TRIP-ING UP: THE FAILURE OF TRIPS ARTICLE 31*BIS*

Nicholas G. Vincent, Ph.D.[*]

[*] *J.D., New York University School of Law, 2020; Ph.D. (Microbiology), Yale University 2017.* *I would like to thank Professor Rochelle C. Dreyfuss for her guidance on this research and for her helpful comments on the draft. I would also like to thank the members of the Spring 2019 International Intellectual Property class at New York University School of Law for providing constructive feedback on this project. Finally, I would like to thank Nicole Carloni, MPH for her helpful discussions on preventing drug sharing in the context of HIV/AIDS, and Christopher Guzman, PhD for helpful comments on addressing biologics-specific concerns of Article 31bis.*

ABSTRACT

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), enacted as part of the World Trade Organization (WTO) in 1995, is the main international agreement covering international intellectual property rights. TRIPS establishes a minimum-standards framework, whereby all member nations are required to fulfill a certain set of intellectual property protections. By 2001, there was some desire to balance public health interests with intellectual property rights, especially with regards to access to medicines in developing and least-developed countries. This resulted in the Doha Declaration on the TRIPS Agreement and Public Health.

The Doha Declaration proposed what would eventually become Article 31bis of the TRIPS Agreement, the first, and to-date only, amendment of the Agreement. Under Article 31bis, a country in need of a particular pharmaceutical product, and without the manufacturing capabilities to produce it, is able to import the drug under a compulsory license from a producing country without violating provisions found elsewhere in the Agreement. Although the framework was expected to be widely used, it has been used only once. Precise reasons abound for why the framework has not been more widely used.

In this paper, I argue that, in practice, the compulsory licensing system under Article 31bis does not meet the standards it aims to establish and represents little more than a patchwork to fix specific problems that arose from Article 31. The compulsory licensing system under Article 31bis does not factor in various considerations that importing countries must consider, including the administrative burden that falls on the importing country and recent developments in pharmaceuticals and clinical therapeutics that present challenges to the framework being applied as proposed. The recommendations and conclusions from this work serve not only to lay the groundwork for how the compulsory license process under Article 31bis could be better used, but also to shed light on future WTO amendment proceedings, should they arise in the future.

I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), enacted as part of the World Trade Organization (WTO) in 1995, is the main international agreement covering intellectual property rights in the international setting. The framework it establishes is one of minimum standards, whereby all member nations are required to fulfill a certain set of obligations as members of the WTO pertaining to issues of intellectual property protection, including, but not limited to, copyrights, trademarks, and patents. By 2001, though, there was some desire to balance public health interests with intellectual property rights, especially with regards to access to medicines in developing and least-developed countries. This resulted in the Doha Declaration on the TRIPS Agreement and Public Health.

The Doha Declaration proposed what would eventually become Article 31*bis* of the TRIPS Agreement, the first, and to-date only, amendment of the Agreement. Under Article 31*bis*, a country in need of a particular pharmaceutical product, and without the manufacturing capabilities to produce it, is able to import the drug under a compulsory license from a producing country without violating provisions found elsewhere in the Agreement. Although the framework was expected to be widely used, it has been used only once. Precise reasons abound for why the framework has not been more widely used.

In this paper, I argue that, in practice, the compulsory licensing system under Article 31*bis* does not meet the standards it aims to establish and represents little more than a patchwork to fix specific problems that arose from Article 31. The compulsory licensing system under Article 31*bis* does not factor in various considerations that importing countries must consider, including the administrative burden that falls on the importing country and recent developments in pharmaceuticals and clinical therapeutics that present challenges to the framework being applied as proposed.

In Part II, the paper will introduce the TRIPS Agreement and various lead-up articles and Declarations from the WTO that, combined together, resulted in the amendment of the Agreement and the enactment of Article 31*bis*. Part III will focus on the text and structure of Article 31*bis* in light of compulsory licensing, the Article 31*bis* annex, and other supplemental information. This section will also discuss the only Article 31*bis* proceedings to date (between Rwanda and Canada) while beginning to propose some context for why the system may not be working as initially expected. In Part IV, I will address how Article 31*bis* has fallen short of its initial goals in light of the unexpected administrative burden placed on importing countries and the development of novel treatments including biologics, cellular therapies, and gene-based therapies. This section will also address potential conflicts that the TRIPS Agreement may have with other international agreements in terms of data exclusivity and use with respect to pharmaceutical products. In Part V, I will address potential solutions and roadblocks. Finally, Part VI, before concluding, will briefly address lessons that have been learned from

the TRIPS amendment process. As the first, and to-date only, amendment of the Agreement, the outcome of this process can help shed light on potential and future amendment proceedings if, and when, they arise.

II. THE TRIPS AGREEMENT AND THE LEAD-UP TO ARTICLE 31BIS

a. The TRIPS Agreement: General Provisions and Scope

On January 1, 1995, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into effect as part of the establishment of the World Trade Organization (WTO).[1] The WTO and the TRIPS Agreement both came about as a result of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade (GATT).[2] Since then, TRIPS has remained the main multilateral agreement on intellectual property, establishing minimum standards of protection for areas including copyright and related rights (Articles 9-14), trademarks (including service marks) (Articles 15-21), geographical indications (Articles 22-24), industrial designs (Articles 25-26), patents (Articles 27-34, including Article 31*bis*), layout-designs of integrated circuits (Articles 35-38), and undisclosed information (including trade secrets and test data) (Article 39).[3] The Agreement also includes enforcement obligations, including procedures and remedies (Articles 42-49), border measures (Articles 51-60), and criminal procedures pertaining to criminal activities (Article 61).[4] It is important to note that the TRIPS Agreement relates to international dealings in an area of private rights that are traditionally nationally, not internationally, based. For example, a trademark grant in one country does not carry those same trademark rights to other countries without appropriate compliance with the other country's trademark laws.[5]

The Agreement is the only multilateral treaty that pertains to intellectual property rights (IPRs), and as such, it has served as a model in the area. The IPR provisions have their basis in the Paris Convention for the Protection of

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197 [hereinafter TRIPS Agreement]; *See, e.g.*, KEITH E. MASKUS, PRIVATE RIGHTS AND PUBLIC PROBLEMS: THE GLOBAL ECONOMICS OF INTELLECTUAL PROPERTY IN THE 21ST CENTURY 94 (2012); *Overview: The TRIPS Agreement,* WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Mar. 24, 2020).

2. *See Intellectual property: protection and enforcement*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 24, 2020).

3. *See* TRIPS Agreement, *supra* note 1.

4. *Id.*

5. Graeme B. Dinwoodie, *Trademarks and Territory: Detaching Trademark Law from the Nation-State*, 41 HOUS. L. REV. (ISSUE 3) 885, 903 (2004).

Industrial Property[6] and the Berne Convention for the Protection of Literary and Artistic Works.[7] Importantly, the TRIPS Agreement contains a mechanism for settling state-to-state disputes through the Dispute Settlement Understanding (DSU).[8] The DSU has its roots in the General Agreement on Tariffs and Trade (GATT), an agreement from the mid-1900s that focused on international trade in goods.[9] The somewhat unlikely pairing of TRIPS being a part of the WTO, its IPR provisions being rooted in the Paris and Berne Conventions, and its main dispute-settlement means, the DSU, being rooted in the GATT has led some commentators to suggest the agreement is, "like a cuckoo's egg, laid and hatched in the nest of another species."[10] That is, the agreement (i.e., the egg) is focused on IPRs, but has been "laid and hatched" in the "nest," or context, of trade and trade-related proceedings.

Despite its influence in the areas of trade law and intellectual property law, TRIPS has been extremely controversial for developing countries.[11] The Agreement has been criticized for favoring developed countries and their IPRs over developing and least-developed countries.[12] The argument has, more or less, taken the form of developing and least-developed countries arguing that TRIPS has led to increased prices for pharmaceuticals, decreased access to medicines, and difficulties and increased costs in obtaining foreign-owned technologies.[13] On the other side of the argument, developed countries

---

6. *See generally* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T 1583, 828 U.N.T.S. 305 (as last revised at the Stockholm Revision Conference on July 14, 1967).

7. *See generally* Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, S. TREATY DOC. NO. 99-27, 1161 U.N.T.S. 31 (as last revised in Paris on July 24, 1971 and amended Sept. 28, 1979).

8. *See generally* Understanding on Rules and Procedures Governing the Settlement of Disputes art. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU].

9. MATTHEW KENNEDY, WTO DISPUTE SETTLEMENT AND THE TRIPS AGREEMENT: APPLYING INTELLECTUAL PROPERTY STANDARDS IN A TRADE LAW FRAMEWORK 1 (2016); *See generally GATT and the Goods Council*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/gatt_e/gatt_e.htm (last visited Mar. 24, 2020).

10. KENNEDY, *supra* note 9, at 1

11. *See, e.g.*, Graham Dutfield, *TRIPS and its impact on developing countries*, SCIDEV.NET (Jan. 10, 2001), https://www.scidev.net/global/policy-brief/trips-and-its-impact-on-developing-countries.html.

12. *See, e.g.*, *Id.*

13. *Id.* Increased costs to obtaining foreign-owned technologies relates to the topic of technology transfer, which is addressed in TRIPS Article 66(2). Part of the problem, perhaps, is that the Article merely states that "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." TRIPS Agreement, *supra* note 1, at art. 66. A quick reading of the text suggests that TRIPS does not provide extensive technology transfer provisions, even in light of Article 7, which mentions "the transfer and dissemination of technology." TRIPS Agreement, *supra* note 1, at art. 7. Some have argued that an agreed upon substantive minimum standard for the implementation of TRIPS Article 66(2) would be beneficial to the developing world. *See* Andrew C. Michaels, *International Technology Transfer*

argue that stronger IPRs serve to attract investment to developing and least-developed countries, which carries along with it important economic growth.[14] Shortly after the TRIPS agreement was negotiated and adopted, it quickly became obvious that the concerns of developing countries may have come to fruition, and that the establishment of IPRs may not have resulted in important economic growth sought by the developed countries.[15] In fact, empirical studies have suggested that the benefit of strong IPRs for developing and least-developed countries is far from clear,[16] but the argument rages on.

The controversy surrounding the TRIPS Agreement was particularly concentrated in developing countries that did not formerly protect pharmaceutical products and that had strong generic drug industries. A prime example of one such country is India, which was able to develop a robust generics industry through a patent regime that covered process patents, but not product patents, and through keeping the patent term for pharmaceuticals relatively short.[17] Under the TRIPS Agreement, however, India was required to issue patents that cover pharmaceutical products.[18] As a result, Indian generics producers were no longer permitted to reverse engineer products, because those products were now likely to be covered by product patents.[19] Although there were significant uncertainties of how the Indian generics market would handle the changes required under TRIPS,[20] India amended its patent laws to come into full compliance with the Agreement.[21] Part of these

---

and TRIPS Article 66.2: Can Global Administrative Law Help Least-Developed Countries Get What They Bargained For?, 41 GEO. J. INT'L L. 223 (2009).

14. Dutfield, *supra* note 11.

15. Rochelle C. Dreyfuss, *Intellectual Property Lawmaking, Global Governance, and Emerging Economies*, *in* PATENT LAW IN GLOBAL PERSPECTIVE 53, 59 (Ruth L. Okediji & Margo A. Bagley eds., 2014) (stating that "access to foreign markets in exchange for raising intellectual property levels . . . turned out to be something of a losing proposition [for developing and least-developed countries]. The profits available on commodities do not offset the supracompetitive prices charged for protected knowledge products. As a result, the fruits of contemporary innovation efforts are beyond the reach of most of the population of these states. . . .").

16. *See, e.g.*, E. Richard Gold, Jean-Frédéric Morin & Erica Shadeed, *Does Intellectual Property Lead to Economic Growth? Insights from a Novel IP Dataset*, 13 REG. & GOVERNANCE 107 (2017).

17. Biswajit Dhar & K.M Gopakumar, *Post-2005 TRIPS scenario in patent protection in the pharmaceutical sector: The case of the generic pharmaceutical industry in India*, UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT 4 (Nov. 2006), https://unctad.org/en/PublicationsLibrary/ictsd-idrc2006d2_en.pdf.

18. *See* TRIPS Agreement, *supra* note 1, at art. 27 (stating that "patents shall be available for any inventions, whether products or processes, in all fields of technology . . . .").

19. *See* Dhar & Gopakumar, *supra* note 17, at 4.

20. *See generally id.*

21. Biswajit Dhar & Reji K. Joseph, *The Challenges, Opportunities and Performance of the Indian Pharmaceutical Industry Post-TRIPS*, *in* INNOVATION, ECONOMIC DEVELOPMENT, AND INTELLECTUAL PROPERTY IN INDIA AND CHINA, 299, 299 (Kung-Chung Liu & Uday S. Racherla eds., 2019); Susan Fyan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.*, 15 VA. J. L. & TECH. 198, 206 (2010). Part of this

amendments were aimed at ensuring the generics industry was not destroyed, including the amendment in Section 3(d) of the Patents Act of 1970 that did not permit patents on minor modifications on existing products.[22] A 2019 analysis suggests that there may be a slowing of the growth rates of the generics industry in India, but overall it is difficult to determine whether the TRIPS Agreement has resulted in an overall growth or contraction of the generics market.[23] In spite of these controversies, the Agreement has persisted and continues to serve as the minimum-standards WTO agreement for international issues of intellectual property.[24]

b. Part II, Section 5 of the TRIPS Agreement: Patents

TRIPS Part II, Section 5 contains nine articles (Articles 27-34, including Article 31*bis*, discussed in detail in Part III) that cover the patent-related provisions of the treaty. Patents, like the other types of intellectual property covered in the Agreement, are territorial in nature, and therefore, must be applied for in each country where protection is sought.[25]

The TRIPS patent-related provisions cover issues that can arguably be divided into several groups. One set of provisions pertains to the patent contents and patent rights that are to be granted by Members under the Agreement. They are the articles covering patentable subject matter (Article 27),[26] rights conferred by a patent (Article 28),[27] and conditions on a patent applicant (Article 29).[28] Another set of provisions pertains to procedural requirements, including revocation and forfeiture/judicial review (Article

---

amendment process involved the controversial exclusion of "the mere discovery of a new form of a known substance . . . or the mere discovery of any new property or new use for a known substance . . . ." Fyan at 206 (quoting Section 3(d) of the Indian Patent Law).

22. Dhar & Joseph, *supra* note 21, at 321.

23. *Id*.

24. *See* TRIPS Agreement, *supra* note 1.

25. Although patent rights are territorial, there are several efforts at streamlining the process across borders. One effort is the Patent Cooperation Treaty (PCT), which is an international patent treaty that allows inventors to file one international application that can then be used to seek protection in various jurisdictions. *See generally PCT – The International Patent System*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://www.wipo.int/pct/en/ (last visited Sept. 21, 2020). A second effort is underway in Europe to issue unitary patents (patents that are protected in up to 26 EU Member States) and to create a Unified Patent Court, which would be an international court established by EU Member States dealing with issues pertaining to patents including validity and infringement. *See generally Unitary Patent & Unitary Patent Court*, EUROPEAN PATENT OFFICE https://www.epo.org/law-practice/unitary.html (last visited Mar. 24, 2020).

26. TRIPS Agreement, *supra* note 1, at art. 27.

27. *Id*. at art. 28.

28. *Id*. at art. 29.

32),[29] the term of protection (Article 33),[30] and the burden of proof in process patents (Article 34).[31]

The remainder of the articles, Articles 30, 31, and 31*bis*, the focus of this paper, address various exceptions to the rights of patent holders.[32] Article 30 (Exceptions to Rights Conferred)[33] is a particularly important provision: it provides member requirements for when limited exceptions to the exclusive rights conferred by a patent can be granted. The limited exceptions[34] must not unreasonably conflict with normal exploitation of a patent, and the limited exception must not unreasonably prejudice the legitimate interests of the patent owner, while taking into account the legitimate interests of third parties.[35]

Article 31: Other Use Without the Authorization of the Right Holder[36] is concerned with "other use," which is defined in the accompanying footnote (original footnote 7), as "use other than that allowed under Article 30."[37] In practice, this is directed toward uses by the government or third parties that are authorized by the government. There are twelve listed provisions that "shall be respected," including that the authorization shall be considered on its individual merits,[38] that the scope and duration of the use shall be limited to the purpose for which it was authorized,[39] and that the use shall be non-exclusive.[40] In short, Article 31 is a compulsory licensing provision with additional provisions to spell out when and how compulsory licenses can be issued.[41]

It is important to note that compulsory licensing is an important TRIPS flexibility because it can promote access to medicines in developing countries.[42] The majority of compulsory licensing of pharmaceuticals under

---

29. *Id*. at art. 32.

30. *Id*. at art. 33.

31. *Id*. at art. 34.

32. *Id*. at art. 30, 31, and 31*bis*.

33. *Id*. at art. 30.

34. Note that no examples of what a limited exception may be are provided in Article 30. This is similar to Article 13 (Copyright: Limitations and Exceptions), but is in contrast to Article 17 (Trademark: Exceptions), which states that, "Members may provide limited exceptions to the rights conferred by a trademark, *such as fair use of descriptive terms . . .*" TRIPS Agreement, *supra* note 1, art. 17.

35. *Id*. at art. 30.

36. *Id*. at art. 31.

37. *Id*.

38. *Id*. at art. 31(a).

39. *Id*. at art. 31(c).

40. *Id*. at art. 31(d).

41. *Compulsory licensing of pharmaceuticals and TRIPS*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Mar. 24, 2020).

42. *See* Sisule F. Musungu, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (CIPIH), WORLD HEALTH ORGANIZATION iii (Aug. 2005), https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf.

the TRIPS agreement has occurred for production of pharmaceuticals for domestic markets,[43] but, even in this situation, the flexibility remains an important one. To understand why, it is first important to acknowledge how and *why* a compulsory license is granted. Typically, those interested in obtaining a compulsory license will have *already* attempted negotiations for a voluntary license with the patent holder, and those negotiations will have failed.[44] Since pharmaceuticals are often thought of as having a special status as a public health good, compulsory licensing allows the rights-seeker an alternative pathway to produce the needed pharmaceutical process, resulting, arguably, in a net benefit to the overall health and welfare of the members of its country, without running afoul of the patent laws and of the patent holder's intellectual property rights.[45]

c. The Unraveling of Article 31

Two of the other enumerated provisions in Article 31 have fueled the impetus behind the first, and to-date only, amendment of TRIPS, single-handedly pointing out the shortcomings of the article and, arguably, of the entire Agreement. The first of the two provisions is Article 31(f), which states that, "any use described in the article shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[46] The second, Article 31(h), states that, "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."[47]

Why these articles have proven to be so problematic requires a brief view as to what the world of pharmaceutical patents looked like prior to TRIPS. Prior to the enactment of the TRIPS Agreement, manufacturers in countries that did not recognize patents on pharmaceutical products were able to produce generic pharmaceutical products through reverse engineering and then sell the drugs to other countries where the product was not patented at a

---

43. *See id*. at v; *see also Compulsory licensing of pharmaceuticals and TRIPS*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Mar. 24, 2020).

44. *Compulsory licensing of pharmaceuticals and TRIPS*, *supra* note 41.

45. To say that compulsory licensing is always viewed as a beneficial flexibility would be an incomplete treatment of the issue. Although the criticisms extend further than this footnote allows, it is thus important to at least acknowledge some of the main arguments *against* the use of compulsory licenses in pharmaceuticals. Some commentators have alleged that compulsory licensing amounts to little more than government theft. Elizabeth Wright, *Compulsory pharmaceutical licensing is little more than government theft*, THE HILL (Aug. 4, 2018, 7:05 PM), https://thehill.com/opinion/healthcare/400415-compulsory-pharmaceutical-licensing-is-little-more-than-government-theft. Furthermore, some commentators have noted that using compulsory licensing could result in trade tensions with countries that produce the patented drug that is the subject of compulsory license. Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An Analysis of Arguments*, 3 INT'L J. SOC. SCI. & HUMAN. 254, 255 (2013).

46. TRIPS Agreement, *supra* note 1, at art. 31(f).

47. *Id*. at art. 31(h).

lower cost than the branded drug both at home and abroad.[48] TRIPS, however, eliminated this possibility wholesale by requiring members of the WTO to grant patents on pharmaceutical products.[49] This affected generic-producing countries, and their customers, the hardest; under this framework, these countries could only purchase patented drugs from the patent owner at prices that often exceeded their level of affordability.[50]

A compulsory license, a license granted by a government that allows another party to use the contents of a patent "without the consent of the patent owner,"[51] provided a potential solution to this problem, but the grant of compulsory license is useless if the country receiving the license does not have the manufacturing capacity to produce and manufacture the drug. As a result, the compulsory license represents an empty, meaningless rubber stamp that preferentially favors patent holders over public health needs.

In this context, it is apparent why Articles 31(f) and 31(h) were problematic: under 31(f), the use can only be for supply to a domestic market. This means that, were a compulsory license granted by a developed country with manufacturing capabilities (or even a developing country like India that had a robust generic drug industry) to ship the drug to a developing or least-developed country, they would be in violation of Article 31(f) since the product would be used to supply an international market.[52] Article 31(h) presented a problem pertaining to ability to pay: the rights holder is entitled to adequate remuneration. Developing or least-developed countries may not only be unable to pay, but there will be difficulties in determining the appropriate "economic value of the authorization"[53] and navigating the differences in the value the two parties may place on the deal. These precise tensions led many to realize that the structure established in Article 31, that is, Member-provided exceptions to patent rights with limitations on export and remuneration, was in stark contrast to goals of advancing medicine availability and access to care.[54]

---

48. Sonja Babovic & Kishor M. Wasan, *Impact of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement on India as a Supplier of Generic Antiretrovirals*, 100 J. PHARMACEUTICAL SCI. 816, 817 (2010).

49. *Pharmaceuticals and the WTO TRIPS Agreement: Questions and Answers*, WORLD TRADE ORGANIZATION (Mar.2000), https://medex.com.bd/downloads/KthHLY8Dav8b5p4ftTMLk4MZB9qcGvoDaLCG4jIyyxZ1gqs3q5/pharmaceuticals-and-trips-agreement.pdf.

50. *See* Jillian Clare Cohen-Kohler, Lisa Forman & Nathaniel Lipkus, *Addressing Legal and Political Barriers to Global Pharmaceutical Access: Options for Remedying the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Imposition of TRIPS-plus Standards*, 3 HEALTH ECON. POL'Y & L. 229, 234-35 (2008) (stating that TRIPS—and the subsequent pharmaceutical patent projection in India—would result in a sharp increase in cost to Indian consumers of pharmaceutical products).

51. *TRIPS and Pharmaceutical Patents: Obligations and Exceptions*, WORLD TRADE ORGANIZATION (Sept.2006), https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

52. See TRIPS Agreement, *supra* note 1, at art. 31(f).

53. *Id*. at art. 31(h).

54. Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT'L L.J. 481, 507 (2001).

The tension between patent protection and the inability of developing countries to access or manufacture various medicines may even be said to flout some of the requirements in the TRIPS Agreement itself. The Agreement contains two provision, Articles 7 and 8, that address the objectives and principles of the Agreement, respectively.[55] Article 7 states that the protection of intellectual property rights that are contained within the Agreement should contribute to the promotion of information and transfer of technology, "to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[56] This implies that the provisions of the Agreement should promote innovation and dissemination to the *mutual* advantage of Members, not *merely* to one side of the coin (i.e., in this situation, the patentees or producers). Article 8(1) further articulates some of the tension with the provisions in Article 31. It states that: "[m]embers may . . . adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development . . . ."[57] Taken together, it is not implausible to argue that these provisions advocate for the consideration of public health and wellness goals as part of the TRIPS Agreement. This tension was eventually addressed in Paragraph 6 of the Doha Declaration.

d. A Proposed Solution: Paragraph 6 of the Doha Declaration

In light of these various tensions, the WTO Ministerial Conference of 2001 adopted the Doha Declaration on the TRIPS Agreement and Public Health on November 14, 2001.[58] The Declaration was viewed as the WTO's attempt to bridge the gap between health policy issues and intellectual property rights,[59] which can be a particularly salient issue in the context of access to medicines in developing and least-developed countries. In general, the Declaration focused on the "gravity of the public health problems afflicting many developing and least-developed countries . . ."[60]

Of particular interest to the issue at hand, and part of the impetus behind the eventual development, introduction, and adoption of Article 31*bis*, is Paragraph 6, which, in full, states:

> "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of

55. TRIPS Agreement, *supra* note 1, at art. 7–8.

56. *Id*. at art. 7.

57. *Id*. at art. 8.

58. World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 14 November, 2001, WTO Doc. WT/MIN(01)/EC/2, 41 ILM 755 (2002) [hereinafter TRIPS Declaration].

59. *See* Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 28 (2002).

60. TRIPS Declaration, *supra* note 58, at ¶ 1.

> 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."[61]

Paragraph 6, as it has come to be known, resulted in the eventual adoption of a Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health on August 30, 2003, which provided for temporary waivers from Articles 31(f) and 31(h).[62] The end goal of these waivers were to address the shortcomings discussed above in Section II.c: now countries without manufacturing capabilities could benefit from compulsory licenses issued in developed countries that had been unable to produce pharmaceutical products for export to developing and least-developed countries in need without violating the provisions of the TRIPS Agreement. Furthermore, the 31(h) waiver prevented resource-poor countries from having to remunerate the developed countries for the pharmaceutical products.

The WTO General Council adopted a Decision on the "Amendment of the TRIPS Agreement" on December 6, 2005.[63] Contained in this Decision was a proposal to make the waivers found in the Doha Declaration permanent.[64] Although it would take another twelve years to come into force, the stage had officially been set for the first, and to-date only, amendment of the TRIPS agreement.

---

61. *Id*. at ¶ 6.

62. General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WTO Doc. WT/L/540 and Corr. 1 (Sept. 1, 2003); *TRIPS Agreement—Article 31*bis *(Practice)*, WTO ANALYTICAL INDEX, https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

63. *TRIPS Agreement—Article 31*bis *(Practice)*, *supra* note 62.

64. *Id*.

III. ARTICLE 31*BIS*[65]

*a. Article 31*bis*: Structure and Contents*

On January 23, 2017, the Protocol from 2005 entered into force after two-thirds of the WTO members accepted it.[66] Procedurally, the Protocol subsequently became known as Article 31*bis* and was inserted directly after

---

65. The full text of Article 31*bis* incorporated into the TRIPS Agreement via amendment reads as follows:

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

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: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), 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 licence 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. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

The text of the Article along with the accompanying Annex and Appendix, can be accessed via this link:

https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm*; See TRIPS Agreement—Article 31*bis *(Practice)*, *supra* note 62.

66. *Id.*; the acceptance was in accordance with the Marrakesh Agreement Establishing the World Trade Organization, Article X, Paragraph 3, which states that "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." Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.

Article 31.[67] The deadline for acceptance by Member countries has been extended several times: the first deadline for acceptance of the provision was December 1, 2007,[68] but after a series of extensions, the deadline was pushed to December 31, 2019.[69] On December 10, 2019, the seventh extension for acceptance was adopted by the General Council, and the deadline was extended to December 31, 2021.[70] At the time of writing, 104 Members had ratified the Article.[71]

Structurally, there are three important components to the enactment, which will be covered in this and subsequent sections: the five paragraphs that comprise the actual article's provisions (covered in this section), the Annex (covered in Section III.b), and the Appendix to the Annex, which deals with assessing the lack of manufacturing capabilities in the exporting country (covered in Section III.b).

The first paragraph of the Article, Article 31*bis*(1) is where the waiver, under particular circumstances, to Article 31(f) is made permanent: "The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) . . ."[72] The focus of this paragraph is to alleviate the issue mentioned above, whereby developed producer countries were unable to distribute pharmaceuticals under a compulsory license to developing and least-developed countries because Article 31(f) required that these goods be produced for use in the domestic market.

The second paragraph is where the waiver, under particular circumstances, to Article 31(h) is made permanent and is subsequently concerned with preventing double remuneration to the patent owner. In particular, the provision states that, "[w]here a compulsory licence is granted by an exporting Member under the system set out in this Article . . . adequate remuneration pursuant to Article 31(h) shall be paid in that Member . . . . Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member."[73] This paragraph has a dual function: first to ensure that the patent owner is compensated, but not doubly, and also that the resource-poor recipient is not

---

67. *Id*. at 1.4, ¶ 4.

68. *TRIPS Agreement—Article 31*bis *(Practice)*, *supra* note 62.

69. *Amendment of the TRIPS Agreement—Sixth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, World Trade Organization, WTO DOC. WT/L/1024 (Nov. 30, 2017).

70. *Amendment of the TRIPS Agreement—Seventh Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, World Trade Organization, WTO DOC. WT/L/1081 (Dec. 10, 2019).

71. *Amendment of the TRIPS Agreement*, WORLD TRADE ORGANIZATION https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Aug. 29, 2020).

72. TRIPS Agreement, *supra* note 1, art. 31*bis*.

73. *Id*. at art. 31*bis*(2).

saddled with costs that it cannot bear. It is possible, however, that the costs may be passed on to other consumers in the form of higher drug prices in countries where the producer has patented and marketed products that are produced for profit. A better option for this paragraph may have been a provision that defined the remuneration as proportional to the ability of the developing country to pay. It is feasible, therefore, that extremely resource-poor, least-developed countries would be expected to pay little, if anything, but developing countries could pay proportionally to their ability, offsetting costs that may otherwise be passed on to others.

The third paragraph in Article 31*bis* is concerned with harnessing economies of scale (reduced costs that come as a result of increased production units) with respect to regional agreements that involve developing and least-developed countries. Under certain conditions, the obligations "under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in [one] 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."[74] In short, this is a permanent waiver for 31(f) in cases where one producing member is part of a regional trade agreement and is producing the pharmaceutical product for other members of that same regional trade agreement.

The fourth paragraph is a non-violation provision that states that member nations cannot challenge any measures taken pursuant to Article 31*bis* under Article XXIII of GATT, subparagraphs 1(b) and 1(c).[75] These subparagraphs provide, in general, for members that consider they are receiving a benefit that has been nullified or impaired, to make a written representation or proposal to the other contracting party (in this case, the producing Member state), at which point that contract party "shall give sympathetic consideration to the representations or proposals made to it."[76] In other words, the article and subparagraphs provide the specific circumstances under which a member of the World Trade Organization is entitled to a remedy.[77] The purpose of the

---

74. *Id*. at art. 31*bis*(3).

75. Paragraph 1 of Article XXIII, Nullification or Impairment, states:

"If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of the failure of another contracting party to carry out its obligations under this Agreement, or the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or the existence of any other situation, the contracting party may, with a view to the satisfactory adjustment of the matter, make written representations or proposals to the other contracting party or parties which it considers to be concerned. Any contracting party thus approached shall give sympathetic consideration to the representations or proposals made to it."

General Agreement on Tariffs and Trade, art. XXIII, paragraph 1.

76. General Agreement on Tariffs and Trade, art. XXIII, 1(b) and 1(c), Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194.

77. *Legal basis for a dispute: Types of complaints and required allegations in GATT 1994*, Dispute Settlement System Training Module: Chapter 4, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c4s2p1_e.htm.

fourth paragraph in Article 31*bis*, then, is to state that Article XXIII:1(b) and 1(c) are *not* eligible paths for challenging member actions, although other paths remain.[78]

Finally, the fifth paragraph emphasizes the maintaining of all existing flexibilities under TRIPS, stating that, "[t]his Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this agreement other than paragraphs (f) and (h) of Article 31 . . . ."[79]

Together, the five Paragraphs of Article 31*bis* provide a framework that is aimed at ameliorating the shortcomings of Articles 31(f) and (h). Interestingly, though, this goal has been overshot, and Article 31*bis* has revealed its own set of severe shortcomings. Whether the Article will function as intended has already been called into question and will be explored in further detail in Section III.c.

*b. The Annex and Appendix to Article 31*bis

The Annex to Article 31*bis* provides, in seven paragraphs, definitions, terms for using the system, and, perhaps one of the greatest concerns related to the Article, prevention of pharmaceutical products being diverted to the wrong markets.

Paragraph 2(a) of the Annex establishes the terms that are required for the Article 31(f) waiver that is found in Article 31*bis*(1) on the part of *importing* members.[80] An eligible importing member must make a notification to the Council for TRIPS that complies with several requirements.[81] First, the notification to the Council must, "specif[y] the

---

Article XXIII:1(a) to 1(c) provides the specific circumstances under which a member of the World Trade Organization is entitled to a remedy. The provisions that are pertinent to Article 31*bis* paragraph 4 are 1(b) and 1(c). Article XXIII:1(b) covers "non-violation complaints," which can be employed in challenges to any measure that are applied by another Member provided that a nullification or impairment in benefits results. Article XXIII:1(c) covers "situation complaints," which can cover any situation that may result in a nullification or impairment of a benefit.

78. This does, however, leave the provision under Article XXIII:1(a) available. "Violation complaints," covered by 1(a), are the most common type of complaint filed under Article XXIII. *Id*.

TRIPS Article 64 states that the provisions in Article XXIII apply to the TRIPS agreement. TRIPS Agreement, *supra* note 1, art. 64(1). It has been clearly stated by the WTO that the inapplicability of Article XXIII:1(b) and 1(c) to Article 31*bis* is without prejudice to the remainder of the TRIPS agreement. In other words, the inapplicability of Article XXIII:1(b) and 1(c) specifically applies to Article 31*bis*. TRIPS Agreement—*Article 64 (Practice)*, WTO Analytical Index,

https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art64_oth.pdf, at 2, n.4, and references therein.

79. TRIPS Agreement, *supra* note 1, art. 31*bis*(5).

80. TRIPS Agreement, *supra* note 1, art. 31*bis*, Annex, ¶ 2(a).

81. TRIPS Agreement, *supra* note 1, art. 31*bis*, Annex ¶¶ 2(a)(i)–(iii).

names and expected quantities of the product(s) needed."[82] Next, the notification must, "confirm that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex"[83] Finally, the notification must confirm that, if the pharmaceutical product is patented in its territory, that Member will grant a compulsory license that is in accordance with the related articles (that is, Articles 31 and 31*bis*), and the Annex accompanying Article 31*bis*.[84]

The Appendix to the Annex to the TRIPS Agreement for Article 31*bis* focuses entirely on assessing manufacturing capacities in the pharmaceutical sector in applying member countries and, thus, relates primarily and directly to Paragraph 2(a)(ii) of the Annex.[85] The Appendix directly states that, "[l]east-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector."[86] As a result, least-developed countries are granted a *per se* bar and do not have to demonstrate insufficient manufacturing capacities. For other eligible importing Members, however, there are two ways to establish insufficient or no manufacturing capacities: through establishing that it has no manufacturing capacity in the pharmaceutical sector,[87] or through showing that its limited manufacturing capacities are currently insufficient for the purposes of meeting its needs.[88]

Paragraph 2(b) of the Annex establishes the terms that are required for the Article 31(f) waiver that is found in Article 31*bis*(1) on the part of the *exporting* members. The issued compulsory license must contain provisions that state that only the amount necessary for meeting the needs of the eligible importing members may be manufactured[89] and products that are produced under the license should be clearly identified as being produced under this particular system.[90] In particular, the labeling requirements state that pharmaceutical products that are produced under this framework "shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packing and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price."[91] In summary, this means that the pharmaceutical products produced under the compulsory license framework must look different and/or be packaged differently than the same products produced outside of the

82. TRIPS Agreement, *supra* note 1, art. 31*bis*, Annex, ¶ 2(a)(i).
83. *Id*. at ¶ 2(a)(ii).
84. *Id*.
85. TRIPS Agreement, *supra* note 1, art. 31*bis*, Annex.
86. TRIPS Agreement, *supra* note 1, art. 31*bis*, Appendix to the Annex.
87. *Id*. at i.
88. *Id*. at ii.
89. TRIPS Agreement, *supra* note 1, art. 31*bis*, Annex, ¶ 2(b)(i).
90. *Id*.
91. *Id*. at ¶ 2(b)(ii).

compulsory licensing system. In addition to the labeling requirements, there are posting and notification requirements, whereby the licensee is required to post on a website (either its own or that of the WTO), information pertaining to the quantities that are supplied to each destination and any distinguishing features of the products, as described in Paragraph 2(b)(ii).[92]

The labeling provisions found in Paragraph 2(b)(ii) and (iii) are some of the defining features of the Article 31*bis* compulsory licensing program and, along with the provisions found in Paragraph 2(b)(i) pertaining to clearly establishing the quantity and destination of the products, clearly frame Article 31*bis* as a pro-patent holder provision, protecting not only the national, but also the international, rights of the patent holder. A careful reading of the labeling provisions that require the pharmaceutical products to be so explicitly identifiable and so meticulously tracked reveals the underlying logic of the requirement: to prevent spillover of the licensed products (or even deliberate re-exportation of the products) into other markets.[93] If the pharmaceutical products produced under Article 31*bis* are able to enter other markets where the compulsory license is not in force, they may be sold at lower, and thus more competitive prices, than the full-priced drug that is being produced in the non-participating, but affected, country. As a result, this can negatively affect the market of a pharmaceutical product in a country (perhaps a member or perhaps a non-member). This, unfortunately, does not address the further concern of dosage sharing among patients who are receiving the therapeutic. Potential solutions to this shortcoming are addressed in Part V.

Despite the pro-patentee leanings of this approach, however, the public health interests of the importing member are still respected: there is no explicit restriction on the quantity that can be imported, and as long as the importing member complies with the requirements in Paragraph 2(a) of the Annex, it appears that the importing member's request will be granted.[94] At first glance then, the provisions in Article 31*bis* seem to provide an exciting mechanism for both the patent holder's rights and the importing member's needs to be respected and met. Unfortunately, and as will be discussed in Part IV, there are other considerations that have not been factored into the framework pertaining to administrative burden of importing countries, and challenges with applying the Article 31*bis* framework to all types of pharmaceuticals outside of chemical-based formulations.

---

92. *Id*.

93. *See* TRIPS Agreement, *supra* note 1, art. 31*bis*, Annex, ¶ 3 (stating as a goal of Article 31*bis* the prevention of re-exportation of the products imported under the Article).

94. TRIPS Agreement, *supra* note 1, art. 31*bis*, Annex, ¶ 2(b)(i) (stating that "the amount necessary . . . may be manufactured under the licence," but not placing an explicit restriction on the quantity that can be produced or imported under the license).

*c. Article 31*bis *in Practice: the Rwanda-Canada Case Study*

One might expect that a proposed solution to a challenge large enough to result in the first-ever amendment of the TRIPS Agreement might have been met with open arms and excited participants among the members of the WTO, but this has not been the case. In fact, to date, the reception has been positively chilled, with the provisions in Article 31*bis* having been used only once.[95]

The process began in July 2007, when Rwanda notified the WTO Council for TRIPS of its intention to import 260,000 packs of TriAvir®[96] for the treatment of HIV/AIDS over the course of two years.[97] The notification contained the information that TriAvir® was manufactured in Canada by Apotex, Inc.[98] Appotex applied for the compulsory license in Canada in 2007, seeking permission to export 15,600,000 tablets, which was the approximate equivalent of the 260,000 packs requested by Rwanda.[99] The license was approved, and in October 2007, Canada filed its notification, compliant with the Canada Access to Medicines Regime (CAMR), which incorporated the Paragraph 6 system into its national laws.[100] The notification included the appropriate information required by paragraph 2(b) of the Annex to Article 31*bis*, including the labeling and listing requirements.[101] As a result, the

---

95. Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?,* SOUTH CENTRE POLICY BRIEF NO. 57 (2019), at 5; William Alan Reinsch, Jack Caporal & Sanvid Tuljapurkar, *Compulsory Licensing: A Cure for Distributing the Cure?,* CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES (2020).

96. TriAvir® is a fixed-dose combination of Zidovudine (azidothymidine; a nucleoside analog reverse transcriptase inhibitor), Lamivudine (3TC; a nucleoside reverse transcriptase inhibitor), and Nevirapine (Viramune; a non-nucleoside reverse transcriptase inhibitor). https://www.thebodypro.com/article/wto-announces-rwanda-plans-import-generic-antiretroviral-canadian; (Zidovudine) https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/019910s0331b1.pdf; (Lamivudine) https://www.accessdata.fda.gov/drugstfda_docs/label/2017/020564s37_020596s036lbl.pdf; (Nevirarpine) https://www.accessdata.fda.gov/drugsatfada_docs/label/2011/020636s039_020933s030lbl.pdf.

97. *Canada is first to notify compulsory license to export generic drug*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm; Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO DOC. IP/N/9/RWA/1 (Jul. 19, 2007).

98. Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO DOC. IP/N/9/RWA/1 (Jul. 19, 2007).

99. *Promoting Access to Medical Technologies and Innovation*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf (page 178) [hereinafter *Promoting Access*].

100. *Id*.

101. Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph*

agreement had been settled, and Canada would provide the requested drugs to Rwanda over the course of two years.

Once the procedural requirements of Article 31*bis* and paragraph 2 of the Annex were met, however, the process began to reveal issues that likely prevented other countries from using the same framework. Member nations began to highlight the fact that it took nearly three years for Rwanda to receive the full shipment of drugs that it had requested under the framework: Canada notified the Council to TRIPS in October 2008 that the first shipment had been delivered, but that a second shipment of the products was not scheduled until 2009.[102] The terms of the compulsory license were completed in September 2009 when the final shipment was delivered.[103]

In the 2010 annual review of the implementation of Article 31*bis* (pursuant to Article X of the annex), Members were interested in hearing, in detail, the experience of Rwanda and Canada in using the compulsory licensing and delivery framework.[104] Canada stated that their two-shipment delivery of TriAvir® to Rwanda showed that the system implemented in Canada was "efficient, effective and timely."[105] During the proceedings of the 2010 review, however, it became clear that many member states were concerned with the efficiency and effectiveness of the program, given that it took approximately three years from the request to the final delivery.[106] Several countries had viewed this framework as particularly useful during so-called national emergencies; it is thus not surprising that the three-year delay was somewhat alarming. In fact, the representative of Indonesia, during the proceedings, argued that, "[t]he utilization of the System was not as easy and expeditious as [Indonesia] had thought."[107] The time lost in waiting for the deliveries of drugs could almost certainly wipe out the possibility of using this in particular circumstances of national emergencies. To give the issue context, it took three years for Apotext to deliver the products to Rwanda.[108]

---

6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. IP/N/10/CAN/1 (Oct. 8, 2007).

102. Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/C/49 (Oct. 12, 2008); Council for Trade-Related Aspects of Intellectual Property Rights, *Review under Paragraph 8 of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/C/W/526 (Oct. 23, 2008).

103. Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Report to the General Council*, WTO Doc. IP/C/53 (2009).

104. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Report to the General Council*, WTO Doc. IP/C/57, (2010).

105. Id. at ¶ 18, (2010).

106. *Id*. at ¶ 18, (2010).

107. *Id*. at ¶ 44.

108. Jerome H. Reichman, *Compulsory licensing of patented pharmaceutical inventions: evaluating the options*, 37 J. LAW. MED. ETHICS 247, 255 (2009).

This timing would be unacceptable and almost certainly unworkable under any conceived definition of "national emergency."[109] National (and international) emergencies do not, and in fact *cannot*, wait for cumbersome bureaucracies. In fact, the Indonesian delegation highlighted a further alarming situation: if an emergency situation developed after a compulsory license had been granted, would the process for a new shipment have to start from the beginning?[110] Canada stated that, in the current situation, if Rwanda had wanted to increase its shipment, including for national emergencies, it would have to start the process from the beginning.[111]

The perceived delays, which Canada denied were significant in light of the full process, attributing them to "other factors" unrelated to the Article 31*bis* system, including the regulatory review of the pharmaceutical product in question,[112] undeniably sounded a note of concern among potential future importers and exporters. As a result, the system has not been used since, and its future as a functional and applicable portion of TRIPS seems to be somewhat in question.

IV. CRACKS IN THE FRAMEWORK: THE SHORTCOMINGS AND FAILINGS OF ARTICLE 31*BIS*

Article 31*bis*, in theory, was meant to ameliorate the shortcomings and challenges presented by Articles 31(f) and (h), but, unfortunately, has served as little more than an ineffective patch that is already showing cracks in its new framework. Here, I argue that there are three main ways that Article 31*bis* fails its mandate: first, it fails to consider the administrative burden placed on the importing, and often resource-poor, member; second, the framework arguably applies well to chemical-based formulation drugs, but novel therapeutics, including biologics, cellular-based therapies, and gene-based therapies present particular challenges that were not addressed in the

109. The 2019 global coronavirus pandemic (COVID-19, caused by the SARS-CoV-2 virus) illustrates how rapidly national health emergencies can evolve. *Naming the coronavirus disease (COVID-19) and the virus that causes it*, WORLD HEALTH ORGANIZATION, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it (last visited Mar. 21, 2020). In mere months, the situation has rapidly evolved from one of a novel virus causing respiratory symptoms in Wuhan, China, to a fulminant, global pandemic. *See* Chaolin Huang, et al., *Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China*, 395 THE LANCET 497 (2020); Helen Branswell & Andrew Joseph, *WHO declares the coronavirus outbreak a pandemic*, STAT (Mar. 11, 2020), https://www.statnews.com/2020/03/11/who-declares-the-coronavirus-outbreak-a-pandemic/; Interestingly, there have already been discussions of, and calls for, compulsory licensing in this rapidly developing area. *See, e.g.*, Ed Silverman, *Chilean lawmakers support compulsory licensing for coronavirus medicines and vaccines*, STAT (Mar. 18, 2020), https://www.statnews.com/pharmalot/2020/03/18/chile-compulsory-licensing-coronavirus-covid19-vaccines/.

110. WTO Doc. IP/C/57, *supra* note 104, at ¶ 44.

111. *Id*. at ¶ 62.

112. *Id*. at ¶ 251.

drafting of Article 31*bis* and its associated components; finally, it fails to consider data exclusivity agreements that are part of other international agreements, and, as a result, it fails to provide any means for how the TRIPS provisions may be reconciled with conflicting provisions in other agreements.[113]

*a. The Administrative and Social Burdens of Article 31*bis

A joint report by the WTO, World Intellectual Property Organization (WIPO), and World Health Organization (WHO), entitled Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property, and Trade, highlighted some of the main views of the compulsory licensing system among members.[114] Relevant to the Canada-Rwanda situation, it highlighted the view that the system was "too complex and administratively unwieldly for further use," requesting the formation of a multi-stakeholder workshop to address the operation of the framework, and also that there were concerns that using the system could result in ramifications (political or trade-related) as a result of using compulsory licensing.[115]

A somewhat problematic and simplistic approach of Article 31*bis* has emerged as a result of the Rwanda-Canada dealings: the importing member files a notification to the TRIPS Council, and the exporting member issues a compulsory license in compliance with the labeling and listing requirements found in the Annex to Article 31*bis*. In reality, the administrative burden falls hardest on the resource-poor country. Although under the Annex to Article 31*bis*, least-developed countries are automatically assumed to have insufficient or no manufacturing capabilities for pharmaceutical products, the same protection is not accorded to developing countries.[116] The burden to prove insufficient or no manufacturing, therefore, falls on an already potentially strapped-for-resources member just to clear the bar for entry to the Article 31*bis* framework.

Furthermore, there are a host of concerns that importing members may face, but that they often put to the side in the face of what they deem to be a more urgent aim: ensuring access to medicines for the people of their country.

---

113. It is, of course, possible that, despite these so-called "cracks in the framework" that another force is at play. It is not unreasonable to think that compulsory license provisions can act as *in terrorem* clauses. In other words, the provisions do not have to be enforced, per se, because the threat of enforcement looms in the background and leads patent holders to issue voluntary licenses. Countries with manufacturing capacities could also threaten producers with a compulsory license. The threats, however, are gutless if Article 31*bis* does not work, as I argue here. The Rwanda-Canada case study is further evidence that Article 31*bis* has not functioned efficiently, and provides further evidence the Article cannot, at least yet, serve or provide this *in terrorem* function.

114. *Promoting Access*, *supra* note 99, at 178.

115. *Id*.

116. TRIPS Agreement, *supra* note 1, art. 31*bis*, Appendix to the Annex.

These have been described as "social costs" to compulsory licensing.[117] First, importing countries that are already potentially resource-poor could face diminished direct investment because patent owners will perceive these countries as places that are potentially not patent- or business-friendly environments, likely due to their lack of production capabilities.[118] Second, there is the thought that the governments of patentees (the exporting countries in the Article 31bis framework) will retaliate against the importing country in other trade-related sanctions in a type of revenge or to recover what the exporting member feels it may have lost by being a part of the compulsory licensing framework deal.[119]

In presenting various social costs, Professor Robert Bird also focuses on ways of fixing them, several of which are applicable to the Article 31*bis* compulsory licensing framework.[120] To prevent the burden from falling onto the importing country, it is important to ensure that the licenses are appropriately tailored to focus on an actual public health need and to focus the public opinion on the suffering that was avoided by those benefitting from the pharmaceutical products that were provided as part of the compulsory licensing framework.[121] It is, however, important to recognize that, in some sense, this proposed solution or approach also places a burden on the importing country to direct and focus public opinion, although this is perhaps something that could be developed as part of a marketing or international communication effort between both the importing and exporting members.

*b. Pharmaceutical Challenges of Article 31*bis

Article 31bis and its accompanying Annex function well with regards to chemical-based formulations, but it is not apparent that their development has taken into account novel developing therapeutics, including biologics, cell-based therapies, and gene-based therapies. Furthermore, the framework was developed well before the advent of any personalized medicine treatments, and, as a result, does not factor in how access to these types of therapeutics could be managed under the framework.

Chemical-based formulations and pharmaceutical products are, relatively speaking, simple. They often consist of a single active ingredient that is formulated in a tablet, capsule, or liquid, combined with various other inert components and fillers that are required for various reasons including stability, delivery, and administration purposes.[122] The active ingredients and

117. Reichman, *supra* note 108, at 258.

118. R.C. Bird, *Developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects*, 37 J. LAW. MED. ETHICS 209 (2009); Reichman, *supra* note 108.

119. *Promoting Access*, *supra* note 99; Bird, *supra* note 118; Reichman, *supra* note 108.

120. Bird, *supra* note 118.

121. Bird, *supra* note 118; Reichman, *supra* note 108.

122. *See Glossary of Terms*, U.S. FOOD AND DRUG ADMIN., (Nov. 14, 2017) https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#D.

formulations are, therefore, identical from pill to pill or capsule to capsule. Examples of chemical-based formulations are acetaminophen (Tylenol®; used in the treatment of pain and fever), statins (e.g., Lipitor®; used in the treatment of high blood cholesterol), and antibiotics (used in the treatment of bacterial infections).[123]

In contrast, biologics, which are produced from biological sources and that include products like vaccines, blood components, cell-based therapies, antibody-based therapies, and gene-based therapies, are mixtures of various components that are far more complex than a simple chemical formulation.[124] Examples of biologics are adalimumab (Humira®; antibody-based treatment for rheumatoid arthritis),[125] CAR T-cell therapies (like Yescarta® and Kymriah™; chimeric antigen receptor T cells, isolated from a patient, reprogrammed, and readministered to the patient; used in the treatment of various types of cancer),[126] and voretigene neparvovec (Luxturna™; gene-therapy-based treatment for congenital eye disease).[127] Biologics are susceptible to various types of contamination and often require refrigeration (or at the very least are heat-sensitive) or special storage conditions.[128] An essential component of global distribution of these drugs is how they will be adequately shipped and stored during their shipment, and upon arrival.[129] Furthermore, some developing and least-developed countries do not yet have the support or resources to adequately store these types of pharmaceutical products, despite vast efforts to implement the "cold chain"—a temperature-

123. *Acetaminophen Information*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/drugs/information-drug-class/acetaminophen-information; *Statins*, U.S. FOOD AND DRUG ADMIN, https://www.fda.gov/drugs/information-drug-class/statins; *Antibiotics and Antibiotic Resistance*, U.S. FOOD AND DRUG ADMIN, https://www.fda.gov/drugs/buying-using-medicine-safely/antibiotics-and-antibiotic-resistance.

124. *What Are "Biologics" Questions and Answers*, U.S. FOOD AND DRUG ADMIN., (Feb. 6, 2018) https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

125. *See* Abbvie Inc., *Highlights of Prescribing Information: Humira*, U.S. FOOD AND DRUG ADMIN. (March 2020), https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125057s4151b1.pdf.

126. *CAR T Cells: Engineering Patients' Immune Cells to Treat Their Cancers*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/treatment/research/car-t-cells (last visited Mar. 24, 2020).

127. *FDA Approves Novel Gene Therapy to Treat Patients with a Rare Form of Inherited Vision Loss,* U.S. FOOD AND DRUG ADMIN. (Dec. 18. 2017), https://www.fda.gov/news-events/press-announcements/fda-approves-novel-gene-therapy-treat-patients-rare-form-inherited-vision-loss.

128. *Impact of Severe Weather Conditions on Biological Products,* U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/impact-severe-weather-conditions-biological-products.

129. *Storage of Essential Medicines,* WORLD HEALTH ORG. https://www.who.int/medicines/areas/access/supply/en/index4.html (last visited Sept. 4, 2020); *Annex 9 Guide to good storage practices for pharmaceuticals*, WORLD HEALTH ORG., https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf?ua=1 (last visited Sept. 4, 2020)

controlled, global logistics network for the shipment and storage of vaccines and biologics.[130]

The first challenge connected to Article 31*bis* and the novel biologic type treatments is that they themselves cannot be directly labeled per the labeling requirements found in the Annex.[131] Although the color, shape, and imprint of a pill can be changed, it is not possible to impose any meaningful physical identifier on a treatment that, to the naked eye, is a liquid in a vial, or that has been isolated from a cell culture.[132] Although the outer packaging can be labeled in a particular manner, also pursuant to the Annex, this type of designation can easily be scratched off, covered, removed, or otherwise altered in a way that a purple pill with a particular labeling cannot be.

This is particularly disconcerting when one considers that biologics tend to be vastly more expensive than chemical-based drugs.[133] As a result, spill over into other markets, where the drugs can still be sold at lower prices, despite their looking identical, can cause negative market effects in countries or markets that are not a part of the particular Article 31*bis* arrangement. Both the risk and the concern are higher with biologics: the pharmaceutical products, unable to be directly labeled, appear the same, so with slight tampering to the labeling, there will be little notice to consumers or purchasers that the drugs are part of a separate program. Since the prices of biologics are naturally higher, there is more of a risk of lower prices affecting markets in non-participating locales.

A second challenge relates to the mode of production of these types of pharmaceutical products. Chemical-based formulations can be synthesized in

---

130. Ozan S. Kumru, Sangeeta B. Joshi, Dawn E. Smith, C. Russell Middaugh, Ted Prusik & David B. Volkin, *Vaccine instability in the cold chain: Mechanisms, analysis and formulation strategies*, 42(5) BIOLOGICALS 237, 245 (2014). An unintended consequence of implementing a robust, global cold chain has been storing vaccines and biologics at temperatures that are too *low*, which can lead to inactivation and lowered efficacy. Traditionally, the concern of vaccine shipment and storage has been temperatures that are too *high*. *Id*.

131. TRIPS AGREEMENT, *supra* note 1, at art. 31*bis*, Annex. This is one of many related legal challenges resulting from advances in novel therapeutics. In general, current statutes and treaties do not contain adequate provisions for these types of therapeutics. *See, e.g.*, Nicholas G. Vincent, Note, *Patent Term Extension and the "Active Ingredient" Problem*, 9(2), N.Y.U. J. INTELL. PROP. & ENT. L. 279 (2020) (discussing challenges of applying the current patent term extension statute to novel clinical therapeutics).

132. It is possible that these types of therapeutics could contain inert molecular or genetic tags that identify the source of the therapeutic, but this type of "labeling" comes with its own set of challenges. First, and perhaps most obviously, determinations about the source of the therapeutic cannot be identified without moderately advanced laboratory capabilities. In short, this is not the same as being able to visually identify physical differences. Second, adding even a non-reactive, inert tag would require additional testing to ensure that it does not alter the safety of efficacy of the therapeutic. These challenges do not necessarily mean that they should not be pursued both scientifically and with regards to improving access to medicines, even though they do not quite capture the ease and efficiency found in, say, changing the color, shape, or imprint of a pill.

133. Thomas Morrow and Linda Hull Felcone, *Defining the difference: What Makes Biologics Unique*, 1 BIOTECHNOL. HEALTHCARE 4, 24, 29 (2004).

a lab, following a standard protocol.[134] Production of biologics is much more complex and requires vastly different lab setups and resources.[135] Under the Appendix to the Annex, then, it would clearly be assumed that least-developed countries do not have the manufacturing capacities necessary for production, and the burden would remain for other countries seeking to enter into an Article 31*bis* agreement that they also lack the capacities. The problems of shelf-life, storage, and shipment then become an immense factor. Biologics are naturally less stable, more complex, and often heat-sensitive.[136] This means that they will have to be shipped in very particular and controlled conditions that an exporting country may or may not be able to guarantee. Furthermore, once the shipments arrive in the importing country, there will have to be some kind of infrastructure in place to further the appropriate storage conditions. Given that importing countries are generally resource-poor, this seems to present a unique challenge that does not have to be considered with chemical-based formulations. Furthermore, the production methods and laboratory input of biologics are demanding, meaning that, even under the compulsory license agreement, the prices may still be higher than some developing and least-developed countries can afford. The incentives may also be lacking in potential exporting countries to take part in such agreements, which could emphasize some of the social-cost concerns described above.

A third challenge relates to the patient-tailored treatment with biologics. Although some biologics, like antibody-based therapeutics, are not patient-specific (similar to chemical-based formulations), there are many types of emerging therapeutics that are patient-specific and rely on autologous cells (cells that are isolated from a patient and readministered after some kind of manipulation to make them better targeted to treating a certain disease).[137] The United States Food and Drug Administration (FDA) has approved several of these types of products, including CAR T-cell therapies for treatment of specific cancers, Provenge (autologous peripheral blood cells used in the treatment of prostate cancer), and MACI (autologous chondrocytes, or collagen-producing cells, used in the treatment of cartilage repairs and defects of the knee).[138]

These pharmaceutical products *cannot* be made in an exporting country and shipped to an importing country. Under the current Article 31*bis* framework, there is no way to provide these therapeutics to patients in developing and least-developed countries. Although one may argue that these

134. *Id*. at 26.

135. *Id*.

136. *Id*.; *What are "Biologics" Questions and Answers*, U.S. FOOD AND DRUG ADMIN. (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

137. *Cellular & Gene Therapy Products*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products (last visited Mar. 24, 2020).

138. *Id*.

are not mainstream clinical therapeutics used in the treatment of endemic diseases, it is not impossible that future clinical therapeutics will continue to move in this direction, nor is it impossible to consider that patients in developing and least-developed countries could and would benefit from these treatments.

*c. Article 31*bis *Conflicts*

Finally, Article 31*bis*, in practice, may conflict with, or at the very least fails to take into account, various other TRIPS and TRIPS-plus provisions,[139] particularly those pertaining to data exclusivity and protected information. Of particular interest are TRIPS Article 39, article 15.10 of the United States-Central America Free Trade Agreement (US-CAFTA), article 22 of the United States- Jordan Free Trade Agreement, and article 18.50 of the Trans-Pacific Partnership (TPP). In this area, the United States-Mexico-Canada Agreement is also relevant.

Article 39 of the TRIPS Agreement covers the protection of undisclosed information.[140] Article 39(3) relates in particular to issues related to Article 31*bis*. Under Article 39(3), members shall protect "undisclosed test or other data" that is required as approving the marketing of a pharmaceutical product (i.e., regulatory review) against "unfair commercial use."[141] This protection of test data becomes a problem when one considers that many members require a drug to be approved in order for it to be used or marketed in their country.[142] This, in turn, means that an importing country that has not already

139. TRIPS AGREEMENT, *supra* note 1, at art. 31*bis*, Annex (recalling that TRIPS is a minimum standard agreement, TRIPS-plus provisions are provisions that go above and beyond what is required by the TRIPS Agreement).

140. TRIPS AGREEMENT, *supra* note 1, at art. 39.

141. TRIPS AGREEMENT, *supra* note 1, at art. 39(3).

142. Member countries often have to approve a pharmaceutical approved in another territory in their own territory before it can be cleared to enter that market. In the cases of a generic drug, the approving member may want to rely on safety and efficacy data from the initial approval. In many developing countries (and in cases where there is no data exclusivity) regulatory authorities may turn to data that are in the public domain or data that are published for their regulatory approval process. *See Data exclusivity and other "TRIPS-plus" measures*, WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR SOUTH-EAST ASIA (2017), https://apps.who.int/iris/handle/10665/272979. When we consider generics production and data exclusivity provisions of bilateral and multilateral trade agreements, however, serious access-to-medicines issues arise. Often, less developed member countries do not have the capacity to undertake a large clinical study to generate the data on their own, but they are also prohibited from relying on data generated in other member countries for safety and efficacy. Even in cases where running a clinical trial would be feasible, giving placebos as part of a clinical trial, when the safety and efficacy have already been established, may run afoul of medical ethics. Rohit Malpani, *All costs, no benefits: How the US-Jordan free trade agreement affects access to medicines*, 6 J. GENERIC MEDICINES 206, 209 (2009); *see also* Lisa Diependaele et al., *Raising the Barriers to Access to Medicines in the Developing World—The Relentless Push for Data Exclusivity*, 17 DEVELOPING WORLD BIOETHICS 11 (2016); Deborah Gleeson et al., *Analyzing the impact of trade and investment agreements on pharmaceutical policy: provisions, pathways and potential impacts*, 15 GLOBALIZATION AND HEALTH 78 (2019).

approved a drug that is to be licensed under the Article 31*bis* framework may be required to approve the drug in its own country before it can be marketed and administered to people in that country. This, in and of itself, represents an additional burden for the importing country, especially if the drug is being imported to deal with a national emergency. Furthermore, as many developing and least-developed countries are resource-poor, it is not likely that they have sufficient resources to respond to such a regulatory request in such a short period of time.

This challenge becomes even more pronounced when considering several of the bilateral and multilateral regional agreements that have provisions on data exclusivity. For example, CAFTA Article 15.10 contains a provision that protects this kind of regulatory test data for five years.[143] For example, if a pharmaceutical product were approved in a country, the data used for that approval pertaining to safety and efficacy would not be able to be used in another member country for at least five years.[144] This creates clear delays and barriers to access, effectively granting a period of exclusivity to the patent holder. Whether this is a benefit or a hindrance lies beyond the scope of this paper, but at the very least, this is an example of the struggle that can emerge between protecting innovation and ensuring adequate access to medicines.

Other bilateral and multilateral agreements contain similar provisions. For example, the United States-Jordan Free Trade Agreement contains a similar provision requiring the protection of testing data, albeit for three years.[145] Article 18.50 of the TPP, "Protection of Undisclosed Test or Other Data," similarly requires that, when a party requires approval of a new pharmaceutical product, undisclosed test or other data related to safety and efficacy cannot be used in another party for at least five years from the marketing approval date in the first party.[146]

An additional free trade agreement that should be mentioned in this context is the United States-Mexico-Canada Agreement (USMCA), which was first signed on November 30, 2018.[147] A revised version was signed on

143. Central American Free Trade Agreement art. 15.10 at 15-17, Aug. 5, 2004, 43 ILM. 514 [hereinafter CAFTA].

144. *Id*.

145. *See* Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, 41 ILM 63 (2002). For more information on the Jordan Free Trade Agreement see https://ustr.gov/sites/default/files/Jordan%20FTA.pdf.

146. The data exclusivity provision (Article 15.80) was not carried over into the CPTPP. *CPTPP vs TPP*, NEW ZEALAND FOREIGN AFFAIRS & TRADE, https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/understanding-cptpp/tpp-and-cptpp-the-differences-explained#data (last visited Sept. 8, 2020).

147. Agreement between the United States of America, the United Mexican States, and Canada, Nov. 30, 2018, *available at* https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between [hereinafter USMCA]; Scott Neuman, *Senate OKs North American Trade Agreement to Replace NAFTA, Giving Trump Much-Needed Win*, NATIONAL PUBLIC RADIO (Jan. 16, 2020, 12:17 PM), npr.org/2020/01/16/796901909/senate-oks-north-american-trade-deal-to-replace-nafta-giving-trump-a-much-needed.

December 10, 2019 and approved by the United States House of Representatives on December 19, 2019[148] and by the United States Senate on January 16, 2020.[149] The USMCA, which will replace the North American Free Trade Agreement (NAFTA), has been referred to as NAFTA 2.0.[150] This multilateral free trade agreement deserves special mention for two purposes. First, it is one of the most recent, and perhaps highest profile, implementations of a free trade agreement that contains provisions related to pharmaceutical patents, access to medicines, and data exclusivity.[151] Second, it represents a recent trade agreement where a data exclusivity provision was completely stripped out prior to the final version being approved by all party members. In fact, the USMCA initially contained a provision that provided for a 10-year data exclusivity period for biologic drugs that was later dropped and that was not included in the final agreement.[152] A ten-year period of data exclusivity would, in turn, result in a period of market exclusivity that could severely chill the availability of generic pharmaceutical products in the markets of other parties to the agreement.[153] It is not clear whether this

148. *See, e.g.*, Jacob Pramuk, *House approves USMCA trade deal after more than a year of talks, sending it to Senate*, CONSUMER NEWS AND BUSINESS CHANNEL (Dec. 19, 2019, 4:15 PM), https://www.cnbc.com/2019/12/19/house-passes-trumps-usmca-trade-agreement.html.

149. *See, e.g.*, Erica Werner & Rachel Siegel, *Senate approves new North American trade deal with Canada and Mexico*, WASHINGTON POST (Jan. 16, 2020, 11:59 AM), https://www.washingtonpost.com/us-policy/2020/01/16/senate-approves-new-usmca-trade-deal-with-canada-mexico/.

150. *See, e.g.*, Heather Long, *The USMCA is finally done. Here's what is in it*, WASHINGTON POST (Dec. 10, 2019, 5:13 PM), https://www.washingtonpost.com/business/2019/12/10/usmca-is-finally-done-deal-after-democrats-sign-off-heres-what-is-it/.

151. United States-Mexico-Canada Agreement Implementation Act, Jan. 29, 2020, 134 Stat. 11.; USMCA, *supra* note 147.

152. *10-Year Data Exclusivity for Biologics Removed from Final USMCA Agreement*, BIG MOLECULE WATCH (Dec. 13, 2019), https://www.bigmoleculewatch.com/2019/12/13/10-year-data-exclusivity-for-biologics-removed-from-final-usmca-agreement/.

153. *Id.;* It is important to note that NAFTA will be in force until the USMCA enters force. *U.S.-Mexico-Canada Agreement (USMCA)*, UNITED SATES CUSTOMS AND BORDER PROTECTION, https://www.cbp.gov/trade/priority-issues/trade-agreements/free-trade-agreements/USMCA (last visited Mar. 23, 2020). Furthermore, "[t]he USMCA enters force on the first day of the third month subsequent to the last country certifying their preparation." USMCA, *supra* note 147, at Preamble ¶ 2. Mexico ratified first in mid-2019. Miguel Angel Lopez & David Graham, *Mexico first to ratify USMCA trade deal, Trump pressures U.S. Congress to do same*, REUTERS (June 19, 2019, 4:00 PM), https://www.reuters.com/article/us-usa-trade-mexico-usmca/mexico-first-to-ratify-usmca-trade-deal-trump-presses-us-congress-to-do-same-idUSKCN1TK2U3. Canada followed on March 13, 2020, just prior to the Canadian parliament shutting down for the 2020 Coronavirus Pandemic. Rafael Bernal, *Canada approves North American trade deal*, THE HILL (Mar. 13, 2020, 8:27 PM), https://thehill.com/policy/international/trade/487546-canada-approves-north-american-trade-deal. According to the fact that the USMCA enters force on the first day of the third month after the last party ratifies the agreement, the USMCA was set to enter force on June 1, 2020. This was confirmed by the United States Trade Representative, but the date was later changed to July 1, 2020. Sabrina Rodriguez, *Lighthizer eyes June for USMCA to enter into force*, POLITICO (Mar. 16, 2020, 10:00 AM), https://www.politico.com/newsletters/morning-trade/2020/03/16/lighthizer-eyes-june-for-usmca-to-enter-into-force-786102; *USMCA To Enter Into Force July 1 After United States Takes Final Procedural Steps For Implementation*,

represents a larger trend away from data exclusivity protection itself, or just a one-off, but, in a discussion of international access to medicines and data exclusivity, it should not be overlooked.

Increasing efforts to protect regulatory data are patentee-friendly, but do present a roadblock to access to medicines and, in particular, to potential Article 31*bis* compulsory licensing frameworks. Coupling the Article 31*bis* framework with requirements in the above-described agreements means that, if a pharmaceutical product is not approved in an importing member, and that importing country requires approval before marketing, that country could be barred for five years before being able to use the regulatory data, or be forced to produce it on its own, which may come with prohibitive costs and burdens.

*d. Competing Views: Article 31*bis *as a Small Piece to a Larger Puzzle*

Importantly, there are competing views that Article 31*bis*, perhaps, has not been plagued by shortcomings. These views focus on the fact that Article 31*bis* is one piece of a much larger complex that is focused on ameliorating issues pertaining to access to medicines.

One argument focuses on the fact that Article 31*bis* has not been used more frequently because compulsory licensing under the framework is just one way of many to access medicines.[154] Under this view, lack of use of the framework cannot be used as a proxy for lack of interest in the program or lack of success. This argument also highlights the fact that no member delegation flagged any major obstacles as the framework was being developed.[155] Unfortunately, however, this is a somewhat shortsighted view of the framework. The functioning of a new program or framework in theory and how it actually works in practice can often result in two radically different visions and outcomes. That no objections or obstacles were brought up by members during the development stage could have been more a feature of enthusiasm for progress in the area and the fact that, on paper, the system was expected to function well.

For this argument to stand, there have to be actual other means for resource-poor countries to have access to the medicines they need. Although there is some suggestion that resources like the Medicines Patent Pool (MPP) and pricing models that facilitate access to medicines could aid in this area, it is not clear that they have played a sufficient role in increasing access to developing and least-developed countries.[156] The MPP, a UN-backed public health organization, allows drugs that are still under patent protection to be

---

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (Apr. 24, 2020), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2020/april/usmca-enter-force-july-1-after-united-states-takes-final-procedural-steps-implementation; *See, e.g.*, Ana Swanson, *As New NAFTA Takes Effect, Much Remains Undone*, N.Y. TIMES (July 1, 2020), https://www.nytimes.com/2020/07/01/business/economy/usmca-takes-effect.html.

154. *Promoting Access*, *supra* note 99.

155. *Id.*

156. Hilde Stevens & Isabelle Huys, *Innovative Approaches to Increasing Access to Medicines in Developing Countries*, 4 FRONTIERS IN MED. 218 (2017).

produced through the issuance of voluntary licenses from the patent holders to generic-producing companies in lower-middle-income countries.[157] Importantly, though, this implies that the country in question already has manufacturing capabilities established, and it operates under a *voluntary*, not a *compulsory* license framework. As a result, it is softer standard and assumes a higher level of manufacturing capacities than does Article 31*bis* and its related provisions.

Although some have argued that increased patent terms may lead to increased access to medicine in resource-poor regions,[158] it is not clear that we should be moving in the direction of increased patent protection when access is already an issue in resource-poor countries. Furthermore, there has been a suggestion to sell drugs at below-market costs in developing and least-developed countries, but this raises the spillover issues related to cheaper drugs infiltrating other markets, which is something that the labeling provision of the Article 31*bis* annex already tries to solve in and of itself.[159]

Another line of argument articulates the idea that perhaps Article 31*bis* is, in a way, ahead of its time and that, the one time it was used, it *did*, in fact, function as expected. This line of argument relies on two additional changes that have occurred since the implementation of Article 31*bis*: the advent of full patent protection for pharmaceutical products in India, and the approaching expiry of transition periods that are listed in the Agreement.[160]

India began to grant pharmaceutical patent protection in 2005 to comply with its TRIPS obligations.[161] Prior to this, generics could be produced at very low cost, and, as a result, under the Article 31*bis* framework, it would have been possible for importing members to seek low-cost drugs from the Indian market rather than through a compulsory licensing scheme. In fact, in the Rwanda-Canada partnership, Rwanda sought, at one point early in the process, to source the generic drugs from India,[162] but Canada slashed the cost per unit, thereby winning the bid.[163]

---

157. *About Us*, MEDICINES PAT. POOL, https://medicinespatentpool.org/who-we-are/about-us/ (last visited Sept. 21, 2020).

158. Tom Andreassen, *Patent Funded Access to Medicines*, 15 DEVELOPING WORLD BIOETHICS 152 (2015).

159. Stevens & Huys, *supra* note 156, at 4-5.

160. *Promoting Access*, *supra* note 99, at 179.

161. Bhaven N. Sampat & Kenneth C. Shadlen, *Indian pharmaceutical patent prosecution: The changing role of section 3(d)*, 13 PLOS ONE 1, 1 (2018).

162. Although this was after 2005 when India began to permit pharmaceutical patents, it is important to note that India still sought to *limit* pharmaceutical patents through Section 3(d) of its Patent Act. This provision attempts to limit the grant of "secondary" pharmaceutical patents. A "secondary" pharmaceutical patent is a patent that protects a new form of an already existing molecule or drug that is used for a new indication. Therefore, there was still an imposed limitation in terms of what types of products would be granted patent protection. The 3(d) provision was later upheld in the Supreme Court of India in the landmark case *Novartis AG v. Union of India*, Supreme Court of India, Civil Appeal No. 2706-2716 of 2013 (Apr. 1, 2013). *See* Sampat & Shadlen, *supra* note 161, at 1.

163. *Promoting Access*, *supra* note 99, at 178.

The view that Article 31*bis* is ahead of its time, and that more compulsory licenses (both as a part of and outside the framework provided by the Article) would be granted, however, is challenged by recent data that show that the issuance of compulsory licenses have actually *decreased* in the years since 2006, the year of the Doha Declaration.[164] Therefore, it is possible that, in time, this may turn out to be the case, but currently, it is not clear that we are headed in this direction.

Articles 65 and 66 of the TRIPS Agreement, pertaining to transitional agreements and least-developed country members, allow for various transition periods after the adoption of the WTO and TRIPS frameworks.[165] In short, these expiration periods are soon to expire (on July 1, 2021, if they are not extended), meaning that the provisions will be in full force, thereby theoretically allowing for potential importing members to fully take advantage of the compulsory licensing framework provided for in Article 31*bis*.[166] It remains to be seen whether the expiration of the transitional grace period will actually result in more usage of the Article 31*bis* provisions, or whether the negative reception of Rwanda-Canada will play a role in preventing this from coming to fruition.

In summary, there are reasonable arguments suggesting that Article 31*bis* is working as planned and that it may pick up speed in the coming years, yet upon a careful analysis of these contentions, the arguments do not stand, and the shortcomings of Article 31*bis* are revealed in even fuller force. At this point, it becomes important to ask what potential solutions can be achieved, and what lessons can be learned from the first-ever amendment to the TRIPS agreement.

V. POTENTIAL SOLUTIONS AND ROADBLOCKS TO THE ARTICLE 31*BIS* PROBLEM

Article 31*bis* has some apparent shortcomings, but that does not mean that it has to be wholesale discarded and swept under the rug. In fact, there are several promising ways to salvage the article, even in light of the development of novel therapeutics (see Section IV.b) and in light of potential conflicts with data exclusivity (see Section IV.c). In general, the path forward likely includes what are called TRIPS-plus provisions, or going above and beyond the TRIPS agreement to enact and implement provisions that are generally viewed as being stricter than what are found in the TRIPS Agreement.

164. Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MEDICINE 1, 7 (2012).

165. TRIPS AGREEMENT, *supra* note 1, art. 65-66.

166. *TRIPS Agreement: Transitional period for implementing the Agreement (Article 66.1)*, UNITED NATIONS, https://www.un.org/ldcportal/trips-agreement-transitional-period-for-implementing-the-agreement-article-66-1/.

a. Regional Agreements and Economies of Scale

One potential path forward is to emphasize the importance of regional agreements and focusing on the economies of scale provision in Article 31*bis*(3), which has three requirements: 1) countries that want to use this provision must be members of a recognized regional trade agreement; 2) at least half of the members from that regional trade agreement must be on the United Nations list of least-developed countries; and 3) the country seeking the compulsory license must be the importing member, but also can distribute the products to other member nations that are a part of the regional trade agreement and that share the same health problem in question without violating other TRIPS provisions.[167]

Encouraging regional agreements will help to address at least some of the shortcomings of Article 31*bis*. These agreements permit countries that are similarly situated to tackle a problem together that they may lack the ability to do on their own, even under the Article 31*bis* system (perhaps because they are unable to shoulder the administrative burden and social costs alone). As a result, encouraging regional agreements may be a powerful player in helping to decrease these administrative burdens and social costs that can come as a result of taking part in the Article 31*bis* compulsory licensing framework in a one-on-one, country-to-country approach.

b. Encouraging Infrastructure Development

Another potential path forward is to emphasize the importance of science-infrastructure building and development in developing and least-developed countries. Although this approach will certainly not be easy, there are several benefits that will likely accrue to the country. There is an immense potential for job creation, including at the planning stage, the construction stage, and the actual implementation and research stage. Importantly, this kind of job creation will focus on targeting differing skill sets and different levels of education and experience, so as not only to focus on a targeted minority in terms of education, ability, or training, in a population. Additionally, this kind of infrastructure-building will help these countries become more self-reliant, a factor that can also lead to additional benefits. For example, self-reliance in a pharmaceutical sector (or, at the very least, a demonstrated interest in developing some kind of manufacturing capacities), could attract outside investment from both private and public sources. There is the risk that reliance on compulsory licenses in a particular country will reduce the desires and incentives to innovate:[168] if a developing or least-developed country can receive a pharmaceutical from an exporting member through the completion of a fairly simple application to the TRIPS Council,

---

167. M. Gumbel, *Is Article 31bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 TEMPLE INT'L & COMP. L.J. 161, 172-73 (2008); TRIPS AGREEMENT, *supra* note 1, art. 31*bis*(3).

168. BIRD, *supra* note 118, at 211.

the incentive may be lacking to put in the required work and investment to establish (or even to work toward establishing) its own pharmaceutical sector.

Forcing production, however, could result in an influx of investment by pharmaceutical companies who may see the promise of a burgeoning sector. In a positive-feedback loop, a relatively small input by a country could result in future interest and funding from outside sources to help the production capabilities grow, which could result in a clear path for addressing the challenges related to developing scientific infrastructure. In this way, the proper functioning of Article 31*bis* could actually result in it phasing itself out of relevance.

Regional agreements hold more heft than Article 67 of the TRIPS Agreement, which pertains to "Technical Cooperation,"[169] but this provision could still help in some of the Article 31*bis* fixes. Article 67 talks of "technical and financial cooperation in favor of developing and least-developed country Members" with respect to facilitating and implementing the TRIPS Agreement, and of providing assistance in the preparation of laws and regulations pertaining to the Agreement, as well as "support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, *including the training of personnel*."[170] Developing and least-developed country members could attempt to emphasize this article to solicit help in administering novel IP regimes.[171] This may not aid in countries becoming more innovative, per se, but it will aid in setting the groundwork for the establishment of an IP regime.[172]

Unfortunately, the therapeutic-related concerns may be harder to overcome, especially in light of the technology required to produce various biologics, particularly with regards to patient-specific clinical therapeutics. As an issue apart from Article 31*bis*, it is not immediately clear how non-chemical-based formulations could be appropriately, easily, and irreversibly, labeled without risk of tampering of outside packages or spill over into neighboring markets.[173] Furthermore, it would be somewhat naïve to assume that even vast amounts of assistance would result in developing and least-developed countries establishing a robust and productive enough pharmaceutical sector and regulatory regime to be able to produce these types

169. TRIPS AGREEMENT, *supra* note 1, art. 67.

170. *Id*.

171. This, in turn, could indirectly help these countries develop their own science infrastructures, which, as described above, can carry quite the heavy economic and administrative burdens. Outside countries that see a commitment to a new IP regime may see opportunities for investment and development in the country, and, thus, may perceive an interest to aid in the establishment and construction of a robust, or at least nascent, scientific infrastructure. It is important to acknowledge, however, that this may be a vast oversimplification of the links between an IP regime and a functional scientific capacity. For a more complete treatment of this issue, *see* Eva Harris, *Building Scientific Capacity in Developing Countries*, 5 EMBO REPS. 7 (2004).

172. *See id*.

173. *See* Morrow & Felcone, *supra* note 133.

of therapeutics in the near future. As a result, solutions to this problem likely lie outside of the TRIPS Agreement and public international law.

c. Preventing Drug Sharing and Promoting Drug Compliance

To address efforts at preventing drug sharing and for promoting drug compliance in countries using the Article 31*bis* framework, it is, perhaps, helpful to turn to strategies that have been put in place to prevent drug sharing among HIV/AIDS patients on antiretroviral therapies (ART) in developing and least-developed countries. Although these systems have been implemented primarily in the context of HIV/AIDS treatments and therapeutics, their overall strategies and lessons can be applied more broadly to other diseases and therapeutics. Two possible strategies that may be implemented are multi-month dosing of drugs and ensuring extended clinic operating hours.[174]

Multi-month drug (MMD) dispensing or multi-month scripting (MMS) provides a structure where patients can receive large amounts of their prescription product at each clinic visit, preventing the need for monthly, or even more frequent, visits.[175] Perhaps somewhat counterintuitively, this has been shown to increase adherence and compliance on the part of patients and to decrease sharing of drugs with others.[176] A more in-depth view explains why this is the case: if an individual patient can receive a larger amount of the product at each visit, that patient can spend less time in a clinic (and also fewer time and money resources on each clinic visit) and may be less likely to feel the pressure to obtain part of their dose from another person when theirs runs out. MMD dispensing is recommended as a best practice by The President's Emergency Plan for AIDS Relief (PEPFAR), the primary United States government initiative aimed at global HIV/AIDS maintenance,

174. The possibilities for increasing access to medications while decreasing the incentives to share dosages among communities extends far beyond these two possibilities. These two possibilities are merely meant to illustrate a few ways in which countries on the receiving end of compulsory licensed produced drugs could prevent drug sharing among affected populations. For more information on potential solutions, *see PEPFAR 2020 Country Operational Plan Guidance for All PEPFAR Countries*, PEPFAR, available at https://www.state.gov/wp-content/uploads/2020/01/COP20-Guidance_Final-1-15-2020.pdf. Another possibility for ensuring adherence to antiretroviral medications has been electronic monitoring. There are, of course, implementation issues with regards to electronic monitoring in low-resource areas, and so, this may be a less reliable or attainable goal for countries receiving pharmaceutical products under Article 31*bis*. *See* JoCarol McNabb, David P. Nicolau, Julie A. Stoner & Jack Ross, *Patterns of adherence to antiretroviral medications: the value of electronic monitoring*, 17 AIDS 1763 (2003).

175. *In Ethiopia, A Focus on Multi-Month ART Scripting at Scale Pays Off*, ICAP, Columbia School of Public Health (Apr. 12, 2019), https://cquin.icap.columbia.edu/news/in-ethiopia-a-focus-on-multi-month-art-scripting-at-scale-pays-off/.

176. I.O Faturiyele, et al., *Outcomes of community-based differentiated models of multi-month dispensing of antiretroviral medication among stable HIV-infected patients in Lesotho: a cluster randomized non-inferiority trial protocol*, 18 BMC PUBLIC HEALTH, 1069 (2018).

prevention, and treatment,[177] and it should be considered in compulsorily licensed distributions of therapeutics under Article 31*bis* since this issue has gone largely unaddressed in both the Article and the Annex. Furthermore, if many patients on therapies in similar communities are on the same drug, increasing the amount of the product that any one patient has at any time may, in some sense, saturate the local community "market," which may prevent dosage sharing.[178]

Similarly, extended clinic hours may ensure that visiting a clinic is less of a burden, ensuring that working patients are able to obtain their medications at a time that is convenient for them. Making the *clinic itself* a more convenient and attractive option for a patient obtaining a drug dosage rather than obtaining that dosage from a friend, family member, or member of the community is key in ensuring patient compliance.[179] Increasing clinic availability through extended hours and implementing MMD can increase patient access to clinics and drugs, which may in turn remove, or at least lessen, the incentives to share drugs among members of the community.[180]

d. Data Exclusivity

Concerns pertaining to data exclusivity also appear to pose a unique challenge with an unclear solution. Currently, data exclusivity, and the subsequent period of exclusivity granted to patent holders, lies in stark tension with increasing access to medicines. It is not unreasonable to expect that this data exclusivity may place an additional burden on members that do not have the ability to produce test data pertaining to safety and efficacy of a pharmaceutical product, but who may require regulatory requirements be in place before a drug can be marketed.

A potential solution would be to waive this data exclusivity requirement under very stringent conditions in an Article 31*bis* compulsory licensing agreement. For example, if a country shows that approval is required for marketing, and that it meets particular criteria proving the lack of ability to produce the regulatory data itself, the data could be transferred under seal between the exporting country and importing country as part of the compulsory licensing framework.

With regards to the shortcomings of Article 31*bis*, it is clear that there will be no blanket fix to resolve each component and disparate issue. Rather, efforts at streamlining Article 31*bis* will likely focus on bolstering some provisions (for example waiving data exclusivity as part of the compulsory licensing framework) and emphasizing regional agreements and the

177. *PEPFAR*, *supra* note 174, at 46.

178. The underlying logic proposed here is that with a "saturated market," there will be little incentive to share doses. In other words, every person will have access to the dosages that she will need. As a result, with an increased supply (and availability) from a local clinic will come a decreased demand for sharing and obtaining dosages from others in the community.

179. *See PEPFAR*, *supra* note 174, at 46.

180. *Id.*; *see also,* footnote 178.

economies of scale provision in Article 31*bis*(3). In short, the solution to the shortcomings of Article 31*bis* are going to have to be multifaceted and multidimensional; there simply is not one easy fix.

VI. Lessons and Conclusions

A valuable lesson in amending an agreement like TRIPS is, first and foremost, not to accept something that is not going to work. Considering the colloquial sayings that hindsight is 20/20, and that theory and practice often do not seem to line up, how then, can parties be sure whether a particular provision is actually going to work in practice? In short, how can the TRIPS Council, and the WTO in general, avoid amending agreements with what amount to be little more than incomplete patches to cover up perceived shortcomings?

First, it is essential that developing and least-developed countries are given a clear voice at the table to ensure that their needs and capabilities, along with their *inabilities*, are clearly and effectively articulated. For example, a developed country may not realize what the precise shortcomings may be with respect to a compulsory licensing program, because it may not occur to that member that a particular scientific infrastructure or requirement (e.g., refrigeration or storage facilities) is not available in potential importing member countries.

Next, it may be worthwhile to consider a trial period for any future implementations or amendments, whereby the proposed amendment undergoes a testing phase, after which it can be altered and updated. It is not impossible to surmise that the Article 31*bis* compulsory licensing framework might have been more broadly used had the Rwanda-Canada arrangement been a "dry run," whereby shortcomings and glitches in the system could be addressed before the actual program went into effect as a proposed amendment. It would also be possible to initiate a notice and comment procedure similar to the process used in United States agency rulemaking. In the context of the TRIPS Council or the WTO, a proposed amendment could be released to members, at which point they are able to provide immediate feedback that may result in the redrafting or reconsideration of the contents of the amendment. In short, both the trial period and the notice and comment period would be aimed at better fine tuning the proposed amendment or framework before it is actually put in force.

Finally, it is important to realize that one amendment or framework that does not go as planned should not torpedo the possibility of any future amendments. Lessons can be learned, and new approaches can be taken. As a result, Article 31*bis* should provide some important guidance but should *not* suggest that the Agreement should not be amended or altered in the future as required, or even as desired.

Taken together, the promises and shortcomings of Article 31*bis* teach an important lesson: sometimes there is the impetus present to fix a problem, but a clearer understanding of the proposed solution in practice should be achieved before moving forward. In the end, TRIPS requires *minimum*, not

maximum standards, by member countries. Article 31*bis* can exist as part of a larger picture, but that larger picture will need to take a more aggressive approach in ameliorating access-to-medicine issues. Currently, therapeutics and need for those therapeutics is expanding at a faster pace than a provision like Article 31*bis* can handle; as a result, Article 31*bis* looks to be outpaced, poorly planned, and ineffective and cumbersome in its execution. This, however, does not have to be the case.

Regional agreements among similarly situated, or even differently situated countries, as well as private-public partnerships[181] can help to expand pharmaceutical manufacturing capacities in resource-poor countries and regions. This, of course, should be done with careful planning and execution as to be true aid and not an incursion upon the rights and cultures of those in the importing or resource-poor countries where the development is planned. With appropriate planning, then, the economies of scale provision of Article 31*bis* could potentially be put to good use, potentially bolstered by outside aid.

In summary, Article 31*bis* is the first amendment to the TRIPS Agreement, but it does not mean, even despite its shortcomings, that it has to be the last. As international relationships continue to develop and evolve, new frameworks may be required to mediate these interactions and to adequately provide for intellectual property rights and protections across borders. With an eye to that aim, patent holder rights and public health needs can be carefully balanced and productively managed.

181. Much of the early research that goes into developing pharmaceutical products is university based (or at the very least funded by government mechanisms like the National Science Foundation (NSF) and National Institutes of Health (NIH) in the United States). Universities should not underestimate the influence they may have in encouraging, and even requiring, pharmaceutical companies to better treat developing countries with respect to access to medicines and related licensing negotiations. Universities could help to change the tenor of how pharmaceutical companies view their treatment of developing countries. Universities hold an important bargaining chip: in public-private partnerships between universities (either funded by government money or conducting research funded by government money) and private companies, the basic research performed at the university often serves as the basis of the future clinical development performed by the pharmaceutical company. If universities withhold these data and the willingness to take part in such partnerships unless pharmaceutical companies provide better access to the developed therapeutic in developing and least-developed countries, pharmaceutical companies could begin to change or, at the very least, to take notice of their lost opportunities. *See* Joris J. Heus, Elmar S. de Pauw, Leloux Mirjam, Morpurgo Margherita, Hamblin Michael R & Heger Michal, *Importance of intellectual property generated by biomedical research at universities and academic hospitals*, 3 J. CLINICAL TRANSLATIONAL RES. 250 (2017); *e.g.,* Mario Cervantes, *Academic Patenting: How universities and public research organizations are using their intellectual property to boost research and spur innovative start-ups*, INDUSTRIAL ELECTRONICS TECH. TRANSFER NEWS, https://iettn.ieee-ies.org/universities-public-research-organizations-using-intellectual-property-boost-research-spur-innovative-start-ups/.