

2019

## A Mathematical Solution to the Sine of Madness that is Pharmaceutical Compulsory Licensing Under the TRIPS Agreement and the Doha Declaration

Ashley E. Sperbeck

Follow this and additional works at: <https://scholarship.law.marquette.edu/iplr>



Part of the [Commercial Law Commons](#), [Food and Drug Law Commons](#), [Health Law and Policy Commons](#), [Intellectual Property Law Commons](#), [International Humanitarian Law Commons](#), [International Law Commons](#), [International Trade Law Commons](#), [Medical Jurisprudence Commons](#), and the [Science and Technology Law Commons](#)

---

### Repository Citation

Ashley E. Sperbeck, *A Mathematical Solution to the Sine of Madness that is Pharmaceutical Compulsory Licensing Under the TRIPS Agreement and the Doha Declaration*, 23 Marq. Intellectual Property L. Rev. 21 (2019).

Available at: <https://scholarship.law.marquette.edu/iplr/vol23/iss1/4>

This Article is brought to you for free and open access by the Journals at Marquette Law Scholarly Commons. It has been accepted for inclusion in Marquette Intellectual Property Law Review by an authorized editor of Marquette Law Scholarly Commons. For more information, please contact [megan.obrien@marquette.edu](mailto:megan.obrien@marquette.edu).

# A MATHEMATICAL SOLUTION TO THE SINE OF MADNESS THAT IS PHARMACEUTICAL COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT AND THE DOHA DECLARATION

ASHLEY E. SPERBECK, M.S., M.S., ESQ.\*

INTRODUCTION .....	22
I. INTERNATIONAL COMPULSORY LICENSING - AMBIGUITIES AND DEFICIENCIES .....	27
A. The TRIPS Agreement.....	27
1. Enactment of the TRIPS Agreement .....	27
2. Chasms in the TRIPS Framework .....	28
3. Historical Basis for Compulsory Licensing.....	29
4. Article 31 .....	29
B. The Doha Declaration .....	32
1. Paragraph 5 .....	33
2. Paragraph 6 and the “Paragraph 6 Problem” .....	33
3. Proposed Solutions to the “Paragraph 6 Problem” .....	35
C. Amendment to the TRIPS Agreement - Article 31bis .....	36
II. PROPOSED SOLUTION .....	39
A. Step One: Initial Inquiries into the Surrounding Circumstances.....	41
1. First Inquiry: Analysis of Emergency Situation .....	42
2. Second Inquiry: Developed Status of the State.....	44
3. Third Inquiry: Type of Pharmaceutical Sought .....	44
4. Fourth Inquiry: Ability to Produce Pharmaceuticals In-House .....	45
B. Step Two: Mathematical Solution.....	46
1. Example Analyses .....	48
(a) Tier One State.....	48
(b) Tier Three State.....	49
CONCLUSION.....	51
APPENDIX.....	52
Table 2. List of Emergency Situations, Circumstances of Extreme Urgency, or Public Health Crises.....	52

---

\*JD, Albany Law School; M.S. Organic Chemistry, University of Notre Dame; M.S. Patent Law, University of Notre Dame; United States Patent and Trademark Office (USPTO) Registered Patent Agent.

## INTRODUCTION

States defined by their severe impediments to sustainable development are designated as “least developed countries” (“LDC”) by the United Nations (“UN”)<sup>1</sup> because they exhibit the lowest indicators of socio-economic development.<sup>2</sup> Socio-economic development is measured by a low-income criterion,<sup>3</sup> a human assets index (“HAI”),<sup>4</sup> and an economic vulnerability index (“EVI”).<sup>5</sup> Some of these States include Zambia, Liberia, Madagascar, Nepal, and the Republic of Tanzania. Based on these socio-economic factors, the LDCs are often powerless to provide medical assistance to their ailing citizens.<sup>6</sup> International patent agreements, which generally support private enterprises, coupled with a lack of manufacturing capabilities to produce pharmaceuticals within the LDC itself further exacerbates this problem.<sup>7</sup> As such, it is not surprising that more than half of all deaths in low-income countries in 2016 were caused by preventable and treatable conditions, such as communicable diseases, maternal causes, and nutritional deficiencies.<sup>8</sup>

While the estimated number of individuals between the ages of zero and forty-nine suffering from HIV/AIDS in the world was 33.2 million by the end of 2007, approximately one-third of those individuals are estimated to live in

1. *Least Developed Countries (LDCS)*, UN: DEV. POL’Y & ANALYSIS DIV., <https://www.un.org/development/desa/dpad/least-developed-country-category.html> [<https://perma.cc/NS79-PHHK>] (last visited Sept. 20, 2018).

2. *About LDCs*, UN-OHRLLS, <http://unohrlls.org/about-ldcs/> [<https://perma.cc/TA5K-6E2E>] (last visited Sept. 20, 2018).

3. *LDC Identification Criteria & Indicators*, UN DEV. POL’Y & ANALYSIS DIV., <https://www.un.org/development/desa/dpad/least-developed-country-category/ldc-criteria.html> [<https://perma.cc/ZPE3-VPVY>] (last visited Sept. 20, 2018) (describing that the low-income criterion is based on a three-year average estimate of gross national income (“GNI”) per capita of \$1,025 for 2018).

4. *See id.* (describing that the HAI is based on indicators of (a) malnourishment, (b) childhood morality rate, (c) maternal mortality rate, (d) secondary school enrolment ratio, and (e) adult literacy rate).

5. *See id.* (describing that the EVI is based on indicators of (a) population size; (b) remoteness, (c) merchandise export concentration, (d) share of agriculture, forestry and fisheries, (e) share of population in low elevated coastal zones, (f) instability of exports of goods and services, (g) victims of natural disasters, and (h) instability of agricultural production).

6. *See* John O. Mugabe, *Health Innovation Systems in Developing Countries Strategies for Building Scientific and Technological Capacities*, COMMISSION ON INTELL. PROP., INNOVATION AND THE PUB. HEALTH WORLD HEALTH ORG. 5 (2005).

7. *See* Zosia Kmietowicz, *Patent Laws Are Keeping Poor Countries in Poverty*, 325 *BMJ* 562, 562 (2002). *See also* Mugabe, *supra* note 6, at 7.

8. *See The Top 10 Causes of Death*, WHO (2018), <http://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death> [<https://perma.cc/M9NW-RA4J>] (last visited Sept. 20, 2018).

LDCs.<sup>9</sup> Furthermore, even though LDCs comprise approximately 80% of the world's population, these States represent approximately 20% of global pharmaceutical consumption.<sup>10</sup> Access to affordable medications could grossly reduce the proportion of the LDC populations hit hardest by these preventable and treatable conditions.<sup>11</sup>

A beautiful contradiction surrounds accessibility of these medications: the innovative vehicle used to create these pharmaceuticals is the very means that limits access to them. That is, promotion of innovation occurs by allowing a once-patented technology to enter the public domain and be openly used<sup>12</sup> but at the cost of granting a patent owner a limited duration monopoly<sup>13</sup> to exclude others from, “making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a set time period.<sup>14</sup> When this rationale is expanded to the international level, humanitarian issues emerge.

In an attempt to remedy the humanitarian concerns posed by patent enforcement in the international sphere, the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”) was negotiated and established in 1995 as the “most comprehensive multilateral agreement on

9. *Immunization, Vaccines and Biologicals: HIV / AIDS*, WHO, <http://www.who.int/immunization/topics/hiv/en/index1.html> [<https://perma.cc/EKR3-TV9U>] (last visited Sept. 20, 2018). See also, *Least Developed Countries*, UNICEF, [https://www.unicef.org/sowc06/pdfs/regional\\_stat\\_sum\\_s21\\_ldc.pdf](https://www.unicef.org/sowc06/pdfs/regional_stat_sum_s21_ldc.pdf) [<https://perma.cc/5FEW-LX9B>] (last visited Sept. 20, 2018).

10. *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, MÉDECINS SANS FRONTIÈRES ACCESS TO ESSENTIAL MED. CAMPAIGN AND THE DRUGS FOR NEGLECTED DISEASES WORKING GROUP, 1, 8 (2001). See also *Fatal Imbalance. The Crisis in Research and Development for Drugs for Neglected Diseases*, THE ACCESS CAMPAIGN, <https://www.msfacecess.org/content/fatal-imbalance-crisis-research-and-development-drugs-neglected-diseases> [<https://perma.cc/5SED-EZF2>] (last visited Sept. 20, 2018).

11. *Cut the Cost – Patent Injustice: How World Trade Rules Threaten the Health of Poor People*, OXFAM GB 1, 3 (2001) (explaining that “much of the premature death and disability associated with infectious disease could be avoided, and the health gap closed, if poor people had access to affordable medicines”).

12. U.S. CONST. art. I, § 8, cl. 8 (establishing this clause as the “patent and copyright clause” since it defines the scope of Congress’ power to enact legislation governing copyrights and patents as “promot[ing] the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries”).

13. These statutory guidelines are based on United States patent law. See 35 U.S.C. § 154(a)(2) (2013) (allowing for a twenty year monopoly for a utility patent or a plant patent, which begins on the date the patent application was filed in the United States Patent and Trademark Office (USPTO)); 35 U.S.C. § 173 (2012) (allowing for a fifteen year monopoly from the date of grant of a U.S. design patent application filed on or after May 13, 2015, and allowing for a fourteen year monopoly from the date of grant of a U.S. design patent application filed prior to May 13, 2015).

14. 35 U.S.C. § 154(a)(1) (2013) (basing this statutory guideline on United States patent law).

intellectual property” to date.<sup>15</sup> The TRIPS Agreement specifies a minimum set of substantive standards for procedural regulation of intellectual property between World Trade Organization (“WTO”) Member States,<sup>16</sup> which allows for protection of inventions in all technological fields upon a finding that the inventions meet the minimal criteria for patentability.<sup>17</sup>

As a means to alleviate the suffering of those Members facing a public health crisis, compulsory licensing language was codified in Article 31 of the TRIPS Agreement.<sup>18</sup> Compulsory licensing enables WTO Members to use a patented technology by third parties without authorization from the patent holder,<sup>19</sup> thus decreasing the LDC’s pharmaceutical drought by increasing its pharmaceutical accessibility.<sup>20</sup> However, Article 31(f) of the TRIPS Agreement restricts the availability of export drugs made under compulsory licenses causing problems for LDCs that lack domestic manufacturing capabilities but desire to import generic copies of pharmaceuticals manufactured in another country.<sup>21</sup>

While these public health concerns were placed on the agenda for the WTO’s Third Ministerial Conference held in Seattle, Washington, in 1999,<sup>22</sup>

15. *Overview: the TRIPS Agreement*, WTO, [https://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) [https://perma.cc/Z58N-SW6Y] (last visited Sept. 20, 2018).

16. ANTHONY TAUBMAN, *A PRACTICAL GUIDE TO WORKING WITH TRIPS* 110 (Oxford University Press 2011).

17. *Overview: the TRIPS Agreement*, *supra* note 17, at 8. *See generally* TRIPS: 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 (1994) (*hereinafter* TRIPS Agreement).

18. *See generally id.* at art. 31.

19. *See id.* at art. 31 ¶ 1. *See also Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Expectations*, WTO (2018), [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm) [https://perma.cc/D6KZ-7FH3] (last visited Sept. 20, 2018) (stating that this exemption can only be exercised subsequent meeting the following criteria: (1) showing an effort was made to obtain a voluntary license from the patent holder on reasonable commercial conditions and (2) paying remuneration to the patent holder, taking into account the economic value of the license, in exchange for use of the patented technology, where the decisions are subject to judicial or other independent review by a higher authority).

20. *See* Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An Analysis of Arguments*, 3 INT’L J. OF SOC. SCI. AND HUMAN. 254, 255 (2013).

21. *See* Brin Anderson, *Better Access to Medicines: Why Countries are Getting “Tripped” Up and Not Ratifying Article 31-bis*, 1 CASE W. RES. J.L. TECH. & INTERNET 165, 171 (2010).

22. *The Third WTO Ministerial Conference*, WTO, [https://www.wto.org/english/thewto\\_e/minist\\_e/min99\\_e/min99\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min99_e/min99_e.htm) [https://perma.cc/CQX7-L8CX] (last visited Sept. 20, 2018). *See, also Ministerial Conferences*, WTO, [https://www.wto.org/english/thewto\\_e/minist\\_e/minist\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/minist_e.htm) [https://perma.cc/Y4N6-JJZW] (last visited Sept. 20, 2018) (identifying the Ministerial Conference

partial resolution of these health issues did not occur until the WTO's Fourth Ministerial Conference held on November 14, 2001, in Doha, Qatar.<sup>23</sup> During the WTO's Fourth Ministerial Conference, WTO Members adopted a Declaration on TRIPS and Public Health ("Doha Declaration"),<sup>24</sup> seen by many, including James Love of the Consumer Project on Technology, as "the strongest and most important international statement yet on the need to refashion national patent laws to protect public health interests."<sup>25</sup> Recognizing the gravity of the public health issues plaguing the international sphere,<sup>26</sup> the Doha Declaration clarified some textual ambiguities of the TRIPS Agreement and affirmed both the inherent flexibility of the TRIPS Agreement and the right of Member States to take precautionary measures to protect public health.<sup>27</sup>

Despite these strides, the Doha Declaration did not adequately respond to the "Article 31(f) Problem" because it failed to provide a viable solution that would increase the availability of compulsory licensing for LDCs suffering from a public health crisis that lacked the ability to manufacture pharmaceuticals in-house.<sup>28</sup> As an attempt to address this issue, on December 6, 2005, an Amendment to the TRIPS Agreement, which introduced Article

as the highest decision-making body of the WTO who meets approximately every two years and makes decisions on all matters under multilateral trade agreements).

23. *The Fourth WTO Ministerial Conference*, WTO, [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/min01\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm) [<https://perma.cc/C53X/NCUP>] (last visited Sept. 20, 2018).

24. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) (*hereinafter* Doha Declaration). *See also The Doha Declaration Explained*, WTO, [https://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm](https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm) [<https://perma.cc/GE7Z-9LFM>] (last visited Sept. 20, 2018).; *The Doha Declaration on the TRIPS Agreement and Public Health*, WHO, [http://www.who.int/medicines/areas/policy/doha\\_declaration/en/](http://www.who.int/medicines/areas/policy/doha_declaration/en/) [<https://perma.cc/6KD7-GST9>] (last visited Sept. 20, 2018).

25. *Views on the Draft Declaration on the TRIPS Agreement and Public Health*, CONSUMER PROJ. ON TECH. (Nov. 13, 2001), <http://www.cptech.org/ip/wto/doha/ngos11132001.html> [<https://perma.cc/V9F8-C4NZ>] (last visited Sept. 20, 2018).

26. *Doha Declaration*, *supra* note 24, ¶ 1 (explaining the recognition of "the gravity of the public health problems afflicting many developing and least developed countries").

27. *Id.* ¶ 4 ("affirm[ing] that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose").

28. Markus Nolf, *Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health and the Decision of the WTO Regarding Its Implementation: An "Expeditious Solution"?*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 291, 293 (2004).

31*bis*, was proposed.<sup>29</sup> It was not until January 23, 2017, that the Amendment was ratified by the two-thirds threshold of WTO Members needed to achieve formal approval.<sup>30</sup>

Introduction of Article 31*bis*<sup>31</sup> into the TRIPS Agreement made permanent the waiver that had been in force since 2003 to empower LDCs facing public health crises or national emergencies and lacking pharmaceutical manufacturing facilities to seek generic pharmaceuticals from other countries under a compulsory licensing agreement.<sup>32</sup> However, a fog surrounded these concessions with regards to the remuneration costs bore by the LDC to the State exporting the generic pharmaceutical under a compulsory license.<sup>33</sup>

A viable economic solution is necessary to address the shortcomings, textual ambiguities, and deficiencies engulfing international patent protection, leading to the inability of LDCs facing public health crises or national emergencies and lacking pharmaceutical manufacturing facilities to obtain generic pharmaceuticals. This Note poses a solution to this problem via another Amendment to the TRIPS Agreement and the Doha Declaration, which provides a mathematical framework to determine when and under what circumstances a compulsory license should be granted. Furthermore, this Note contemplates establishment of a WTO subcommittee to oversee this proposed solution and to ensure compliance with this Amendment. This concrete solution will drastically improve access to pharmaceuticals for the LDC's in dire need of them.

---

29. World Trade Organization, Amendment of the TRIPS Agreement, Decision of 6 December 2005, WT/L/641 (Dec. 8, 2005) (*hereinafter* Amendment of the TRIPS Agreement). *See also* Amendment of the TRIPS Agreement, WTO, [https://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) [https://perma.cc/MJZ8-E5MW] (last visited Sept. 20, 2018).

30. World Trade Organization, Amendment of the TRIPS Agreement – Sixth Extension of the Period for the Acceptance by Members of the Protocol amending the TRIPS Agreement, WT/L/1024 (Nov. 30, 2017). *See also* WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines, WTO (Jan. 23, 2017), [https://www.wto.org/english/news\\_e/news17\\_e/trip\\_23jan17\\_e.htm](https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm) [https://perma.cc/3GAJ-XCWQ] (last visited Sept. 20, 2018).

31. Amendment of the TRIPS Agreement, *supra* note 29, at Annex to the Protocol Amending the TRIPS Agreement (*hereinafter* Article 31*bis*). *See also* Amendment of the TRIPS Agreement, WTO (Dec. 8, 2005), [https://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm) [https://perma.cc/AZN8-H49S] (last visited Sept. 20, 2018).

32. WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines, *supra* note 30.

33. *See* Maura Nuno, *A Fair Return Approach to Pharmaceutical Compulsory Licensing*, 48 CASE W. RES. J. INT'L L. 395, 399 (2016).

## I. INTERNATIONAL COMPULSORY LICENSING - AMBIGUITIES AND DEFICIENCIES

### A. The TRIPS Agreement

#### 1. Enactment of the TRIPS Agreement

On January 1, 1995, not only did the WTO commence as the largest international economic organization in the world<sup>34</sup> under the Marrakesh Agreement,<sup>35</sup> but the TRIPS Agreement was established with the aim of, “protect[ing] and enforce[ing] [] intellectual property rights[,] [while] [] promot[ing] [] technological innovation and [] the transfer and dissemination of technology.”<sup>36</sup> Derived from existing intellectual property conventions, such as the Berne Convention for the Protection of Literary and Artistic Works adopted in 1886,<sup>37</sup> the TRIPS Agreement provides a similar framework to that guiding the U.S. patent law system.<sup>38</sup> For example, the TRIPS Agreement provides the patent owner a right to exclude other “parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product”<sup>39</sup> for a term of twenty years from the filing date of the patent application.<sup>40</sup> However, despite these substantive intellectual property protections, LDCs objected to the TRIPS

34. Anne O. Krueger, *International Economic Organizations, Developing Country Reforms, and Trade*, THE NAT’L BUREAU OF ECON. RES., <http://www.nber.org/reporter/winter00/krueger.html> [https://perma.cc/87ZL-8BY7] (last visited Sept. 22, 2018); *The GATT years: from Havana to Marrakesh*, WTO, [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact4\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm) [https://perma.cc/R7KG-JWT5] (last visited Sept. 22, 2018); *What is the World Trade Organization?*, WTO, [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact1\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm) [https://perma.cc/9VE7-U6B6] (last visited Sept. 22, 2018).

35. Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 (*hereinafter* Marrakesh Agreement). *See also Marrakesh Declaration of 15 April 1994*, WTO (2018), [https://www.wto.org/english/docs\\_e/legal\\_e/marrakesh\\_decl\\_e.htm](https://www.wto.org/english/docs_e/legal_e/marrakesh_decl_e.htm) [https://perma.cc/4H2S-VQ6Z] (explaining that the Marrakesh Agreement replaced the GATT agreement).

36. *TRIPS Agreement*, *supra* note 17, at art. 7.

37. *Berne Convention for the Protection of Literary and Artistic Works*, WIPO, <http://www.wipo.int/treaties/en/ip/berne/> [https://perma.cc/G3HU-EWLB] (last visited Sept. 20, 2018); *Summary of the Berne Convention for the Protection of Literary and Artistic Works (1886)*, WIPO, [http://www.wipo.int/treaties/en/ip/berne/summary\\_berne.html](http://www.wipo.int/treaties/en/ip/berne/summary_berne.html) [https://perma.cc/GC6X-SJPY] (last visited Sept. 20, 2018).

38. Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 25 U. PA. J. INT’L ECON. L. 1079, 1105 (2004).

39. *TRIPS Agreement*, *supra* note 17, at art. 28(1)(a).

40. *Id.* at art. 33. *See also Part II — Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*, WTO, [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04c\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm) (last visited Sept. 20, 2018).

Agreement for fear of more stringent pharmaceutical patent protection and the associated price increases of these pharmaceuticals.<sup>41</sup>

## 2. Chasms in the TRIPS Framework

WTO Member States have exposed chasms in the foundation of the TRIPS Agreement. These chasms include a lack of absoluteness associated with international patent rights, as well as patent right exemptions.<sup>42</sup> The TRIPS Agreement patent right exemptions include (1) a research exemption, which, despite any patent protection, allows research and testing in preparation for regulatory approval (e.g., Food and Drug Administration regulatory approval in the U.S.) prior to the expiration of the patent term;<sup>43</sup> (2) a compulsory licensing exemption;<sup>44</sup> (3) an anti-competitive exemption;<sup>45</sup> (4) an exhaustion of intellectual property rights exemption;<sup>46</sup> and (5) a public health exemption.<sup>47</sup>

41. See *Rich and Poor Countries Divided on Patent Treaty*, WTO (2006), <http://www.who.int/bulletin/volumes/84/5/news20506/en/> [<https://perma.cc/F9VX-VMJ6>] (last visited Sept. 20, 2018).

42. *Pharmaceutical Patents and the TRIPS Agreement*, WTO (2006), [https://www.wto.org/english/tratop\\_e/trips\\_e/pharma\\_ato186\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm) [<https://perma.cc/5DPB-TND8>] (last visited Sept. 22, 2018).

43. *TRIPS Agreement*, *supra* note 17, at art. 30. See also 35 U.S.C. § 271(e)(1) (2003) (codifying this provision in the United States as the “Hatch-Waxman exemption”); *Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Expectations*, *supra* note 19; *Canada Patent Act § 55.2(1) (R.S.C., 1985, c. P-4)*, WIPO (2013), <http://www.wipo.int/wipolex/en/details.jsp?id=8553> [<https://perma.cc/GC22-AG8K>] (last visited Sept. 22, 2018) (codifying this provision as the “Bolar exemption” in Canada); *Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004*, OFFICIAL J. OF THE EU, 34, 39 (2004).

44. *TRIPS Agreement*, *supra* note 17, at art. 31; *Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Expectations*, *supra* note 19 (stating that this exemption can only be exercised subsequent meeting the following criteria: (1) showing an effort was made to obtain a voluntary license from the patent holder on reasonable commercial conditions and (2) paying remuneration to the patent holder, taking into account the economic value of the license, in exchange for use of the patented technology, where the decisions are subject to judicial or other independent review by a higher authority).

45. *Id.* at art. 8(2).

46. *Id.* at art. 6.

47. *Id.* at art. 27(2). “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect . . . including to protect human . . . health . . . provided that such exclusion is not made merely because the exploitation is prohibited by their law,” where this exemption has been interpreted to exclude harmful inventions for public health interests (i.e., smoking pipes), rather than creating a general public health exception. *Id.*

### 3. Historical Basis for Compulsory Licensing

Arising in the nineteenth century,<sup>48</sup> compulsory licensing has been historically utilized, “[(1)] to deal with a situation in which a patent owner is unwilling to work his invention; [(2)] to satisfy an unmet demand from the public for a patented product; [and (3)] to introduce price-reducing competition for important but expensive products [(e.g. some drugs)].”<sup>49</sup> It is not surprising that the compulsory licensing provisions have become commonplace, as justifications for issuing the licenses include protecting local industry; increasing access to pharmaceuticals and medicinal products; and reducing an issuing country’s dependence on imports.<sup>50</sup> Though it has been estimated that, “[a]bout one hundred countries [have] recogni[z]ed some form of non-voluntary licensing in their patent laws by the early 1990s,”<sup>51</sup> the grant of compulsory licenses has been rare in parts of the developed world.<sup>52</sup> Under the TRIPS Agreement, however, the purposes and requirements for issuing a compulsory license are targeted at allowing States to produce lower cost generic pharmaceuticals.<sup>53</sup>

### 4. Article 31

Article 31 of the TRIPS Agreement allows a compulsory license to be granted on a case-by-case basis, which may be useful in the production of lower cost generic pharmaceuticals.<sup>54</sup> As described *supra*, “a compulsory license is a license granted to a third-party by a government,” which allows

---

48. Graham Dutfield, *Delivering Drugs to the Poor: Will the TRIPS Amendment Help?*, 34 AM. J. L. & MED. 107, 111 (2008).

49. GRAHAM DUTFIELD & UMA SUTHERSANEN, *GLOBAL INTELLECTUAL PROPERTY LAW* 126 (Edward Elgar, 2008).

50. Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1307–08 (2002).

51. Jerome H. Reichman & Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*, UNCTAD-ICTSD PROJECT ON IPRS AND SUSTAINABLE DEV., 1, 1 (2003).

52. Dutfield, *supra* note 48, at 112. See also Ellen FM’t Hoen et al., *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 WORLD HEALTH ORGANIZATION BULLETIN 185, 187 (2018).

53. See Toni Johnson, *The Debate Over Generic-Drug Trade*, COUNCIL ON FOREIGN RELATIONS (2011), <https://www.cfr.org/background/debate-over-generic-drug-trade> [<https://perma.cc/D3UN-YN7W>] (last visited Sept. 22, 2018).

54. Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 252 (2009).

for use of the patented technology without the consultation of the patent holder and in exchange for royalties paid to the patent holder.<sup>55</sup>

Of greatest weight to this licensing framework includes both Section (b) and Section (f) of Article 31 of the TRIPS Agreement.<sup>56</sup> For example, Article 31, Section (b) of the TRIPS Agreement requires demonstration, by a Member, of prior (unsuccessful) negotiations with the patent owner for a voluntary license.<sup>57</sup> As the public interest associated with accessing patented medications outweighs the private interest associated with a patent holder exerting their protected rights,<sup>58</sup> this provision is waived in the case of public non-commercial use or a “national emergency or other circumstances of extreme urgency.”<sup>59</sup> Despite the conditions, issuance of a compulsory license requires “adequate” remuneration paid to the patent holder to account for the economic value of the license.<sup>60</sup> The definition of “adequate” varies based on the given circumstances, but it is typically less than the potential royalties freely negotiated.<sup>61</sup>

However, the most ominous condition, found in Article 31(f) of the TRIPS Agreement, requires that any compulsory use needs to “be authorized predominantly for the supply of the domestic market of the Member authorizing such use,”<sup>62</sup> which restricts products produced under a compulsory license and intended for the licensing Member’s domestic market.<sup>63</sup> Therefore, a State seeking to invoke a compulsory license *must* also have the infrastructure necessary to manufacture the sought pharmaceutical.<sup>64</sup> As such, Article 31(f) creates problems for LDCs lacking domestic

---

55. Vishal Gupta, *Note: A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals under the TRIPS Agreement*, 13 CARDOZO J. INT’L & COMP. L. 631, 639 (2005).

56. Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 221–22 (2004).

57. *TRIPS Agreement*, *supra* note 17, at art. 31(b).

58. Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT’L ECON. L. 73, 77 (2004).

59. *TRIPS Agreement*, *supra* note 17, at art. 31(b).

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

61. See James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, WORLD HEALTH ORGANIZATION TECHNICAL COOPERATION FOR ESSENTIAL DRUGS AND TRADITIONAL MEDICINE 6 (2005).

62. *TRIPS Agreement*, *supra* note 17, at art. 31(f).

63. *Id.* See also Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT’L ECON. L. 469, 499 (2002) (explaining that more than 50% of that which is manufactured is for the domestic market).

64. Dina Halajian, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access to Medicine Program*, 38 BROOK. J. INT’L L. 1191, 1200 (2013).

manufacturing capabilities and suffering from a pharmaceutical drought.<sup>65</sup> Further, Article 31(f) fails to account for States that may need to import or export products in order to be able to use compulsory licensing at all.<sup>66</sup>

Several States have utilized the framework provided by Article 31. For example, in response to the Anthrax scare in 2001, the U.S. government threatened issuance of a compulsory license for the anthrax medication, ciprofloxacin, unless the patent holder, Bayer, drastically reduced their prices.<sup>67</sup> Bayer struck a deal with the U.S. government to supply the medication at a reduced cost.<sup>68</sup> Further, in January of 2007, Thailand utilized this framework to issue a license for a generic HIV/AIDS drug, efavirenz, produced by Merck.<sup>69</sup> Also, in March of 2012, India granted its first compulsory license to an Indian generic drug manufacturer, Natco Pharma Ltd, for Sorafenib tosylate, a cancer drug patented by Bayer.<sup>70</sup>

Other States, particularly in the Eastern Mediterranean Region, have veered away from the compulsory licensing framework and have attempted to patch the voids of the TRIPS Agreement by engaging in bilateral agreements, named TRIPS PLUS agreements, to adopt higher standards of protection than that offered by TRIPS.<sup>71</sup> The U.S. has additionally sought to utilize these heightened agreements domestically for issues relating to anti-competitive matters.<sup>72</sup> However, these TRIPS PLUS agreements represent a shift from the policy underlying the TRIPS Agreement, which provided that there are no restrictions on when a compulsory license may be issued subsequent a set of

---

65. Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT'L L.J. 101, 110 (2003).

66. *See id.*

67. Reichman, *supra* note 54, at 250.

68. Jill Carroll & Ron Winslow, *Bayer to Slash by Nearly Half Price U.S. Pays for Anthrax Drug*, THE WALL STREET JOURNAL (Oct. 25, 2001), <https://www.wsj.com/articles/SB1003966074330899280> [<https://perma.cc/8J9U-K2DX>] (last visited Sept. 22, 2018).

69. *Thailand Issues Compulsory Licence For Patented AIDS Drug*, INT'L CTR. FOR TRADE AND SUSTAINABLE DEV. (2006), <https://www.ictsd.org/bridges-news/bridges/news/thailand-issues-compulsory-licence-for-patented-aids-drug> [<https://perma.cc/V2B7-LYH2>] (last visited Sept. 22, 2018).

70. Maricel Estavillo, *India Grants First Compulsory Licence, For Bayer Cancer Drug*, INTELLECTUAL PROP. WATCH (Dec. 3, 2012), <https://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/> [<https://perma.cc/FE5B-2K8V>] (last visited Sept. 22, 2018).

71. Mohammed K. El Said, *A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region*, WHO AND INT'L CTR. FOR TRADE AND SUSTAINABLE DEV., 15 (2010).

72. Rohit Malpani & Mohga Karmal-Yanni, *Patents Versus Patients: Five Years After the Doha Declaration*, 95 OXFAM INT'L 13 (Nov. 14, 2006).

conditions being met.<sup>73</sup> Furthermore, these added protections have failed to fully remedy the outstanding problems because many terms are ambiguous and left open to interpretation, such as what constitutes a “national emergency” or a “circumstance of extreme urgency” under Article 31(b) and the definition of “adequate” with regards to remuneration under Article 31(h).<sup>74</sup>

### B. The Doha Declaration

Drafted in an attempt to quash “divergent interpretations” on the text and purpose of the TRIPS Agreement, the Doha Declaration responded to LDC’s concerns regarding promoting access to affordable medications and further sought to address the associated pricing concerns.<sup>75</sup> The first three paragraphs of the Doha Declaration acknowledge a need to balance public welfare interests with the needs of the patent holders associated with the sought pharmaceuticals.<sup>76</sup> Where Paragraph 2 of the Doha Declaration acknowledges the striking cost of these medications, making them unaffordable to LDCs,<sup>77</sup> Paragraph 3 of the Doha Declaration acknowledges the need for patent protection for the development of new pharmaceuticals.<sup>78</sup>

As a strong affirmative statement, Paragraph 4 of the Doha Declaration echoes principles that the WHO has advocated by re-affirming the right of WTO Members to use the safeguard provisions of the TRIPS Agreement to protect public health.<sup>79</sup> Paragraph 4 specifies, “[t]he TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. . . . [W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. . . .”<sup>80</sup> and emphasizes the ability of WTO Members to enact exceptions to patent protection for the purpose of increasing access to pharmaceuticals.<sup>81</sup>

73. Mike Gumbel, *Is Article 31bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 TEMP. INT’L & COMP. L.J. 161, 172 (2008).

74. Arun J. Mohan, *Worldwide Accountability: The WTO’s Failure to Create an Infrastructure that Delivers Pharmaceutical Drugs to Developing Countries*, 29 EMORY INT’L L. REV. 2001, 2010 (2015).

75. See James T. Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties*, 15 Harv. J.L. Tech. 291, 292 (2002).

76. Mercurio, *supra* note 56, at 226.

77. *Doha Declaration*, *supra* note 24, at ¶ 2.

78. *Id.* ¶ 3.

79. *Id.* ¶ 4.

80. *Id.*

81. Mercurio, *supra* note 56, at 226.

## 1. Paragraph 5

Additionally, Paragraph 5 of the Doha Declaration<sup>82</sup> defines the TRIPS Amendment flexibilities as: (1) “[e]ach Member ha[ving] the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”<sup>83</sup> and (2) “[e]ach Member ha[ving] the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”<sup>84</sup> The appeal and facial freedom provided by Paragraph 5 is especially troubling, as it results in exploitation and importation of non-life saving pharmaceuticals.<sup>85</sup> Moreover, the textual and interpretive ambiguities lead to inconsistent enactment and use of compulsory licensing.<sup>86</sup>

## 2. Paragraph 6 and the “Paragraph 6 Problem”

In response to Article 31(f) of the TRIPS Agreement,<sup>87</sup> Paragraph 6 of the Doha Declaration attempted to solve the acknowledged problem regarding use of compulsory licensing by LDCs suffering from a public health crisis and having little to no manufacturing ability to produce the pharmaceuticals in-house.<sup>88</sup> Paragraph 6 of the Doha Declaration acknowledges that “WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement,” and instructed “the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”<sup>89</sup>

82. *Doha Declaration*, *supra* note 24, at ¶ 5.

83. *Id.* ¶ 5(b).

84. *Id.* ¶ 5(c).

85. See Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT’L BUS. & L. 137, 151 (2009).

86. *See id.* at 154.

87. *TRIPS Agreement*, *supra* note 17, at art. 31(f) (which has been interpreted to mean that most of the products produced under a compulsory license must be intended for the licensing Member’s domestic market).

88. *Current Issues in Intellectual Property*, WTO, [https://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_issues\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/trips_issues_e.htm) [<https://perma.cc/JZ6U-9F9M>] (last updated Dec. 7, 2011).

89. *Doha Declaration*, *supra* note 24, at ¶ 6.

In 2004, Paragraph 6 was implemented in practice.<sup>90</sup> In the absence of any specific requesting importation State, the international humanitarian organization, “Médecins Sans Frontières (MSF), approached a Canadian company to produce a triple combination antiretroviral” (“ARV”) pharmaceutical, including: zidovudine, lamivudine, and nevirapine, to combat HIV/AIDS.<sup>91</sup> In July of 2007, the Canadian company attempted to secure, without success, voluntary licenses from three patent holders in accordance with Member State requirements under Article 31 (b) of the TRIPS Agreement.<sup>92</sup>

Though not obliged to notify the WTO of an intention to use the system, in 2007, the LDC of Rwanda notified the WTO of its intention to import 260,000 packs of the combination ARV pharmaceutical.<sup>93</sup> In September of 2007, the Canadian company successfully obtained a compulsory license to export 15,600,000 tablets (the equivalent of 260,000 packs) over a two-year period.<sup>94</sup> The Canadian government then notified the WTO that it was using the system as an exporting country.<sup>95</sup> Though the Canadian company had offered its ARV pharmaceutical at the price of \$ 0.39 USD per tablet, there were other Indian manufacturers that could supply the product at a reduced cost.<sup>96</sup> However, if Rwanda had received the ARV pharmaceuticals from any of these Indian manufacturers, Rwanda would not have needed to rely on implementation of the Paragraph 6 framework because the medication was not patented in India.<sup>97</sup> The Canadian company voluntarily waived the royalty offered for use of the patent,<sup>98</sup> and in the time span of the compulsory license, approximately 14,413,000 tablets of the ARV pharmaceutical were shipped to Rwanda.<sup>99</sup>

However, successful tales like the one in Rwanda are few and far between. Since the compulsory license needs to be used “predominantly for the supply of the domestic market” of the Member State, States lacking manufacturing infrastructure cannot utilize this provision for the importation

---

90. *Fact Sheet: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, WTO, [https://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_e.htm) [<https://perma.cc/N5N4-SBDB>] (last visited Sept. 8, 2018).

91. *Id.*

92. *See id.*

93. *See id.*

94. *See id.*

95. *See id.*

96. *See id.*

97. *See id.*

98. *See id.*

99. *See id.*

of pharmaceuticals.<sup>100</sup> Despite the optimistic outlook, what has come to be known as the “Paragraph 6 Problem” arose from these conditions that a Member State must meet to issue a compulsory license under Article 31(f) of the TRIPS Agreement.<sup>101</sup> Ultimately affecting States with little or no manufacturing capabilities, the “Paragraph 6 Problem” can be summarized as follows: LDCs lacking the capability or capacity to manufacture drugs domestically cannot reap the benefits of international pharmaceutical compulsory licensing.<sup>102</sup>

### 3. Proposed Solutions to the “Paragraph 6 Problem”

Various solutions have been proposed to combat this problem. From amending Article 31(f) of the TRIPS Agreement (which would be time-consuming), to creating a waiver system with regards to the requirements of Article 31(f) of the TRIPS Agreement (which would be beneficial but would require an individual case-by-case analysis and consistent supervision to prevent abuse), none of these solutions proved fruitful.<sup>103</sup> Further posed solutions have included introducing a dispute-settlement solution, which, again, prove theoretically applicable.<sup>104</sup>

A further proffered solution included creating a new exception under Article 30 of the TRIPS Agreement, posed by some LDCs with a desire to read Paragraph 6 in light of the entire context of the Doha Declaration and the TRIPS Agreement.<sup>105</sup> Numerous developed countries have argued against this proposal, emphasizing that an exception would encourage patent infringement and prejudice rights of those consenting to the TRIPS Agreement.<sup>106</sup> Essentially, this exception option would invoke a conflict with Article 21.7 of

---

100. Mercurio, *supra* note 56, at 213.

101. Jennifer May Rogers, *The TRIPS Council's Solution to the Paragraph 6 Problem: Toward Compulsory Licensing Viability for Developing Countries*, 13 MINN. J. GLOBAL TRADE 443, 450 (2004).

102. See Alexandra Nightingale, *WTO 'Paragraph 6' System For Affordable Medicine: Time for Change?*, INTELLECTUAL PROP. WATCH (Nov. 14, 2016), <http://www.ip-watch.org/2016/11/14/wto-paragraph-6-system-affordable-medicines-time-change/> [<https://perma.cc/GJ6X-VTAG>].

103. See Rogers, *supra* note 101, at 453–54.

104. See *id.* at 455–56.

105. *Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health: Submission by Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela*, CONSUMER PROJECT ON TECH. (Mar. 22, 2004), <http://www.cptech.org/ip/wto/southsubmission.html> [<https://perma.cc/W76Y-QSFS>]; *Submission by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela*, CONSUMER PROJECT ON TECH. (Sep. 18, 2001), <http://www.cptech.org/ip/wto/africagroup09182001.html> [<https://perma.cc/49YU-JNYV>].

106. Mercurio, *supra* note 56, at 232–33.

the TRIPS Agreement, which requires “patents [to] be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology[,] and whether products are imported or locally produced”<sup>107</sup> if it is invoked with respect to a single technology, such as pharmaceuticals.<sup>108</sup>

*C. Amendment to the TRIPS Agreement - Article 31bis*

Despite the call for a solution prior to the end of 2002,<sup>109</sup> a resolution to the “Paragraph 6 Problem” occurred on August 30, 2003,<sup>110</sup> prior to the WTO’s Fifth Ministerial Conference in Cancún, Mexico on September 10, 2003.<sup>111</sup> The resolution implemented a collective and interim system where the requirements of Article 31(f) of the TRIPS Agreement were waived.<sup>112</sup>

Then, on December 6, 2005, the WTO General Council adopted the Protocol Amending the TRIPS Agreement, which was the first multi-lateral treaty amendment agreed to by WTO Members since the formation of the WTO.<sup>113</sup> On January 23, 2017, the Amendment to the TRIPS Agreement achieved formal approval.<sup>114</sup> The Amendment inserted a second version of Article 31, Article 31*bis*, into the TRIPS Agreement, as well as an Annex and an Appendix to further clarify this Amendment.<sup>115</sup> Not only did introduction of Article 31*bis* formalize Paragraph 6 of the Doha Declaration, but Article 31*bis* made permanent the waiver that had been in force since 2003 to empower LDCs facing public health crises and lacking pharmaceutical manufacturing facilities to seek pharmaceuticals from other countries via compulsory licensing.<sup>116</sup> As such, a major implication of Article 31*bis* included allowing LDCs to issue compulsory licenses to domestic

107. *TRIPS Agreement*, *supra* note 17, at art. 27.1.

108. Mercurio, *supra* note 56, at 233.

109. *Doha Declaration*, *supra* note 24, at ¶ 6.

110. World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540/Corr.1 (Aug. 30, 2003) (*hereinafter* Paragraph 6).

111. *The Fifth WTO Ministerial Conference*, WTO [https://www.wto.org/english/thewto\\_e/minist\\_e/min03\\_e/min03\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min03_e/min03_e.htm) [<https://perma.cc/7Y6B-6A9T>] (last visited Sept. 9, 2018); *What is the Cancún Ministerial Conference?*, WTO, [https://www.wto.org/english/thewto\\_e/minist\\_e/min03\\_e/min03\\_whatiss\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min03_e/min03_whatiss_e.htm) [<https://perma.cc/89UU-29G9>] (last visited Sept. 9, 2018).

112. *Paragraph 6*, *supra* note 110, at ¶ 2.

113. *See Amendment of the TRIPS Agreement*, *supra* note 31.

114. *WTO IP Rules Amended to Ease Poor Countries’ Access to Affordable Medicines*, *supra* note 30.

115. *See generally Amendment of the TRIPS Agreement*, *supra* note 29.

116. *WTO IP Rules Amended to Ease Poor Countries’ Access to Affordable Medicines*, *supra* note 30.

pharmaceutical manufacturers, which allows the domestic manufacturers to export these medications to the LDCs.<sup>117</sup>

Specifying new guidelines for States seeking to issue compulsory licenses, Paragraph 1 of Article 31*bis* explains, “[t]he obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license 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,”<sup>118</sup> where an “eligible importing Member(s)” is defined as (a) a LDC Member having little to no manufacturing capacity or (b) any Member that has submitted an application to the TRIPS Council with the intention of utilizing the Article 31*bis* system as an importing Member.<sup>119</sup> With the application process, the Member must specify: (a) the specific medication sought, (b) the quantity of the medication sought, and (c) the State intended to issue the compulsory license.<sup>120</sup> In response, the “eligible exporting Member(s)” will issue a compulsory license domestically to satisfy the needs for the “eligible importing Member(s).”<sup>121</sup>

On the other hand, the “eligible exporting Member(s)” must negotiate a pricing scheme to remunerate the patent holder.<sup>122</sup> The “eligible exporting Member(s)” must further ensure, in accordance with the generic manufacturer, that the, “products produced under the licence [are] clearly identified as being produced under the system through specific labelling or marking . . . provided that such distinction is feasible and does not have a significant impact on price.”<sup>123</sup> Examples of this “specific labelling or marking” include: (a) an alternative packaging, (b) an alternative shape of the product, and/or (c) an alternative coloring of the product than that utilized by the name-branded pharmaceutical.<sup>124</sup> Additionally, before the shipment begins, the licensee must post, on a website, the quantities being supplied to

117. Gumbel, *supra* note 73, at 162–63.

118. Article 31*bis*, *supra* note 31, at ¶ 1.

119. *Amendment of the TRIPS Agreement*, *supra* note 29, at Annex to the TRIPS Agreement ¶ 1(b). See also, *Annex and Appendix to the TRIPS Agreement*, WTO (2018), [https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_annex\\_e.htm](https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm) [<https://perma.cc/HK9B-6ZEE>]; *Notifications by Importing WTO Members*, WTO (2018), [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_import\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm) [<https://perma.cc/8FA2-QCVA>].

120. *Id.* at Annex to the TRIPS Agreement ¶¶ 2(a)(i), (b)(i), and (c).

121. *Id.* at Annex to the TRIPS Agreement ¶¶ 1(c) and 2(c).

122. Paragraph 6, *supra* note 110, at ¶ 3.

123. *Amendment to the TRIPS Agreement*, *supra* note 29, at Annex to the TRIPS Agreement ¶ 2(b)(ii).

124. See *id.*

each State and the alternative packaging, shape, and/or coloring of the generic pharmaceutical.<sup>125</sup> The “specific labelling or marking” of the generic product is essential to prohibit parallel importation (e.g., to prohibit the generic pharmaceutical from being circulated in the economies of one or more “exporting Member State(s)”).<sup>126</sup>

Despite these enhancements, deficiencies persisted under this modified framework. First, Article 31*bis* failed to restrict the type of pharmaceuticals for which a compulsory license may be granted, which lead to abuse of the system and importation of non-life saving pharmaceuticals.<sup>127</sup> Second, many States (e.g., Australia, Canada, the United States, and Japan) had opted-out of being classified as “eligible importing Member(s).”<sup>128</sup> This is especially troubling since these States are unable to utilize the Article 31*bis* framework if a public health crisis or emergency ensues at a future time.<sup>129</sup> Moreover, the Amendment failed to provide a formula to determine the monetary scope of “adequate remuneration” for the patent holder in exchange for use of the patented technology.<sup>130</sup> Moreover, many States failed to notify the WTO of an intention to utilize this framework due to fears of retaliatory actions or criticism.<sup>131</sup> Furthermore, the Amendment failed to provide enhanced incentives under an economy of scale viewpoint, where, as production of the pharmaceutical product increases, a reduction in the overall cost per pharmaceutical unit would occur, resulting in a lower average cost associated with producing each pharmaceutical unit.<sup>132</sup> These deficiencies make clear the outstanding need for reform of the current international compulsory licensing framework.

---

125. *Id.* at Annex to the TRIPS Agreement ¶¶ 2(b)(ii)-(iii).

126. Gumbel, *supra* note 73, at 170–71.

127. See Aileen M McGill, *Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis Under the DOHA Declaration*, 10 WAKE FOREST INTELL. PROP. L.J. 69, 89 (2009).

128. Gumbel, *supra* note 73, at 171. See also *Amendment to the TRIPS Agreement*, *supra* note 29, at Annex to the TRIPS Agreement, par. 1(b); *Annex and Appendix to the TRIPS Agreement*, *supra* note 119, at n. 3.

129. Gumbel, *supra* note 73, at 171.

130. *Id.*

131. Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 392 (2011).

132. Gumbel, *supra* note 73, at 171. See e.g., *Article 31bis*, *supra* note 31, at par. 3 (assuming all other requirements of Article 31*bis* have been satisfied, the language of paragraph 3 permits developing countries to realize economies of scale if three conditions are met: (1) countries seeking to utilize economies of scale must be a member of a WTO recognized regional trade agreement (“RTA”); (2) at least half of the members of that RTA must be on the United Nations list of least-developed countries; and (3) the country seeking the compulsory license is responsible for importing the medications).

## II. PROPOSED SOLUTION

As a solution to these discussed problems, an Amendment to both the TRIPS Agreement and the Doha Declaration is proposed. The proposed Amendment would provide a framework and mathematical analysis universally applicable to quantitatively determine when a compulsory license should be issued under a given set of circumstances. The proposed solution includes the following three components: (a) initial inquiries regarding the State's current circumstances; (b) a Tier system in which the States are categorized based on (a); and (c) a mathematical formula to determine if a compulsory license should be issued to the State based on both (a) and (b). This proposed solution would define ambiguities present within the international compulsory licensing framework.

Furthermore, despite being tasked to find a solution to the Paragraph 6 Problem by the end of 2002, the TRIPS Council failed to do so for fifteen years until the approval of Article 31*bis*, which still contained deficiencies. As such, despite the support of one author,<sup>133</sup> the TRIPS Council is ill equipped to remedy these outstanding problems. This Note proposes establishment of a WTO subcommittee to oversee and ensure compliance with this proposed solution.

From a practical standpoint, because the TRIPS Amendment was the first ever to a WTO Agreement since the organization was established,<sup>134</sup> this proposed Amendment would have to clear high hurdles to achieve formal approval. Specifically, Member States intending to be bound to this proposed Amendment might express their consent to comply with this proposal in various ways.<sup>135</sup> This expression of consent could occur, for example, by depositing an "instrument of acceptance"<sup>136</sup> with the Depositary Assistant in the WTO Legal Affairs Division within the period of acceptance, which is

---

133. Gupta, *supra* note 55, at 650 (suggesting utilization of the TRIPS Council as an oversight body with expansive control over the issuance of compulsory licenses).

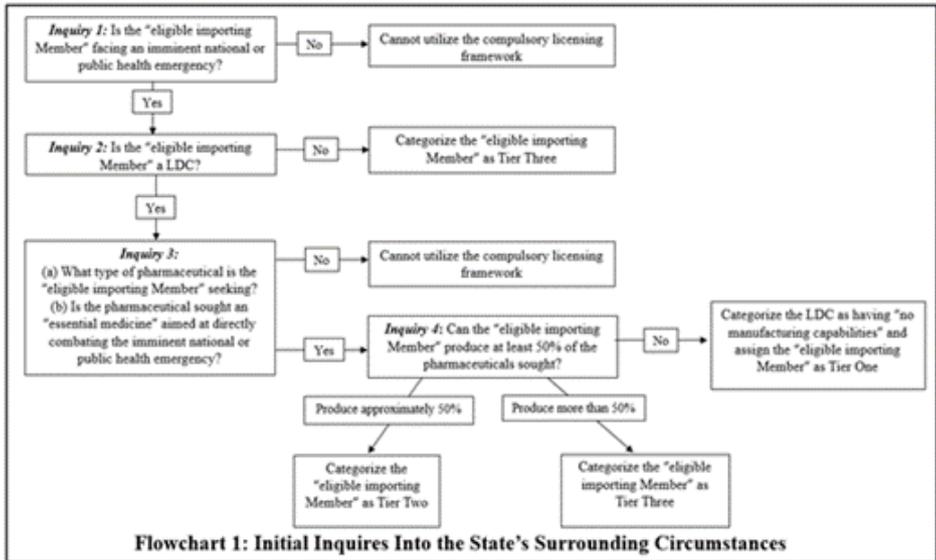
134. William New, *It's Official: TRIPS Health Amendment In Effect, First Ever to a WTO Agreement*, INTELLECTUAL PROP. WATCH (Jan. 23, 2017), <http://www.ip-watch.org/2017/01/23/official-trips-health-amendment-effect-first-ever-wto-agreement/> [<https://perma.cc/64CE-GWPM>].

135. *General Guidance on Officially Accepting WTO Legal Instruments*, WTO., [https://www.wto.org/english/docs\\_e/legal\\_e/depositary\\_guide\\_e.htm](https://www.wto.org/english/docs_e/legal_e/depositary_guide_e.htm) [<https://perma.cc/BM36-W864>] (last visited Sept. 8, 2018).

136. *Id.* It should be appreciated that there is no uniform approach for drafting an "instrument of acceptance" or formalized letter of acceptance, yet it must provide an unambiguous expression to consent to be bound by the agreement.

currently until December 31, 2019; as such, for an instrument of acceptance to be valid, it needs to be deposited by this date.<sup>137</sup>

The “instrument of acceptance” must contain the following: (a) a clear identification of the specific protocol by its full title, (b) an explicit intention by the associated Member State to be bound to it, (c) a date and location of



the acceptance, which is (d) signed, and (e) acknowledges the signor by name and title.<sup>138</sup> The “instrument of acceptance” is typically signed by one of the “Big Three,”<sup>139</sup> but may, alternatively, be signed by another official, provided that the other official has documentation displaying that one of the “Big Three” has authorized him or her to issue and sign the instrument.<sup>140</sup> Furthermore, the Member State may also have a supplementary domestic approval process to ratify the proposed Amendment in the associated Member State.<sup>141</sup>

137. *Id.*; How to Accept the Protocol Amending the TRIPS Agreement, [https://www.wto.org/english/tratop\\_e/trips\\_e/accept\\_e.htm#faqs](https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#faqs) [https://perma.cc/FRB2-TKWP] (last visited Sept. 8, 2018).

138. *General Guidance on Officially Accepting WTO Legal Instruments*, *supra* note 135.

139. *Id.* (identifying the “Big Three” as the Head of State, the Head of Government, and the Minister for Foreign Affairs).

140. *Id.*

141. *Id.*

### A. Step One: Initial Inquiries into the Surrounding Circumstances

The proposed framework is multi-pronged and attempts to remedy any unconscionability by replacing the case-by-case analysis provided by Paragraph 5 of the Doha Declaration<sup>142</sup> with a uniform system aimed at determining whether a compulsory license should be granted under given circumstances. Furthermore, this proposed system removes the following requirements of Article 31(b) of the TRIPS Agreement: (1) requiring a Member wishing to utilize a compulsory licensing framework to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary license, and (2) the waiver system for this provision in the case of a “national emergency or other circumstances of extreme urgency.”<sup>143</sup>

This proposed multi-step framework is depicted in Flowchart 1. The WTO subcommittee would perform an initial inquiry into the surrounding circumstances of the State. Description of these inquiries will be discussed *infra*. Through answers to these pending questions, each State seeking a compulsory license or “eligible importing Member” is placed into a tier. The tier system includes three tiers, depicted in Table 1.<sup>144</sup>

Tier Level	Developed State Status	Public Health Crisis or Emergency Need	Pharmaceutical Need	In-House Manufacturing Capabilities	Amount of Pharmaceuticals that can be produced in-house
Tier One	LDC	High	High	Little to None	0 – 49%
Tier Two	Developing State	High	Medium	Some	~ 50%
Tier Three	Developed State	High	Low	High	51% - 100%

Each tier is associated with a high public health crisis or emergency need, as this instant proposal only contemplates dire public health crises or emergency situations. As LDCs, Tier One States are most dependent on compulsory licensing and have little to no manufacturing abilities to produce

142. *Doha Declaration*, *supra* note 24, at ¶ 5(b) (explaining that “[e]ach Member ha[ving] the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”).

143. *TRIPS Agreement*, *supra* note 17, at art. 31(b).

144. This Tier system is designed to help clarify the meaning of “insufficient manufacturing capacity,” which is not defined in any international agreement or protocol and is furthermore left unanswered by *Gupta*, *supra* note 55, at 648.

pharmaceuticals in-house.<sup>145</sup> As such, States within this tier may receive a compulsory license under identical circumstances that States in Tier Two<sup>146</sup> or Tier Three<sup>147</sup>

would not, since States in Tier Two and Tier Three have additional infrastructure and increased manufacturing capabilities to produce the needed pharmaceutical. The Tier system further removes the obligations and waiver regime under Paragraph 2 of Article 31*bis* for eligible importing Member(s).<sup>148</sup>

### 1. First Inquiry: Analysis of Emergency Situation

The first inquiry of this framework poses the following question: is the “eligible importing Member” facing an imminent national or public health emergency? To remedy the ambiguity Paragraph 5 of the Doha Declaration,<sup>149</sup> which allows each Member State to define these emergency situations,<sup>150</sup> given circumstances will be classified by the WTO subcommittee as an “emergency situation, a circumstance of extreme urgency, or a public health crisis” if the circumstances are predicted to “imminently” affect a portion of the State’s population within a six-month time period. This definition<sup>151</sup> was formalized in light of: (a) the WHO definition of a “public

145. *The World Factbook: Appendix B: International Organizations and Groups*, CIA, <https://www.cia.gov/library/publications/the-world-factbook/appendix/appendix-b.html#D> [<https://perma.cc/UZE8-KJ6L>] (last visited Sept. 12, 2018). See also *List of Least Developed Countries (as of March 2018)*, UN COMM. FOR DEV. POL’Y & ANALYSIS DIV. DEP’T OF ECON. & SOC. AFFAIRS (2018), taken from: [https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc\\_list.pdf](https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf) [<https://perma.cc/H2L4-W6HE>]; *Least-developed Countries*, WTO, [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm) [<https://perma.cc/2VLM-KSXC>] (last visited Sept. 25, 2018).

146. *World Factbook*, *supra* note 145. See also *Countries or Areas / Geographical Regions*, UN STATISTICS DIV., <https://unstats.un.org/unsd/methodology/m49/> [<https://perma.cc/EQ92-KKQU>] (last visited Sept. 8, 2018) (where these may include developing States or underdeveloped States, which are States with a less developed industrial base and a low Human Development Index (“HDI”) relative to other countries. There are no universally agreed-upon criteria for what makes a country developing versus developed and which countries fit these two categories, although there are general reference points such as a nation’s GDP per capita compared with other nations).

147. *The World Factbook: Appendix B: International Organizations and Groups*, CIA, <https://www.cia.gov/library/publications/the-world-factbook/appendix/appendix-b.html#D> [<https://perma.cc/BEK3-GMV5>] (last visited Sept. 12, 2018)

148. *Article 31bis*, *supra* note 31, at ¶ 2.

149. *Doha Declaration*, *supra* note 24, at ¶ 5.

150. *Id.* at ¶ 5(c).

151. *Cf. Gupta*, *supra* note 55, at 650 (explaining that “[i]n order to avoid divergent interpretations of the agreement and to achieve uniformity in decision, the first portion of the solution would involve amending the TRIPS Agreement in order to give the TRIPS Council the authority to review decisions of compulsory licensure and Article 31(f) waiver. The TRIPS Council, acting as a

health emergency;<sup>152</sup> (b) a current dictionary definition of “imminent;”<sup>153</sup> (c) the Caroline Test;<sup>154</sup> and (d) a concern for public health emergencies or crises affecting remote areas of a State.<sup>155</sup>

Despite the fact that the Caroline Test is used to determine the justifiability of anticipatory self-defense under customary international law, the definition of the necessity factor as an “instant, overwhelming, leaving no choice of means, and no moment of deliberation” is being correlated to the definition of “imminent.” The six-month time period was selected, since a shorter time period, such as a three-month time period, would be seen as “immediately” and a longer time period, such as a twelve-month time period, would be seen as “distant.” A non-exhaustive list of examples of these emergency situations, circumstances of extreme urgency, or public health crises is codified in Table 2 in the Appendix. These narrow circumstances help ensure that this compulsory licensing framework is not utilized for non-life-saving pharmaceuticals.

If the “eligible importing Member” does not face an imminent national or public health emergency, the State may not utilize the compulsory licensing framework. If the “eligible importing Member” faces an imminent national or public health emergency, the WTO subcommittee will move the analysis to the second injury.

central and unbiased body, would decide both when a compulsory license should be issued and when a public health emergency exists in accordance with the treaty’s language”).

152. *Humanitarian Health Action: Definitions: Emergencies*, WHO (2018), <http://www.who.int/hac/about/definitions/en/> [<https://perma.cc/D9R5-6UPV>] (defining a public health emergency as “an occurrence or imminent threat of an illness or health condition, caused by bio terrorism, epidemic or pandemic disease, or (a) novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents or permanent or long-term disability”).

153. *Definition of Imminent*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/imminent> [<https://perma.cc/ADS4-SG3M>] (last visited Sept. 9, 2018) (defining imminent as “ready to take place”).

154. The Caroline Test is a 19th-century formulation of customary international law arising from the Caroline Affair, which was a diplomatic crisis beginning in 1837 between Britain, the United States, and the Canadian independence movement. The Caroline Test states that “anticipatory self-defense” refers to a State’s right to strike first in self-defense when faced with an imminent attack. To justify such an action, the Caroline Test requires: (1) a necessity factor and (2) a proportionality factor. The necessity factor describes that the use of force must be necessary because the threat is imminent. The proportionality factor describes that the response must be proportionate to the threat. See HELEN DUFFY, *THE ‘WAR ON TERROR’ AND THE FRAMEWORK OF INTERNATIONAL LAW*, 263–64 (Cambridge University Press, 2nd ed. 2015). See also Anthony Clark Arend, *International Law and the Preemptive Use of Military Force*, 26 THE WASH. Q., 89, 96 (Spring 2003).

155. For this reason, the portion of affected population is not defined so as ensure treatment of public health crises affecting only a subset of the population (e.g., a disease only affecting individuals in a remote area of a State).

## 2. Second Inquiry: Developed Status of the State

Under the second inquiry, the WTO subcommittee will tackle the pending issue of whether the “eligible importing Member” is labeled an LDC. An LDC is defined by the characteristics described *supra* in Part I, which include (1) a low-income criterion,<sup>156</sup> (2) a HAI,<sup>157</sup> and (3) an EVI.<sup>158</sup> Currently, there are forty-seven States labeled LDCs by the UN.<sup>159</sup> As circumstances change between years, a State may lose the LDC title and therefore may be moved into a different tier. If the State fails to fit within the LDC category, the State is categorized under Tier Three. If the State fits within the LDC category, the WTO subcommittee will move the analysis to the third inquiry.

## 3. Third Inquiry: Type of Pharmaceutical Sought

Under the third inquiry, the WTO subcommittee would elucidate which pharmaceutical the “eligible importing Member” is seeking. Once the pharmaceutical is identified, the WTO subcommittee would determine if that pharmaceutical is an “essential medicine” aimed at directly combating the imminent national or public health emergency. To determine if a pharmaceutical falls into the category of an “essential medicine,” the WTO subcommittee would assess the following parameters: (a) the severity of the disease or the emergency, (b) a degree to which the medication targets the disease or the emergency, (c) an availability of alternative treatments to the disease or emergency, and (d) the capacity of the patent holder to supply market demand for the product. Through assessment of these parameters, the WTO subcommittee could correlate specific pharmaceuticals to specific diseases or emergency situations. It should be noted that this step does not contemplate additional medical care associated with the given pharmaceutical, such as gauzes, crutches, splints, etc.

This step is essential to ensure that compulsory licenses are only issued in circumstances for pharmaceuticals aimed at directly targeting the imminent national or public health emergency. This inquiry would further remedy current abuses of the TRIPS Agreement, which allows for a compulsory

---

156. *Criteria for Identification and Graduation of LDCs*, UN-OHRLLS (2018), <http://unohrlls.org/about-ldcs/criteria-for-ldcs> [<https://perma.cc/5FWJ-SH6Z>] (stating that the low-income criterion is based on a three-year average estimate of the GNI per capita of under \$1,035 for the 2011-2013 time period).

157. *Id.* (stating that the HAI is based on indicators of (a) malnourishment, (b) childhood mortality rate, (c) secondary school enrolment ratio, and (d) adult literacy rate).

158. *Id.* (stating that the EVI is based on indicators of (a) population size; (b) remoteness, (c) merchandise export concentration, (d) share of agriculture, forestry and fisheries, (e) share of population in low elevated coastal zones, (f) instability of exports of goods and services, (g) victims of natural disasters, and (h) instability of agricultural production).

159. *List of Least Developed Countries (as of March 2018)*, *supra* note 145.

license to be issued for non-life saving pharmaceuticals, such as Viagra.<sup>160</sup> If the “eligible importing Member” is seeking a pharmaceutical or treatment that does not directly target the imminent national or public health emergency, the State would be unable to utilize the compulsory licensing framework. However, if the State satisfies this inquiry, the process moves onward to the next inquiry.

#### 4. Fourth Inquiry: Ability to Produce Pharmaceuticals In-House

Under the fourth inquiry, the WTO subcommittee determines whether the “eligible importing Member” is competent to produce at least 50% of the pharmaceuticals sought. The WTO subcommittee will assess the manufacturing capabilities of the “eligible importing Member” by looking to the guidelines of the Appendix to Article 31*bis*, which explains, “[l]east-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.”<sup>161</sup> As such, an LDC will always be categorized as Tier One. For non-LDCs, the Appendix to Article 31*bis* explains that:

Insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) [] the Member has some manufacturing capacity in this sector, [but] it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs.<sup>162</sup>

This generic and vague framework is insufficient and open to abuse. A proposed solution to this includes tasking the WTO subcommittee with determining the manufacturing capabilities of a given State subsequent analyzing the following parameters: (a) the current manufacturing gross-domestic product (“GDP”) of the State, which will reflect the State’s production capabilities;<sup>163</sup> (b) results of a current global manufacturing

---

160. Mercurio, *supra* note 56, at 239.

161. *Amendment to the TRIPS Agreement*, *supra* note 29, at Appendix to the Annex.

162. *Id.*

163. *Analysis: 2016 Global Manufacturing Competitiveness Index*, DELOITTE (2018), <https://www2.deloitte.com/us/en/pages/manufacturing/articles/global-manufacturing-competitiveness-index.html> [https://perma.cc/4K9R-RAKJ]. See also *Glossary of Statistical Terms*:

competitiveness index study;<sup>164</sup> (c) a percentage of the sought pharmaceutical produced within the past five years within the State; and (d) a current production projection of the sought pharmaceutical within the given State.

If the State is capable of producing approximately 50% of the pharmaceuticals sought, the State is categorized as Tier Two. If the State is capable of producing more than 50% of the pharmaceuticals sought, the State is categorized as Tier Three, realizing the need, but not dire need, of a compulsory license to be issued. Classifying the given State into the tier system (associated with a need level for the sought pharmaceutical and based on the States manufacturing capabilities) aligns with the obligations of Paragraph 2(b) of Article 31*bis*, which requires submission of an application associated with an intended use of such compulsory licensing system to the TRIPS Council.<sup>165</sup>

### B. Step Two: Mathematical Solution

Subsequent to completing Step One, as described *supra*, the WTO subcommittee will move onto Step Two, including application of a mathematical formula to the outstanding circumstances. This mathematical formula executes a cost-benefit analysis<sup>166</sup> by comparing (a) the cost or economic loss suffered by the patent holder for granting a compulsory license to (b) the societal benefit achieved responsive to issuance of the compulsory license. The mathematical formula for Tier One States can be found in Equation 1, the mathematical formula for Tier Two States can be found in Equation 2, and the mathematical formula for Tier Three States can be found in Equation 3, respectively.

---

Gross Domestic Product (GDP), OECD (Jul. 1, 2002), <http://stats.oecd.org/glossary/detail.asp?ID=1163> [<https://perma.cc/663M-F7NU>].

164. The study was prepared by the Council on *Competitiveness* and Deloitte Touche Tohmatsu Limited (DTTL). The predictions are based on an in-depth analysis of *manufacturing* companies around the world. See also *2016 Global Manufacturing Competitiveness Index*, DELOITTE (2016). <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Manufacturing/gx-global-mfg-competitiveness-index-2016.pdf> [<https://perma.cc/62ZV-WWD2>] (last visited Sept. 8, 2018).

165. *Amendment to the TRIPS Agreement*, *supra* note 29, at Annex to the TRIPS Agreement ¶ 2(b).

166. Rodreck David, et al., *A Cost-Benefit Analysis of Document Management Strategies Used at a Financial Institution in Zimbabwe: A Case Study*, 15(2), J. OF INFO. MGMT. (2013).

$C > B$ ,

where  $C = [P - R]$ , where  $B = \left[ \frac{(N) * (X)}{(L)} \right]$ , and  $X = (M) * (D)$ ,

and taken together as:  $[P - R] > \left[ \frac{(N) * ((M) * (D))}{(L)} \right]$

Equation 1.

$C \cong B$

where  $C = [P - R]$ , where  $B = \left[ \frac{(N) * (X)}{(L)} \right]$ , and  $X = (M) * (D)$ ,

and taken together as:  $[P - R] \cong \left[ \frac{(N) * ((M) * (D))}{(L)} \right]$

Equation 2

$C < B$

where  $C = [P - R]$ , where  $B = \left[ \frac{(N) * (X)}{(L)} \right]$ , and  $X = (M) * (D)$ ,

and taken together as:  $[P - R] < \left[ \frac{(N) * ((M) * (D))}{(L)} \right]$

Equation 3.

According to the above-referenced Equation 1, Equation 2, and Equation 3, the variables are defined as follows:  $C$  is the monetary loss to the patent holder for issuing a compulsory license. The monetary loss to the patent holder is assessed based on (a) the  $P$  variable, or the projected free market profit for all dosages of the generic pharmaceutical sought and (b) the  $R$  variable, or the projected remuneration being paid by the eligible importing Member for all dosages of the generic pharmaceutical sought under the compulsory license. It should be noted that the  $R$  variable fails to take into account what “adequate remuneration” to the patent holder should be. The  $R$  variable will be assessed and determined by the WTO subcommittee based on the given circumstances. Further, the  $C$  variable does not take into account any additional losses to the patent holder, such as loss of reputation, loss of company equity, etc., associated with issuance of the compulsory license because these items are difficult to foresee or quantitatively define with certainty.

The societal benefit achieved from issuing the compulsory license, or the *B* variable, is based on the following parameters: *N*, or the number of citizens affected within the State for a six-month time period; *X*, or an average cost of the pharmaceutical to assist one citizen; and *L*, or the likelihood that the national emergency or public health crisis will affect citizens of another State, which is measured as a percentage. The *N* factor is estimated based on epidemic studies, which assess (a) the severity of the emergency or public health crisis, (b) statistics surrounding individuals within the State affected previously, (c) statistics surrounding individuals within other States affected previously, and (d) potential mutations. The *L* variable is estimated based on an ability of the disease or the emergency circumstance to spread. Further, the *X* variable is defined as:  $(M) * (D)$ , where the *M* variable is the monetary cost for one dosage of the generic pharmaceutical, and the *D* variable is the number of dosages needed to treat one citizen.

As such, for Equation 1 (and Tier One States), a compulsory license will be granted even if the monetary loss to the patent holder is greater than the societal benefit achieved from issuing the compulsory license for humanitarian reasons. Since Tier One States are LDCs, which have little to no in-house manufacturing capabilities, these States are least likely to produce pharmaceuticals on their own and thus are most likely to be incapable of remedying the contemplated emergency situations without assistance from one or more additional States.

In Equation 2 (and associated with Tier Two States), a compulsory license will be granted if the monetary loss to the patent holder is approximately equal to the societal benefit achieved from issuing the compulsory license. In Equation 3 (and associated with Tier Three States), a compulsory license will be granted if the monetary loss to the patent holder is less than the societal benefit achieved from issuing the compulsory license, since Tier Three States are those developed States which have the greatest manufacturing capabilities and greatest potential to produce the pharmaceuticals themselves.

## 1. Example Analyses

Utilizing this mathematical formula, the following example analyses are contemplated. It should be acknowledged that these are mere examples and do not include precise numbers or circumstances.

### (a) *Tier One State*

Zambia, a UN-designated LDC and categorized as Tier One, is hit with a malaria epidemic in 2020, assuming that Zambia is still a UN-designated LDC in the year 2020. In response, Zambia seeks a compulsory license from the Indian company, Lincoln Pharmaceuticals, to obtain a

generic version of Artesunate to combat this outbreak, assuming this company is the current patent holder of the pharmaceutical in 2020. The  $P$  variable, or the free market profit for all sought dosages of the generic pharmaceutical, is approximately \$120,000,000 USD.

Let us additionally assume that the projected remuneration, or the  $R$  variable, that Zambia will pay to Lincoln Pharmaceuticals is low due to the low GDP of Zambia in 2020, at \$25,000 USD. The  $N$  variable, or the number of citizens in Zambia that are projected to be affected with malaria within a six-month time period, is 500,000 citizens. Additionally, the  $M$  variable, or the average cost to treat one of these 500,000 citizens is approximately \$0.40 USD. Further, each of these 500,000 citizens needs three doses of Artesunate to combat malaria, and as such, the  $D$  variable is three. Based on the  $M$  variable and the  $D$  variable, the  $X$  variable is 1.2.

Since malaria spreads quickly, the  $L$  variable, or the percent likelihood that the national emergency or public health crisis will affect citizens of another State, is 70%. With these values in hand, Equation 1 becomes:

$$C > B$$

$$[P - R] > \left[ \frac{(N) * (X)}{(L)} \right]$$

$$[P - R] > \left[ \frac{(N) * ((M) * (D))}{(L)} \right]$$

$$[120,000,000 - 25,000] > \left[ \frac{(500,000) * ((0.40) * (3))}{(0.70)} \right]$$

$$[119,975,000] > [857,142.86]$$

As such, even though the  $C$  variable, or the cost to the patent holder for issuing a compulsory license is greater than the  $B$  variable, or the approximate societal benefit achieved from issuing the compulsory license, this framework would allow a compulsory license to be issued to Zambia for the ARV pharmaceutical, since Zambia is an LDC and a Tier One State.

#### (b) Tier Three State

Assume now that an anthrax attack occurs in several middle schools in Washington D.C. in 2020. Assuming further that the United States remains

a developed country in the year 2020, the U.S. will be categorized as a Tier Three State. The United States is seeking a compulsory license from a Japanese drug manufacturer, Daiichi Pharmaceutical Co., for the pharmaceutical Levaquin to treat anthrax poisoning in children, assuming that this company is the current patent holder of this pharmaceutical. The  $P$  variable, or the free market profit for the sought dosages of this generic pharmaceutical, is approximately \$1,000,000 USD.

Let us additionally assume that the projected remuneration, or the  $R$  variable, that the United States will pay to Daiichi Pharmaceutical Co. is higher, due to the increased GDP of the U.S., at \$500,000 USD. The  $N$  variable, or the number of citizens in the United States that are projected to be affected with anthrax within a six-month time period, is 100,000 citizens. Additionally, the  $M$  variable, or the average cost to treat one of these 100,000 citizens is \$0.50 USD. Further, each of these 100,000 citizens needs one dose a day of Levaquin for sixty days, or a total of sixty doses per citizen, and as such, the  $D$  variable is sixty. Based on the  $M$  variable and the  $D$  variable, the  $X$  variable is 30.

Assuming the anthrax was discovered quickly and therefore it was estimated that it could be contained, the  $L$  variable, or the percent likelihood that the national emergency or public health crisis will affect citizens of another State, is 10%. With these values in hand, Equation 3 becomes:

$$C < B$$

$$[P - R] < \left[ \frac{(N) * (X)}{(L)} \right]$$

$$[P - R] < \left[ \frac{(N) * ((M) * (D))}{(L)} \right]$$

$$[1,000,000 - 500,000] < \left[ \frac{(100,000) * ((0.50) * (60))}{(0.10)} \right]$$

$$[500,000] < [30,000,000]$$

As such, since the  $B$  variable, or the approximate societal benefit achieved from issuing the compulsory license is less than the  $C$  variable, or the cost to the patent holder for issuing a compulsory license, this framework would allow a compulsory license to be issued to the United States for the Levaquin pharmaceutical. The standard framework for achieving a compulsory license

for a Tier Three State is higher than for a Tier One State because Tier Three States are developed States with higher in-house manufacturing capabilities and generally higher GDPs.

#### CONCLUSION

As we share this planet with limited natural resources, supporting the world's most vulnerable populations is not only our duty as citizens but is our moral obligation as fellow human beings. Since the TRIPS Council has failed to remedy the outstanding deficiencies and ambiguities engulfing international compulsory licensing to date, a new solution must be implemented to assist these LDCs for the humanitarian reasons discussed *supra*. The proposed Amendment provides both a framework and a mathematical analysis applicable universally to quantitatively determine when a compulsory license should be issued under given circumstances. Moreover, creation of a WTO subcommittee will assist in the oversight of this proposed solution and will ensure compliance with this Amendment. Until a universal solution is implemented, such as the one proffered, the citizens of LDCs with little to no manufacturing capabilities will continuously suffer due to their inability to achieve generic pharmaceuticals through the international compulsory licensing framework.

## APPENDIX

*Table 2. List of Emergency Situations,**Circumstances of Extreme Urgency, or Public Health Crises*

## A

Acquired immunodeficiency syndrome (AIDS)  
Acute Flaccid Myelitis (AFM)  
Anthrax (*Bacillus anthracis*)  
Arenaviruses  
Argentinian hemorrhagic fever (AHF)  
Avalanche

## B

*Bacillus anthracis* (anthrax)  
Bird Flu  
Blizzard  
Bolivian hemorrhagic fever (BHF)  
Botulism (*Clostridium botulinum* toxin)  
Brucella species (brucellosis)  
*Burkholderia mallei* (glanders)  
*Burkholderia pseudomallei* (melioidosis)

## C

Campylobacteriosis (*Campylobacter*)  
Carbapenem-resistant Infection (CRE/CRPA)  
Chancroid  
Chikungunya virus (CHIKV)  
*Chlamydia psittaci* (psittacosis)  
Cholera (*Vibrio cholerae*)  
Ciguatera  
*Clostridium Difficile* Infection  
*Clostridium perfringens* (Epsilon toxin)  
*Coxiella burnetii* (Q fever)  
Creutzfeldt-Jacob Disease

## D

Dengue fever  
Diphtheria

## Drought

## E

E. coli O157:H7 (Escherichia coli)

Earthquake

Eastern equine encephalitis (EEE)

Ebola virus hemorrhagic fever

Ehrlichiosis

Encephalitis

Enterovirus Infection , D68 (EV-D68)

Epsilon toxin of Clostridium perfringens

## F

Flooding

Francisella tularensis (tularemia)

## G

Giardiasis (Giardia)

Glanders (Burkholderia mallei)

Granuloma inguinale

## H

Haemophilus Influenza disease, Type B (Hib or H-flu)

Hantavirus Pulmonary Syndrome

Hemolytic Uremic Syndrome (HUS)

Hepatitis

Histoplasmosis infection (Histoplasmosis)

Human Immunodeficiency Virus (HIV)

Human Papillomavirus (HPV)

Hydrological disasters

## I

Influenza

## L

Landslide

Lassa fever

Late blight of potato

Lead Poisoning

Legionellosis (Legionnaires Disease)

Leprosy (Hansens Disease)

Leptospirosis  
Limnic eruptions  
Listeriosis (*Listeria*)  
Lyme Disease  
Lymphogranuloma venereum infection (LVG)

## M

Malaria  
Marburg virus hemorrhagic fever  
Measles  
Melioidosis (*Burkholderia pseudomallei*)  
Meningococcal Disease, Bacterial (Meningitis, Meningitis, Viral (Meningitis, viral)  
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)  
Mumps

## N

Norovirus

## P

Paralytic Shellfish Poisoning (Paralytic Shellfish Poisoning, Ciguatera)  
Pediculosis (Lice, Head and Body Lice)  
Pelvic Inflammatory Disease (PID)  
Pertussis (Whooping Cough)  
Plague (*Yersinia pestis*)  
Pneumococcal Disease (Pneumonia)  
Poliomyelitis (Polio)  
Powassan  
Psittacosis  
Pustular Rash diseases (Small pox, monkeypox, cowpox)

## Q

Q fever (*Coxiella burnetii*)

## R

Rice blast  
Ricin toxin from *Ricinus communis* (castor beans)  
*Rickettsia prowazekii* (typhus fever)  
Rickettsiosis (Rocky Mountain Spotted Fever)  
Rift Valley fever (RVF)  
Rinderpest  
Rubella, Including congenital (German Measles)

## S

Salmonella species (salmonellosis)  
Salmonella Typhi (typhoid fever)  
Scabies Infestation (Scabies)  
Scombroid  
Severe Acute Respiratory (SAR) Syndrome  
Shigella (shigellosis)  
Smallpox (variola major)  
Staphylococcal Infection, Methicillin-resistant (MRSA)  
Staphylococcal enterotoxin B

## T

Tornado  
Tsunami  
Tularemia (Francisella tularensis)  
Typhoid fever (Salmonella Typhi)  
Typhus fever (Rickettsia prowazekii)

## V

Varicella (Chickenpox)  
Variola major (smallpox)  
Vibrio cholerae (cholera)  
Vibriosis (Vibrio)  
Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])  
Viral Hemorrhagic Fever (Ebola, Lassa, Marburg)  
Volcanic eruption

## W

Water safety threats  
West Nile Virus  
Western equine encephalitis (WEE)  
Wildfire

## Y

Yersinia pestis (plague)  
Yellow fever

## Z

Zika Virus Infection