulsory licensing); Joel Lexchin, *Pharmaceuticals, Patents, and Politics: Canada and Bill C-22*, 23 INT'L J. HEALTH SERVS. 147 (1993) (detailing the history of Canada's pharmaceuticals compulsory licensing regime).

available because they were subject to local compulsory licenses or there was no patent regime in place for medical inventions.<sup>16</sup>

This all changed dramatically in 1994 with the birth of the WTO and TRIPS. Following years of tense negotiations between “developed” and “developing” countries,<sup>17</sup> it was agreed that access to the free-trade benefits of joining the WTO would be conditional on strict compliance with the intellectual property standards articulated by TRIPS.<sup>18</sup> Crucially, this treaty required all signatory countries to implement patent protection for all types of inventions, including pharmaceutical products and processes.<sup>19</sup> Moreover, it imposed limitations on compulsory licenses, specifying that they must be utilized “predominantly” to supply the issuing country.<sup>20</sup>

As WTO members gradually implemented TRIPS, it became evident that access to medicines was dramatically reduced in countries that lacked pharmaceutical production capabilities.<sup>21</sup> By mandating the adoption of pharmaceutical patents and barring the export of medicines manufactured under compulsory licenses, TRIPS had abruptly shut down all the avenues previously available to procure expensive drugs at affordable prices.<sup>22</sup>

Unsurprisingly, the TRIPS regime for medical inventions and compulsory licenses attracted sharp criticisms, with some commentators going so far as to call it “structural violence.”<sup>23</sup> Critics accused the Global North of foisting its law on the Global South,<sup>24</sup> establishing a “neo-colonial” international trade law framework that coerced developing countries into recognizing and

---

16. See generally Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921 (2007); Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005); Finger & Schuler, *supra* note 6.

17. Though almost never precisely defined, the developed/developing countries dichotomy is commonly used by international organizations, including the WTO, the United Nations, and the World Bank. See *How Does the World Bank Classify Countries?*, WORLD BANK, <https://datahelpdesk.worldbank.org/knowledgebase/articles/378834-how-does-the-world-bank-classify-countries> [<https://perma.cc/MB6N-GWQM>] (last visited Mar. 6, 2023). Throughout this Article, the expression “developed countries” is used to refer to “high income” countries as defined by the World Bank’s “Atlas method.” See *id.* Similarly, the expression “developing countries” is used as an umbrella term to encompass “upper-middle income,” “lower-middle income,” and “low income” countries, as defined by the World Bank’s Atlas method. See *id.*

18. See *infra* Part II.A.

19. See *infra* Part II.B.

20. See *infra* Part II.C.

21. See *infra* Part II.E.

22. See *infra* Part II.E.

23. See Vanni, *supra* note 3, at 484; see also *infra* Part II.E.

24. The terms “Global South” and “Global North” are used diversely in social sciences. In this Article, we use these terms as borrowed from Professor Alfred J. López:

What defines the global South is the recognition by peoples across the planet that globalization’s promised bounties have not materialized, that it has failed as a global master narrative. The global South also marks the recognition among the world’s subalterns of their shared condition at the margins of the brave new neoliberal world of globalization.

ALFRED J. LÓPEZ, *THE GLOBAL SOUTH* 1 (2007).

enforcing the property rights of developed countries.<sup>25</sup> Above all, this new international legal order was accused of making medicines unaffordable for the world's poor.

In 2001, at the WTO's Fourth Ministerial Conference in Doha, Qatar, under pressure from activists and the public, the WTO conceded that TRIPS had markedly reduced access to medicines for countries with limited resources and agreed that an "expeditious solution" was necessary.<sup>26</sup> After two years of labored negotiations, article 31bis was born. This provision allowed WTO members with insufficient pharmaceutical manufacturing capabilities to import patented medicines from generic drug producers operating under a special export compulsory license issued by another WTO member.<sup>27</sup>

Upon its adoption, this amendment to TRIPS was welcomed enthusiastically. There were high hopes that export compulsory licenses would evolve into powerful tools that facilitate access to medicines for the citizens of the poorest countries.<sup>28</sup> The collaborative nature of this novel legal device was also praised for forging a solidaristic pathway through which the Global South might benefit from the know-how and technological advancements of the Global North.<sup>29</sup>

Regrettably, this optimism slowly faded, as only one export compulsory license has been successfully executed since 2001, puzzling scholars and activists alike.<sup>30</sup> Blame has been apportioned to different elements of article 31bis, yet no consensus on a single cause has emerged.<sup>31</sup> This Article explores this conundrum.

First, this Article examines all the possible factors that might be responsible for the underutilization of export compulsory licenses and identifies those that create the most substantial obstacles. Challenging a popular narrative among scholars and activists, this Article contends that

---

25. See Rahmatian, *supra* note 6, at 40.

26. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001, ¶ 6, WTO Doc. WT/MIN(01)/DEC/W/2, 41 I.L.M. 755 (2002).

27. See *infra* notes 206–21 and accompanying text.

28. See *infra* Part II.F.

29. See generally Abbott & Reichman, *supra* note 16; Abbott, *supra* note 16; see also *infra* note 235 and accompanying text.

30. See WORLD HEALTH ORG., WORLD INTELL. PROP. ORG. & WORLD TRADE ORG., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION 242 (2d ed. 2020).

31. See generally Nicholas G. Vincent, *TRIP-ing Up: The Failure of TRIPS Article 31bis*, 24 GONZ. J. INT'L L. 1 (2020); Tolulope Anthony Adekola, *Has the Doha Paragraph 6 System Reached Its Limits?*, 15 J. INTELL. PROP. L. & PRAC. 525 (2020); CORREA, *supra* note 6; Stacey B. Lee, *Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?*, 44 GEO. J. INT'L L. 1387 (2012); Donald Harris, *TRIPs After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 392 (2011); Brin Anderson, Note, *Better Access to Medicines: Why Countries Are Getting Tripped Up and Not Ratifying Article 31-Bis*, 1 CASE W. RES. J.L. TECH. & INTERNET 165 (2009); George Tsai, Note, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes Under the WTO Doha Declaration*, 49 VA. J. INT'L L. 1063 (2008); Christina Cotter, Note, *The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT'L L. REV. 177 (2008).

there is no evidence that governmental and corporate interferences constitute a critical impediment.<sup>32</sup> Similarly, this Article refutes the widespread belief that domestic laws and international trade agreements fundamentally hinder recourse to export compulsory licenses.<sup>33</sup> These critiques are superficial and fail to get to the heart of the problem.

Relying on a law and economics methodology, we advance the view that the primary flaws undermining this novel legal device are the complexity of its procedural dimensions and, above all, its inability to offer an economically viable proposition to generic medicines manufacturers. Our analysis highlights that the bureaucratic and lengthy information disclosures required by article 31bis, combined with its unnecessarily burdensome anti-counterfeit measures, actively deter WTO members from making recourse to export compulsory licenses.<sup>34</sup> Moreover, we demonstrate that the body of rules under consideration burdens prospective pharmaceutical producers with unnecessary costs, makes it harder for them to achieve economies of scale, and exposes them to significant litigation risk from patentees.<sup>35</sup>

As its second contribution, this Article suggests actionable interventions to realize the full potential of export compulsory licenses. We advance the view that, under current law, the only strategy available to overcome economic and procedural challenges is for WTO members to rely on pooled procurement. We highlight that, under certain circumstances, the existing legal framework allows multiple countries to act together and aggregate their demand for a patented pharmaceutical, thus offering generics manufacturers a better chance to achieve sustainable production levels.<sup>36</sup> Nevertheless, our analysis reveals that even this strategy has significant limitations, leading us to propose that TRIPS must be revised if export compulsory licenses are ever to function as intended.

Having established that reform is required, we assess the merits and viability of a broad range of alternative interventions. This analysis

---

32. See Dina Halajian, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing Is Not a Viable Solution to the Access to Medicine Program*, 38 BROOK. J. INT'L L. 1191, 1213–15 (2012); Harris, *supra* note 31; CORREA, *supra* note 6, at 9–11.

33. See generally HENNING GROSSE RUSE-KHAN, *THE PROTECTION OF INTELLECTUAL PROPERTY IN INTERNATIONAL LAW* (2016); ERMIAS TEKESTE BIADGLEN & JEAN-CHRISTOPHE MAUR, *THE INFLUENCE OF PREFERENTIAL TRADE AGREEMENTS ON THE IMPLEMENTATION OF INTELLECTUAL PROPERTY RIGHTS IN DEVELOPING COUNTRIES: A FIRST LOOK* (2011); Hafiz Aziz ur Rehman, *India, TRIPS-Plus Free Trade Agreements and the Future of Access to Essential Medicines*, 19 INFO. & COMM. TECH. L. 267 (2010); Jillian C. Cohen-Kohler, Joel Lexchin, Victoria Kuek & James Orbinski, *Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?*, 5 HEALTHCARE POL'Y 40 (2010); Amir Attaran, *Why Canada's Access to Medicines Regime Can Never Succeed*, 60 U. NEW BRUNSWICK L.J. 150 (2010); Bryan C. Mercurio, *Trips-Plus Provisions in FTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM 215 (Lorand Bartels & Federico Ortino eds., 2006); Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79 (2004).

34. See *infra* Part III.C.

35. See *infra* Part III.D.

36. See *infra* Part IV.B.

concludes that radical revisions to the entire TRIPS patent regime would be unlikely to ever attract the necessary political support, even if they might succeed. Instead, we recommend targeted amendments aimed at enhancing the flexibility and economic viability of export compulsory licenses, submitting that they would both bolster flows of know-how and patented pharmaceuticals from the Global North to the Global South and stand a chance of garnering the necessary political support.<sup>37</sup>

This Article proceeds in four parts. Part I provides a historical and comparative analysis of the right of access to medicines, patent protection for pharmaceutical inventions, and compulsory licensing. Part II offers an assessment of the TRIPS patent regime, followed by a critical examination of the provisions adopted to implement export compulsory licenses. Part III investigates the causes of the limited utilization of export compulsory licenses and presents our thesis that procedural complexities and economic challenges fundamentally undermine this otherwise promising legal instrument. Part IV focuses on approaches to fulfill the potential of export compulsory licenses, both within the confines of current law and through treaty reform.

## I. ACCESS TO MEDICINES, PHARMACEUTICAL PATENTS, AND COMPULSORY LICENSING

This part explores access to medicines, patent protection for pharmaceutical inventions, and compulsory licensing. The aim of this analysis is threefold. First, it highlights the significant extent to which these topics are intertwined. Second, it charts the evolution of this entanglement over time and across jurisdictions. Third, it explains key concepts that are foundational for the discourse in Parts II–IV. Making an original contribution to the existing body of scholarship, this part considers and scrutinizes issues through historical and comparative lenses, revealing the depth and breadth of their roots, as well as their international nature.

### A. Access to Medicines

Access to medicines is a composite legal concept comprising a public law dimension and an individual right dimension. Both must be understood to fully appreciate the social, legal, and economic issues caused by the TRIPS pharmaceutical patents regime.

First, consider public law. Sovereign nations have a long history of taking collective actions to promote public health.<sup>38</sup> Ancient Indian, Mayan, and

---

37. See *infra* Part IV.C.

38. See generally Christopher Hamlin, *The History and Development of Public Health in Developed Countries*, in OXFORD TEXTBOOK OF GLOBAL PUBLIC HEALTH 19 (Roger Detels, Martin Gulliford, Quarraisha Abdool Karim & Tan Chorh Chuan eds., 6th ed. 2015); Than Sein, *The History and Development of Public Health in Low- and Middle-Income Countries*, in OXFORD TEXTBOOK OF GLOBAL PUBLIC HEALTH, *supra*, at 37; JOHN TOBIN, *THE RIGHT TO HEALTH IN INTERNATIONAL LAW* 14–41 (2012); DOROTHY PORTER, *HEALTH, CIVILIZATION*

Mycenaean civilizations built sophisticated sewage networks, water conduits, and public baths for communal use.<sup>39</sup> Ancient Greek city-states appointed public physicians to prevent and cure illnesses, establishing a custom that would later be embraced by the Persian, Macedonian, and Roman Empires.<sup>40</sup> Nevertheless, throughout antiquity, the Middle Ages, and the Enlightenment, public health initiatives focused exclusively on building sanitary infrastructure, preventing contagious illnesses, and offering palliative care.<sup>41</sup> Little attention was devoted to medicines due to the relative underdevelopment of pharmacology as a science.<sup>42</sup>

It was not until the twentieth century that public health policies started grappling with access to medicines.<sup>43</sup> Between the 1950s and 1990s, most developed and developing countries, with the conspicuous exception of the United States, established publicly subsidized systems intended to provide “all individuals and communities with the health services they need without suffering financial hardship”<sup>44</sup> (i.e., universal health coverage).<sup>45</sup> Notably, the adoption of this model coincided with the meteoric rise of pharmacology. As governments assumed an expanding role in health care, the sourcing, distribution, and development of drugs became paramount to treating illnesses.<sup>46</sup> In this novel scientific environment, access to medicines became vital to the success of universal health-care systems.

During the second half of the twentieth century, alongside its mounting relevance in the public health sphere, access to medicines acquired an ulterior dimension as an individual right. In international law, it flourished as a derivative human right, stemming from the rights to life and health.<sup>47</sup> The right to life lies at the heart of every major international human rights

---

AND THE STATE: A HISTORY OF PUBLIC HEALTH FROM ANCIENT TO MODERN TIMES 9–163 (1999); GEORGE ROSEN, A HISTORY OF PUBLIC HEALTH 1–17 (1958).

39. See generally PORTER, *supra* note 38, at 10–23; ROSEN, *supra* note 38, at 1–5.

40. See generally PORTER, *supra* note 38, at 18–23; ROSEN, *supra* note 38, at 6–26.

41. See generally PORTER, *supra* note 38, at 23–45; ROSEN, *supra* note 38, at 26–100.

42. See generally PORTER, *supra* note 38, at 10–23; ROSEN, *supra* note 38, at 1–5.

43. See generally PORTER, *supra* note 38, at 61–147; TOBIN, *supra* note 38, at 37–39; Hamlin, *supra* note 38; Sein, *supra* note 38.

44. The World Health Organization defines “universal health coverage” as “all individuals and communities receiv[ing] the health services they need without suffering financial hardship.” *Universal Health Coverage*, WORLD HEALTH ORG. (Dec. 12, 2022), [https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)) [<https://perma.cc/3B6W-3GRP>]. “It includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care across the life course.” See *id.*

45. See generally GBD 2019 Universal Health Coverage Collaborators, *Measuring Universal Health Coverage Based on an Index of Effective Coverage of Health Services in 204 Countries and Territories, 1990–2019: A Systematic Analysis for the Global Burden of Disease Study 2019*, 396 LANCET 1250 (2020).

46. See generally Hamlin, *supra* note 38; Sein, *supra* note 38.

47. See generally HOLGER HESTERMAYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES (2008); Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. INT’L L.J. 325 (2003).

convention<sup>48</sup> and has been widely recognized as *jus cogens*.<sup>49</sup> The prevailing view is that this human right obliges countries not only to abstain from depriving people of their life arbitrarily, but also to enable individuals to survive and live with dignity.<sup>50</sup> The conclusion that the right to life includes a right to access life-saving medicines followed syllogistically from this premise as soon as pharmaceuticals became essential to survive illnesses. For example, the United Nations Human Rights Committee that monitors the enforcement of the International Covenant on Civil and Political Rights<sup>51</sup> has implied that the right to life enshrined in article 6(1) of this treaty encompasses access to life-saving medical treatments.<sup>52</sup> Similarly, the Inter-American Commission on Human Rights admitted a case in which the petitioners argued that El Salvador's refusal to purchase essential HIV/AIDS medicines had violated their right to life under article 4 of the American Convention on Human Rights.<sup>53</sup>

The international human right to health has provided an even stronger platform for the development of access to medicines as a derivative human right.<sup>54</sup> Numerous international law instruments expressly recognize a right to health.<sup>55</sup> Mirroring the interpretive trajectory of the right to life, the right

48. See, e.g., G.A. Res. 217(III) A, Universal Declaration of Human Rights art. 3 (Dec. 10, 1948) (“[E]veryone has the right to life, liberty and the security of the person”); International Covenant on Civil and Political Rights art. 6(1), Dec. 19, 1966, 999 U.N.T.S. 171 (“Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”); Organization of American States, American Convention on Human Rights art. 4, Nov. 22, 1969, O.A.S.T.S. No. 36, 1144 U.N.T.S. 123 (“Every person has the right to have his life respected.”).

49. For a judicial example of the right to life being recognized as *jus cogens*, see *Morales v. Guatemala*, Inter-Am. Ct. H.R. (ser. C) No. 63, ¶ 139 (Nov. 19, 1999); W. Paul Gormley, *The Right to Life and the Rule of Non-Derogability: Peremptory Norms of Jus Cogens*, in *THE RIGHT TO LIFE IN INTERNATIONAL LAW* 120, 122 (Bertrand G. Ramcharan ed., 1985) (describing the right to life as the “most fundamental human right”); Karen Parker, *Jus Cogens: Compelling the Law of Human Rights*, 12 *HASTINGS INT’L & COMP. L. REV.* 411, 431–32 (1989) (providing an overview of the right to life as *jus cogens*). The Vienna Convention on the Law of Treaties, in article 53, describes *jus cogens* as “a peremptory norm of general international law . . . accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted.” Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331, 340.

50. See HESTERMEYER, *supra* note 47, at 116–17; Yamin, *supra* note 47, at 330–32; cf. Frank Przetacznik, *The Right of Living as a Basic Human Right*, 6 *SRI LANKA J. INT’L L.* 203 (1994) (suggesting a narrow interpretation of the right to life).

51. See *infra* note 66.

52. See *Report of the Human Rights Committee*, 37 U.N. GAOR Supp. No. 40, §§ 1–5, U.N. Doc. A/37/40 (1982); Consideration of Reps. Submitted by State Parties Under Article 40 of the Covenant, U.N. Doc. CCPR/C/79/Add.72 (1996); HESTERMEYER, *supra* note 47, at 116–17; Yamin, *supra* note 47, at 331–32.

53. See *Odir Miranda v. El Salvador*, Case 12,249, Inter-Am. Comm’n H.R., Report No. 29/01, OEA/Ser.L./V/II.111, doc. 20 rev. (2001).

54. For a history of the right to health as a human right, see generally TOBIN, *supra* note 38; HESTERMEYER, *supra* note 47, at 83–84.

55. See, e.g., G.A. Res. 217(III) A, *supra* note 48, art. 25 (“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including . . . medical care.”); International Covenant on Economic, Social and Cultural Rights, art. 12, Dec. 16, 1996, 993 U.N.T.S. 3 (“The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical

to health has been construed ever more broadly to include access to medicines.<sup>56</sup> For example, article 12 of the International Covenant on Economic, Social and Cultural Rights states that individuals have a right to “the highest attainable standard of physical and mental health” and requires signatory countries to take the necessary steps for “[t]he prevention, treatment and control of epidemic, endemic . . . and other diseases.”<sup>57</sup> Providing the authoritative interpretation of this provision, the Committee on Economic, Social and Cultural Rights expressly specified that it includes a right to access “essential drugs”<sup>58</sup> of appropriate quality, in sufficient quantities, and without discrimination.<sup>59</sup>

Both bolstering and resonating with these international law developments, during the second half of the last century, access to medicines was increasingly recognized as an individual right in domestic laws. The national constitutions and primary legislations of many countries have gradually incorporated individual rights to health and health care that include access to pharmaceuticals required for a dignified standard of living.<sup>60</sup> Moreover, these rights are often directly justiciable, with individuals entitled to take legal action against their governments if they fail to adequately cater to their health needs, including when they are denied medicines.<sup>61</sup>

Thus, over the course of the twentieth century, public health and human rights laws increasingly demanded that countries ensure access to medicines for their citizens. The approval, procurement, distribution, and affordability of pharmaceuticals inexorably became fundamental priorities of national governments.<sup>62</sup> In the years preceding the birth of WTO and TRIPS, this issue was increasingly prevalent in developing countries, bringing unprecedented attention to pharmaceutical patents and compulsory licenses.

---

and mental health. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for . . . [t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases.”). For an exhaustive list, see HESTERMEYER, *supra* note 47, at 83.

56. See Yamin, *supra* note 47, at 336–41 (documenting this trajectory).

57. International Covenant on Economic, Social and Cultural Rights, *supra* note 55, art. 12.2(c).

58. Comm. on Econ., Soc. & Cultural Rts. Gen. Comment No. 14, ¶ 12, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000). The Committee on Economic, Social, and Cultural Rights defined “essential drug” by referring to the World Health Organization’s list of essential drugs. See WORLD HEALTH ORG., MODEL LIST OF ESSENTIAL MEDICATIONS (2019), <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf> [<https://perma.cc/Y4D4-BV9T>].

59. See Comm. on Econ., Soc. & Cultural Rts. Gen. Comment No. 14, *supra* note 58, ¶ 12.

60. See generally Courtney Jung, Ran Hirschl & Evan Rosevear, *Economic and Social Rights in National Constitutions*, 62 AM. J. COMPAR. L. 1043 (2014); Jody Heymann, Adèle Cassola, Amy Raub & Lipi Mishra, *Constitutional Rights to Health, Public Health and Medical Care: The Status of Health Protections in 191 Countries*, 8 GLOB. PUB. HEALTH 639 (2015).

61. See generally Lawrence O. Gostin, Jenny C. Kaldor, John T. Monahan & Katie Gottschalk, *The Legal Determinants of Health: Harnessing the Power of Law for Global Health and Sustainable Development*, 393 LANCET 1857 (2019); ALICIA ELY YAMIN & SIRI GLOPPEN, LITIGATING HEALTH RIGHTS: CAN COURTS BRING MORE JUSTICE TO HEALTH? (2011).

62. See generally PORTER, *supra* note 38, at 169–287.

*B. Patents and Pharmaceutical Inventions*

Patent law grants a person a time-limited, exclusive right to exploit economically a technical invention within a specific territory in return for a complete disclosure of its inner workings.<sup>63</sup> Throughout history, diverse normative justifications have been offered for patent protection.<sup>64</sup> Most lawmakers and courts worldwide currently embrace the utilitarian view that the purpose of this branch of commercial law is to incentivize research, development, and marketing of inventions for their economic and societal welfare benefits.<sup>65</sup>

The birth of modern patent systems is typically linked to the English Statute of Monopolies of 1623.<sup>66</sup> This law sparked the evolution of patents from arbitrarily awarded sovereign privileges to statutory property rights conferred pursuant to a regulated, administrative process.<sup>67</sup> The patent custom traveled across the Atlantic Ocean<sup>68</sup> and bloomed on the branches of the first federal U.S. Patent Act of 1790,<sup>69</sup> shortly after the ratification of the U.S. Constitution.<sup>70</sup> Over the following century, most European countries, Russia, and Japan followed suit, creating their own patent regimes.<sup>71</sup> Though these laws were not entirely homogenous, their policy aims and key tenets aligned.<sup>72</sup>

---

63. See generally PETER S. MENELL, MARK A. LEMLEY, ROBERT P. MERGES, SHYAMKRISHNA BALGANESH, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 2020—VOL. I: PERSPECTIVES, TRADE SECRETS AND PATENTS 153–502 (2020).

64. See Giuliano G. Castellano & Andrea Tosato, *Commercial Law Intersections*, 72 HASTINGS L.J. 999, 1040–41 (2021) (describing the different normative justifications for patent rights).

65. See generally Mark A. Lemley, *Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 993–94 (1997).

66. Statute of Monopolies 1623, 21 Jac. c. 3 (Eng.); see also Chris Dent, “Generally Inconvenient”: *The 1624 Statute of Monopolies as Political Compromise*, 33 MELB. U. L. REV. 415 (2009).

67. For an analysis of this transformation across jurisdictions, see generally Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents* (pt. 1), 76 J. PAT. & TRADEMARK OFF. SOC’Y 697, 697–849 (1994); Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents* (pt. 3 continued), 77 J. PAT. & TRADEMARK OFF. SOC’Y 771 (1995).

68. Under English law, the North American colonies were classified as non-English holdings of the Crown and not parts of the kingdom. The Crown alone dictated the laws applicable to these overseas territories. Statutes of Parliament and English common law did not extend to them de jure. For an analysis of the influence of English law on the American patents system, see generally Frank D. Prager, *A History of Intellectual Property from 1545 to 1787*, 26 J. PAT. OFF. SOC’Y 711 (1944).

69. Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (repealed 1793).

70. See generally Edward C. Walterscheid, *Charting a Novel Course: The Creation of the Patent Act of 1790*, 25 AIPLA Q.J. 445 (1997).

71. See generally Zorina B. Khan, *Intellectual Property and Economic Development: Lessons from American and European History* 9 (Comm’n on Intell. Prop. Rts., Study Paper No. 1a, 2002).

72. This picture emerges lucidly from a variety of studies into the historical trajectory of patent law. See, e.g., STEPHEN PERICLES LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION 19–27 (1975); SAM RICKETSON, THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY: A COMMENTARY § 1.17 (2015).

Historically, the patent systems of each country developed introspectively, with minimal regard for international harmonization. This changed during the nineteenth century, when the growth of transnational trade prompted inventors to increasingly seek patent protection in multiple international jurisdictions.<sup>73</sup> Such attempts were often unsuccessful due to substantive and procedural obstacles, as well as outright discrimination against foreigners.<sup>74</sup> To curtail this international fragmentation, governments forged a treaty that would harmonize the granting of patents across jurisdictions: the 1883 Paris Convention for the Protection of Industrial Property<sup>75</sup> (the “Paris Convention”).

The Paris Convention simplified and standardized the process for obtaining patents across borders by introducing the principle of national treatment<sup>76</sup> and the right of priority.<sup>77</sup> However, this treaty did not meaningfully harmonize substantive patent law. Despite holding numerous revision conferences throughout the twentieth century,<sup>78</sup> signatory countries were never able to bridge their differences on key issues, such as which types of inventions should be patentable, the requirements to be satisfied for protection, the duration of the protection term, and the types of remedies available in the case of infringement.<sup>79</sup> It is also notable that the Paris Convention did not require its signatories to grant patents for medical inventions, nor did it address compulsory licensing.<sup>80</sup>

Absent mandatory international standards, countries maintained heterogenous rules on patentable subject matter throughout the twentieth century. This disharmony was especially noticeable in the realm of medical

73. See LADAS, *supra* note 72, at 19–27; RICKETSON, *supra* note 72, § 1.17.

74. See RICKETSON, *supra* note 72, §§ 2.01–3.09.

75. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 2, 828 U.N.T.S. 107. This was last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1538, 828 U.N.T.S. 303.

76. Pursuant to this principle, every Paris Convention country must award to foreigners the same patent rights granted to its own nationals. See RICKETSON, *supra* note 72, §§ 9.16–9.65.

77. See Paris Convention for the Protection of Industrial Property, *supra* note 75, art. 4 (“Any person who has duly filed an application for a patent . . . in one of the countries of the Union . . . shall enjoy, for the purpose of filing in the other countries, a right of priority” for 12 months from the date of filing of the first application); RICKETSON, *supra* note 72, §§ 10.01–10.138.

78. Following the original Paris Convention in 1883, signatory countries agreed to convene periodic revision conferences to further harmonize industrial property law. They were held in Rome (1886), Madrid (1890), Brussels (1897–1900), Washington (1911), the Hague (1925), London (1934), Lisbon (1934), and Stockholm (1967). See RICKETSON, *supra* note 72, §§ 4.01–4.25, 10.46–10.48 (discussing these revision conferences).

79. See *id.* §§ 9.01–9.65; Andrea Tosato, *Secured Transactions and IP Licenses: Comparative Observations and Reform*, 81 LAW & CONTEMP. PROBS. 155 (2018) (highlighting divergences across jurisdictions in the use of intellectual property licenses as collateral); Andrea Tosato, *Security Interests over Intellectual Property*, 6 J. INTELL. PROP. L. & PRAC. 92 (2011).

80. See Paris Convention for the Protection of Industrial Property, *supra* note 75, art. 5A (“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.”).

inventions.<sup>81</sup> The United States had a long-standing tradition of granting patents both for pharmaceutical products and processes.<sup>82</sup> Patentees' rights were further reinforced by the fact that federal law only allowed the issuance of compulsory licenses for governmental use and to remedy antitrust violations.<sup>83</sup> Western European countries, Canada, and Japan similarly offered patent protection for medical inventions, albeit with lesser intensity.<sup>84</sup> For example, Canada, France, and the United Kingdom recognized both process and product patents for pharmaceuticals, yet subjected them to compulsory licensing mechanisms that diluted the exclusive rights of patentees by enabling competing manufacturers to sell generics.<sup>85</sup>

Taking a different approach, a broad group of countries, including Argentina, Austria, Egypt, Greece, India, Spain, and Turkey, only granted patents for pharmaceutical manufacturing processes.<sup>86</sup> In these countries, inventors could obtain protection for techniques used to synthesize medicines but not for the product itself. Competitors could freely produce and sell the same pharmaceutical if obtained through an alternative manufacturing process.<sup>87</sup> A small group of countries, including Brazil and Ecuador, took the opposite approach and excluded patentability of pharmaceutical

---

81. See generally Jean-Paul Gaudillière, *How Pharmaceuticals Became Patentable: The Production and Appropriation of Drugs in the Twentieth Century*, 24 HIST. & TECH. 99 (2008) (detailing the historic role of intellectual property law in biomedicine).

82. See Dutfield, *supra* note 8, at 135–46 (describing the history of pharmaceutical entrepreneurship and pharmaceutical patents in the United States).

83. See *id.*

84. See *id.* at 147–49 (documenting the history of patent protection in the United Kingdom and European continental countries); Lexchin, *supra* note 15 (detailing Canada's legislative trajectory); Akihiko Kawaura & Sumner J. La Croix, *Japan's Shift from Process to Product Patents in the Pharmaceutical Industry: An Event Study of the Impact on Japanese Firms*, 33 ECON. INQUIRY 88 (1995) (documenting Japan's legislation on pharmaceutical inventions).

85. See generally Maurice Cassier, *Brevets Pharmaceutiques et Santé Publique en France: Oppositions et Dispositifs Spécifiques d'Appropriation du Médicament Entre 1791 et 2004* [*Pharmaceutical Patents and Public Health in France: Oppositions to and Appropriations of Medications Between 1791 and 2004*], ENTREPRISES & HISTOIRE, Oct. 2004, at 29 (Fr.) (discussing the history of pharmaceutical patent protection in France); John M. Wechkin, *Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection*, 5 PAC. RIM L. & POL'Y J. 237 (1995) (describing the history of New Zealand's pharmaceuticals patent protection); see also Slinn, *supra* note 15, at 191 (charting the history of the United Kingdom's legislation on pharmaceuticals compulsory licensing); Lexchin, *supra* note 15 (detailing the history of Canada's pharmaceuticals compulsory licensing regime).

86. See D.C. Jayasuriya, *Pharmaceuticals: Patents and the Third World*, 22 J. WORLD TRADE 117 (1988) (detailing that, as of 1988, forty-nine countries did not grant patents for pharmaceutical products, including Argentina, Brazil, Chile, Columbia, the Congo, Ecuador, Egypt, India, Indonesia, Mexico, South Korea, Syria, and Thailand); Hernan L. Bentolila, *Lessons from the United States Trade Policies to Convert a Pirate: The Case of Pharmaceutical Patents in Argentina*, 5 YALE J.L. & TECH. 57 (2002) (charting the history of Argentinian protection for pharmaceutical inventions before and after TRIPS); see also Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 278–90 (2006) (offering a detailed account of Indian patent law and its choice to grant only process patents for medicines).

87. See *supra* note 86.

inventions altogether, regardless of whether they involved a product or a process.<sup>88</sup>

The heterogeneity that characterized the protection of pharmaceutical inventions internationally during the twentieth century was not a fortuitous accident of history. Across jurisdictions, lawmakers faced the same challenge of achieving equilibrium between providing access to medicines at affordable prices and in adequate quantities, while concurrently stimulating pharmaceutical research and development through patent awards. However, they arrived at profoundly different solutions, as each country took a different view on what constituted a palatable balance, based on their legal, economic, social, and political milieu. There was no single recipe suitable for every jurisdiction.

Crucially, this landscape started to evolve during the 1980s. Through unilateral, bilateral, and multilateral initiatives, the United States and other countries with established pharmaceutical industries mounted a relentless campaign to enhance patent protection for medical inventions worldwide. Canada, Japan, and most Western European countries expanded the patentability of pharmaceutical products and processes while narrowing the breadth of their compulsory licensing systems.<sup>89</sup> Over the span of eight short years (1985 to 1993), China pivoted from offering no protection for medical inventions to granting both product and process patents.<sup>90</sup> Following the dissolution of the Soviet Union, Russia and many Eastern European countries enacted patent regimes that provided ample protection to pharmaceutical inventions.<sup>91</sup>

Developing countries reacted diversely to political and economic pressures urging them to introduce patent protection for medical inventions.<sup>92</sup> A few, including Mexico, South Korea, Thailand, and Turkey, ultimately conceded in return for preferential regional and international trade links.<sup>93</sup> Most developing countries in Africa, Asia, and Latin America, including Brazil

88. See generally Balasubramaniam, *supra* note 9 (describing the laws of developing countries that did not protect pharmaceutical inventions); Corn, *supra* note 9, at 71–75 (documenting Brazil’s pharmaceutical patents stance).

89. See generally Lexchin, *supra* note 15 (charting the history of patent protection for pharmaceutical inventions in Canada); Kawaura & La Croix, *supra* note 84 (for a comprehensive analysis of Japan’s implementation of product patents for pharmaceutical inventions); Lewis, *supra* note 14, at 835.

90. See generally Xuan Li, *The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries Under the TRIPS Agreement—a Comparative Study of China and India*, 31 *WORLD ECON.* 1367 (2008) (detailing this swift evolution).

91. See generally Elizabeth F. Enayati, *Patent Protection for Biotechnology Inventions in Eastern Europe*, *NATURE BIOTECHNOLOGY*, Feb. 1994, at 191 (detailing the adoption of patent protection for pharmaceutical inventions in Eastern European countries).

92. See generally Lewis, *supra* note 14, at 835; Julio J. Nogués, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries* 3–10 (World Bank Working Paper Series, Paper No. 502, 1990).

93. See Lewis, *supra* note 14, at 840–42 (charting the shift in the legislation of these countries); Shadlen, *supra* note 8, at 41–43 (explaining that Mexico did not award patents for pharmaceutical inventions until 1991 but subsequently reversed this policy to join a free trade agreement with the United States and Canada).

and India, resisted such pressures. They maintained that it was their sovereign right to not implement pharmaceutical patents, both to foster their domestic biomedical sector and facilitate access to medicines.<sup>94</sup> By the time TRIPS negotiations commenced, patent protection for medical inventions had become a highly contentious matter in international relations.

### C. Compulsory Licensing

Compulsory licenses have a rich history. A primordial form of compulsory licensing can be traced back the Venetian Patent Act of 1474.<sup>95</sup> Under this law, the Venetian government could “take and use any [patented] device and instrument, with this condition however that no one but the author shall operate it.”<sup>96</sup> Although innovative, the Venetian law never penetrated the borders of other jurisdictions and eventually faded into obscurity, in lockstep with La Serenissima’s economic and military decline.<sup>97</sup>

Three centuries later, another embryonic compulsory licensing scheme surfaced in the South Carolinian Act for the Encouragement of Arts and Sciences of 1784.<sup>98</sup> This law established a common regime for copyrights and patents.<sup>99</sup> Thus, patentees were subject to a provision establishing that if a copyright holder “neglected to furnish the public with sufficient editions [of the protected work], or shall sell the same at a price unreasonable,” a person could petition a court to obtain a “license to reprint and publish such [work], in such numbers, and for such term, as said court shall judge just and reasonable.”<sup>100</sup> While the Venetian compulsory licensing system permitted government use, the South Carolinian law provided for the first implementation of court-sanctioned compulsory licenses between private persons.<sup>101</sup> Be that as it may, the South Carolinian act never bore fruit, as it was swiftly superseded by the United States’s Patent Act of 1790. It should be noted that the lawmakers who drafted the federal statute consciously chose

---

94. See generally Verena Schüren, *Two TRIPs to Innovation: Pharmaceutical Innovation Systems in India and Brazil* (SFB-Governance Working Paper Series, Paper No. 37, 2012) (analyzing India and Brazil).

95. This Venetian law is considered the first patent statute in history. See Stefania Fusco, *Lessons from the Past: The Venetian Republic’s Tailoring of Patent Protection to the Characteristics of the Invention*, 17 NW. J. TECH. & INTELL. PROP. 301 (2019); Giulio Mandich, *Venetian Origins of Inventors’ Rights*, 42 J. PAT. OFF. SOC’Y 378 (1960).

96. See Giulio Mandich, *Venetian Patents (1450–1550)*, 30 J. PAT. OFF. SOC’Y 166, 177 (1948) (quoting the Venetian Patent Act); *id.* at 176–77 (analyzing the history).

97. See *supra* note 95.

98. See Act of Mar. 26, 1784, No. 1221, *reprinted in* 4 THE STATUTES AT LARGE OF SOUTH CAROLINA 618–20 (Thomas Cooper ed., 1838).

99. See BRUCE W. BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 119 (1967) (analyzing this statute and noting that it was largely inspired by the Connecticut Copyright Statute of 1783).

100. See *id.* at 119–20 (quoting the South Carolinian Act for the Encouragement of Arts and Sciences of 1784).

101. See Francine Crawford, *Pre-Constitutional Copyright Statutes*, 23 BULL. COPYRIGHT SOC’Y U.S.A. 11, 35 (1975) (analyzing the applicable procedural rules and noting that the choice of the South Carolinian 1784 act to extend the rules for copyright to patents engendered numerous difficulties).

not to introduce compulsory licensing. Presented with a U.S. Senate amendment proposing a compulsory licensing regime that was modeled after the South Carolinian act, the U.S. House of Representatives soundly rejected it, following a debate during which compulsory licenses were criticized as an intolerable encroachment on patentees' rights.<sup>102</sup>

Venetian and South Carolinian antecedents notwithstanding, the first fully fledged compulsory licensing regime was enacted in the English Patents, Designs, and Trade Marks Act of 1883<sup>103</sup> (the "Patents Act of 1883").<sup>104</sup> Under section 22 of this law, a person could petition the Board of Trade to obtain a compulsory license over a patent if the invention in question was "not being worked in the United Kingdom," if the "reasonable requirements of the public" were unmet, or if the petitioner were trying to exploit a derivative invention and was "prevented" from doing so due to the patentee's unwillingness to grant a voluntary license.<sup>105</sup> This compulsory licensing framework had a long-lasting impact in the United Kingdom<sup>106</sup> and served as a blueprint for many common-law<sup>107</sup> and civil-law jurisdictions.<sup>108</sup>

During the twentieth century, numerous countries incorporated domestic compulsory licensing mechanisms in their patent laws.<sup>109</sup> These regimes diverged significantly. In some jurisdictions, compulsory licenses could only be granted on narrow grounds, primarily to redress anticompetitive practices, unjustifiably high prices, and low or negligible production levels. In others, patent legislation liberally provided for the issuance of compulsory licenses on broad grounds, including public health, national defense, technology

---

102. See William Maclay, Journal Entry of April 5th, Monday (Apr. 5, 1790), in THE JOURNAL OF WILLIAM MACLAY: UNITED STATES SENATOR FROM PENNSYLVANIA, 1789–1791, at 226 (Albert & Charles Boni Inc. 1927); BUGBEE, *supra* note 99, at 143; see also Stefan A. Riesenfeld, *Compulsory Licenses and United States Industrial and Artistic Property Law*, 47 CALIF. L. REV. 51 (1959) (charting the history of compulsory licenses in United States intellectual property federal statutes).

103. 46 & 47 Vict. c. 57 (Eng.).

104. On the history of compulsory licensing, see generally David J. Brennan, *The First Compulsory Licensing of Patents and Copyright* (2017) (unpublished manuscript), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3012345](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3012345) [https://perma.cc/ZFR4-83BR] (focusing on Anglo-American law); Oliver Brand, *The Dawn of Compulsory Patent Licensing*, 11 INTELL. PROP. Q. 216 (2007) (analyzing compulsory licensing from the Venetian Patent Act to the English patent law reform of 1883); James Roberts, *Compulsory Licences to Work Patented Inventions*, 6 J. SOC'Y COMPAR. LEGIS. 82 (1905) (applying comparative insights).

105. 46 & 47 Vict. c. 57, § 22.

106. The current British compulsory licensing regime largely replicates that of the 1883 act. See The Patents Act 1977, c. 37, §§ 48A, 48B, 49–54 (UK). See generally RICHARD MILLER, GUY BURKILL, COLIN BIRSS & DOUGLAS CAMPBELL, *TERRELL ON THE LAW OF PATENTS* ch. 17 (19th ed. 2021).

107. For example, the Singaporean Patents Act and Australian Patents Act echo the provisions of the British Patents Act of 1883.

108. See generally Jarrod Tudor, *Compulsory Licensing in the European Union*, 4 GEO. MASON J. INT'L COM. L. 222 (2012).

109. See JEROME H. REICHMAN, *NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS* 10–12 (2003), [https://unctad.org/system/files/official-document/ictsd2003ipd5\\_en.pdf](https://unctad.org/system/files/official-document/ictsd2003ipd5_en.pdf) [https://perma.cc/XZ97-DCU9]; LADAS, *supra* note 72, at 533–35.

transfers, and environmental protection.<sup>110</sup> There were also marked dissimilarities regarding the scope, breadth, and duration of compulsory licenses, and whether affected patentees were entitled to compensation.<sup>111</sup> These differences reflected divergent normative aims. In some jurisdictions, compulsory licenses were deployed as exceptional remedies to redress patentees' abuses, whereas in others, they were viewed as instruments to loosen patent protection, in active pursuit of public policy aims.<sup>112</sup> Conspicuously, several countries systematically subjected all pharmaceutical patents to compulsory licenses with the explicit aim of increasing access to medicines for their citizens.<sup>113</sup>

This dissonance among national compulsory licensing regimes eventually became a contentious international matter, as evidenced by the history of the Paris Convention. In the original treaty of 1883, compulsory licenses went unmentioned.<sup>114</sup> During the revision conferences that took place between then and 1958,<sup>115</sup> signatory countries agreed without incident that compulsory licensing should be implemented as the default remedy to tackle patentees' abuses, whereas outright revocations should only be a measure of last resort.<sup>116</sup> It was at the Lisbon Revision Conference of 1958 that, for the first time, divergent national attitudes to compulsory licensing truly came to the fore.<sup>117</sup> Negotiators discussed the possibility of introducing both limits to the grounds on which compulsory licenses could be granted, as well as procedural and substantive safeguards for patentees.<sup>118</sup> After fraught negotiations, no real consensus emerged. Save for minor amendments, signatory parties retained almost unfettered discretion in their domestic regimes for compulsory licenses.<sup>119</sup>

Following the Lisbon Revision Conference, the international community grew increasingly divided in its views on patents and compulsory licensing.<sup>120</sup> These divergences emerged starkly during the failed Paris

---

110. See REICHMAN, *supra* note 109, at 10–12; LADAS, *supra* note 72, at 533–35.

111. See REICHMAN, *supra* note 109, at 10–12; LADAS, *supra* note 72, at 533–35.

112. See LADAS, *supra* note 72, at 533–34 (featuring an international survey of compulsory licensing regimes in force between 1960 and 1975).

113. See *supra* Part I.A.

114. See LADAS, *supra* note 72, at 522–27 (charting the history of compulsory licensing provisions in the Paris Convention).

115. See *supra* note 78.

116. See Reichman, *supra* note 109, at 11; RICKETSON, *supra* note 72, § 10.50.

117. This was the seventh revision convention. RICKETSON, *supra* note 72, § 10.51.

118. See *id.* (detailing the different limitations considered).

119. See Paris Convention for the Protection of Industrial Property, *supra* note 75, art. 5A(4); RICKETSON, *supra* note 72, § 10.51 (detailing the minor amendments to compulsory licensing rules agreed to at the Lisbon Revision Conference); see also REICHMAN, *supra* note 109 (emphasizing that limits on the issuance of compulsory licenses were actually loosened).

120. See World Intellectual Property Organization [WIPO], *General Report Adopted by WIPO Coordination Committee, the Paris Union Executive Committee and the Berne Executive Committee*, WIPO Document AB/V/13 (Sept. 30, 1974) (detailing how divisions grew wider during informal meetings organized by the World Intellectual Property Organization to promote the revision of the Paris Convention).

Convention revision process of 1980–1984.<sup>121</sup> Seeking easier access to patented inventions, developing countries arrived at the conference wanting greater freedom to attenuate patentees' exclusive rights.<sup>122</sup> They proposed that the Paris Convention should explicitly encourage liberal recourse to compulsory licenses on grounds of public interest and that countries should have the power to bar affected patentees from competing with compulsory licensees.<sup>123</sup> Conversely, developed countries pressed for elevating patent protection standards.<sup>124</sup> They posited that these instruments were grossly abused in many jurisdictions to the detriment of foreign patentees, and they proposed limiting the grounds of issuance, breadth, and scope of compulsory licenses, as well as introducing mandatory compensation for patent holders.<sup>125</sup>

After four years of contentious and inconclusive negotiations, countries abandoned all aspirations for a substantive revision of the Paris Convention. Developing and developed countries had reached complete deadlock. Notably, compulsory licenses for pharmaceutical patents were one of the flash points in this principled disagreement.

## II. TRIPS, PHARMACEUTICAL PATENTS, AND EXPORT COMPULSORY LICENSES

Part I described the diverging approaches to the intricate entanglement of access to medicines, pharmaceutical patents, and compulsory licensing across jurisdictions. Furthermore, it explained that this heterogeneity led to a stalemate between developed and developing countries by the early 1990s. This impasse was conclusively resolved with the creation of the WTO and the concurrent adoption of TRIPS. Part II expounds on this momentous development, describing first the WTO negotiating history and then delving into TRIPS patent rules for medical inventions and compulsory licensing. This analysis aims to explore the path that led to the creation of export compulsory licenses, bringing into sharp relief both the grave defect that this new legal instrument was designed to resolve and its manner of operation.

### A. *From the General Agreement on Tariffs to the World Trade Organization*

The WTO is the offspring of the 1947 General Agreement on Tariffs and Trade<sup>126</sup> (GATT). Enacted at the end of World War II, GATT was designed

---

121. See RICKETSON, *supra* note 72, §§ 5.05–5.11.

122. These proposals were put forward by the “Group of 77,” which included all African (except South Africa), South American, Caribbean, and Asian (except Japan) countries. *See id.* § 5.05 (explaining the history of the different state groupings).

123. *See id.* §§ 5.09–5.11, 10.59–10.63 (describing the proposals presented at the Nairobi (1981) and Geneva (1982, 1984, 1985) revision conferences).

124. These proposals were advanced by Western European countries, Australia, Canada, Japan, New Zealand, and the United States. *See id.* § 5.05.

125. *See id.* §§ 5.09–5.11, 10.59–10.63.

126. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194.

to bolster cross-border commerce among formerly belligerent nations.<sup>127</sup> Over the subsequent four decades, this international trade agreement blossomed, as countries regularly engaged in rounds of negotiations to broaden its scope.<sup>128</sup> From its inception, GATT was centered on tangible goods, with intellectual property law issues only considered at the margins.<sup>129</sup> This changed drastically in the round of negotiations held in Uruguay between 1986 and 1994 (the “Uruguay Round”).<sup>130</sup>

During the Uruguay Round, negotiating countries committed to an ambitious overhaul of the extant GATT framework. They decided to cover a wide range of trade areas by drafting multiple parallel treaties developed individually but signed as a single package. Performing a sharp “regime-shifting” maneuver,<sup>131</sup> a group of developed countries, led by the United States and several members of the European Economic Community, advocated for the inclusion of a treaty on “trade-related aspects of intellectual property rights.”<sup>132</sup>

Initially, this project had a narrow scope, only addressing cross-border trade in counterfeit goods, until a “coalition”<sup>133</sup> of developed countries insisted on expanding this agenda significantly. Despite remonstrations from developing nations,<sup>134</sup> it was ultimately decided that the treaty being negotiated would impose mandatory minimum protection standards for a raft of intellectual property rights—including patents—that signatory countries would be required to implement domestically.<sup>135</sup>

This expanded scope required far broader negotiations. Restocking old divisions, the treatment of medical inventions and compulsory licenses

127. See generally DOUGLAS A. IRWIN, PETROS C. MAVROIDIS & ALAN O. SYKES, *THE GENESIS OF THE GATT* 5–97 (2008).

128. See GIUSEPPE LA BARCA, *THE US, THE EC AND WORLD TRADE: FROM THE KENNEDY ROUND TO THE START OF THE URUGUAY ROUND* (2016) (analyzing all GATT negotiating rounds preceding the Uruguay Round).

129. See DANIEL J. GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* ¶¶ 1.05–1.07 (5th ed. 2021) (explaining that the GATT recognized a country’s right to seize goods that infringed on intellectual property rights).

130. The Uruguay Round was the eighth round of GATT negotiations. See generally *id.* ¶¶ 1.12–1.29 (extensively detailing the Uruguay Round negotiations); Charles Clift, *Why IPR Issues Were Brought to GATT: A Historical Perspective on the Origins of TRIPS*, in *RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES* 3, 10–20 (Carlos M. Correa ed., 2010).

131. See Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 *YALE J. INT’L L.* 1, 14 (2004) (defining “regime shifting” as “an attempt to alter the status quo ante by moving treaty negotiations, lawmaking initiatives, or standard setting activities from one international venue to another”).

132. See Clift, *supra* note 130 (for a detailed history of these negotiations).

133. See Sonia E. Rolland, *Developing Country Coalitions at the WTO: In Search of Legal Support*, 48 *HARV. INT’L L.J.* 483, 485–90 (2007) (providing a history of country coalitions in the GATT and WTO).

134. See JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 27–28 (2001) (describing these negotiations from the perspective of the Indian delegation).

135. The Uruguay Round midterm meetings were held in Montreal (December 5–8, 1988) and continued in Geneva (April 5–8, 1989). See *id.* (lamenting that developing countries surrendered “too much” to developed countries in this meeting).

immediately emerged as profoundly problematic issues in the patent sphere.<sup>136</sup> Developing countries advocated for the complete or partial exclusion of pharmaceuticals from patentable subject matter, as well as absolute freedom to issue compulsory licenses without compensation for patent holders.<sup>137</sup> Conversely, developed countries insisted that medical inventions should be protectable through both product and process patents.<sup>138</sup> Moreover, they contended that compulsory licensing should be permissible in only narrow circumstances, subject to judicial review and with adequate compensation for patent holders.<sup>139</sup>

This polarization was never fully resolved. After contentious negotiations, the draft presented for final approval largely reflected the stance of developed countries.<sup>140</sup> It required full patentability for both pharmaceutical products and processes.<sup>141</sup> Regarding compulsory licensing, it provided that each country could determine the grounds on which they would grant compulsory licenses, yet it imposed mandatory procedural and substantive safeguards for affected patent holders.<sup>142</sup> Confronted with a “take it or leave it” proposition, developing countries begrudgingly accepted that internationally harmonized, mandatory minimum protection standards for intellectual property—including pharmaceutical patents—and compulsory licenses were the price to be paid in return for unconstrained access to the agricultural and manufacturing markets of developed countries.<sup>143</sup>

In 1994, at the Ministerial Conference in Marrakesh, Morocco, the WTO was born. Protection of intellectual property pursuant to the substantive and procedural standards established by TRIPS had become one of the cornerstones of the new international legal order.

136. See *supra* Parts I.B–C.

137. For example, see Peru’s submission. Communication from Peru, *Guidelines for Negotiations That Strike a Balance Between Intellectual Property Rights and Development Objectives*, GATT Doc. MTN.GNG/NG11/W/45 (Oct. 27, 1989) (proposing that pharmaceutical inventions should be excluded from patentable subject matter and that countries should have absolute discretion in granting compulsory licenses).

138. See *id.*

139. For example, see Canada’s submission. Submission from Canada, *Standards for Trade-Related Intellectual Property Rights*, GATT Doc. MTN.GNG/NG11/W/47 (Oct. 25, 1989) (proposing patentability for both pharmaceutical products and processes, coupled with stringent limitations on compulsory licensing).

140. See Chairman’s Report to the GNG, *Status of Work in the Negotiating Group*, GATT Doc. MTN.GNG/NG11/W/76 (July 23, 1990); see also GERVAIS, *supra* note 129, ¶¶ 1.22–1.28 (providing a detailed history of these negotiations).

141. See *infra* Part II.C.

142. See *infra* Part II.D.

143. For a contemporary perspective, see generally Jerome H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement Symposium: Uruguay Round—GATT/WTO*, 29 INT’L L. 345 (1995); Frederick M. Abbott, *The WTO TRIPS Agreement and Global Economic Development*, 72 CHI.-KENT L. REV. 385 (1996).

*B. The TRIPS Framework*

The TRIPS preamble begins with the express acknowledgement that both excessive and inadequate protection of intellectual property rights distort and impede international trade.<sup>144</sup> This is followed by a sequence of statements that, as observed by Professor Daniel J. Gervais, express the aim of TRIPS to achieve “a series of equilibriums: between intellectual property protection and free trade . . . between highly industrialized and developing nations; [and] between the private rights of intellectual property owners and cases where the public interest may trump some aspects of the protection of intellectual property.”<sup>145</sup>

Part I of TRIPS establishes general provisions and basic principles that underpin the whole treaty. For present purposes, articles 7 and 8 deserve special attention. The former asserts that intellectual property protection and enforcement “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology” for the benefit of both right holders and users “in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”<sup>146</sup>

In a similar vein, article 8 provides that signatory countries may adopt measures to safeguard “public health and nutrition” and promote sectors of vital importance to their socioeconomic and technological development.<sup>147</sup> This provision positively recognizes that WTO members may introduce measures to prevent rights holders from abusing their intellectual property rights.<sup>148</sup> Nevertheless, article 8 expressly specifies that all such domestic interventions must be consistent with TRIPS.<sup>149</sup>

Part V of TRIPS makes a significant addition to the international intellectual property landscape by providing that the GATT “Dispute Settlement Understanding”<sup>150</sup> applies to “the settlement of disputes” concerning TRIPS.<sup>151</sup> One WTO member may bring an action before the WTO Dispute Settlement Body alleging that another WTO member has failed to implement or enforce the protection standards imposed by TRIPS.<sup>152</sup> This adjudication mechanism is considerably more robust and incisive than any enforcement processes associated with other major, multilateral instruments dealing with substantive intellectual property law.<sup>153</sup>

---

144. TRIPS, *supra* note 5, pmb1.

145. *See generally* GERVAIS, *supra* note 129, ¶ 3.13; CORREA, *supra* note 6, at 1–17.

146. TRIPS, *supra* note 5, art. 7.

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

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

149. *Id.*

150. *See Understanding on Rules and Procedures Governing the Settlement of Disputes*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401. *See generally* WORLD TRADE ORG., A HANDBOOK ON THE WTO DISPUTE SETTLEMENT SYSTEM (2017).

151. TRIPS, *supra* note 5, art. 64.

152. *See generally* WORLD TRADE ORG., *supra* note 150, at 40–47.

153. *See generally* MATTHEW KENNEDY, WTO DISPUTE SETTLEMENT AND THE TRIPS AGREEMENT 40–106 (2016) (providing an analysis of the TRIPS compliance instruments).

Lastly, Part VI of TRIPS formulates transitional rules to support signatory countries in their progressive implementation of the treaty. Under article 65, developed signatory countries were required to comply with TRIPS within one year of the treaty coming into force,<sup>154</sup> while developing countries were given a five-year window, with an additional five years to implement product patents, including for pharmaceutical inventions.<sup>155</sup> Coextensively, article 66(1) afforded ten years to “least-developed country Members”<sup>156</sup> (LDC) to comply with all TRIPS obligations.<sup>157</sup> This deadline has been postponed repeatedly,<sup>158</sup> and a new extension until 2034 was recently granted.<sup>159</sup> Article 66(1) embodies the principles expressed in articles 7 and 8, providing jurisdictions in the early stages of their industrial and technological development with a loose timeline for the gradual implementation of intellectual property protections.

This provision affords great flexibility to LDCs regarding pharmaceutical patents. They can tailor their laws in whatever way best suits their socioeconomic realities, such as by electing not to protect inventions, only award process patents, or making patentees’ rights conditional on local investments. Additionally, even if an LDC chooses to introduce patent protection for pharmaceutical innovations, they can later revise, suspend, or revoke this recognition, as article 66(1) does not forbid signatory countries from lowering protection levels.

### C. The TRIPS Patent Regime

Part II of TRIPS articulates the protection standards that WTO members are required to implement for copyright, trademarks, geographical indications, industrial designs, patents, topographies of integrated circuits, and trade secrets. Patents are covered in articles 27 to 34.

The fundamental elements of this body of rules can be summarized as follows. First, signatory countries must grant patents for both products and process inventions “in all fields of technology,” with a term of protection no

154. TRIPS, *supra* note 5, art. 65(1).

155. *Id.* art. 65(2)–(4).

156. In 1971, the United Nations General Assembly endorsed a list of “least developed among the developing countries” as a special group of developing countries characterized by a low level of income, by structural impediments to growth, and as requiring special measures for dealing with those problems. This list has been updated annually and currently comprises forty-six countries. See UNCTAD, THE LEAST DEVELOPED COUNTRY REPORT 2021 (2021), [https://unctad.org/system/files/official-document/ldc2021\\_en.pdf](https://unctad.org/system/files/official-document/ldc2021_en.pdf) [https://perma.cc/TZK9-ALAB]; UNITED NATIONS DEP’T FOR ECON. & SOC. AFFS., HANDBOOK ON THE LEAST DEVELOPED COUNTRY CATEGORY: INCLUSION, GRADUATION AND SPECIAL SUPPORT MEASURES (2021), <https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/LDC-Handbook-2021.pdf> [https://perma.cc/XP9V-G9YP].

157. TRIPS, *supra* note 5, art. 66(1).

158. See GERVAIS, *supra* note 129, ¶¶ 3.792–3.796 (detailing the history of these extensions).

159. See *WTO Members Agree to Extend TRIPS Transition Period for LDCs Until 1 July 2034*, WORLD TRADE ORG. (June 29, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/trip\\_30jun21\\_e.htm](https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm). [https://perma.cc/UHS2-Z683].

shorter than twenty years.<sup>160</sup> Pharmaceutical inventions are included without exception. The only admissible exclusions are for inventions considered harmful to “*ordre public* or morality,”<sup>161</sup> as well as “diagnostic, therapeutic and surgical methods” and “plants and animals other than micro-organisms.”<sup>162</sup>

Second, article 27 articulates three requirements for an invention to be patentable: novelty, inventiveness, and industrial application.<sup>163</sup> In line with GATT and WTO general principles, discrimination based on the place of invention or production of the patented item, or its field of application, is expressly forbidden.<sup>164</sup>

Third, signatory countries are required to award a bundle of “negative rights”<sup>165</sup> to patentees that must include the rights to exclude others from making, using, selling, or importing either the protected invention (for product patents)<sup>166</sup> or the products obtained through the protected process (for process patents).<sup>167</sup> Moreover, the assignment and licensing of these exclusive rights must be allowed.<sup>168</sup>

The TRIPS protection standards for patents are both substantively higher and less flexible than those enshrined in the Paris Convention.<sup>169</sup> This is especially noticeable regarding the regime applicable to pharmaceutical inventions. The requirement that WTO members implement both product and process patents in this field of technology stands out as especially disruptive when considering the nuanced landscape that existed prior to the birth of the WTO.<sup>170</sup> Nevertheless, TRIPS also includes flexibilities that were incorporated expressly to enable WTO members to tailor their patent regime to better suit their domestic reality.

Pursuant to article 30, signatory countries may forge generally applicable “exceptions”<sup>171</sup> to curtail the exclusive rights conferred by patents, as long as they are “limited” and neither “unreasonably conflict with a normal exploitation of the patent” nor “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of

---

160. TRIPS, *supra* note 5, arts. 27(1), 33.

161. *Id.* art. 27(2).

162. *Id.* art. 27(3).

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

164. *Id.*; see also Panel Report, *Canada—Patent Protection of Pharmaceutical Products* at 170–71, WTO Doc. WT/DS114/R (Mar. 17, 2000) (distinguishing between “differentiation” and “discrimination” and specifying that “Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas”).

165. *Black’s Law Dictionary* defines a negative right as “[a] right entitling a person to have another refrain from doing an act that might harm the person entitled.” See *Right*, BLACK’S LAW DICTIONARY (11th ed. 2019).

166. TRIPS, *supra* note 5, art. 28(1)(a).

167. *Id.* art. 28(1)(b).

168. See Andrea Tosato, *Intellectual Property License Contracts: Reflections on a Prospective UNCITRAL Project*, 86 U. CIN. L. REV. 1251 (2018) (highlighting that TRIPS does not harmonize the substantive rules governing these transactions).

169. See *supra* Part II.B.

170. See *supra* Part II.B.

171. TRIPS, *supra* note 5, art. 30.

third parties.”<sup>172</sup> Albeit subject to these three requirements, TRIPS does not impose any substantive or procedural restrictions on WTO members, leaving them with discretion to introduce any exceptions deemed appropriate.<sup>173</sup>

Beyond article 30, TRIPS affords additional flexibility to WTO members regarding interventions that impair the rights of individual patent holders.<sup>174</sup> Most significantly, it recognizes that WTO members have the power to issue compulsory licenses while establishing detailed conditions for their scope and duration, as well as procedural and substantive safeguards for patentees.

#### *D. The TRIPS Compulsory Licensing Regime: Article 31*

The TRIPS compulsory licensing framework was originally enshrined in its entirety within article 31. This provision was the object of lengthy and difficult negotiations.<sup>175</sup> It spawned the first international regime for compulsory licenses, breaking new ground in an area of patent law that was previously unharmonized.<sup>176</sup> From a sociopolitical perspective, it represented a momentous development in the dispute between developing and developed countries that had thwarted the progress of the Paris Convention and continued throughout the Uruguay Round.<sup>177</sup>

The key tenets of article 31 can be summarized as follows.<sup>178</sup> First, compulsory licenses can only be granted by governmental bodies, although no restrictions are imposed on their nature, composition, or function.<sup>179</sup>

Second, each compulsory license application must be considered “on its individual merits.”<sup>180</sup> This does not preclude WTO members from enacting laws that establish presumptions in favor of issuing compulsory licenses, but it does exclude “blanket” grants.<sup>181</sup>

Third, the lawful award of a compulsory license is conditional on the prospective licensee having first undertaken “efforts” to obtain a consensual license from the patentee on “reasonable commercial terms and conditions,” and that such efforts were not “successful within a reasonable period of

172. *Id.*

173. For an exhaustive analysis of all of these exceptions, see ANDREW LAW, PATENTS AND PUBLIC HEALTH 93–94 (2009).

174. Notably, article 32 recognizes that WTO members have the power to revoke patents and only requires “an opportunity for judicial review.” TRIPS, *supra* note 5, art. 32.

175. *See supra* Part II.A.

176. *See supra* Part I.C.

177. *See* GERVAIS, *supra* note 129, ¶¶ 3.439–3.449 (analyzing the history of this provision throughout the Uruguay Round).

178. The summary provided here does not cover articles 31(k) and 31(l), which deal with the grant of compulsory licenses to remedy “anti-competitive practices” and to permit the “the exploitation of a patent . . . which cannot be exploited without infringing another patent,” respectively. Compulsory licenses granted on these grounds lie outside the scope of this Article.

179. TRIPS, *supra* note 5, art. 31(a).

180. *Id.*

181. *See* UNCTAD & ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 468 (2005) (explaining that governments cannot grant “blanket” compulsory licenses that affect all the patents granted in a determined field of technology).

time.”<sup>182</sup> This requirement does not apply in “circumstances of extreme urgency” or for “public non-commercial use,” though the issuing WTO member must notify the patent holder of such compulsory licenses without delay.<sup>183</sup>

Fourth, any governmental act awarding a compulsory license must specify its scope and duration, and such limitations must legally bind the licensee.<sup>184</sup>

Fifth, WTO members can only issue compulsory licenses that are nonexclusive and nonassignable.<sup>185</sup>

Sixth, article 31(f) specifies that compulsory licenses must be “authorized predominantly for the supply of the domestic market” of the issuing country.<sup>186</sup> Notably, this provision does not impose a methodology for quantifying such predominance, allowing WTO members to choose their own measuring parameters. Nevertheless, the elasticity of the word “predominantly” is not boundless, making the substance of this restriction unequivocal.<sup>187</sup>

Seventh, WTO members must confer an “adequate remuneration” to patent holders that are subject to compulsory licenses, based on the relevant circumstances and the economic value of the protected invention.<sup>188</sup>

Eighth, consistently with the rule of law principle permeating the entirety of TRIPS,<sup>189</sup> WTO members must ensure that patentees have a right to judicially challenge both the issuance of a compulsory license and the amount of compensation received.<sup>190</sup>

Since its adoption, article 31 has attracted spirited criticism. Commentators have averred that it unjustifiably hinders WTO members’ sovereign prerogatives to issue compulsory licenses to pursue public policy objectives and remedy abusive conduct by entrenching impregnable safeguards for patentees.<sup>191</sup> We disagree.

---

182. TRIPS, *supra* note 5, art. 31(b). *See generally* Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L. REV. 71 (2011) (considering the range of possible meanings attributable to “reasonable commercial terms and conditions”).

183. TRIPS, *supra* note 5, art. 31(b).

184. *Id.* art. 31(c).

185. *Id.* art. 31(d)–(e).

186. *Id.* art. 31(f).

187. *See* Andrew D. Mitchell & Tania Voon, *Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law*, 43 J. WORLD TRADE 571 (2009) (suggesting that predominance may be measured on the basis of diverse parameters); Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health* (Quaker United Nations Office, Occasional Paper No. 9, 2002) (suggesting several possible interpretations for this predominance test).

188. TRIPS, *supra* note 5, art. 31(h).

189. *See id.* art. 41(4).

190. *Id.* art. 31(j)–(j).

191. *See, e.g.,* Halajian, *supra* note 32, at 1197–98; Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 453–54 (2011); Cameron Hutchison, *Over 5 Billion Not Served: The TRIPS Compulsory Licensing Export Restriction*, 5 U. OTTAWA L. & TECH. J. 43, 63–67 (2008); Bryan C.

It is unquestionable that article 31 establishes mandatory minimum standards regulating the process for the issuance of compulsory licenses, their scope, duration, distribution, and remuneration. However, this regime is built on the premise that WTO members may subject any patent, including patents on pharmaceuticals, to a compulsory license, regardless of the nature of the invention or whether it covers a product or a process at any moment in time during their protection term. Article 31 does not curtail the grounds on which a WTO member may issue compulsory licenses, nor does it dictate minimum substantive or evidentiary thresholds for such grants. Furthermore, all procedural and substantive protections for patentees mandated by this provision are built around broad and general standards, such as “reasonable commercial terms and conditions,” “circumstances of extreme urgency,” “purpose,” and “adequate remuneration,” that afford ample flexibility in their implementation.<sup>192</sup> In our view, article 31 unequivocally enshrines into international intellectual property law the principle that compulsory licenses are a highly adaptable instrument that countries are free to tailor as broadly or narrowly as they deem appropriate for their domestic socioeconomic milieu. It is this ample discretion that constitutes the normative core of the TRIPS compulsory licensing regime, not the relatively narrow safeguards that it affords to patentees.

*E. The Impact of TRIPS on WTO Members Lacking Pharmaceutical Manufacturing Capabilities*

The creation of the WTO and the advent of TRIPS were highly controversial.<sup>193</sup> One view was that developing countries were being forced to implement and enforce high protection levels for intellectual property rights that they would have never introduced otherwise, for the meager recompense of smoother access to the agricultural and manufacturing markets of the Global North.<sup>194</sup> Concerns were voiced that the world’s poor would have their access to technological inventions and creative works restricted for the economic benefit of corporations based in developed countries.<sup>195</sup> Some commentators went as far as describing this new international trade law framework as an inequitable bargain reminiscent of colonialism.<sup>196</sup>

The counterargument was that the advent of globalized international trade had made internationally accepted minimum standards for the protection and

---

Mercurio, *TRIPs, Patents, and Access To Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 222–23 (2004).

192. TRIPS, *supra* note 5, art. 31(b)–(h).

193. *See generally* Yu, *supra* note 6; Scherer, *supra* note 6; CORREA, *supra* note 6, at 3–10; SELL, *supra* note 6; Finger & Schuler, *supra* note 6; DRAHOS & BRAITHWAITE, *supra* note 6.

194. *See generally* Scherer, *supra* note 6, at 1127–32; Okediji, *supra* note 6, at 819. *See generally* SELL, *supra* note 6.

195. *See supra* note 193.

196. *See generally* Rahmatian, *supra* note 6; Hamilton, *supra* note 6; DRAHOS & BRAITHWAITE, *supra* note 6, at 197–207.

enforcement of intellectual property rights an absolute necessity to reduce counterfeiting and free-riding.<sup>197</sup> Proponents of this view observed that TRIPS had mostly reiterated rules and principles already present in other international conventions, with only minor substantive and procedural additions.<sup>198</sup> Moreover, they emphasized that the WTO would create a forum for international dispute resolution based on the rule of law, protecting developing WTO members from overbearing, unilateral actions of richer countries.<sup>199</sup>

Initially conducted in the abstract, this debate soon assumed concrete features in the realm of patents. Historically, countries that sought greater access to unavailable or expensive patented inventions made recourse to compulsory licensing only if there was at least one domestic manufacturer with the necessary infrastructure and know-how to fabricate the invention in question and compete with the patentee.<sup>200</sup> When the necessary means for local production were absent, issuing a compulsory license was a vacuous exercise. In such circumstances, countries looked to foreign markets where the product or process in question was cheaply and abundantly available, either due to not being patented (“Avenue 1”) or because it was subject to a compulsory license (“Avenue 2”).<sup>201</sup>

In the years following TRIPS’s entry into force, it became apparent that the TRIPS patent and compulsory licensing regimes had the combined effect of rendering both these avenues almost unviable.<sup>202</sup> Article 27 disrupted Avenue 1. By requiring that all WTO members implement patent protections for inventions in all fields of technology, this provision all but eliminated the possibility that a product or process would be patented in one country but not in others.<sup>203</sup> Simultaneously, article 31(f) almost completely precluded Avenue 2 by mandating that WTO members could only issue compulsory licenses “predominantly” for the supply of their domestic markets.<sup>204</sup> Contradicting the objectives articulated in article 7, the TRIPS patent and compulsory licensing regimes made it harder for WTO members to access patented technologies in fields in which they had limited manufacturing capabilities.<sup>205</sup>

---

197. See generally Daniel J. Gervais, *TRIPS and Development*, in *INTELLECTUAL PROPERTY, TRADE, AND DEVELOPMENT* 3, 13–16 (Daniel J. Gervais ed., 1st ed. 2007); Jerome H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 *INT’L LAW.* 345 (1995); BANKOLE SODIPO, *PIRACY AND COUNTERFEITING: GATT TRIPS AND DEVELOPING COUNTRIES* 274–77 (1997).

198. See Gervais, *supra* note 197, at 13–17. See generally Jerome H. Reichman, *Beyond the Historical Lines of Demarcation: Competition Law, Intellectual Property Rights, and International Trade After the GATT’s Uruguay Round*, 20 *BROOK. J. INT’L L.* 75 (1993).

199. See generally Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 *VA. J. INT’L L.* 275 (1997).

200. See *infra* Part II.C.

201. See Abbott, *supra* note 16, at 318–22 (describing thoroughly both these avenues).

202. See Abbott & Reichman, *supra* note 16, at 923–30.

203. See *supra* notes 150–51 and accompanying text.

204. See *supra* note 172 and accompanying text.

205. See *supra* notes 178–91 and accompanying text.

Critically, this facet of TRIPS affected developing WTO members most acutely with respect to medical inventions.<sup>206</sup> Throughout the twentieth century, those countries overcame their limited manufacturing capabilities in this sector by purchasing pharmaceuticals from Argentina, Brazil, India, and other countries that either did not recognize patent protections in this field or permitted the export of drugs manufactured under compulsory licenses.<sup>207</sup> As these WTO members gradually reformed their domestic patent laws to conform with articles 27 and 31, this long-established international procurement route for pharmaceuticals began to unravel. Tragically, the ensuing disruption in access to medicines solidified precisely at the time when developing WTO members were desperately scrambling to obtain the patented drugs necessary to contain the surging HIV/AIDS epidemic.<sup>208</sup>

*F. The Doha Declaration and Export Compulsory Licenses: Article 31bis*

As the twentieth century concluded, still-louder condemnation was leveled at the diminution in access to medicines foisted by TRIPS onto developing WTO members with limited pharmaceutical manufacturing capabilities.<sup>209</sup> At the 2001 Fourth Ministerial Conference in Doha, bolstered by swelling support from scholars and activists,<sup>210</sup> a group of WTO members submitted a proposal to fundamentally reform articles 27 and 31 of TRIPS.<sup>211</sup> Though this initiative was resisted by developed WTO members,<sup>212</sup> it laid the ground for the unanimous adoption of the WTO Declaration on the TRIPS Agreement and Public Health (the “Doha Declaration”).<sup>213</sup> The opening paragraphs of the Doha Declaration recognized the importance of patent

---

206. See Abbott & Reichman, *supra* note 16, at 318–22 (assessing the impact of the TRIPS patent and compulsory licensing regimes on WTO members with limited production capabilities).

207. See generally Abbott, *supra* note 16; Finger & Schuler, *supra* note 6.

208. See Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 *IND. INT’L & COMPAR. L. REV.* 613, 620–21 (2003).

209. See ‘T HOEN, *supra* note 6, at 31–73.

210. On the access to medicines movement, see *infra* notes 316–17 and accompanying text.

211. See Draft Ministerial Declaration, *Council for Trade-Related Aspects of Intellectual Property Rights*, WT/GC/W/450 (Oct. 4, 2001), [https://www.wto.org/english/tratop\\_e/trips\\_e/mindecdraft\\_w312\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm) [<https://perma.cc/N8C2-BAJE>] (proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, the Philippines, Peru, Sri Lanka, Thailand, and Venezuela); see also Abbott & Reichman, *supra* note 16, at 935 (providing an extensive analysis of this proposal and suggesting that it would have been superior to article 31bis).

212. The proposal by the African Group and others was met with stark opposition from the United States and the European Union. GERVAIS, *supra* note 129, ¶¶ 2.75–2.76.

213. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, ¶ 6, WTO Doc. WT/MIN(01)/DEC/W/1, 41 *ILM* 746 (2002) [hereinafter Doha Declaration]; World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(0)/DEC/2 (2001); see James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 *HARV. J.L. TECH.* 291 (2002) (investigating the legal status of the Doha Declaration in international law and suggesting that it would be applied by the Dispute Settlement Body as a formal amendment to the TRIPS agreement).

protection for medical inventions but coextensively acknowledged “concerns about its effects on prices.”<sup>214</sup> This was followed by a statement reaffirming the sovereign prerogative of WTO members to grant compulsory licenses and their “freedom to determine the grounds” on which they are issued.<sup>215</sup> Expressing the key concern of the Doha Declaration, paragraph 6 accepted the difficulties faced by countries with insufficient pharmaceutical manufacturing capabilities in “making effective use of compulsory licensing under the TRIPS Agreement,” and it instructed the Council for TRIPS to develop an “expeditious solution.”<sup>216</sup> This was an explicit admission that the original TRIPS framework was flawed.

In 2003, after two years of contentious negotiations,<sup>217</sup> the TRIPS Council adopted the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the “Waiver Decision”), under which it instituted a temporary “waiver” allowing WTO members to grant compulsory licenses free from the obligations imposed by articles 31(f) and 31(h).<sup>218</sup> In 2005, the WTO’s General Council adopted the Protocol Amending the TRIPS Agreement (the “Amendment Protocol”), which incorporated the substance of the Waiver Decision into TRIPS via the addition of article 31bis, its annex, and the appendix to the annex (the “Article 31bis System”).<sup>219</sup> The Amendment Protocol entered into force in 2017 after ratification by two-thirds of WTO members.<sup>220</sup>

The Article 31bis System allows a WTO member with “insufficient or no manufacturing capacities in the pharmaceutical sector”<sup>221</sup> (the “Importing State”) to import patented “pharmaceutical products”<sup>222</sup> produced under a

---

214. Doha Declaration, *supra* note 213, ¶3 (“We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.”).

215. *Id.* ¶5.

216. *Id.* ¶6 (“We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”).

217. See Abbott, *supra* note 16, at 326–40 (explaining that three issues were at the heart of these negotiations: scope of covered diseases, eligible importing countries, and which article(s) of the TRIPS agreement would be addressed by the solution).

218. See General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 (Aug. 30, 2003) [hereinafter the Waiver Decision]. This waiver is permissible because any requirement of a WTO agreement, including TRIPS, may be waived. See Marrakesh Agreement, *supra* note 5, art. IX(3)–(4).

219. See General Council Decision, *Amendment of the TRIPS Agreement*, WTO Doc. WT/L/641 (Dec. 6, 2005).

220. This threshold is established by the Marrakesh Agreement, *supra* note 5, art. X (“Amendments to provisions of this Agreement . . . shall take effect for the Members that have accepted them upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance by it.”). At the time of writing, 107 WTO members have ratified the protocol amending the TRIPS agreement.

221. See TRIPS, *supra* note 5 (annex to the TRIPS agreement at 2(a)(ii)).

222. See *id.* (annex to the TRIPS agreement at 1(a), defining “pharmaceutical product” as “any patented product, or product manufactured through a patented process, of the

special export compulsory license granted by another WTO member (the “Exporting State”). Procedurally, this mechanism is structured as a dialogical interaction between an Importing State and an Exporting State. At the outset, the Importing State must send a notice to the TRIPS Council. This notice document is not subject to approval but must contain determinate information, including the pharmaceutical product(s) that will be imported and the “expected quantity” required.<sup>223</sup> Moreover, unless the Importing State is an LDC,<sup>224</sup> it must self-certify its lack of capabilities to produce the drug in question domestically<sup>225</sup> and confirm that it has granted, or intends to grant, a compulsory license in accordance with article 31 for the patented pharmaceutical product in question.<sup>226</sup>

Once the TRIPS Council has received the Importing State’s notification, the Exporting State can issue an export compulsory license that must still conform with article 31 but which, crucially, is exempt from article 31(f) “to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s).”<sup>227</sup> The terms of this compulsory license must bind the licensee both to manufacture the patented pharmaceuticals in a quantity no greater than that notified to the TRIPS Council and to export all of them to the Importing State.<sup>228</sup> Additionally, these products must be clearly identifiable “through specific labelling or marking,” as well as distinguishable through special “packaging and/or colouring/shaping of the products themselves.”<sup>229</sup>

The Exporting State must also promptly notify the TRIPS Council that it has issued the export compulsory license and provide its terms.<sup>230</sup> Prior to shipment, the licensee must create a website through which it discloses the exact quantities of pharmaceuticals supplied to the Importing State and the markings that render them distinguishable.<sup>231</sup> The Exporting State is required to pay compensation to the patent holder, “taking into account the

---

pharmaceutical sector needed to address the public health problems” and stating that “[i]t is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included”).

223. *Id.* (annex to the TRIPS agreement at 2(c)).

224. *Id.* (appendix to the annex to the TRIPS agreement, stating “[l]east-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector”).

225. *Id.* (appendix to the annex to the TRIPS agreement, stating that “insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs”).

226. *Id.* (annex to the TRIPS agreement at 2(a)(iii)).

227. *Id.* (annex to the TRIPS agreement at 2(c)).

228. *Id.* (annex to the TRIPS agreement at 2(b)(i)).

229. *Id.* (annex to the TRIPS agreement at 2(b)(ii)).

230. *Id.* (annex to the TRIPS agreement at 2(c)).

231. *Id.* (same).

economic value to the importing Member of the use that has been authorized in the exporting Member.”<sup>232</sup>

Notably, a WTO member is eligible to be an Importing State only if it has notified the TRIPS Council of its intention to use the Article 31bis System.<sup>233</sup> At the time of writing, thirty-seven developed WTO members have elected either not to rely on export compulsory licenses or to only rely on them in circumstances of extreme urgency.<sup>234</sup> These opt-outs were expressed when the Amendment Protocol was adopted, almost as an informal political pact among technologically advanced countries not to encroach on pharmaceutical patentees’ rights.<sup>235</sup> Ironically, the COVID-19 pandemic has exposed the short-sightedness of this accord. As several developed WTO members began to confront the inadequacy of their mRNA vaccine production capabilities and struggle to secure sufficient supplies to protect their populations, sensitivity toward the plight of patentees appears to have suddenly diminished.<sup>236</sup>

The Article 31bis System was received with excitement.<sup>237</sup> Government representatives, activists, and legal scholars welcomed the creation of a compulsory licensing mechanism purposely tailored to enable WTO members with insufficient pharmaceutical manufacturing capabilities to source patented pharmaceuticals from markets with greater technical know-how.<sup>238</sup> Equally, the prospect of the Article 31bis System opening a new pathway for greater collaboration between developing and developed WTO members was celebrated. There was hope that this reform would be the first step toward a more equitable and solidaristic TRIPS.<sup>239</sup>

Regrettably, this optimism has gradually dissipated as several attempts to make recourse to the Article 31bis System have failed. In 2005, Ghana reportedly considered notifying the TRIPS Council of its intention to import HIV pharmaceuticals, yet ultimately abandoned this attempt and procured

---

232. *Id.* art. 31bis(2).

233. *Id.* (annex to the TRIPS agreement at 1(b), defining “eligible importing member” as “any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex (‘system’) as an importer”).

234. The list of countries that have notified the TRIPS Council of their intention to use the Article 31bis System is available online. See *Notifications by Importing WTO Members*, WORLD TRADE ORG., [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_import\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm) [<https://perma.cc/7XCR-QA2V>] (last visited Mar. 6, 2023).

235. See Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT’L. ECON. LAW 535, 558–60 (2020).

236. See *id.* (emphasizing that the COVID-19 pandemic has revealed how such opt-outs were “ill-considered” and suggesting legal avenues for “opting back in”).

237. See Council for Trade-Related Aspects of Intellectual Prop. Rights, *Minutes of Meeting*, WTO Doc. IP/C/M/84/Add.1 (Feb. 17, 2017).

238. See *id.*; see also Abbott & Reichman, *supra* note 16, at 969; S.K. Verma, *The Doha Declaration and Access to Medicines by Countries Without Manufacturing Capacity*, in RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES, *supra* note 130, at 623.

239. See Council for Trade-Related Aspects of Intellectual Prop. Rights, *supra* note 237.

the required medications in the open market.<sup>240</sup> In 2008, Nepal notified the TRIPS Council that it wanted to import the chemotherapeutic drug erlotinib.<sup>241</sup> Natco, an Indian generic pharmaceuticals manufacturer, applied for an export compulsory license to supply Nepal, yet withdrew its application later after it was sued for infringement by the local patent holder.<sup>242</sup> In 2021, in response to the COVID-19 pandemic, Bolivia notified the TRIPS Council of its intention to import fifteen million doses of a vaccine patented by U.S. pharmaceutical company Johnson & Johnson and, simultaneously, entered into a supply agreement with Biolyse Pharma, a Canadian pharmaceutical manufacturer.<sup>243</sup> At the time of writing, Biolyse had lodged an application with the Canadian government for an export compulsory license.<sup>244</sup> It remains to be seen whether this attempt to use the Article 31bis System will come to fruition.

The Article 31bis System has been used successfully only once.<sup>245</sup> In July 2007, following three years of preparations spearheaded by Médecins Sans Frontières, Rwanda notified the TRIPS Council of its intention to import a fixed-dose combination of three HIV/AIDS drugs.<sup>246</sup> Two months later, Canada granted an export compulsory license to Apotex, a local manufacturer of generic pharmaceuticals, and notified the TRIPS Council pursuant to article 31bis. After several delays, Apotex began its exports to Rwanda in late 2008.

Eighteen years after its introduction, the extremely limited recourse to the Article 31bis System and its low success rate calls into question its effectiveness in redressing the very flaw it was designed to solve.

### III. FACTORS HINDERING EXPORT COMPULSORY LICENSES

This part seeks to determine the factors responsible for the stagnation of the Article 31bis System. This topic has attracted significant attention, spawning a large but fragmented body of opinion. The TRIPS Council has

240. See WORLD HEALTH ORG. ET AL., *supra* note 30, at 242 (describing Ghana's attempt to make recourse to the Article 31bis System).

241. The pharmaceutical company Roche holds the patent for erlotinib internationally.

242. See Harris, *supra* note 31, at 390 (detailing Nepal's failed attempt to use the Article 31bis System).

243. See *Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic*, WORLD TRADE ORG. (May 12, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/dgno\\_10may21\\_e.htm](https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm) [<https://perma.cc/H9KQ-43EU>].

244. See Allison Martell, *Bolivia Signs J&J Vaccine Deal with a Twist—It Needs WTO Patent Waiver*, REUTERS (May 11, 2021, 5:41 PM), <https://www.reuters.com/world/americas/bolivia-signs-jj-vaccine-deal-with-twist-someone-else-would-make-it-2021-05-11/> [<https://perma.cc/W89U-H8AD>].

245. See generally Vincent, *supra* note 31; Adekola, *supra* note 31; Correa, *supra* note 4; Lee, *supra* note 31; Harris, *supra* note 31; Anderson, *supra* note 31; Tsai, *supra* note 31; Cotter, *supra* note 31.

246. See WORLD HEALTH ORG. ET AL., *supra* note 30, at 243 (providing a detailed analysis of Médecins Sans Frontières's preparatory work, Rwanda's notification to the TRIPS Council, and a description of the antiviral drugs in question); see also Vincent, *supra* note 31, at 19 n.96 (providing a description of this composite drug and its formants).

addressed this issue in annual reviews since 2006;<sup>247</sup> moreover, in 2010, it held a session for WTO members to discuss the implementation issues affecting export compulsory licenses.<sup>248</sup> The WTO, the World Intellectual Property Organization, and the World Health Organization have also candidly acknowledged the inactivity of the Article 31bis System in a jointly issued report on access to medical technologies and innovation.<sup>249</sup> Furthermore, academics and activists have produced a panoply of diverse theories to account for the lack of success of export compulsory licenses.<sup>250</sup> Considered holistically, we find that these sources have identified four broad groups of issues: (1) governmental and corporate interferences, (2) obtrusions caused by domestic laws and free trade agreements, (3) procedural complexities, and (4) economic challenges. We now analyze each in turn.

#### A. Governmental and Corporate Interferences

Mindful of the contentious past of compulsory licensing,<sup>251</sup> commentators have suggested that developing WTO members do not make recourse to the Article 31bis System due to fear of retaliation from developed WTO members and pharmaceutical companies.<sup>252</sup> In support of this view, scholars and activists have long decried the manner in which the United States's federal government has historically weaponized section 301 of the Trade Act of 1974<sup>253</sup> to pressure and sanction states that are deemed to endanger American intellectual property interests.<sup>254</sup> Moreover, they point to

---

247. For the most recent report, see Council for Trade-Related Aspects of Intellectual Prop. Rights, *Annual Review of the Special Compulsory Licensing System*, WTO Doc. IP/C/86 (Nov. 11, 2020).

248. See Council for Trade-Related Aspects of Intellectual Prop. Rights, *Minutes of Meeting Held in the Centre William Rappard on 2 March 2010*, at 35–42, WTO Doc. IP/C/M/62 (June 1, 2010).

249. See WORLD HEALTH ORG. ET AL., *supra* note 30, at 241–44.

250. See *supra* Parts III.A–D.

251. See *supra* Part I.C.

252. See Halajian, *supra* note 32, at 1213–15; see also Harris, *supra* note 31, at 392; Correa, *supra* note 4, at 5–7.

253. Pub. L. No. 93-618, 88 Stat. 1978 (codified as amended in scattered sections of the U.S.C.); see *id.* § 301, 88 Stat. at 2041–43 (codified as amended at 19 U.S.C. § 2411). Pursuant to this provision, the Office of the United States Trade Representative (USTR) annually prepares a report (the “Special 301 Report”) examining how foreign countries protect intellectual property rights. Those that are considered to have adopted laws and practices with an “adverse impact (actual or potential) on the relevant United States’ products” are placed on a “Priority Watch List” and may be subject to unilateral trade sanctions. All Special 301 Reports are available from USTR at *Special 301*, OFF. OF THE U.S. TRADE REPRESENTATIVE, <https://ustr.gov/issue-areas/intellectual-property/Special-301> [<https://perma.cc/R9WV-LWNX>] (last visited Mar. 6, 2023). See generally Michael Palmedo, *United States: Unilateral Norm Setting Using Special 301*, in *INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES* 274 (Srividhya Ragavan & Vanni Amaka eds., 2021).

254. See Palmedo, *supra* note 253 (offering an exhaustive analysis of the use of Special 301 Reports over the past two decades); see also Suzanne Zhou, *Challenging the Use of Special 301 Against Measures Promoting Access to Medicines: Options Under the WTO Agreements*, 19 J. INT'L ECON. L. 51 (2016) (analyzing a large number of cases in which the Special 301 Report was used against developing countries).

troubling episodes that have occurred in the recent past when developing WTO members issued compulsory licenses.<sup>255</sup> For example, between 2006 and 2008, Thailand issued compulsory licenses for several patented pharmaceuticals used to treat HIV/AIDS, heart disease, and cancer.<sup>256</sup> Without negotiating with patent holders, compensation was set at 0.5 to 2 percent of the total sale value.<sup>257</sup> As Thailand provides health care to all residents free of cost at the point of access, the government projected that these measures would reduce its costs for the selected pharmaceuticals tenfold.<sup>258</sup>

Some developed WTO members and the affected pharmaceutical companies responded aggressively. In 2007, the United States placed Thailand on its “Special 301 Report” “Priority Watch List.”<sup>259</sup> By way of sanction, the United States barred Thai exports from its domestic market on a duty-free basis.<sup>260</sup>

The European Union had a mixed reaction. On one hand, the European Commission wrote to the Thai government expressing reservations regarding the lawfulness of its compulsory licensing practices.<sup>261</sup> On the other hand, the European Parliament passed a resolution expressing support for developing WTO members that take advantage of TRIPS’s flexibilities to protect their citizens’ right of access to medicines.<sup>262</sup> Meanwhile, Sanofi, one of the affected patent holders, threatened to sue the Indian company

255. See generally Brook K. Baker, *Access to Medicines Activism: Collaboration, Conflicts, and Complementarities*, in *INTELLECTUAL PROPERTY LAW AND THE RIGHT TO HEALTH: A HISTORY OF TRIPS AND ACCESS TO MEDICINES* 295 (Srividhya Ragavan & Amaka Vanni eds., 2020) (recounting the pressure that developed countries and pharmaceutical corporations directed at South Africa in 1997, Brazil in 2001, Malaysia in 2003, Indonesia in 2004, and several others in response to compulsory licensing initiatives).

256. These drugs were efavirenz, lopinavir/ritonavir, clopidogrel, letrozole, docetaxel, erlotinib, and imatinib. For an explanation of Thailand’s approach to the granting of these compulsory licenses, see MINISTRY OF PUB. HEALTH & NAT’L HEALTH SEC. OFF., *FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND* (2007), <http://www.cptech.org/ip/health/c/thailand/thai-cl-white-paper.pdf> [<https://perma.cc/2S66-F7ND>]. See also Cynthia M. Ho, *Patent Breaking or Balancing: Separating Strands of Fact from Fiction Under Trips*, 34 N.C. J. INT’L L. & COM. REGUL. 371, 411–41 (2009) (providing an extensive legal and political analysis of Thai compulsory licenses).

257. MINISTRY OF PUB. HEALTH & NAT’L HEALTH SEC. OFF., *supra* note 256, at 11.

258. *Id.* at 11–15.

259. See OFF. OF THE U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 27 (2007), <https://ustr.gov/sites/default/files/2007%20Special%20301%20Report.pdf> [<https://perma.cc/2B3W-XP6K>].

260. HIGH-LEVEL PANEL ON ACCESS TO HEALTH TECHS., REPORT ON THE UNITED NATIONS SECRETARY-GENERAL’S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES 7 (2016), <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> [<https://perma.cc/VKQ6-CTV4>].

261. Letter from Peter Mandelson, Comm’r, Eur. Comm’n, to Krirk-krai Jirapaet, Minister of Com., Thailand (July 10, 2007), <https://www.keionline.org/wp-content/uploads/mandelson07102007.pdf> [<https://perma.cc/C7GY-Z7JH>].

262. Resolution of 12 July 2007 on the TRIPS Agreement and Access to Medicines, EUR. PARL. DOC. P6\_TA(2007)0353, ¶ 9 (2007).

involved in exporting the required medicines into Thailand.<sup>263</sup> Another patent holder, Abbott Laboratories, withdrew an array of new medicines for blood clots, kidney diseases, arthritis, high blood pressure, viral infection, and inflammation from the Thai market.<sup>264</sup> Although this vindictive measure was later reversed, a private foreign actor deprived Thai patients of access to essential treatments, some of which had no substitute, for the duration of the entire dispute.

We agree that compulsory licenses, both under article 31 and the Article 31bis System, are vulnerable to governmental and private retaliatory initiatives, including punitive trade policies and pharmaceutical product withdrawals. Such actions should be condemned unreservedly. They show arrogant disregard for articles 7 and 8,<sup>265</sup> the flexibilities included in the TRIPS patent regime,<sup>266</sup> the WTO Dispute Settlement Understanding,<sup>267</sup> the Doha Declaration,<sup>268</sup> and article 31bis(4) (which explicitly prohibits WTO members from challenging legitimately issued export compulsory licenses).<sup>269</sup> Even worse, these maneuvers encroach on the national sovereignty of targeted WTO members. They constitute a contemptible exploitation of the asymmetrical power relationship that exists between the Global North and the Global South.

This notwithstanding, we believe that there is robust evidence to counter the view that the Article 31bis System has been scarcely utilized due to the fear of governmental and corporate reprisals. First, the stance of developed WTO members and pharmaceutical companies toward compulsory licensing has evolved considerably in the years since the adoption of TRIPS, and especially following the Doha Declaration. During the late 1990s and early 2000s, almost every instance of developing WTO members issuing compulsory licenses for a pharmaceutical product was characterized by political pressure and trade sanctions from national governments—often led by the United States—as well as staunch opposition from patent holders.<sup>270</sup>

---

263. See Abbott & Reichman, *supra* note 235, at 953–54.

264. See generally V. Kuek, K. Phillips & J.C. Kohler, *Access to Medicines and Domestic Compulsory Licensing: Learning from Canada and Thailand*, 6 GLOB. PUB. HEALTH 111 (2011). See also Paul Cawthorne, Nathan Ford, David Wilson, Kannikar Kijtiwatchakul, Virat Purahong, Nimit Tianudom & Supatra Nacapew, *Access to Drugs: The Case of Abbott in Thailand*, 7 LANCET 373 (2007) (for a contemporaneous account of these events).

265. See *supra* notes 131–34 and accompanying text.

266. See *supra* Part II.B.

267. See *supra* Part II.B.

268. See *supra* Part II.F.

269. TRIPS, *supra* note 5, art. 34bis(4) (“Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement . . .”).

270. See Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with US Firms and Politicians*, 29 INT’L J. HEALTH SERVS. 765 (1999) (describing the political pressure exercised by the United States on South Africa due to its compulsory licensing policy); Haroon Ashraf, *USA and Brazil End Dispute over Essential Drugs*, 357 LANCET 2112 (2001) (analyzing the contrast between United States and Brazil regarding patent protection of HIV/AIDS pharmaceuticals); Cynthia M. Ho, *Patent Breaking or Balancing: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT’L L. & COM. REGUL. 371, 411–41 (2009) (detailing the political and corporate pressures encountered by Thailand).

However, over the past ten years, such hostile responses have become infrequent and less intense.<sup>271</sup> Analyzing the conduct of the United States in recent cases, Professor Brook K. Baker has gone so far as stating that “its bark is much worse than its bite.”<sup>272</sup> This shift has largely been attributable to the “heroic civil society struggle” of the access to medicines movement (A2M).<sup>273</sup> Crucially, between 1999 and 2008, the A2M coordinated global awareness campaigns to oppose the retaliatory initiatives directed at Brazil, Indonesia, Malaysia, South Africa, and Thailand following their grants of compulsory licenses.<sup>274</sup> As a result, in all of these cases, the patent holders and national governments responsible for these punitive actions received widespread condemnation from the international public, suffered substantial reputational damage, and ultimately withdrew their opposition.<sup>275</sup>

Second, domestic and export compulsory licenses curtail patentees’ rights in the exact same ways. If there were reluctance to use the Article 31bis System due to fear of retaliatory actions, the same would be true for compulsory licenses granted to supply the internal market of the issuing country. However, recent empirical evidence shows that WTO members at all economic levels are regularly and effectively making recourse to domestic compulsory licensing for a growing range of patented pharmaceutical products.<sup>276</sup> Kyung-Bok Son and Tae-Jin Lee have documented 108

271. See Baker, *supra* note 255, at 302–19 (describing both the progressive shift in stance of developed WTO members and the increasingly more collaborative attitude of pharmaceutical companies).

272. *Id.* at 306; see also Brook K. Baker, *Don’t Be Afraid of Compulsory Licenses Despite US Threats: Special 301 Reports 1998–2017—Listing Concerns but Taking Little Action*, HEALTH GAP (Feb. 20, 2018), <https://healthgap.org/dont-be-afraid-of-compulsory-licenses-despite-us-threats-special-301-reports-1998-2017-listing-concerns-but-taking-little-action/> [<https://perma.cc/V5FU-PH4K>].

273. See generally Baker, *supra* note 255; ‘T HOEN, *supra* note 6, at 31–73; Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804 (2008); Susan K. Sell, *Trips and the Access to Medicines Campaign Proceedings of the 2002 Conference—Access to Medicines in the Developing World: International Facilitation or Hindrance*, 20 WIS. INT’L L.J. 481 (2001).

274. See Baker, *supra* note 253, at 302–19 (providing numerous bibliographical references to contemporary accounts of the unfolding events); see also Thomas Owen, *The ‘Access to Medicines’ Campaign vs. Big Pharma*, 11 CRITICAL DISCOURSE STUD. 288 (2014); Nathan Ford, David Wilson, Onanong Bunjumnong & Tido von Schoen Angerer, *The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand*, 363 LANCET 560 (2004).

275. See Baker, *supra* note 255, at 302–19.

276. See *Medicines Law & Policy*, TRIPS FLEXIBILITIES DATABASE, <http://tripsflexibilities.medicineslawandpolicy.org/> [<https://perma.cc/J5RN-W4NK>] (last visited Mar. 6, 2023); Kyung-Bok Son & Tae-Jin Lee, *Compulsory Licensing of Pharmaceuticals Reconsidered: Current Situation and Implications for Access to Medicines*, 13 GLOB. PUB. HEALTH 1430 (2018) (“[T]here have been more attempts to issue compulsory licensing and for more pharmaceuticals, especially for oncology, than previously reported. This means that compulsory licensing that had been devised to cope with the HIV/AIDS pandemic in low-income countries has become a practical measure in several Asian and Latin American countries, even for non-HIV/AIDS medicines.”); Ellen F.M. ‘t Hoen, Jacquelyn Veraldi, Brigit Toebes & Hans V. Hogerzeil, *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 BULL. WORLD HEALTH ORG. 185, 190 (2018) (carrying out a comprehensive

attempts to issue compulsory licenses, for forty different pharmaceuticals products, across twenty-seven countries, between 1995 and 2018.<sup>277</sup> These efforts yielded fifty-three compulsory licenses, eighteen price reductions, and sixteen voluntary licenses, failing to achieve tangible results in just twenty-one cases. More than half of these attempts involved patented pharmaceuticals for the treatment of HIV/AIDS, yet influenza and cancer medicines have been increasingly subject to compulsory licenses over the past decade.<sup>278</sup> Between 2018 and 2020, there have been ten additional applications for compulsory licenses for pharmaceuticals treating HIV/AIDS and cancer—some of which came from high-income countries—but also hepatitis C, cystic fibrosis, and opioid overdoses.<sup>279</sup> Even more recently, Hungary, Israel, and Russia have issued compulsory licenses for pharmaceuticals that treat COVID-19, with commentators and activists encouraging other countries to follow suit.<sup>280</sup>

### B. Domestic Law and Free Trade Agreements Obtrusions

The WTO legal order does not preclude WTO members from entering into multilateral, regional, or bilateral free trade agreements (FTA) that introduce higher intellectual property protection standards than those established by TRIPS (commonly referred to as “TRIPS-Plus”), including restrictions on export compulsory licenses.<sup>281</sup> Equally, WTO members are free to enact

empirical study on the use compulsory licensing and concluding that “our study shows that TRIPS flexibilities have been used more frequently than is commonly assumed and have proven effective for procuring generic versions of essential medicines, particularly for treating HIV infection”); see also Eduardo Urias & Shyama V. Ramani, *Access to Medicines After TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices?: A Review of the Existing Evidence*, 3 J. INT’L. BUS. POLICY 367 (2020) (reviewing a large body of empirical evidence and concluding that compulsory licenses on pharmaceutical patents yield material price reductions).

277. See generally Son & Lee, *supra* note 276. These data are consistent with those of the TRIPS Flexibilities Database and those gathered by Professor Ellen F.M. ‘t Hoen. See ‘t Hoen et al., *supra* note 276; Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS MED., Jan. 2012, at 1.

278. See Son & Lee, *supra* note 276; *Medicines Law & Policy*, *supra* note 276.

279. See *Medicines Law & Policy*, *supra* note 276.

280. For a discussion of the compulsory licenses issued by Hungary, Israel, and Russia, see generally Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, J. GLOB. HEALTH, June 2020, at 1; Xiaoping Wu & Bassam Peter Khazin, *Patent-Related Actions Taken in WTO Members in Response to the COVID-19 Pandemic* (World Trade Org. Econ. Rsch. & Stats. Div., Staff Working Papers, Paper No. ESRD-2020-12, 2020), <https://doi.org/10.30875/fb500072-en> [<https://perma.cc/3CW8-GGN2>]; MÉDECINS SANS FRONTIÈRES, COMPULSORY LICENSES, THE TRIPS WAIVER AND ACCESS TO COVID-19 MEDICAL TECHNOLOGIES (2021), [https://msfaccess.org/sites/default/files/2021-05/COVID\\_TechBrief\\_MSF\\_AC\\_IP\\_CompulsoryLicensesTRIPSWaiver\\_ENG\\_21May2021\\_0.pdf](https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf) [<https://perma.cc/CD2F-A7CV>].

281. As a general proposition, WTO rules encourage members to enter into free trade agreements. See General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 ILM 1153 (1994), art. XXIV(4) (“The contracting parties recognize the desirability of increasing freedom of trade by the development, through voluntary agreements, of closer integration between the economies of the countries parties to such agreements.”). See

domestic patent legislation that either directly or indirectly limits export compulsory licenses.

Commentators have advanced the view that there is a growing body of domestic laws<sup>282</sup> and TRIPS-Plus FTAs that undermine the Article 31bis System.<sup>283</sup> Regarding the former, Canada's Access to Medicines Regime (CAMR) has been highlighted as a worrisome example.<sup>284</sup> At the time of its enactment, CAMR was heralded as a regime expressly designed to aid developing countries.<sup>285</sup> Nevertheless, the legislative text imposes restrictions that are not demanded by TRIPS. Notably, it sets the maximum duration of compulsory export licenses to two years.<sup>286</sup> Moreover, it circumscribes the pharmaceuticals that may be manufactured under such licenses to those included in a special list, the amendment of which is subject to a dedicated administrative procedure.<sup>287</sup> Placing an additional onus on licensees, Canada's Patent Act<sup>288</sup> also requires that all medicines produced for export must meet Canadian marketing standards, rather than those of the Importing State.<sup>289</sup>

Regarding TRIPS-Plus FTAs, concerns have been raised about bilateral agreements that directly limit compulsory licensing.<sup>290</sup> For example, under

---

*generally* Pedro Roffe, *Intellectual Property Chapters in Free Trade Agreements: Their Significance and Systemic Implications*, in EU BILATERAL TRADE AGREEMENTS AND INTELLECTUAL PROPERTY: FOR BETTER OR WORSE? 17 (Josef Drexler, Henning Grosse Ruse-Khan & Souheir Nadde-Phlix eds., 2014) (offering an exhaustive survey of FTAs that introduce standards above those dictated by TRIPS).

282. See Halajian, *supra* note 32, at 1216; Cohen-Kohler et al., *supra* note 33.

283. See generally RUSE-KHAN, *supra* note 33; BIADGLENGL & MAUR, *supra* note 33; Rehman, *supra* note 33; Sell, *supra* note 191; Mercurio, *supra* note 33; Correa, *supra* note 33.

284. Canada was the first to implement the Article 31bis System domestically. In 2005, it amended the 1985 Canadian Patent Act to include new sections 21.01–21.19. See The Jean Chrétien Pledge to Africa Act, S.C. 2004, c 23 (Can.). See generally Cohen-Kohler et al., *supra* note 33; Attaran, *supra* note 33; Richard Elliott, *Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export*, 1 INT'L J. INTELL. PROP. MGMT. 94 (2006); Tsai, *supra* note 31; Paige E. Goodwin, *Right Idea, Wrong Result—Canada's Access to Medicines Regime Notes and Comments*, 34 AM. J.L. & MED. 567 (2008); Mark D. Penner & Prakash Narayanan, *Amendments to the Canadian Patent Act to Address Drug Access: Is Help on the Way?*, 60 FOOD & DRUG L.J. 459 (2005).

285. Elliott, *supra* note 284, at 107 (criticizing this unnecessary time restriction).

285. See *id.* at 94; Goodwin, *supra* note 284, at 567.

286. See Attaran, *supra* note 33 (highlighting that no other country has introduced such a restriction in their implementation of the Article 31bis System); Elliott, *supra* note 284, at 107 (criticizing this unnecessary time restriction).

287. See Elliott, *supra* note 284, at 100–01 (detailing the political debate that led to this policy); Goodwin, *supra* note 284, at 574, 578–79 (emphasizing that no other country has imposed a comparable limitation); Tsai, *supra* note 31, at 1094–95.

288. R.S.C. 1985, c P-4 (Can.).

289. See Attaran, *supra* note 33, at 159 (suggesting that this requirement is necessary). *Contra* Elliott, *supra* note 284, at 103 (expressing a negative view of this requirement).

290. See generally Henning Grosse Ruse-Khan, *Protecting Intellectual Property Rights Under BITs, FTAs and TRIPS: Conflicting Regimes or Mutual Coherence?*, in EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION 485 (Chester Brown & Kate Miles eds., 2011); Mercurio, *supra* note 33; Correa, *supra* note 33.

the United States-Jordan FTA,<sup>291</sup> the United States-Singapore FTA,<sup>292</sup> and the United States-Australia FTA,<sup>293</sup> signatory countries agree to only issue compulsory licenses, both for domestic purposes and when acting as an Exporting State to address anticompetitive practices of patent holders, for public noncommercial use, and in circumstances of extreme urgency.<sup>294</sup> Going even further, the United States-Singapore FTA and the United States-Australia FTA also provide that patent holders cannot be compelled to assist compulsory licensees by sharing “undisclosed information or technical know-how.”<sup>295</sup>

Equally, TRIPS-Plus FTAs, which contain data exclusivity provisions,<sup>296</sup> have been denounced as detrimental to the Article 31bis System.<sup>297</sup> For example, the United States-Singapore FTA, the United States-Jordan FTA,<sup>298</sup> the United States-Australia FTA, the United States-Chile FTA,<sup>299</sup> and the United States-Morocco FTA<sup>300</sup> provide that if a signatory country requires the submission of information concerning the safety and efficacy of a pharmaceutical to authorize its marketing and sale, patentees cannot be

---

291. United States-Jordan Free Trade Agreement, Jordan-U.S., art. 1.2, Oct. 24, 2000, 41 ILM 63; Hamed El-Said & Mohammed El-Said, *TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from Jordan-United States Free Trade Agreement*, 10 J. WORLD INTELL. PROP. 438 (2007).

292. United States-Singapore Free Trade Agreement, Sing.-U.S., art. 16.7(2), May 6, 2003, 42 ILM 1026.

293. United States-Australia Free Trade Agreement, Austl.-U.S., art. 17.9(7)(b)(iii), May 18, 2004, 43 ILM 1248.

294. See Gaëlle P. Krikorian & Dorota M. Szymkowiak, *Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine*, 10 J. WORLD INTELL. PROP. 388, 402–04 (2007) (analyzing the provisions that directly limit compulsory licensing in all major FTAs negotiated by the United States between 1994 and 2007); Harris, *supra* note 31, at 384 (analyzing the reach of TRIPS-Plus FTAs negotiated by the United States).

295. See United States-Singapore Free Trade Agreement, *supra* note 292, art. 16.7; United States-Australia Free Trade Agreement, *supra* note 293, art. 17.9.

296. Albeit with differences across jurisdictions, data exclusivity regimes typically provide that safety and efficacy clinical trial data submitted by a patent holder to obtain sale approval by the national authorities of a state cannot be relied on by competitors for a fixed period of time. See generally Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1 (2009); Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement*, 45 HARV. INT'L L.J. 443 (2004); Carlos Maria Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69 (2002).

297. See generally MÉDECINS SANS FRONTIÈRES, *DATA EXCLUSIVITY IN INTERNATIONAL TRADE AGREEMENTS: WHAT CONSEQUENCES FOR ACCESS TO MEDICINES?* (2004), <http://www.citizen.org/documents/DataExclusivityMay04.pdf> [https://perma.cc/NS8Z-YTS5].

298. See El-Said & El-Said, *supra* note 291.

299. United States-Chile Free Trade Agreement, Chile-U.S., art. 17.10(b), June 6, 2003, 42 ILM 1026.

300. United States-Morocco Free Trade Agreement, Morocco-U.S., art. 15.10(4), June 15, 2004, 44 ILM 544.

mandated to share their own data with compulsory licensees for a period of three to five years from the date when the patent was granted.<sup>301</sup>

We agree that domestic legislation and multilateral FTAs that directly or indirectly impede the issuance of export compulsory licenses are troubling. If the majority of the WTO members with mature pharmaceutical industries choose this path, the Article 31bis System might be rendered dead letter. Nevertheless, in our view, this is not the situation at present, and there is encouraging evidence that the international community is moving in the opposite direction. First, almost all WTO members with advanced pharmaceutical manufacturing capabilities have enacted domestic laws implementing the Article 31bis System in a manner that does not restrict the grant of compulsory export licenses.<sup>302</sup>

Second, the problematic FTAs negotiated by the United States in the early 2000s were met by a wave of criticism by activists and scholars, and engendered significant public backlash.<sup>303</sup> In recent times, the United States has entered into multilateral arrangements negotiated with Peru, Colombia, Panama, and South Korea that expressly refer to the Doha Declaration and do not contain any restrictions on the granting of compulsory export licenses.<sup>304</sup> In a similar vein, the recently ratified United States-Mexico-Canada Agreement<sup>305</sup> (USMCA) was ultimately stripped of data exclusivity provisions that would have undermined the Article 31bis System.<sup>306</sup> This is especially significant when considering that the previous North American Free Trade Agreement<sup>307</sup> (NAFTA) contained restrictions

---

301. See Krikorian & Szymkowiak, *supra* note 294, at 399–402 (analyzing the data exclusivity provisions of all major FTAs negotiated by the United States between 1994 and 2007).

302. An exhaustive database of the national laws adopted by WTO members to implement the Article 31bis System is available at *Members' Laws Implementing the 'Paragraph 6' System*, WORLD TRADE ORG., [https://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm) [<https://perma.cc/5TRJ-C9AH>] (last visited Mar. 6, 2023). See generally Roger Kampf, *Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation* (World Trade Org. Econ. Rsch. & Stats. Div., Staff Working Papers, Paper No. ERSD-2015-07, 2015) (providing a comparative analysis of all the national legislations adopted to implement the Article 31bis System up to 2015).

303. On the access to medicines movement, see *supra* note 264 and accompanying text.

304. See United States-Peru Trade Promotion Agreement, Peru-U.S., art. 16.10(2), Apr. 12, 2006, 121 Stat. 1455; United States-Colombia Trade Promotion Agreement, Colom.-U.S., art. 16.10(2), Nov. 22, 2006, 125 Stat. 462; United States-Panama Trade Promotion Agreement, Pan.-U.S., art. 15.10, June 28, 2007, 125 Stat. 497; United States-South Korea Free Trade Agreement, S. Kor.-U.S., art. 18.11, June 30, 2007, 125 Stat. 428. See generally Krikorian & Szymkowiak, *supra* note 294, at 402–04.

305. Agreement Between the United States of America, the United Mexican States, and Canada, Nov. 30, 2018, 134 Stat. 11.

306. See Ronald Labonté Eric Crosbie, Deborah Gleeson & Courtney McNamara, *USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health*, 15 GLOBALIZATION & HEALTH 35 (detailing how negotiations in the House of Representatives ultimately resulted in the elimination of terms that would have assured ten years of data exclusivity for newly approved biologic medicines).

307. North American Free Trade Agreement, United States-Canada-Mexico, Dec. 17, 1992, 32 I.L.M. 289.

on export compulsory licensing.<sup>308</sup> It should also be noted that FTAs negotiated by the European Union have generally not included restrictions to export compulsory licenses.<sup>309</sup> This is also true of recent multilateral agreements signed by Asian and Oceanic countries, including the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)<sup>310</sup> and the Regional Comprehensive Economic Partnership (RCEP).<sup>311</sup>

### C. Procedural Complexities

The Article 31bis System is governed by a protracted and onerous multistep procedure, punctuated by detailed requirements.<sup>312</sup> The Importing State must comply with a series of information disclosure obligations in its notification to the TRIPS Council.<sup>313</sup> Simultaneously, the Exporting State must issue highly specific compulsory licenses, pay compensation to the affected patentee, and keep the TRIPS Council duly informed.<sup>314</sup> The licensee must also make public disclosures regarding the manufactured pharmaceuticals.<sup>315</sup>

Commentators have vigorously contended that the procedural dimensions of the Article 31bis System are acutely problematic for developing WTO members, going so far as describing it as a “labyrinth.”<sup>316</sup> As a general criticism, they remark that, when assessed in its entirety, the process is too protracted and demands an unrealistic degree of coordination among parties.<sup>317</sup> Regarding Importing States, the obligation for non-LDC WTO members to supply evidence of their insufficient manufacturing capabilities has been singled out as a heavy burden for “an already potentially strapped-for-resources member.”<sup>318</sup> Scholars and activists have also

308. *See id.* art. 1709(10)(f) (restricting compulsory licenses to the supply of the domestic market of the issuer and not contemplating exceptions to accommodate the Article 31bis System).

309. *See* Roffe, *supra* note 281 (noting that the European Union has focused on geographical indications in its TRIPS-Plus FTAs, rather than patents and compulsory licensing). The notable exception is the trade agreement between the European Union and its member states, on one end, and Colombia and Peru, on the other. *Id.*

310. *See* Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357, 396–98 (2019) (emphasizing that provisions to strengthen patent protection and data exclusivity after the United States withdrew from negotiations).

311. *See* Deborah K. Elms, *Getting RCEP Across the Line*, 20 WORLD TRADE REV. 373 (2021) (detailing the content of this FTA and highlighting the absence of provisions that go beyond TRIPS’s substantive minima for patent protection).

312. *See supra* Part II.F.

313. TRIPS, *supra* note 5 (annex to the TRIPS agreement at 2(a)).

314. *Id.* (annex to the TRIPS agreement at 2(b)(i)–(ii)).

315. *Id.* (annex to the TRIPS agreement at 2(b)(iii)).

316. *See* Baker, *supra* note 208, at 655; Vincent, *supra* note 31; Correa, *supra* note 4, at 6–8; Halajian, *supra* note 32, at 1202–04; Harris, *supra* note 31; Muhammad Z. Abbas & Shamreeza Riaz, *WTO “Paragraph 6 System” for Affordable Access to Medicines: Relief or Regulatory Ritualism?*, 21 J. WORLD INTELL. PROP. 32, 39 (2018); Lee, *supra* note 31, at 1402; Verma, *supra* note 238; Cohen-Kohler et al., *supra* note 33.

317. *See* Correa, *supra* note 4, at 6–8; Baker, *supra* note 208, at 655.

318. *See* Vincent, *supra* note 31, at 22.

denounced the requirement that Importing States specify the exact required quantity of the pharmaceutical in question, not only because this might be a challenging estimation *ex ante*, but also particularly because the Article 31bis System does not contemplate a renewal or amendment mechanism to increase supply of the imported product after an export compulsory license has been granted.<sup>319</sup>

Still sharper criticisms have been levied at the procedural burdens imposed on Exporting States and licensees. The prerequisite to negotiate with patent holders before an export compulsory license can be issued<sup>320</sup> has been decried as a likely source of significant delays, especially when multiple patentees are involved.<sup>321</sup> Commentators have also expressed reservations about the obligation to differentiate products manufactured under an export compulsory license through special coloring and shaping of the pharmaceutical itself.<sup>322</sup> Such alterations are time-consuming and can often involve a biomolecular investigation of the patented medicine to ensure that the generic being manufactured has the same bioequivalence and bioavailability.<sup>323</sup>

We share the view that the procedural dimension of the Article 31bis System materially hinders export compulsory licensing. The issue lies with the normative aims that shape this body of rules. This entire procedure appears to be designed to ensure that medicines produced under an export compulsory license are not surreptitiously diverted into more affluent markets and, to a lesser extent, to verify that the Importing State is eligible to use the Article 31bis System. Regrettably, the rules under consideration do not prioritize efficiency, simplicity, or expediency for the relevant stakeholders. This is both disappointing and surprising, given that the explicit mandate of the Doha Declaration was to create a “solution” to the difficulties faced by WTO members with insufficient manufacturing capabilities in the pharmaceutical sector by making effective use of compulsory licensing.

We are not especially troubled by the information disclosures demanded of Importing States regarding their lack of manufacturing capabilities. This condition is easily satisfied through self-certification, which is not subject to approval by the TRIPS Council and which could only be called into question in the unlikely event of a WTO member contesting its accuracy before the

319. See Correa, *supra* note 4, at 3; Abbas & Riaz, *supra* note 316, at 39; Lee, *supra* note 31, at 1404.

320. This is a consequence of the fact that export compulsory licenses must comply with the requirements of article 31, including article 31(b). See *supra* notes 177–81 and accompanying text. See generally Jillian C. Cohen-Kohler, Laura C. Esmail & Andre Perez Cosio, *Canada’s Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?*, 3 GLOBALIZATION & HEALTH 12 (2007) (emphasizing the negative impact of this requirement in the Canada-Rwanda export compulsory license).

321. See Correa, *supra* note 4, at 4; Abbas & Riaz, *supra* note 316, at 40; Vincent, *supra* note 31, at 18.

322. TRIPS, *supra* note 5 (annex to the TRIPS agreement at 2(b)(ii)).

323. See Baker, *supra* note 208, at 650; Correa, *supra* note 4, at 9; Abbas & Riaz, *supra* note 316, at 40; Vincent, *supra* note 31, at 18.

Dispute Settlement Body (DSB).<sup>324</sup> By contrast, we find that the provisos established to prevent diversion are problematic due to their lack of flexibility, complexity, and protracted nature. They are in no way calibrated according to the actual circumstances of the case in question, such as the type of pharmaceutical involved, the nature of the illness (acquired, acute, chronic, congenital, genetic, or infectious), the market size and purchasing power of the Importing State, or whether there is an ongoing emergency. The assumption that permeates these rules appears to be that export compulsory licenses immanently and invariably carry an extremely high risk of diversion, the avoidance of which is paramount.

It is hard to quantify the extent to which these procedural burdens deter recourse to article 31bis. Nevertheless, it is emblematic that Apotex, the Canadian manufacturer that was involved in Rwanda's case, has repeatedly denounced the "complexity of the process" as one of the primary reasons for the many delays that afflicted the project and, ultimately, its decision to not participate in such initiatives in the future.<sup>325</sup>

#### *D. Economic Challenges*

The Article 31bis System is built on the unstated premise that WTO members with mature pharmaceutical industries harbor a sizeable constituency of manufacturers interested in fulfilling the demand of Importing States. The underlying view appears to be that the international patent system is the main obstacle preventing these producers from entering these markets, and that export compulsory licensing will remove this barrier. We believe that these assumptions are flawed in that they underappreciate the economic challenges of these transactions in many ways.

First, manufacturing, distributing, and selling pharmaceuticals under export compulsory licenses are capital-intensive activities that require large upfront investment. Production costs are substantial. For synthetic drugs, research is required to determine the composition of the compound in

---

324. See Paul Vandoren & Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making It Work*, 6 J. WORLD INTELL. PROP. 779, 785 (2003) (observing that the "the self-assessment of the available capacity and the subsequent conclusion fall under the exclusive responsibility of the Member itself").

325. Letter from John Hems, Dir., Regul. Affs., Apotex Inc., to Douglas Clark, Dir., Pat. Pol'y Directorate, Indus. Canada & Brigitte Zirger, Dir., Therapeutic Prods. Directorate, Health Canada (Jan. 23, 2007), [https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr\\_rcam\\_apotex\\_18-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_apotex_18-eng.pdf) [<https://perma.cc/2U9R-GQ8Y>]; see also Press Release, Apotex Inc., Second Shipment of Life-Saving AIDS Drugs Leaving for Africa (Sept. 18, 2009), <https://www.newswire.ca/news-releases/second-shipment-of-life-saving-aids-drug-leaving-for-africa-538566052.html> [<https://perma.cc/PQR8-HERF>].

question and synthesize a stable formulation.<sup>326</sup> In the case of “biologics,”<sup>327</sup> this reverse-engineering exercise is still more challenging due to the inherent difficulties associated with the creation of biosimilars.<sup>328</sup> This initial step is followed by the planning and realization of the processes necessary for reliable and quality-consistent manufacturing. Throughout, compulsory licensees must experiment by way of trial and error, as they generally receive no technical assistance from the patent holder. All these operations are time-consuming and expensive.

Regulatory costs are also significant. All pharmaceutical manufacturers must bear the expenditures involved in obtaining the necessary authorizations from the competent governmental authorities in the jurisdictions where they want to market and sell their products. For drugs that are molecularly identical to previously approved patented ones, this process can be relatively painless.<sup>329</sup> By contrast, for biologics, approval of biosimilars can be lengthy and expensive, going so far as requiring clinical trials.<sup>330</sup> Notably, export compulsory licensees may have to cover these outlays twice if they are required to obtain regulatory approval both in the Exporting State and Importing State. In addition, the Article 31bis System imposes its own cost layer. Export compulsory licensees must cover all the expenses associated with anti-diversion obligations, including that of using special packaging and labeling, as well as making information disclosures through a dedicated website.<sup>331</sup> Moreover, they might also be required to pay the “adequate remuneration” owed to patentees under article 31(h).<sup>332</sup>

Second, export compulsory licensees are confronted with a difficult and narrow path to profitability. Typically, Importing States will be developing WTO members, with very low yearly health spending per capita, that can only afford low prices for any one pharmaceutical product.<sup>333</sup> This reality

326. See generally Prabir Basu, Girish Joglekar, Saket Rai, Pradeep Suresh & John Vernon, *Analysis of Manufacturing Costs in Pharmaceutical Companies*, 3 J. PHARM. INNOVATION 30 (2008); Pradeep Suresh & Prabir K. Basu, *Improving Pharmaceutical Product Development and Manufacturing: Impact on Cost of Drug Development and Cost of Goods Sold of Pharmaceuticals*, 3 J. PHARM. INNOVATION 175 (2008).

327. See 42 U.S.C. § 262(i)(1) (defining a “biological product” as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings”).

328. See generally Leyre Zuñiga & Begoña Calvo, *Biosimilars: Pharmacovigilance and Risk Management*, 19 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 661 (2010); Simon D. Roger, *Biosimilars: How Similar or Dissimilar Are They?*, 11 NEPHROLOGY 341 (2006); Anoop Misra, *Are Biosimilars Really Generics?*, 10 EXPERT OP. ON BIOLOGICAL THERAPY 489 (2010).

329. See generally Blackstone & Fuhr, *supra* note 4.

330. See generally Steven Simoens & Arnold G. Vulto, *A Health Economic Guide to Market Access of Biosimilars*, 21 EXPERT OP. ON BIOLOGICAL THERAPY 9 (2021).

331. See *supra* Part II.F.

332. See TRIPS, *supra* note 5, art. 31(h).

333. See WORLD HEALTH ORG., GLOBAL SPENDING ON HEALTH: WEATHERING THE STORM 2 (2020), <https://www.who.int/publications/i/item/9789240017788> [<https://perma.cc/LQ7Z-ZE2E>] (click “Download”) (estimating that, in 2018, yearly health spending per capita was

significantly narrows the range of pricing strategies that export compulsory licensees can implement to generate the revenues needed to make the whole endeavor sustainable. In such circumstances, a low volume, high margin approach will be entirely unworkable. The only viable avenue will be to employ a high volume, low margin strategy.

In theory, the export compulsory licensee would manufacture the patented pharmaceutical product in question in large volumes with the aim of achieving economies of scale.<sup>334</sup> Progressively, this would reduce marginal production costs, making it possible to attain a price point that is both affordable for the Importing State and sufficiently profitable for the manufacturer. In practice, however, such a strategy is not always feasible. Crucially, the compulsory licensee will be unable to reach economies of scale if only a small quantity of pharmaceutical products is requested by the Importing State in its notification to the TRIPS Council.<sup>335</sup> Similarly, even if economies of scale were achieved, the investments required to produce, distribute, and sell the patented pharmaceutical may be too great to be recoverable at a price that is sustainable for the Importing State.

Third, export compulsory licensees face substantial risk to revenue and risk of heavy losses on their investment. Above all, they are extremely vulnerable to patentees lowering the prices of their pharmaceutical products—or even donating them—for the purpose of defending their position in the Importing State's market. This risk can materialize at any moment, and the export compulsory licensee has no effective mitigating strategy. This is compounded by the fact that the Article 31bis System does not contemplate confidentiality safeguards. The notifications sent to the TRIPS Council by both the Importing State and Exporting State are public, effectively providing patentees with all the information necessary to monitor the unfolding process and react at the most opportune moment.

It has been suggested that it would be desirable for Importing States for patentees to cut prices voluntarily when faced with the prospect of a WTO member making recourse to Article 31bis.<sup>336</sup> However, this view overlooks the risk that pharmaceutical manufacturers might decline to engage with the Article 31bis System as a whole, in fear that patentees could undercut their prices at any time.

Export compulsory licensees are also exposed to litigation risk. Patentees can take legal action to challenge the compulsory license granted by the

---

\$40 in low-income countries, \$115 in lower-middle-income countries, \$466 in upper-middle-income countries, and \$3,313 in high-income countries).

334. Economies of scale refers to the phenomenon in which the average costs per unit of output decrease with the increase in the scale or magnitude of the output being produced by a firm. See generally Aubrey Silberston, *Economies of Scale in Theory and Practice*, 82 *ECON. J.* 369 (1972); George J. Stigler, *The Economies of Scale*, 1 *J.L. & ECON.* 54 (1958).

335. Under the Article 31bis System, export compulsory licensees can manufacture no more than the exact quantity requested by the Importing State. See *supra* notes 245–60 and accompanying text. See generally Mike Gumbel, *Is Article 31BIS Enough?: The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 *TEMP. INT'L & COMPAR. L.J.* 161 (2008).

336. See Correa, *supra* note 4, at 9.

Exporting State. Even if ultimately unsuccessful, such maneuvers can cause delays and financial stress.<sup>337</sup> In like fashion, patentees can promote infringement proceedings against the export compulsory licensee if they have evidence that pharmaceutical products have been diverted away from the Importing State into a different market. Albeit to a lesser degree, export compulsory licenses may also be exposed to the risk of political instability. Military conflict, civil unrest, and regime change can either impede the compulsory licensee from generating the revenues necessary to recover its investment or cause the Importing State to default on its obligation to purchase the pharmaceuticals.

We believe that the primary reason that the Article 31bis System has remained largely unutilized to date is that the market conditions that would make a particular export compulsory license economically viable are seldom present. In general, compulsory licensing is an instrument that ontologically only has situational usability. For it to be viable, the compulsory licensee must be in a position to manufacture the patented product and sell it at a price that is lower than that charged by the patentee but is high enough to generate revenues sufficient to cover its costs and make a small profit.<sup>338</sup>

The Article 31bis System makes achieving this threshold markedly harder. In an already expensive industry, the system's procedural and substantive rules impose significant extra costs, engender litigation risks, and concurrently impede the possibility of achieving economies of scale. For prospective export compulsory licensees that are already in the difficult position of having to deal with WTO members with limited purchasing power, these obstacles become all but insurmountable.

Emblematically, representatives of the Canadian generic drug industry who were involved in the Canada-Rwanda export compulsory license negotiations have claimed that they are unwilling to engage with the Article 31bis System again due to the quasi-impossibility of operating profitably.<sup>339</sup> Echoing this sentiment, a representative of the Indian generic drug manufacturer Cipla expressed skepticism toward export compulsory licensing, remarking that the economics of this mechanism were unworkable in cases such as that of Rwanda due to its minimal financial resources and small market size.<sup>340</sup> In a similar vein, Médecins Sans Frontières pointedly criticized the Article 31bis System, stating that "it . . . ignores the fact that

---

337. Notably, to block this tactic, Argentinian patent law does not suspend the efficacy of a compulsory license pending an appeal from the patent holder. *See* *Patentes de Invención y Modelos de Utilidad* [Patents of Invention and Models of Utility], Law No. 24,481, art. 49, May 23, 1995, [34.130] B.O. 3 (Arg.). However, most WTO members lack equivalent rules.

338. *See* Daniel R. Cahoy, *Breaking Patents*, 32 MICH. J. INT'L L. 461, 491–85 (2011).

339. *See* Cohen-Kohler, *supra* note 320, at 4 (interviewing executives of Canadian generic drugs manufacturers and finding that they had strong reservations regarding the possibility of operating profitably under an export compulsory license).

340. *See* WTO 'Paragraph 6' System for Affordable Medicine: Time For Change?, INTELL. PROP. WATCH (Nov. 14, 2016), <https://www.ip-watch.org/2016/11/14/wto-paragraph-6-system-affordable-medicines-time-change/> [<https://perma.cc/KCL6-35J7>] (reporting that head of government affairs at Cipla observed that "the amount of drugs supplied in the 2 years was lower than the amount Cipla produces per month").

economies of scale are needed to attract interest of producers,” and concluding that “without the pull of a viable market for drugs, generics manufacturers will not seek to produce for export.”<sup>341</sup>

#### IV. FULFILLING THE PROMISE OF EXPORT COMPULSORY LICENSES

Part III illuminated the flaws of the Article 31bis System, but this vessel is both salvageable and worthy of rescue. This part highlights the unique and unprecedented features that export compulsory licenses possess and their potentially transformative effect on access to medicines for WTO members lacking pharmaceutical manufacturing capabilities. We posit that it would be unwise to abandon the Article 31bis System in favor of alternative approaches, such as public medicine patent pools and humanitarian aid campaigns.<sup>342</sup> From this premise, we expound strategies available under the current law to circumvent some of the issues that presently undermine export compulsory licenses. Thereafter, we consider a broad range of possible reforms to the Article 31bis System, starting with surgical interventions aimed at progressively augmenting the flexibility and efficiency of the extant TRIPS architecture and venturing as far as fundamental revisions to the structure of the treaty.

##### A. *The Unique Potential of Export Compulsory Licenses*

The fallow state of the Article 31bis System has not gone unnoticed. Commentators have posited that export compulsory licenses have been an unsuccessful experiment that was doomed to failure by the limitations imposed by developed WTO members.<sup>343</sup> They propose that both human and financial resources should be concentrated instead on obtaining cheap voluntary licenses from patentees,<sup>344</sup> bolstering medicine patent pools,<sup>345</sup> and arranging humanitarian aid campaigns,<sup>346</sup> as these avenues have proven to be far more fruitful in supporting access to medicines worldwide.

---

341. See MÉDECINS SANS FRONTIÈRES, REVIEW OF THE CANADIAN ACCESS TO MEDICINES REGIME (2007), [https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr\\_rcam\\_msf\\_11-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/camr-rcam/review-reviser/camr_rcam_msf_11-eng.pdf) [<https://perma.cc/W8N3-AYKT>].

342. See *supra* Part IV.A.

343. See generally Halajian, *supra* note 32; Vincent, *supra* note 31; Harris, *supra* note 33.

344. See generally Brook K. Baker, *A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines*, 10 N.E. L. REV. 226 (2018).

345. The most notable example is the Medicines Patent Pool (MPP) established by WHO's Unitaid in 2010. The MPP negotiates licenses with HIV medicine patent holders and enters sublicensing contracts with generics manufacturers agreeing to sell low-cost, high-quality treatments in underdeveloped regions. See 'T HOEN, *supra* note 6, at 73–76 (detailing analysis of the history and track record of the MPP). Similarly, the WHO recently created the COVID-19 Technology Access Pool (C-TAP) to enable voluntary licensing of intellectual property rights for COVID-19 treatments. See WORLD HEALTH ORG., OPERATIONALISING THE COVID-19 TECHNOLOGY ACCESS POOL (C-TAP) (2020), <https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf> [<https://perma.cc/YQH7-2TZ4>].

346. See Rachel Silverman, Janeen Madan Keller, Amanda Glassman & Kalipso Chalkidou, *Tackling the Triple Transition in Global Health Procurement*, CTR. GLOB. DEV. (2019), <https://www.cgdev.org/better-health-procurement> [<https://perma.cc/3PUW-8ZF7>].

We fully recognize and welcome the successes achieved through these pathways over the past decade, especially in the fight against the global HIV/AIDS epidemic. Nevertheless, we believe that it would be a mistake to jettison the Article 31bis System and discard export compulsory licenses entirely. First, voluntary licensing, medicine patent pools, and humanitarian aid campaigns are inextricably dependent on the collaboration and goodwill either of patent holders or third-party organizations. By contrast, having access to an effective export compulsory licensing framework enables WTO members to act unilaterally and on their own terms.

Second, pharmaceutical patent holders are far more likely to make concessions, such as price reductions, transfers of know-how, and grants of voluntary licenses, if they are confronted by the specter of compulsory licensing.<sup>347</sup> For WTO members that cannot rely on domestic compulsory licensing while their pharmaceutical industries are developing, this tactic is only available if the Article 31bis System is perceived as a functioning mechanism rather than a hollow threat.

Third, empirical evidence reviewed in Part III shows that WTO members with established medicinal production capabilities regularly use domestic compulsory licensing to access otherwise unobtainable patented medicines. A corollary of this data is that voluntary arrangements with patent holders and aid programs are not always viable or convenient. In such cases, export compulsory licenses are the only option for WTO members without a developed domestic pharmaceutical industry.<sup>348</sup>

Fourth, historically, compulsory licensing has been an inward-looking instrument that countries deployed either to curtail patentee conduct that was disruptive to local markets or to promote domestic policy aims. The Article 31bis System aspires to add a new dimension to this legal device, expanding and transforming its functional profile. Export compulsory licenses are intended to equip WTO members with a tool, the reach of which crosses borders, despite the territorial nature of the patent system. They embody a solidaristic mechanism designed to allow developing countries to benefit from the technological prowess of foreign pharmaceutical industries at affordable prices. Though it is undeniable that the Article 31bis System has not yet borne fruit, the ambitious idea at its core holds great promise. It

---

(showing that aid campaigns coordinated by nongovernmental organizations and private corporations finance over 40 percent of health expenditures in developing countries); Baker, *supra* note 255, at 300–05 (analyzing a Pfizer donation program and similar initiatives).

347. See Urias & Ramani, *supra* note 276 (concluding that compulsory licenses generally reduce the price of the affected patented drugs); Beatrice Stirner, *Learning from Practice: Compulsory Licensing Cases and Access to Medicines*, 1 PHARM. PAT. ANALYST 555 (2012) (highlighting the impact of compulsory licensing in lowering drug prices). *But see* Reed F. Beall, Randall Kuhn & Amir Attaran, *Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement*, 34 HEALTH AFFS. 493 (2015) (warning that compulsory licensing can yield “suboptimal value when compared to the alternative of international procurement . . . when used by low-income countries to manufacture medicines locally”).

348. See *supra* Part II.F.

should not be abandoned due to a flawed implementation. We believe that, instead, efforts should be made to maximize its potential.

*B. Pooled Procurement Strategies*

Part III.D highlighted that economic challenges are a key factor undermining the Article 31bis System. In particular, one of the primary obstacles faced by prospective export compulsory licensees is achieving economies of scale due to the typically small market size of WTO members eligible to be Importing States. We believe that the TRIPS legal framework presents latent opportunities to countervail this issue through pooled procurement strategies. Two approaches warrant close consideration.

First, article 31bis(3) establishes that a WTO member participating in a customs union or a free-trade association, half the membership of which is comprised of LDCs, can export any patented pharmaceutical that it has manufactured or imported under a compulsory license throughout that economic area.<sup>349</sup> This is a meaningful exception to the restriction imposed by article 31(f)<sup>350</sup> that has the declared aim of “harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.”<sup>351</sup>

Article 31bis(3) has substantial implications for export compulsory licensing. By virtue of this provision, rather than having to act separately, WTO members party to an eligible trade agreement can notify the TRIPS Council jointly and express their intent to import a pharmaceutical in the quantity required for their collective need.<sup>352</sup> By pooling their demand, Importing States can present a more palatable risk-reward proposition for prospective licensees by offering better economies of scale and, in turn,

---

349. See TRIPS, *supra* note 5, art. 31bis(3) (“[W]here a developing or least developed country WTO Member is a party to a regional trade agreement . . . at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.”). In addition, the customs union or trade agreement in question must comply with article XXIV of the 1994 GATT and the Decision on Differential and More Favourable Treatment, Reciprocity, and Fuller Participation of Developing Countries. See General Agreement on Tariffs and Trade 1994, *supra* note 281, art. XXIV; *Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries*, L/4903 (Nov. 28, 1979).

350. See *supra* Part II.D.

351. TRIPS, *supra* note 5, art. 31bis(3) (“With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.”).

352. See *id.* (appendix to the annex to the TRIPS agreement at note 4, stating that “[j]oint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties”).

reducing marginal production costs to a level that renders a high volume, low margin business strategy viable.

Beyond its effect on the economic dimension of export compulsory licensing—and as suggested first by Professors Frederick M. Abbott and Jerome H. Reichman<sup>353</sup>—article 31bis(3) can be leveraged to significantly improve the position from which WTO members participating in eligible regional trade arrangements negotiate with pharmaceutical patent holders. Imagine that a group of states, half of which are LDCs, entered into a multilateral treaty designed to eliminate all duties and nontariff barriers affecting the commerce of pharmaceutical and medical equipment. Consider further that this international agreement provided that its signatories agreed to the creation of a regional entity to which they conferred the necessary powers to organize the procurement of pharmaceuticals and issue export compulsory licenses on their behalf. Pursuant to its members' instructions, this regional entity would negotiate directly with pharmaceutical patent holders to source the required medicines to satisfy the entire trading bloc's needs. Article 31bis(3) would decisively strengthen the bargaining position of the regional entity in question, as patentees would be aware that failure to reach an acceptable voluntary agreement would likely lead to one of the following two scenarios.<sup>354</sup>

First, if one of the countries had the necessary manufacturing capabilities to produce the pharmaceutical product involved, it would issue a domestic compulsory license with the aim of supplying all other countries party to the trade agreement. Second, if the required technology and know-how were not present in any one of the countries involved in the regional trade agreement, the regional entity could notify the TRIPS Council, triggering the Article 31bis System on behalf of the whole trading bloc.<sup>355</sup> Confronted with such prospects and provided that the offered terms were not beneath their marginal costs, patent holders would likely prefer to strike a deal with the regional entity, as they would at least preserve their presence in the region, secure market share, and increase their goodwill and trademark visibility.

We believe that the Article 31bis(3) System holds great promise and has not received the attention it deserves. Only recently have WTO members party to eligible regional trade agreements begun to explore its possibilities with conviction. For example, the Southern African Development Community (SADC)<sup>356</sup> has recently developed an interest in exploiting

---

353. See Abbott & Reichman, *supra* note 235, at 973–76 (discussing extensively the potential benefits of regionally organized pool procurement).

354. See *id.* (arriving at this same conclusion).

355. See *supra* note 349 and accompanying text.

356. Originally stemming from the Southern African Development Coordination Conference of 1980, the SADC is a regional economic community founded in 1992 that consists of sixteen countries: Angola, Botswana, the Comoros, the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia, and Zimbabwe. See S. AFR. DEV. CMTY., CONSOLIDATED TEXT OF THE TREATY OF THE SOUTHERN AFRICAN DEVELOPMENT COMMUNITY (2015), <https://ihda.uwazi.io/api/files/1511366513316rdmdw4r657jzmuw457ki6bt9.pdf> [<https://perma.cc/YM8S-VC32>].

articles 31 and 31bis through regionally pooled procurement, as evidenced in its Pharmaceutical Business Plan and, more recently, with the creation of its Strategy for Pooled Procurement of Essential Medicines and Health Commodities for pharmaceuticals.<sup>357</sup> The East African Community (EAC)<sup>358</sup> has similarly striven to establish a regionally pooled procurement mechanism for some time,<sup>359</sup> although it has only recently taken more resolute steps in this direction.<sup>360</sup>

Unfortunately, these encouraging steps have not generated meaningful progress to date. WTO members involved in these regional trade agreements have struggled to institute and operate an entity responsible for pharmaceutical procurement on their behalf. It can only be hoped that, in the wake of the COVID-19 pandemic, these initiatives will gain momentum.<sup>361</sup> Some encouraging early evidence has been seen in a recent agreement signed by Cabo Verde, the Comoros, Guinea-Bissau, Madagascar, Mauritius, São

---

357. See Ellen F.M. 't Hoen, Tapiwanashe Kujinga & Pascale Boulet, *Patent Challenges in the Procurement and Supply of Generic New Essential Medicines and Lessons from HIV in the Southern African Development Community (SADC) Region*, 11 J. PHARM. POL'Y & PRAC., Dec. 4, 2018, at 6 (detailing that the SADC's Pharmaceutical Business Plan for 2015–2019 expressly proposes to utilize “Article 31bis of the TRIPS Agreement to facilitate local production for export; or importation for re-exportation within SADC as a regional bloc”). See generally Chikosa Banda, *Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region*, 31 MD. J. INT'L L. 44 (2016) (detailing reforms across SADC members aimed at exploiting article 31bis).

358. Originally founded in 1967, the EAC in its present incarnation was founded in 1999. See Treaty Establishing the East African Community, Nov. 30, 1999, 2144 U.N.T.S. 255. It is a regional economic community consisting of six countries: Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda. *Id.*

359. See *id.* art. 118 (“Partner States undertake to: (a) take joint action towards the prevention and control of communicable and non-communicable diseases and to control pandemics and epidemics of communicable and vector-borne diseases . . .; (c) develop a common drug policy which would include establishing quality control capacities and good procurement practices.”).

360. See generally Hiiti Sillo, Aggrey Ambali, Samvel Azatyan, Chimwemwe Chamdimba, Eliangiringa Kaale, Joseph Kabatende, Murray Lumpkin, Jane H. Mashingia, David Mukanga, Bonaventure Nyabenda, Gordon Sematiko, Margareth Sigonda, Burhani Simai, Fred Siyoi, Stanley Sonoiya, Mike Ward & Vincent Ahonkhai, *Coming Together to Improve Access to Medicines: The Genesis of the East African Community's Medicines Regulatory Harmonization Initiative*, 17 PLOS MED., Aug. 12, 2020, at 1 (describing the African Medicines Regulatory Harmonization (AMRH) initiative). In addition to the AMRH, the EAC adopted a legal common market protocol in 2019, introducing a nondiscrimination clause for public procurement among member states. See generally Joseph Agutu Omolo & Eurallyah J. Akinyi, *The National Treatment Rule and the Regulation of Public Procurement Under the East African Community Common Market Protocol*, 5 J. CORP. & COM. L. & PRAC. 115 (2019).

361. For a description of the regional response to COVID-19 in Africa, see generally Samuel Ojo Oloruntoba, *Unity Is Strength: COVID-19 and Regionalism in Africa*, 56 INT'L SPECTATOR 56 (2021); Abbott & Reichman, *supra* note 235, at 550–58 (suggesting that pooled procurement strategies could help overcome the COVID-19 pandemic in Africa).

Tomé and Príncipe, and Seychelles, with the aim of jointly procuring drugs and vaccines to improve access to medicines.<sup>362</sup>

Having established the inherent value of article 31bis(3), it should also be acknowledged that this provision has an intrinsic ceiling. The condition restricting the scope of application of this provision to regional trade agreements, half the membership of which is comprised of LDCs, sharply restricts its reach. At present, only multilateral trade arrangements involving WTO members in sub-Saharan Africa satisfy the requirement in question. WTO members in the Caribbean, Latin America, the Middle East, and Southeast Asia that would equally benefit from the demand aggregation mechanism afforded by article 31bis(3) are precluded from accessing it due to the absence of a sufficient number of LDCs in these regions.<sup>363</sup> This is particularly lamentable when considering that some of these geographies already have regional procurement entities in operation, such as the Organisation of Eastern Caribbean State's Pharmaceutical Procurement Service and the Gulf Cooperation Council Group Purchasing Program.

Second, even for WTO members not party to regional trade agreements within the scope of article 31bis(3), there are still pooled procurement strategies that might be pursued to maximize the potential of the Article 31bis System. TRIPS does not preclude WTO members from engaging the Article 31bis System in unison. Acting as a *de facto* consortium, a group of countries could contemporaneously but separately notify the TRIPS Council of their intention to import a particular patented pharmaceutical product. Leveraging their joint demand, these WTO members could then bargain collectively and offer terms that would be more likely to attract prospective licensees. A material shortcoming of pooled procurement strategies falling outside of the perimeter of article 31bis(3) is that each individual Importing State would be barred from reexporting the drugs in question. Nevertheless, this hurdle could be overcome through careful planning on the part of each participant in these consortia. In areas such as Latin America, where there are almost no LDCs but many economies with limited pharmaceutical manufacturing capabilities, coordinated recourse to export compulsory licensing could muster significantly greater bargaining power than a single WTO member acting alone could.

### *C. Law Reform*

The preceding sections have suggested that pooled procurement strategies can enable WTO members to overcome some of the economic obstacles that impede the extant Article 31bis System. Nevertheless, these are mitigating strategies. It is irrefutable that the current body of rules is deficient. We believe that for export compulsory licenses to fulfill their promise, law reform is required.

---

362. See *African Island States Launch Joint Medicines Procurement Initiative*, WORLD HEALTH ORG. (Sept. 29, 2020), <https://who-africa.africa-newsroom.com/press/african-island-states-launch-joint-medicines-procurement-initiative> [<https://perma.cc/A4ZU-BFS9>].

363. See *supra* note 156 (listing the LDCs).

In the first instance, the procedural dimension of the Article 31bis System should be radically recalibrated. The normative aim guiding this intervention should be to rebalance the current fixation on preventing diversion and verifying the eligibility of the Importing State with equivalent, if not greater, attention to simplicity, flexibility, and expediency. When notifying the TRIPS Council, rather than having to specify the exact quantity of pharmaceuticals required, Importing States should be allowed to state an indicative range. Moreover, they should have the option to amend their notification to increase the previously specified total.

The application of article 31(b) to the compulsory licenses granted by Exporting States should also be reconsidered. Under this provision, prospective licensees must make “efforts” to obtain a voluntary license from patentees “on reasonable commercial terms and conditions” for a “reasonable period of time,” before a compulsory license can be lawfully granted. The ratio of these preconditions is rooted in the assumption that the ensuing production will enter the issuing country’s domestic market, where the prospective compulsory licensee will be in competition with the patentee. However, the prerequisites under consideration suit neither the aims nor the dynamics of the Article 31bis System. Reflecting the aims of the Doha Declaration, the objective standard for the article 31(b) negotiations should be revised from “reasonable commercial terms and conditions” to “terms and conditions that reflect the humanitarian, social, and economic circumstances of the Importing State.” Similarly, keeping in mind the lengthy multistep nature of the Article 31bis System procedure, the prescribed time limit for negotiations should be reduced from a “reasonable” period of time to a “brief” one.

In a similar vein, the obligations imposed on the export compulsory licensee to prevent diversion of the manufactured pharmaceuticals should be reconfigured. To move away from the current rigid set of measures, the Article 31bis System should introduce a flexible standard. Exporting States should be allowed to grant compulsory licenses that prescribe anti-diversion countermeasures that are appropriate to the actual circumstances of each case. Such a rule would allow for a scalable approach. The onus placed on export compulsory licensees would be minimal when the risk of diversion is low due to, for example, the pharmaceutical in question being in scarce demand in developed markets or being difficult to smuggle owing to its storage and conservation properties. By contrast, if the risk of diversion were elevated, the Exporting State would be at liberty to prescribe more onerous monitoring duties that extend across production, transport, and distribution. This elasticity would open the door to innovative and cost-efficient technological solutions to diversion—such as those using NFC chips, GPS tracking, and distributed ledgers—rather than those that rely on coloring, shaping, and packaging requirements.

Lastly, pooled procurement should be facilitated and further incentivized within the Article 31bis System. The current requirement that confines the operation of article 31bis(3) to regional trade agreements, half the current membership of which is comprised of LDCs, is extremely restrictive. A

different threshold should be set with sensitivity not just for LDCs but also developing WTO members, as these countries often lack pharmaceutical manufacturing capabilities, especially for biologics. Pooled procurement outside of article 31bis(3) should also be facilitated. When an Importing State notifies the TRIPS Council of its need for a pharmaceutical product, other WTO members should be allowed to join their request at any point in time by sending their own notification. Such an adhesion mechanism would greatly reduce coordination challenges and perhaps give rise to a snowball effect, with a growing number of WTO members incrementally aggregating their demand and, in turn, rendering the transaction more appealing for prospective licensees.

An alternative approach to buttressing the flow of patented pharmaceuticals from the Global North to the Global South might involve reforming the TRIPS patent regime rather than just the Article 31bis System. The most direct avenue would be to fundamentally recast the legal treatment governing the export of patented medicines. WTO members could agree to modify article 30 by instituting a mandatory limit on the rights of patentees whereby the production of a patented pharmaceutical for the purpose of distributing it into the market of a WTO member without manufacturing capacity would be positively qualified as a noninfringing activity. Arguably, such a rule would be consistent with the general conditions set in article 30(1) for patent rights “exceptions,” as it would be “limited” and would neither “unreasonably conflict with a normal exploitation of the patent” nor “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>364</sup> An amendment of this nature would require all WTO members to adopt this rule within their domestic legal order. Marking a stark departure from current law, it would completely unshackle flows of patented pharmaceuticals from WTO members that have developed manufacturing capabilities toward those that do not.

A less drastic approach would involve WTO members agreeing to an authoritative interpretation of article 30 through a TRIPS Council decision.<sup>365</sup> This declaratory act would clarify that it is consistent with the TRIPS patent regime for WTO members to enact—into their domestic patent laws—limited carve-outs that prevent patentees from taking action against persons who produce patented pharmaceuticals to export them to WTO members without manufacturing capabilities. This reform would not mandate that WTO members adopt this exception, yet it would make this possible for those that so desire.

---

364. *See supra* Part II.C.

365. Marrakesh Agreement, *supra* note 5, art. IX(2) (“The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements. In the case of an interpretation of a Multilateral Trade Agreement in Annex 1, they shall exercise their authority on the basis of a recommendation by the Council overseeing the functioning of that Agreement. The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members.”).

A still-narrower intervention would be for WTO members to amend TRIPS by eliminating article 31(f). More restrained than the previous options, this excision would not introduce an exception designed to allow unrestricted export of patented pharmaceuticals generally. Rather, it would only allow this activity within the confines of the TRIPS compulsory licensing regime. Accordingly, a manufacturer in a developed WTO member country that wanted to export a patented drug to another WTO member country without the consent of the patentee would have to obtain a compulsory license while abiding by all the procedural and substantive requirements under article 31.

Setting aside the legal implications for importing WTO members,<sup>366</sup> the crucial problem shared by all these prospective interventions is that they are unlikely to ever attract the necessary political support. Similar proposals were considered extensively in the months preceding the Doha Declaration, and especially during the lapse of time between the Doha Declaration and the Waiver Decision.<sup>367</sup> Developed WTO members never showed any genuine interest in endorsing the compression of pharmaceutical patentees' rights that such interventions would entail.<sup>368</sup> Considering that both TRIPS modifications and authoritative interpretations equally necessitate the support of three-fourths of all WTO members to be approved, it is highly improbable that such profound revisions of articles 30 and 31 will occur in the foreseeable future.

Thus, it is our view that it would be pragmatic to concentrate efforts on reforming the Article 31bis System, as developed WTO members would find it difficult to reject such initiatives, given their ostensible commitment to its success.

#### CONCLUSION

The original TRIPS framework contained a crucial flaw. It sharply curtailed access to patented medicines for some of the world's most vulnerable populations. In the 2001 Doha Declaration, the TRIPS Council contritely acknowledged this failing and resolved to rectify it. Their solution was the Article 31bis System and the mechanism of export compulsory licensing. Regrettably, this novel instrument has failed to deliver on its promised outcomes.

In this Article, we have contended that this failure is due neither to governmental and corporate interferences nor to conflicting national laws and international treaties. Though not insignificant, these factors are not

---

366. Notably, WTO members would have to issue a parallel compulsory license authorizing the importation of the pharmaceutical in question if it were protected by a patent in their jurisdiction.

367. See Abbott, *supra* note 187 (analyzing a range of possible TRIPS reforms involving articles 30 and 31 that would address the issue highlighted in paragraph 6 of the Doha Declaration).

368. See generally Abbott, *supra* note 16 (detailing the negotiations that followed the Doha Declaration and explaining how most developed WTO members rejected reform proposals that would have fundamentally recast articles 30 and 31).

dispositive. Our view is that the Article 31bis System is impaired by suffocating procedural and substantive requirements that deter both WTO members and generics manufacturers from making recourse to export compulsory licenses.

Despite acknowledging the severity of these defects, we believe that the Article 31bis System holds great potential. Rather than being dismissed unceremoniously, it should be revised through targeted interventions to address its current shortcomings. Within a reformed framework, export compulsory licenses could cut across the territorial boundaries of the patent system and enable developing countries to draw on the technology and know-how of developed pharmaceutical industries at affordable prices. Such a seed of solidarity is rarely, if ever, sown in the field of international intellectual property law. Given time and care, it may yet blossom.