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## Finding a Forest Through the Trees: *Georgia-Pacific* as Guidance for Arbitration of International Compulsory Licensing Disputes

Karen McKenzie

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# FINDING A FOREST THROUGH THE TREES: *GEORGIA-PACIFIC* AS GUIDANCE FOR ARBITRATION OF INTERNATIONAL COMPULSORY LICENSING DISPUTES

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## INTRODUCTION

According to the United States Patent Act, a patent holder is granted exclusivity for twenty years.<sup>1</sup> Within this bundle of exclusive rights is the right to make, use, offer for sale, sell, or import into the United States.<sup>2</sup> In addition, it

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1. 35 U.S.C. § 154(a)(2) (2012), *amended by* Pub. L. 112-211 (Supp. V 2018). Generally, the term of a new patent is twenty years from the date on which the application for the patent was filed in the United States. *Id.*

2. 35 U.S.C. § 154(a)(1) (2012) (“Every patent . . . grant[s] to the patentee . . . the right 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 . . .”). A patent is a property right issued by the United States Patent and Trademark Office (the “USPTO”). 35 U.S.C. § 261 (2012), *amended by* Pub. L. 112-211 (Supp. V 2018). The patent right is for a limited time. 35 U.S.C. § 154(a)(2) (2012),

provides for the exclusive right to license the use of a named and described invention.<sup>3</sup> However, the exception to these rights is compulsory licensing.<sup>4</sup> Compulsory licensing operates when government authorities license a patent, under certain conditions, without the patent holder's permission.<sup>5</sup> On the international stage, the original authority is the Paris Convention for the Protection of Industrial Property (the "Paris Convention"), which protects patents filed in a foreign country where the patented product or process is marketed and sold.<sup>6</sup>

"The Paris Convention has been revised from time to time . . . . Each of the revision conferences, starting with the Brussels Conference in 1900, ended with the adoption of a revised Act of the Paris Convention."<sup>7</sup> With a few exceptions,<sup>8</sup> all those earlier Acts are still current and form the legal basis of the Trade

*amended* by Pub. L. 112-211 (Supp. V 2018); *see also* U.S. CONST. art. I, § 8, cl. 8 ("Congress shall have power . . . to promote 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."). In exchange for the patent right, a public disclosure of the invention is required. *Patent*, LEGAL INFO. INST., <https://www.law.cornell.edu/wex/patent> [<https://perma.cc/X4NL-C4GV>] (last visited Sept. 30, 2019).

3. 35 U.S.C. § 261 (2012), *amended* by Pub. L. 112-211 (Supp. V 2018) ("Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents . . .").

4. *Exceptions and Limitations to Patent Rights*, WIPO, [https://www.wipo.int/patents/en/topics/exceptions\\_limitations.html](https://www.wipo.int/patents/en/topics/exceptions_limitations.html) [<https://perma.cc/722W-L5QR>] (last visited Sept. 30, 2019).

5. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO: TRIPS AND HEALTH: FREQUENTLY ASKED QUESTIONS, [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faqs\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faqs_e.htm) [<https://perma.cc/M7AF-3B2F>] (last visited May 9, 2017). Compulsory licensing is one of the flexibilities on patent protection included in the WTO's Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement. *Id.*

6. *Summary of the Paris Convention for the Protection of Industrial Property (1883)*, WIPO (Sept. 21, 2019), [https://www.wipo.int/treaties/en/ip/paris/summary\\_paris.html](https://www.wipo.int/treaties/en/ip/paris/summary_paris.html) [<https://perma.cc/BT6Q-RFU2>]; John N. Adams, *History of the Patent System*, in RESEARCH HANDBOOK ON PATENT LAW AND THEORY 2, 25 (Toshiko Takenaka ed., 2019). "A Diplomatic Conference convened in Paris in 1883, which ended with final approval and signature of the Paris Convention for the Protection of Industrial Property . . . signed by 11 States: Belgium, Brazil, El Salvador, France, Guatemala, Italy, the Netherlands, Portugal, Serbia, Spain, and Switzerland." *WIPO Intellectual Property Handbook: Policy, Law and Use*, WIPO 241 (2004), [https://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_489.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_489.pdf) [<https://perma.cc/72LS-ETV6>]. Great Britain, Tunisia and Ecuador also joined when the Paris Convention went into effect on July 7, 1884. *Id.* After 1950, membership increased significantly. *See generally Contracting Parties > Paris Convention (Total Contracting Parties: 177)*, WIPO: WIPO-ADMINISTERED TREATIES, [https://www.wipo.int/treaties/en/Show-Results.jsp?country\\_id=ALL&start\\_year=ANY&end\\_year=ANY&search\\_what=C&treaty\\_id=2](https://www.wipo.int/treaties/en/Show-Results.jsp?country_id=ALL&start_year=ANY&end_year=ANY&search_what=C&treaty_id=2) [<https://perma.cc/MA94-AU9X>] (last visited Sept. 30, 2019).

7. *WIPO Intellectual Property Handbook: Policy, Law and Use*, *supra* note 6, at 241–42.

8. *Id.* at 242. "With the exception of the Acts concluded at the revision conferences of Brussels (1897 and 1900) and Washington, D.C. (1911), which are no longer in force," the remainder of the Paris Convention is largely intact; it forms the statutory framework for the Intellectual Property agreements to follow. *Id.*

Related Aspects of Intellectual Property (“TRIPS”) Agreement.<sup>9</sup> The World Trade Organization (the “WTO”) adopted the Declaration on the TRIPS Agreement and Public Health (the “Doha Declaration”) in 2001, which reaffirmed compulsory licensing as a way to combat global public health issues of access to medicines in low- and middle-income countries (“LMICs”).<sup>10</sup> Notably, India and China have been late additions to the early agreements but extremely punctual in adopting the Doha Declaration, which allows broader compulsory licensing.<sup>11</sup>

This paper will examine the challenges of international compulsory licensing by examining the issue historically and legally as well as offer possible solutions. Thus, this paper will explore the challenge of balancing corporate interests against the affordability and availability of pharmaceuticals by focusing on discrete situations in developing countries, the history of compulsory licensing, and how the World Health Organization (the “WHO”) and the WTO have attempted to tackle these challenges through compulsory licensing, and it will suggest a possible framework for use in arbitration, which balances equities through a *Georgia-Pacific* analysis.

Part I discusses the equities of patent owners versus consumers who live in developing countries. Part II discusses the history of compulsory licensing. Part III reviews some of the WTO’s attempts to settle international disputes, along with the financial implications of settlement with individual countries on a case-by-case basis. Part IV examines how *Georgia-Pacific*<sup>12</sup> can be used as a guide for arbitration in international patent disputes in compulsory licensing as applied to some discrete compulsory licensing cases.

9. See *Part I—General Provisions and Basic Principles*, WTO: URUGUAY ROUND AGREEMENT: TRIPS, [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_03\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm) [<https://perma.cc/G4CX-6CVX>] (last visited Sept. 30, 2019) (stating the text of Article 2, which is about intellectual property conventions).

10. See Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED. 1, 2 (2012).

11. See Vanessa Bradford Kerry & Kelley Lee, *TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps for Protecting Access to Medicines?*, 3 GLOBALIZATION & HEALTH 1, 3 (2007) (“The 2005 date of compliance for most LMICs includes countries that are major suppliers of generic drugs such as India, Brazil and China.”) (citing Janice M. Mueller, *Taking Trips to India—Novartis, Patent Law and Access to Medicines*, 356 NEW ENG. J. MED. 541–43 (2007)); see also *India Accedes to Paris Convention*, INST. FOR AGRIC. & TRADE POL’Y: THE HINDU BUS. LINE (Feb. 15, 1999), <https://www.iatp.org/news/india-accedes-to-paris-convention> [<https://perma.cc/PM5W-WL3N>] (discussing the Indian government’s decision to join the Paris Convention in 1998); *Paris Notification No. 114: Paris Convention for the Protection of Industrial Property, Accession by the People’s Republic of China*, WIPO: WIPO-ADMINISTERED TREATIES: NOTIFICATIONS, [https://www.wipo.int/treaties/en/notifications/paris/treaty\\_paris\\_114.html](https://www.wipo.int/treaties/en/notifications/paris/treaty_paris_114.html) [<https://perma.cc/U8JP-Q2DF>] (last visited Nov. 2, 2019) (stating that China will become a member of the Paris Union on March 19, 1985).

12. *Georgia-Pacific v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), *modified sub nom. Georgia-Pacific Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971).

## I. BALANCING EQUITIES: PATENT HOLDERS VS. THIRD WORLD CONSUMERS

The affordability and availability of pharmaceuticals are often viewed, and generally framed, as one of supply and demand; yet the issue is much more complicated than that.<sup>13</sup> The cost of bringing a single drug to market is staggering.<sup>14</sup> The cost to bring one new drug to market is now estimated at more than 2.6 billion dollars.<sup>15</sup> Most companies seek to recoup these research and development expenses after a drug becomes successful in the marketplace.<sup>16</sup> This success also has to offset the expenses of complex double-blind clinical trials, the greater focus on chronic and degenerative diseases, and test-seeking to demonstrate comparative drug effectiveness data.<sup>17</sup> In addition to these costs, the cost of drugs that are unsuccessful must also be figured into the analysis.<sup>18</sup>

In stark contrast to corporate billions spent on pharmaceutical development are individual consumers in impoverished developing and third-world countries with limited resources to spend on medicines.<sup>19</sup> In LMICs, up to 90% of the population pays for medicine on an out-of-pocket basis; it is the largest household expense after food.<sup>20</sup> The burden is especially great for a family needing

13. See Glenna M. Crooks et al., *Pharmaceutical Marketplace Dynamics*, NAT'L POL'Y HEALTH F., No. 755 1, 2 (2000), [https://www.nhpf.org/library/issue-briefs/IB755\\_RxMarketplace\\_5-31-00.pdf](https://www.nhpf.org/library/issue-briefs/IB755_RxMarketplace_5-31-00.pdf) [<https://perma.cc/D92G-5U9L>] (“Hardly a day has gone by lately without some new reflection of the tension between commercial and scientific accomplishments of the drug companies on one hand, and the disparity of the spread of the benefits of those accomplishments [on the other].”).

14. See Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5 Billion*, SCIENTIFIC AMERICAN (Nov. 24, 2014), <https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/> [<https://perma.cc/4J4Z-UKY2>]; see also Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, CHEMICAL & ENGINEERING NEWS (Nov. 20, 2014), <https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html> [<https://perma.cc/G4KW-NBX8>] (“[T]he cost of developing a prescription drug that gains market approval [is] \$2.6 billion, a 145% increase, correcting for inflation, over the estimate the center made in 2003.”).

15. *Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5 Billion*, *supra* note 14 (“[T]he Pharmaceutical Research & Manufacturers of America in particular, is really going to use [the cost of research and development] to justify the high cost of drugs.” (quoting John LaMattina, senior partner at PureTech and former Pfizer R&D head) (internal quotation marks omitted)).

16. Ingrid Torjesen, *Drug Development: The Journey of a Medicine from Lab to Shelf*, PHARMACEUTICAL J.: TOMORROW'S PHARMACIST (May 12, 2015), <https://www.pharmaceutical-journal.com/publications/tomorrows-pharmacist/drug-development-the-journey-of-a-medicine-from-lab-to-shelf/20068196.article?firstPass=false> [<https://perma.cc/3MDE-U45J>].

17. *Cost to Develop New Pharmaceutical Drug Now Exceeds \$ 2.5 Billion*, *supra* note 14.

18. *Tufts Study Finds Big Rise in Cost of Drug Development*, *supra* note 14 (providing that the principal investigator and director of economic analysis commented that the high cost of failure in drug development figured into the analysis).

19. See Suerie Moon, *Powerful Ideas for Global Access to Medicines*, 376 NEW ENG. J. MED. 505, 505–06 (2017) (noting that a U.N. work group recommended drug pricing transparency as one of the solutions to access in LMICs).

20. *WHO Guideline on Country Pharmaceutical Pricing Policies*, WHO 1 (2015), [https://apps.who.int/iris/bitstream/handle/10665/153920/9789241549035\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/153920/9789241549035_eng.pdf?sequence=1)

treatment for several conditions at the same time. For example, using the lowest priced generic medicines would take at least 17 days' wages for the lowest paid, unskilled government worker to purchase medicine for a child with asthma, or an adult with diabetes, or an adult with a peptic ulcer.<sup>21</sup> When one examines utilizing treatment with an innovative brand, it would require 106 days' salary for a month's worth of treatment.<sup>22</sup>

According to the WHO, generic medicines can range from 1.9 to 3.5 times the International Reference Price (the "IRP"), while in India, for example, essential medicines cost between 1.6 to 2.3 days' wages for the lowest-paid government worker—and 80% of the population earns less than this wage.<sup>23</sup> In these countries, medicine accounts for 20% to 60% of health spending compared to 18% in countries with more advanced economic development.<sup>24</sup> This means that for over 90% of the population in developing countries, medicine is no longer affordable, and the cost is a major burden on government budgets.<sup>25</sup>

In India, for example, the cost of asthma medicine can amount to nearly three days' wages for a government worker.<sup>26</sup> However, as previously mentioned, most of the population earns less than an average government worker.<sup>27</sup> In terms of availability, Beclomethasone<sup>28</sup> and Salbutamol<sup>29</sup> were available in only 25% to 30% of the public health care facilities in only one of the five Indian states included in the study.<sup>30</sup> The price of these medications was 0.74 and 0.56 times higher than the IRP.<sup>31</sup>

[<https://perma.cc/KT5L-QH7E>].

21. See *Medicine Price Surveys and Proposed Interventions to Improve Sustainable Access to Affordable Medicines in 6 Sub-Saharan African Countries*, WHO 1 (2006), <https://apps.who.int/medicinedocs/documents/s14864b/s14864b.pdf> [<https://perma.cc/BHE7-STUW>].

22. *Id.*

23. Alexandra Cameron, Margaret Ewen, Martin Auton & Dele Abegunde, *The World Medicines Situation 2011: Medicine Prices, Availability and Affordability*, WHO 1 (2011), [https://www.who.int/medicines/areas/policy/world\\_medicines\\_situation/WMS\\_ch6\\_wPricing\\_v6.pdf](https://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf) [<https://perma.cc/5Y5X-4SH5>] (“[The] average prices of generic medicines range from 1.9 to 3.5 times international reference prices . . . .”); A. Kotwani, *Availability, Price and Affordability of Asthma Medicines in Five Indian States*, 13 INT’L J. TUBERCULOSIS & LUNG DISEASE 574, 574 (2009).

24. *WHO Guideline on Country Pharmaceutical Pricing Policies*, *supra* note 20, at 1.

25. *Id.*

26. Kotwani, *supra* note 23, at 574.

27. *Id.*

28. See *Beclomethasone Inhalation*, DRUGS.COM, <https://www.drugs.com/mtm/beclomethasone-inhalation.html> [<https://perma.cc/TBP2-XGRA>] (last visited May 9, 2017) (stating that Beclomethasone is a steroid that prevents the release of substances in the body that cause inflammation, and it is used to prevent asthma).

29. See *Salbutamol (Inhalation)*, DRUGS.COM, <https://www.drugs.com/cons/salbutamol.html> [<https://perma.cc/7L2T-CA6T>] (last visited May 9, 2017) (stating that the generic name of Salbutamol is Albuterol). Albuterol was originally approved by the FDA in 1981. See *id.* at *Approval History*.

30. See Kotwani, *supra* note 23, at 574.

31. *Id.*

When it comes to an integrated delivery system, like an inhaler, the availability of asthma medicine continues to plummet. In India, the availability of inhalers was poor in the private sector of four of the states studied, with some as low as only 10% of the private facilities having access to inhalers.<sup>32</sup> Moreover, when it comes to price, Beclomethasone was 0.87 to 1.49 times higher than the IRP, and Salbutamol was 0.86 to 1.12 times higher than the IRP.<sup>33</sup> Thus, essential medicines for asthma, which are used daily and on a long-term basis, are unaffordable.<sup>34</sup> Finally, in the public sector, where low-income populations seek treatment, “[s]teroid inhalers were not [as] readily available [as] in the private sector.”<sup>35</sup> Thus, essential asthma medicines were either unaffordable for the majority of the population<sup>36</sup> and/or largely unavailable for the low-income population.<sup>37</sup> Consequently, it becomes difficult to strike a balance between pharmaceutical companies’ interests in their patents—and related income streams that fund new research and development—and individual countries’ public health concerns exacerbated by the weaknesses within their economies. For these reasons, an enormous tension exists between the rights of the international patent holder and the public health needs within developing and third-world countries.

## II. THE HISTORY OF COMPULSORY LICENSING

Meanwhile, the subject of compulsory licensing has rarely surfaced in the United States in association with pharmaceutical patents.<sup>38</sup> This is largely due to the public interest, property rights, and the perception that it would impact future research and development.<sup>39</sup> Some have argued that corporate interests

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32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. Grace K. Avedissian, Comment, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of “Super-Terrorism,”* 18 AM. U. INT’L L. REV. 237, 252, 245 n. 35 (2002) (citing Amy C. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2469 (1995)). Compulsory licensing in the United States has been used in copyright in literary and artistic works, but rarely in pharmaceuticals due to the public interest in the development of technology, an interest in property rights, and, arguably, by the lobbying efforts of pharmaceutical companies. See generally Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT’L L. REV. 941, 953–54 (2000); William N. Monte, *Compulsory Licensing of Patents*, 25 INFO. & COMM. TECH. L. 247, 247–71 (2016).

39. See, e.g., Jerome H. Reichman, Comment: *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. L., MED. & ETHICS 247, 247–48 (2009). During the 2001 anthrax attacks, the United States government threatened to issue a compulsory license for

in the United States outweigh individual interests. Lobbying by large corporations generally overshadows individual and small-group lobbying efforts by consumers.<sup>40</sup> However, on an international level, due to the large disparity in cost and unavailability, developing countries are seeking compulsory licenses of pharmaceuticals.<sup>41</sup> This disparity between the cost and availability of pharmaceuticals was never more apparent than during the AIDS epidemic in Sub-Saharan Africa, like Kenya, for example.<sup>42</sup> At that time, the WTO called compulsory licensing and access to AIDS medications a pressing public health issue.<sup>43</sup> In fact, other countries like Canada temporarily manufactured some AIDS and anti-malaria medicines in response to this public health issue and exported them to African countries under a compulsory licensing scheme.<sup>44</sup> The program was later rescinded.<sup>45</sup>

Many impoverished third-world countries have made compelling cases for the expansion of compulsory licensing as a public health initiative.<sup>46</sup> The past ten years have seen the introduction of several initiatives to support countries in managing pharmaceutical prices.<sup>47</sup> However, it was felt that special

Ciprofloxacin if Bayer did not lower the price for the government. *Id.* Bayer lowered the price, and the government backed down on the threat. *Id.*

40. See Amy C. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2469 (1995); see also Ellen Daniel, *US Pharma Lobbying Spend Surged to 25.4 million in 2017*, PHARMACEUTICAL TECH. (Jan. 26, 2018), <https://www.pharmaceutical-technology.com/news/us-pharma-lobbying-spend-surged-25-4m-2017> [<https://perma.cc/RDV6-6G6V>].

41. See generally *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade: Extract From the WHO-WIPO-WTO Trilateral Study*, WTO (Mar. 7, 2017), [https://www.wto.org/english/tratop\\_e/trips\\_e/who-wipo-wto2013\\_par6\\_extract\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/who-wipo-wto2013_par6_extract_e.pdf) [<https://perma.cc/S496-4XQ9>]; see also *Chapter 4: Medical Technologies: The Access Dimension*, WTO: INTELLECTUAL PROPERTY: WHO-WIPO-WTO BOOK, [https://www.wto.org/english/tratop\\_e/trips\\_e/trilatweb\\_e/ch4c\\_trilat\\_web\\_13\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4c_trilat_web_13_e.htm) [<https://perma.cc/E33V-K5TQ>] (last visited Nov. 2, 2019); John LaMattina, *India's Solution to Drug Costs: Ignore Patents and Control Prices Except for Home Grown Drugs*, FORBES (Apr. 8, 2013), <https://www.forbes.com/sites/johnlamattina/2013/04/08/indias-solution-to-drug-costs-ignore-patents-and-control-prices-except-for-home-grown-drugs/#491c664f2cba> [<https://perma.cc/3KTX-6TSC>] (“The Glivec situation is not unique. . . . [Compulsory] licenses allow India generic drug manufacturers to make these drugs without impunity.”).

42. See Ben Sihanya, *Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya*, WTO: MANAGING THE CHALLENGES OF WTO PARTICIPATION: CASE STUDY 19 (July 8, 2011), [https://www.wto.org/english/res\\_e/booksp\\_e/casestudies\\_e/case19\\_e.htm](https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm) [<https://perma.cc/M6Y3-4M6N>].

43. *Id.*

44. See *Promoting Access to Medical Technologies and Innovation, Intersections Between Public Health, Intellectual Property and Trade: Extract From the WHO-WIPO-WTO Trilateral Study*, *supra* note 41.

45. *See id.*

46. *See id.*

47. See Moon, *supra* note 19, at 506.

consideration was needed in low-income and developing countries, in which the pharmaceutical sector was less regulated.<sup>48</sup>

Eventually, a committee of countries was formed at the WTO Ministerial Conference to address the issue over a period of several years.<sup>49</sup> This committee of countries, working under the auspices of the WTO, determined that the public health issues in the countries seeking a compulsory license is of greater importance than the rights of an individual corporate patent holder.<sup>50</sup> Countries such as India, Canada, Mexico, Qatar, and several Sub-Saharan countries, and even China, have been seeking compulsory licenses.<sup>51</sup> Each of these countries has been lobbying the WTO to expand the compulsory licensing on several classes of pharmaceuticals.<sup>52</sup>

By 2001, via the Doha Declaration, a compulsory licensing exception was allowed under the TRIPS Agreement—provided that certain procedures and conditions were fulfilled.<sup>53</sup> These criteria are the following: (1) a generic copy of a drug is produced mainly for the domestic market of that country; (2) it should not be made for export; (3) used for a pressing public health need or emergency public health situation; (4) the producer of the generic copy has attempted to negotiate a voluntary license on reasonable commercial terms; (5) only if the negotiations fail can a compulsory license be issued; and (6) some countries require that the patent be active for three to six years before a compulsory license application can be considered.<sup>54</sup>

48. WHO *Guideline on Country Pharmaceutical Pricing Policies*, *supra* note 20, at 3.

49. *The Doha Declaration on the TRIPS Agreement and Public Health*, WHO, [https://www.who.int/medicines/areas/policy/doha\\_declaration/en](https://www.who.int/medicines/areas/policy/doha_declaration/en) [<https://perma.cc/BAF3-S9CP>] (last visited Oct. 3, 2019); *see also* *Module IX: TRIPS and Public Health*, WTO, [https://www.wto.org/english/tratop\\_e/trips\\_e/ta\\_docs\\_e/modules9\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules9_e.pdf) [<https://perma.cc/9H2G-NDWZ>] (last visited Nov. 2, 2019).

50. Reichman, *supra* note 39, at 250.

51. *Decision Removes Final Patent Obstacle to Cheap Drug Imports*, WTO NEWS: 2003 PRESS RELEASES (Aug. 30, 2003), [https://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](https://www.wto.org/english/news_e/pres03_e/pr350_e.htm) [<https://perma.cc/8EH8-PZSB>]; *see also* *Draft Reference Document on the Exception Regarding Compulsory Licensing: Annex, SCP/30/3*, WIPO 20 (May 21, 2019), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_30/scp\\_30\\_3-main1.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf) [<https://perma.cc/2296-MYC9>].

52. Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH L. J. 853, 871 (2003); *Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part I)*, SCP/21/4 Rev., WIPO 5 (Nov. 3, 2014), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_21/scp\\_21\\_4\\_rev.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_4_rev.pdf) [<https://perma.cc/YLA2-PKKS>] (referencing additional reasons given by developing countries to allow extended compulsory licensing).

53. *See Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, WTO (Nov. 20, 2001), [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf) [<https://perma.cc/2YRB-467B>]; *see also* *Draft Reference Document on the Exception Regarding Compulsory Licensing: Annex*, *supra* note 51, at 7–8.

54. *See Draft Reference Document on the Exception Regarding Compulsory Licensing: Annex*, *supra* note 51, at 6–8; *Id.* at 7–8 (stating that under Article 31 of the TRIPS Agreement, a compulsory

The conditions for maintenance of the compulsory license are: (1) the patent holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; and (2) the generic copy produced cannot be exported out of the country seeking the compulsory license.<sup>55</sup> Additionally, after the Doha Declaration, the requirement to attempt to obtain a license was relaxed in cases of “national emergency,” “other circumstances of extreme urgency,” and “public non-commercial use,” so that the first step of negotiating a voluntary license can be bypassed in order to save time.<sup>56</sup> Despite this expansion of rights by the licensee, the patent owner still has to be paid.<sup>57</sup>

### III. ENFORCEMENT

A compulsory license creates a quasi-contractual obligation between the patent holder and the licensee, which originates in a Member State and is

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license is authorized only under specific conditions, including: (1) the “user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time,” (2) the compulsory license is limited to domestic use, (3) the compulsory license is non-exclusive (generic), (4) the compulsory license is not used to create product for export, (5) and the compulsory license is used for a pressing public health or emergency); *see also id.* at 17 (“According to Article 46, at the request of any person made after the expiry of a period of four years from the filing date of the patent application or three years from the date of grant of the patent . . . .”); *Id.* at 30 (“In most countries, the time period during which compulsory licenses may not be granted on the grounds of non-working or insufficient working is three years from the date of the grant of the patent or four years from the filing date of the application. The applicable laws of many of those countries further specify that the said time period lasts three years from the date of grant or four years from the filing date, whichever period expires later. In addition, in a few countries, a compulsory license may be granted if the exploitation of the patented invention has been interrupted for more than one year [Argentina and Costa Rica], and in two countries, for more than three years [Turkey and Ukraine]. Some other variations found in the applicable laws are, for example, ‘three years from the date of the grant of the patent’ [Azerbaijan, Brazil, Honduras, Hong Kong (China), India, Netherlands, Qatar, and the United Kingdom], ‘three’ or ‘five’ years from the date of publication of the mention of the grant [Turkey, Ukraine, and Tajikistan] ‘3 years after sealing’ [Australia], or ‘three years of non-working’ [Monaco].”).

55. *See Draft Reference Document on the Exception Regarding Compulsory Licensing: Annex, supra* note 51, at 78. According to Article 31, compulsory licensing is allowed provided “the following conditions [are] respected: . . .

(f) such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; . . . (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization . . . .” *Id.* Under the Paris Convention, a special compulsory license is required in order to export a pharmaceutical. *See id.* at 6–9.

56. Dianne Nicol & Olasupo Owoeye, *Using TRIPS Flexibilities to Facilitate Access to Medicines*, 91 BULL WORLD HEALTH ORGAN. 533, 533–34 (2013).

57. *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO (Sept. 1 2003), [https://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm) [<https://perma.cc/678R-JXUS>].

enforced by the WTO.<sup>58</sup> Generally, as previously mentioned, there are clear criteria that must be satisfied in order to obtain the license and distinct actions to avoid.<sup>59</sup> But what happens when the contractual compulsory license is breached? Who decides what payment is “adequate” or what constitutes an “emergency” or an “urgent situation”? Which country or organization has jurisdiction? What, if any, enforcement power does that court have? Some of these inherent unresolved issues involved in compulsory licensing, such as jurisdiction and enforcement, have been exacerbated by recent compulsory licensing disputes.

The TRIPS Agreement states that the patent owner must be given the right to appeal the compensation or the validity of the compulsory license.<sup>60</sup> The appeal is filed in the country in possession of the compulsory license.<sup>61</sup> Additionally, the 2001 WTO Ministerial Conference in Doha decided that countries that are unable to manufacture pharmaceuticals should be given opportunities to obtain cheaper copies elsewhere.<sup>62</sup> This expands the requirement that drugs be restricted to the domestic market, provided that certain conditions are met.<sup>63</sup>

To make matters more complicated, eleven countries announced that they would only import in situations of a national emergency or other circumstances of extreme urgency: China (including Hong Kong and Macao), Israel, Korea, Kuwait, Mexico, Qatar, Singapore, Taiwan, Turkey, and the United Arab

58. See *Draft Reference Document on the Exception Regarding Compulsory Licensing: Annex*, *supra* note 51, at 7 (“WTO Member [States] have an obligation to comply, *inter alia*, with Articles 5A of the Paris Convention concerning compulsory licenses.”).

59. See discussion *supra*.

60. See *Draft Reference Document on the Exception Regarding Compulsory Licensing: Annex*, *supra* note 51, at 8 (“According to Article 31, where the law of the Member allows for other use of the subject matter of patent without authorization of the right holder, the following conditions shall be respected: . . . (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; (j) the decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member . . . .”); see also *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 5.

61. See *Draft Reference Document on the Exception Regarding Compulsory Licensing: Annex*, *supra* note 51, at 41–42 (discussing many pharmaceutical compulsory licensing appeals filed in Member States, one of which was the Raltegravir compulsory patent case filed in Federal Court of Justice in Germany).

62. See *Decision Removes Final Patent Obstacle to Cheap Drug Imports*, *supra* note 51; see also *Declaration on the TRIPS Agreement and Public Health*, *supra* note 53, at 2 (“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.”).

63. See *Decision Removes Final Patent Obstacle to Cheap Drug Imports*, *supra* note 51; see also Sisule F. Musungu & Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*, COMMISSION ON INTELL. PROP. RIGHTS, INNOVATION & PUB. HEALTH (CIPIH) 15 (Aug. 2005), <https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> [<https://perma.cc/J3L9-WGXJ>].

Emirates.<sup>64</sup> However, the TRIPS Agreement requires that if a country plans to export a generic copy, they must change the laws within their country that recognize patented materials.<sup>65</sup> This is known as the “Paragraph 6” decision, which came out of the Doha Declaration in 2003.<sup>66</sup> Thus far, nineteen countries have formally informed the TRIPS Council that they have made the required changes.<sup>67</sup>

In terms of a challenge to a compulsory license, one of the most well-reported compulsory license cases to date is in regard to Novartis’ drug, Gleevec,<sup>68</sup> a treatment for leukemia.<sup>69</sup> The Indian government issued a compulsory license to manufacturer, copy, and produce the drug.<sup>70</sup> Novartis sued to block the ruling of the Chennai senior court of India, saying that “it violated [the] . . . WTO rules on intellectual property that India had adopted.”<sup>71</sup> Novartis also argued that an adverse ruling against their patent would “stifle the

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64. See Roger Kampf, *Special Compulsory Licences for Export of Medicines: Key Features of WTO Members’ Implementing Legislation*, WTO ECON. RES. & STAT. DIVISION (July 31, 2015), [https://www.wto.org/english/res\\_e/reser\\_e/ersd201507\\_e.pdf](https://www.wto.org/english/res_e/reser_e/ersd201507_e.pdf) [<https://perma.cc/JS75-UPBM>].

65. *Id.*

66. *Id.*

67. *Id.*; *Members’ Laws Implementing the ‘Paragraph 6’ System*, WTO: INTELLECTUAL PROPERTY: TRIPS AND HEALTH, [https://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm) [<https://perma.cc/EDH4-ZVSV>] (last visited Nov. 2, 2019) (listing the following countries that have changed their laws in order to have the ability to export: Albania, Australia, Botswana, Canada, China, Croatia, Cuba, European Union, Hong Kong, India, Kazakhstan, New Zealand, Norway, Oman, Philippines, Korea, Singapore, Switzerland, and Chinese Taipei).

68. See Leslie A. Pray, *Gleevec: The Breakthrough in Cancer Treatment*, 1 NATURE EDUC. 37 (2008) (finding that there was a phenomenal success rate of patient’s white blood cell production, which returned to a normal range while on Gleevec); see also *Gleevec*, DRUGS.COM. (July 1, 2019), <https://www.drugs.com/gleevec.html> [<https://perma.cc/9ZB2-ZGZA>] (stating that Gleevec is approved for leukemia, bone marrow disorders, and certain tumors of the stomach and digestive system).

69. LaMattina, *supra* note 41.

70. See Vikas Bajaj & Andrew Pollack, *India’s Supreme Court to Hear Dispute on Drug Patents*, N.Y. TIMES, at B1 (Mar. 6, 2012), <https://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?mtr-ref=www.google.com&gwh=F46019393E275FAA4D4D24E6E9405F26&gwt=pay&assetType=RE> GIWALL [<https://perma.cc/RTJ7-9S6G>]; see also Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CANADIAN MED. ASS’N E385, E385–86 (2013) (discussing the Indian Supreme Court’s refusal to issue a patent to Novartis for a new version of its cancer drug Gleevec). The Indian government allowed some generic manufacturers in India to produce Gleevec in India. See Sarah Hiddleston, *Finally, the Patents Prevail*, THE HINDU (Apr. 7, 2013), <https://www.thehindu.com/news/national/finally-the-patents-prevail/article4588890.ece> [<https://perma.cc/LC4N-8V63>]. Novartis applied for exclusive marketing rights under the Indian Patent Act—which would effectively prohibit the generic manufacture of Gleevec in India. See *id.* In 2005, India notified the TRIPS Council of changes to its intellectual property standards dealing with incremental changes in a drug which extends the life of a patent. See *id.* Minor changes to extend the patent life of a drug is otherwise known as “evergreening.” See *id.*

71. T.V. Padma, *Indian Court Rejects Novartis Patent*, NATURE (Apr. 1, 2013), <https://www.nature.com/news/indian-court-rejects-novartis-patent-1.12717> [<https://perma.cc/9K3K-GETE>].

country's access to new medicines."<sup>72</sup> In 2007, the court rejected Novartis' challenge.<sup>73</sup> Novartis then appealed to the Indian Supreme Court in 2009.<sup>74</sup> However, the Indian Supreme Court rejected Novartis' claim based on section 3(d) of the Indian Patent Act,<sup>75</sup> which states that:

the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.<sup>76</sup>

The Indian Supreme Court also rejected Novartis' expectation that making minor changes to their drug would provide extended patent protection for another twenty years.<sup>77</sup> The Court ruled that minor modifications to a drug, known as "evergreening," is a tactic that would not work in India, saying that marketing the modified version of Gleevec, also known as Glivec, "fails in both the tests of invention and patentability."<sup>78</sup>

The WTO has an arbitration and mediation division that has jurisdiction over compulsory licensing disputes under the TRIPS Agreement.<sup>79</sup> However, it has admitted that it cannot agree on how to settle the cases of compulsory licensing.<sup>80</sup> The United States Food and Drug Administration ("FDA") has no

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*; Hiddleston, *supra* note 70.

76. The Patents Act, 1970 § 3(d), No. 39 of 1970, INDIA CODE (2017), [http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1\\_31\\_1\\_patent-act-1970-11march2015.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf) [<https://perma.cc/7ZJV-HP2H>].

77. Padma, *supra* note 71.

78. *Id.*

79. See *Disputes Concerning the TRIPS Agreement*, WTO, [https://www.wto.org/english/tratop\\_e/trips\\_e/intel5\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel5_e.htm) [<https://perma.cc/C9VG-J4DF>]; *Dispute Settlement 3.1 Overview*, U.N. CONF. ON TRADE & DEV. 43 (2003), [https://unctad.org/en/Docs/edmmisc232add11\\_en.pdf](https://unctad.org/en/Docs/edmmisc232add11_en.pdf) [<https://perma.cc/X7DS-CJ8Z>] (last visited Oct. 5, 2019).

80. See *Little-Used 'Par.6' System Will Have Its Day, WHO Tells Intellectual Property and Health Review*, WTO: 2010 NEWS ITEMS (Oct. 26–27, 2010), [https://www.wto.org/english/news\\_e/news10\\_e/trip\\_26oct10\\_e.htm](https://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm) [<https://perma.cc/BZ37-WTX3>] ("The WTO Secretariat explained the legal difference between countries introducing laws to implement the system and their notifying the WTO that they have accepted the amendment. The two are separate and do not depend on each other. . . . When a country accepts the amendment, it effectively affirms that it accepts an additional flexibility in the TRIPS agreement, and that other countries have the legal right to use the system if they choose to do so. Accepting the amendment does not mean that the country necessarily wants to use the system itself. Nor does it mean the country has to implement the system through its own laws or regulations.").

jurisdiction over international compulsory licensing disputes other than to exercise some quality control from time to time during spot inspections over drugs that are produced for import into the United States market.<sup>81</sup>

#### IV. GEORGIA-PACIFIC FRAMEWORK FOR COMPULSORY LICENSING DISPUTES

When one considers that a violation of an involuntary, or compulsory, license<sup>82</sup> is really an infringement case,<sup>83</sup> we can review tests that currently exist to determine what damages, if any, an infringer should pay the patent holder. Recall that under the TRIPS Agreement and Doha Declaration, regardless of how expansive the ability is to obtain a compulsory license, the patent holder must still be given reasonable compensation.<sup>84</sup> Furthermore, whether a framework exists—either within that country or at the WTO—to analyze the competing equities of the case to help the parties reach a resolution of the matter and a conclusion on reasonable compensation is still up for debate.

Some outlying issues revolve around the definition of “adequate remuneration in the circumstances,” which is referred to in the TRIPS Agreement.<sup>85</sup> Generally, this is considered the royalty on the license.<sup>86</sup> If a license was not

81. See 21 C.F.R. § 10.90 (2019) (governing the FDA’s regulatory authority over domestic manufacturers, repackaging of pharmaceuticals, and engagement in Memorandum of Understanding with foreign manufacturers); see also *International Agreements*, U.S. FOOD & DRUG ADMIN. (July 7, 2019), <https://www.fda.gov/international-programs/international-arrangements> [https://perma.cc/U8UB-Y4ZD] (discussing Cooperative Agreements and Memorandum of Understanding); *Foreign Pharmaceutical Manufacturers (5/96): Guide to Inspection of Foreign Pharmaceutical Manufacturers*, U.S. FOOD & DRUG ADMIN. (Aug. 26, 2014), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/foreign-pharmaceutical-manufacturers-596> [https://perma.cc/D8UV-3T8T] (“[T]he authority to inspect foreign drug facilities does not come from Section 704 of the Food, Drug and Cosmetic Act (the Act.) but from the agency’s ability to exercise Section 801 of the Act and commitments made by the sponsors of applications, if applicable. For that reason, the agency is not required to provide stringent documentary evidence to establish violations of the Act. However, the inspection team is expected to collect sufficient records to substantiate its findings and to aid in the further review process by the agency.”).

82. See *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 5.

83. See *Icahn Sch. of Med. at Mount Sinai v. Neurocrine Biosciences, Inc.*, 191 F. Supp. 3d 322, 334 (S.D.N.Y. 2016) (holding that “Neurocrine’s grant of an unauthorized de facto sublicense that arose when Neurocrine transferred to AbbVie the right to exclusively direct and control use of the Sealfon drug discovery tools” alleged a prima facie case for damages and royalties).

84. See discussion *supra*.

85. *Part II—Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*, URUGUAY ROUND AGREEMENT: TRIPS, [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) [https://perma.cc/UPV3-Z7DW] (last visited Sept. 30, 2019). 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.” *Id.*

86. See *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1127 (S.D.N.Y. 1970) (“[T]he recovery of a reasonable royalty for the very purpose of affording fair compensation in cases such as this, where the victimized patentee is unable to prove that he lost a measurable amount

obtained, it would be an infringement of the patent, and the party could sue for damages.<sup>87</sup> In infringement cases, one approach to determine damages is to calculate what the reasonable royalty rate would have been had the license been obtained.<sup>88</sup> Thus, damages are based on the amount of the product sold and the prejudice to the patent holder's development of the patent.<sup>89</sup>

This is not unlike the Indian Patent Act requirement that the patented invention must be "worked in," or manufactured in, the country.<sup>90</sup> In the Novartis case, the Indian Supreme Court determined that Novartis was not even active in the market where the compulsory license was being used, or was so inactive, that the damages were negligible.<sup>91</sup> What could also be relevant would be the sales in other markets in which the patent holder may become active.<sup>92</sup>

What if the country only wants the license for use in a discrete market in their country, like for the extremely poor and underserved, much like how the Department of Health and Human Services in the United States serves the poor under Medicaid<sup>93</sup> and seeks to carve out government discount prices for this discrete group? Recall the Cipro case, in which the United States government

of profits as the result of the infringement."); *see also* *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009).

87. *See Georgia-Pacific*, 318 F. Supp. at 1127 ("[A] reasonable royalty is an alternative way of recovering general compensatory damages and that it is not equitable or commensurable with actual damages computed in terms of demonstrably proved lost profits.").

88. *See id.*; *see also Lucent Techs., Inc.*, 580 F.3d at 1324.

89. *See Georgia-Pacific*, 318 F. Supp. at 1141 (discussing the effect that the infringement had on the development of the product in a certain market). "[T]he two most important factors to be considered in negotiating a license are 'probably, the nature of the product' and how competitive the market was for that product." *Id.*

90. *See* Rahul Chaudhry, *Local Working of Patents in India: An Analysis*, IAM (Sept. 12, 2016), <https://www.iam-media.com/local-working-patents-india-analysis> [<https://perma.cc/TVY8-PAEM>]; *Georgia-Pacific*, 318 F. Supp. at 1120 ("The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter."); Peter Roderick & Allyson M. Pollok, *India's Patent Laws Under Pressure*, 380 LANCET e2, e3 (Sept. 15, 2012) (commenting that the Indian Patent Act requires "that the patented invention is not worked in the territory of India"); *see also* The Patents Act, 1970 § 84, No. 39 of 1970, INDIA CODE (2017), [http://www.ipindia.nic.in/writereaddata/Portal/IPO-Act/1\\_31\\_1\\_patent-act-1970-11march2015.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPO-Act/1_31_1_patent-act-1970-11march2015.pdf) [<https://perma.cc/7ZJV-HP2H>].

91. *See* Roderick & Pollok, *supra* note 90, at e3 (commenting on the Indian Patent Act and the view that "'worked in the territory of India' means 'manufactured to a reasonable extent in India'").

92. *See Georgia-Pacific*, 318 F. Supp. at 1120 ("The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.").

93. *See Medicaid Drug Rebate Program*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> [<https://perma.cc/NZT5-MPGC>] (last visited Nov. 2, 2019) ("The Medicaid Drug Rebate Program . . . is a program that includes . . . participating drug manufacturers that helps to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Approximately 600 drug manufacturers currently participate in this program.").

pressured Bayer to lower the price for government contract use, under the threat of imposing a compulsory license on the product.<sup>94</sup>

There are several factors to consider in a licensing analysis, including market size, target groups, ability to produce the product, amount sold, whether it is sold in a competing market, what profit would the company have made, actual versus lost profit and the like, and whether it is being exported to another market.<sup>95</sup> Thus, the damages/royalty (or remuneration portion) of the breach of a compulsory license calls for a more nuanced approach.

Arguably, the most detailed analysis of royalty damages in a patent infringement case comes from the *Georgia-Pacific* case.<sup>96</sup> It is the seminal case that identifies what a reasonable royalty would be in a patent infringement case.<sup>97</sup> In *Georgia-Pacific*, the court compiled a list of factors to determine reasonable royalty rates.<sup>98</sup> These factors have been “widely cited in patent litigation, although . . . criticized for looking at the issue as if products required only one patent and ignored the royalty rate stacking present in many complex high technology products.”<sup>99</sup> However, since we are examining a single drug patent, the shoe fits. The *Georgia-Pacific* factors are:

1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
4. The licensor’s established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.

94. See Reichman, *supra* note 39, at 250.

95. See generally *Georgia-Pacific*, 318 F. Supp. at 1120–21 (“[T]here is a multiplicity of interpenetrating factors bearing upon the amount of a reasonable royalty. But there is no formula by which these factors can be rated precisely in the order of their relative importance or by which their economic significance can be automatically transduced into their pecuniary equivalent.”).

96. *Id.* at 1120 (discussing a dispute namely over patented wood products and plywood made from trees).

97. See Glenn S. Newman et al., *How Reasonable Is Your Royalty*, J. ACCOUNTANCY (Sept. 1, 2008) (noting that Mr. Newman is the principal in charge of Parente Randolph LLC’s Forensic & Litigation Services based practice in Philadelphia).

98. *Georgia-Pacific*, 318 F. Supp. at 1120.

99. *Georgia-Pacific Factors*, TECH. & IP L. GLOSSARY, <http://www.ipglossary.com/glossary/georgia-pacific-factors/#.XZLYQS2ZPxU> [<https://perma.cc/G4ZH-XVJL>] (last visited Sept. 30, 2019) (elaborating on the *Georgia-Pacific* factors).

5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
6. The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or conveyed sales.
7. The duration of the patent and the term of the license.
8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.
10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.
11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.
12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
14. The opinion testimony of qualified experts.
15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount that a prudent licensee - who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention - would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.<sup>100</sup>

The *Georgia-Pacific* factors provide a more structured analysis than the TRIPS Agreement and Doha Declaration, which left many terms undefined and

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100. *Georgia-Pacific*, 318 F. Supp. at 1120.

vague.<sup>101</sup> Obviously, these factors would be up to a factfinder to determine.<sup>102</sup> However, they can be a useful tool in mediation and arbitration of compulsory licensing disputes by helping the parties employ a more objective and fact-based approach.<sup>103</sup>

With a more structured and uniform approach, a company can also look forward to some level of predictability in compulsory licensing disputes. Companies do not like vagueness because it breeds uncertainty.<sup>104</sup> Pharmaceutical corporations detest uncertainty because it prohibits them from making concrete plans for allocating risk and making determinations of liability or exposure to patent challenges, as well as in royalty litigation.<sup>105</sup> “[T]he IP landscape remains decidedly murky, and the sector is not in for an easy time as it continues to fight its corner.”<sup>106</sup>

In order to provide strategic planning regarding infringement litigation, licensing, and/or concession of the royalty owed, a patent holder also needs to know what types of evidence are required, including how many years the product needs to be marketed in a certain country, and what the potential of that market—or market share—is in that country.<sup>107</sup> For instance, if the market share is so slight, the company may not have made any effort to establish sales

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101. See, e.g., Ford, *supra* note 38, at 960.

102. See *Georgia-Pacific*, 318 F. Supp. at 1121 (“In discharging its responsibility as fact finder, the Court has attempted to exercise a discriminating judgment reflecting its ultimate appraisal of all pertinent factors in the context of the credible evidence”).

103. See *id.* (commenting on using a fact-based approach). In comparison to the fact-based approach outlined in *Georgia-Pacific*, in India, there is what has been described as a hit or miss approach used by pharmaceutical companies seeking to do business in India. See generally Ravinder Gabble & Jillian Clare Kohler, “To Patent or Not to Patent? The Case of Novartis’ Cancer Drug Glivec in India,” 10 GLOBAL HEALTH 1, 2 (2014).

104. Brian D. Smith, *Managing Pharma’s Uncertainty*, PMLIVE (July 25, 2014), [http://www.pmlive.com/pharma\\_news/managing\\_pharmas\\_uncertainty\\_588689](http://www.pmlive.com/pharma_news/managing_pharmas_uncertainty_588689) [<https://perma.cc/LP8U-GEMZ>] (“Historically, strategic planning in life sciences has been about estimating risks and placing bets accordingly; the best estimators won a blockbuster. But what about when, as now, a period of intense turbulence makes some risks, especially long term and strategic risks, impossible to estimate?”).

105. See, e.g., Dylan Scott, *Supreme Court’s Ruling in Patent Case a Blow to Drug Industry*, STAT NEWS: POLITICS (June 20, 2016), <https://www.statnews.com/2016/06/20/supreme-court-rules-against-drug-industry-in-patent-case/> [<https://perma.cc/V3D8-HFNZ>] (commenting that “uncertainty . . . stifles innovation” in the pharmaceutical industry (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016) with regard to uncertainty in reviewing patent claims) (internal quotation marks omitted)); see also Smith, *supra* note 104 (commenting that quantitative data is easier to use to track risks associated with bringing a pharmaceutical product to market and managing it throughout its patent lifecycle). See generally Helen Sloan, *More Fears for Pharma IP Rights in India as Novartis Heads for the Supreme Court*, IAM (Aug. 20, 2012), <https://www.iam-media.com/law-policy/more-fears-pharma-ip-rights-india-novartis-heads-supreme-court> [<https://perma.cc/T2WZ-KBV5>].

106. Sloan, *supra* note 105.

107. See generally *Georgia-Pacific*, 318 F. Supp. at 1120.

or production in that country, and thus, the company would not have any damages.

Additionally, the *Georgia-Pacific* factors take into consideration the issue of “evergreening.”<sup>108</sup> *Georgia-Pacific* factor (9) states: “The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.”<sup>109</sup> If the product that is allegedly infringed actually has no discernable additional market value or improvement over the previous product, under *Georgia-Pacific*, the damages would also be negligible.<sup>110</sup> An infringement of a patent that is only incrementally different is dispositive for the party bringing the infringement case.<sup>111</sup>

LMICs have been critical of the practice of “evergreening” and extending patent protection by adding marginally valuable changes to the patented invention, such as an enteric coating, splitting the product into twice a day delivery system, or adding a non-active irrelevant ingredient for the purpose of extending the patent life.<sup>112</sup> Regarding the effect of “working in” or producing, selling, and manufacturing a product in a specific market, we look to *Georgia-Pacific* factors (4) and (6), which state:

4. The licensor’s established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.

...

6. The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.<sup>113</sup>

Thus, the factors provide a more detailed description of “worked in” than the TRIPS Agreement, the Doha Declaration, and other countries’ amended Paris Convention agreements. For instance, “Bayer acquired an importing

108. See Collier, *supra* note 70, at E385–86.

109. *Georgia-Pacific*, 318 F. Supp. at 1120.

110. See *id.* at 1121 (“[T]he patentee could ‘show the value by proving what would have been a reasonable royalty, considering the nature of the invention, its utility and advantages, . . . the extent of the use involved’ . . . [,] and commercial value as evidenced by its advantages over other devices . . .”).

111. See, e.g., *id.* at 1138 (commenting that a product that was completely different than Weldtex or GP Striated did not, therefore, have a bearing on the license infringement issue before the court).

112. See Collier, *supra* note 70, at E385 (discussing evergreening and the impact on developing countries).

113. *Georgia-Pacific*, 318 F. Supp. at 1120.

license for Nexavar—the company’s brand name for sorafenib tosylate—in 2007” (which is approved for the treatment of kidney cancer).<sup>114</sup> The patent was granted one year later.<sup>115</sup> Bayer claimed that Nexavar’s sales in India were undermined by the marketing of a similar drug by another domestic generic producer, CIPLA, which Bayer sued for infringement.<sup>116</sup> However, according to the Indian Patent Office, Bayer did not begin importing the drug into India in 2008 and had only small quantities on hand during the following two years.<sup>117</sup> The Indian Patent Office determined that Bayer did not “take adequate steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.”<sup>118</sup>

In terms of “adequate compensation,” the world of compulsory licensing becomes even murkier. Compensation is deemed reasonable within the context of the sales in that particular territory.<sup>119</sup> *Georgia-Pacific* also provides a more detailed analysis in this area under factors (2), (8), (12), (13), and (15), which each state:

2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.

...

8. The established profitability of the product made under the patent; its commercial success; and its current popularity.

...

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

...

13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.

...

15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount that a prudent licensee - who desired,

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114. *See India Grants First Compulsory license to Generic Drug Producer*, 16 BRIDGES 6, 7 (2012).

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. *See Georgia-Pacific*, 318 F. Supp. at 1124 (beginning the reasonable royalty rate analysis with the amount of sale in the territory in question).

as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention – would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.<sup>120</sup>

Therefore, the factors provide us with an economic and factual analysis, rather than a vague statement of “the patent holder must be paid adequately.” These factors point to an analysis in the context of what has been paid before, what is traditionally the going price for a license in the specific market, what does a manufacturer of generics typically make in profits, and what, if any, would they be willing to pay to license the drug to produce it domestically. This analysis fleshes out the statutory protections afforded to a patent holder when the patent is infringed.<sup>121</sup> This structured analysis provides a starting point for a fact-based economic analysis that uses historical data.

*Georgia-Pacific* also provides for the use of expert testimony to analyze and assist the factfinder in determining a contested issue.<sup>122</sup> It also examines the nature of the invention and whether it provides any appreciable difference to the consumer, as stated in factors (10) and (14):

10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

...

14. The opinion testimony of qualified experts.<sup>123</sup>

#### CONCLUSION

In conclusion, the equities of pharmaceutical companies and the interests of consumers in LMICs, as well as the countries themselves, cannot be more diametrically opposed to one another. At the same time, a statutory scheme has laid out a solution to affordability and availability in the form of compulsory licensing. If pharmaceutical companies hope to navigate these murky waters and seek to regain any portion of their lost profits, they would do well to study the *Georgia-Pacific* factor analysis as they prepare to argue their case under the authority of the TRIPS Agreement, the Doha Declaration, and local government patent laws.

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120. *Id.* at 1120.

121. 35 U.S.C. § 284 (2012); *Draft Reference Document on the Exception Regarding Compulsory Licensing*, *supra* note 51, at 8.

122. *Georgia-Pacific*, 318 F. Supp. at 1117.

123. *Id.* at 1120.

Similarly, the WTO has expressed frustration with the mediation and arbitration division in terms of settlement of compulsory licensing disputes. The Doha Declaration expanded the rights of licensees, but left little concrete explanations of the terms “adequate,” “emergency,” and “urgent situations.”

The uncertainty within the Doha Declaration does not lend itself to the settlement of cases. In some ways, the solution to compulsory licensing can seem as difficult as “seeing a forest through the trees.”<sup>124</sup> There are so many competing interests, and so much at stake, that it seems impossible to pick out salient issues for parties to agree upon. Without a fact-based and clear-eyed analysis, mediation of these disputes cannot make any headway. Rather, it leads to more litigation.

Notably, the Novartis case lasted several years before the issue was settled. If countries believe that the availability and affordability of medications is a pressing public health issue, they would do well to tighten up the definitions and requirements of compulsory licensing, so parties may have a clear roadmap to navigate these highly contested issues.

With a fact-based framework, such as *Georgia-Pacific* as a guide, the WTO can apply a more comprehensive and fact-based analysis to compulsory licensing disputes. If the WTO wishes to reengage in international mediation and arbitration in these complex disputes, adopting a mediation framework—as laid out in *Georgia-Pacific*—would help each party understand the key issues in dispute. In this way, parties may be able to realistically understand their exposure, realistically understand their obligations under their agreements, and approach negotiations much sooner, rather than litigate these issues while the general public in their country suffers under the high cost of medications.

The WTO should consider amending the Doha Declaration with more fact-specific criteria for the issuance of a compulsory license, criteria to challenge the license, as well as historical fact-based information to determine the reasonable compensation for the patent holder. With such a fact-based and detailed framework for analyzing this complex issue, patent holders will be better informed of their rights and licensees can become better-informed stakeholders. Both the drug company and the LMIC are stakeholders in this quasi-contractual agreement called a compulsory license—an agreement created by the pressing public health need for medication, availability, and affordability.

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124. See *the Forest for the Trees*, WIKTIONARY, [https://en.wiktionary.org/wiki/see\\_the\\_forest\\_for\\_the\\_trees](https://en.wiktionary.org/wiki/see_the_forest_for_the_trees) [https://perma.cc/49BD-HTC7] (last visited Oct. 4, 2019); see also *Miss the Forest for the Trees*, REVERSO ENGLISH DICTIONARY, <https://dictionary.reverso.net/english-definition/miss%20the%20forest%20for%20the%20trees> [https://perma.cc/9UHF-QU4A] (last visited Sept. 21, 2019). This phrase can also mean that one is so focused on the details or intricacies of something that they miss the big picture or the main point. See *the Forest for the Trees*, supra note 124.

By adopting the reasoned, carefully laid out framework as presented in *Georgia-Pacific*, and using it to determine a fair compensation in compulsory licensing, it can allow factfinders, mediators, and stakeholders to find the “forest through the trees” among the complex competing equities within the myriad of details of international compulsory licensing of pharmaceuticals.