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# A Fair Return Approach to Pharmaceutical Compulsory Licensing

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# A FAIR RETURN APPROACH TO PHARMACEUTICAL COMPULSORY LICENSING

*Maura Nuno\**

*This article argues that universal access to drugs requires not only collaboration between nations and patent holders, but also the creation of a neutral International Panel. Under the supervision of a Neutral International Panel, the disequilibrium created by the current system of global intellectual property protection can be equalized to improve access to drugs without undermining pharmaceutical companies and intellectual property rights.*

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## I. INTRODUCTION

Innovation is the solution to global health problems, but as long as innovators are not inherently altruistic, the developing world will be deprived of access to life saving drugs. Under the current framework for the protection of intellectual property, pharmaceutical companies receive property protection and set market prices. The framework allows pharmaceutical companies to justify their supra-competitive prices based on the need to recuperate innovation

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expenses. Because drug development is timely and expensive, with a high risk of failure, governments are inclined to provide pharmaceutical companies with strong intellectual property protection and greater profit margins than would exist in a competitive system to induce them to assume the risks.<sup>1</sup> The genius of the patent system is that it harnesses the market system to determine the reward for patent holders. However, this means that access is determined by the ability to pay, and some people may be deprived of access.

The World Trade Organization (WTO) established the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement to strike a balance between protecting patent holders and giving the public access to inventions. The agreement included a provision for compulsory licensing that would permit a government to allow someone else, usually a generic manufacturer, to produce a drug without the explicit consent of the patent owner. Although TRIPS defined certain qualifications for issuing compulsory licenses, countries retained broad discretion over when to grant compulsory licenses and how to establish adequate remuneration. The Doha Declaration,<sup>2</sup> enacted in 2001, was intended to clarify some of the confusion about compulsory licenses but instead left the adequate remuneration language untouched and did little to coordinate the international system.<sup>3</sup>

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1. Industry figures show that on average, pharmaceutical companies spend \$1.3 billion on research and development of a new drug over a period of ten to twelve years. This figure suggests not all drugs cost the same but fails to detail the distribution of cost around this average. WAYNE TAYLOR, PHARMACEUTICAL ACCESS IN LEAST DEVELOPED COUNTRIES: ON THE GROUND BARRIERS AND INDUSTRY SUCCESS 8 (2010), <http://apps.who.int/medicinedocs/documents/s17815en/s17815en.pdf> [<https://perma.cc/5JYW-3AWH>].
  2. The Doha Declaration recognized that member nations should not strive to uphold the TRIPS Agreement at the expense of the nations' public health. The clarification embodied in the Doha Declaration resulted from an increasing concern over public health problems affecting the developing and least-developed countries. *See* World, Trade Organization, Ministerial Declaration of 14 November 2001, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) [<https://perma.cc/Z6MD-AZV8>].
  3. The Doha declaration did try to improve access to some drugs by allowing countries to use their power to issue compulsory licenses to support the production of generic drugs for export. However, the effort has proven to be insufficient and leaves the current system of state-by-state policy making relatively untouched. *See* Alan O. Sykes, *Public Health and International Law: TRIPS Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47 (2002).

Even if consumers from countries housing the top-ten largest pharmaceutical companies can feasibly pay the market price for drugs, these same prices shut out consumers in the developing world. The existing framework of TRIPS creates a reciprocal arrangement between countries where all member countries must recognize and protect each others' domestic intellectual property rights.<sup>4</sup> The arrangement is challenged when developing nations are forced to choose between upholding intellectual property rights and granting their citizens access to medicines. In those instances, developing nations resort to compulsory licensing. As a result, both patent holders and countries are subject to criticism, litigation, and monetary loss for their respective actions concerning the compulsory license.

This Note proposes the establishment of a neutral International Panel to review pharmaceutical compulsory licenses and provide patent holders with an impartial review of adequate remuneration. Part I introduces the paradigm created by the need for innovation matched against society's ability to pay market prices. Part II outlines the global system of intellectual property protection under TRIPS and Part III deconstructs the consequences of imposing a global patent system with no global coordination. Part IV proposes the creation of an International Panel specifically designed to exclusively entertain disputes over pharmaceutical compulsory licenses. Establishing a neutral International Panel for compulsory license disputes should ameliorate the struggle between pharmaceutical companies and developing countries while increasing global access to life saving drugs.

## II. INNOVATION COSTS VS. ABILITY TO PAY

The patent system is premised on compensating innovators for the costs and risks associated with developing new ideas through temporary market control.<sup>5</sup> Patent rights assume a system at equilibrium where innovators will recover the costs of innovation without surplus or supra-competitive gains. On a national scale, this system is thought to assure that innovators will have the incentive to invest in research and that the public will enjoy the benefits of their innovation. The system harnesses the market by requiring those who benefit from the drug to pay the cost of investing in the drug. But, once domestic patent protection rights are engrafted on other

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4. *Frequently Asked Questions About TRIPS in the WTO*, WORLD TRADE ORG., available at [https://www.wto.org/english/tratop\\_e/trips\\_e/tripfq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm) [<https://perma.cc/8XUU-HV7U>] (last visited Feb. 10, 2016).

5. See Stanley M. Bensen & Leo J. Raskind, *An Introduction to the Law and Economics of Intellectual Property*, 5 J. ECON. PERSP. 3, 4 (1991).

countries who make individual and disconnected decisions about access to medicines, the equilibrium of the system is disturbed.

In developed countries, access to drugs is regulated by national governments and insurance systems, which can determine “how to spread the financial burden of the system among potential beneficiaries.”<sup>6</sup> Governments can also choose to subsidize the cost of innovation through government-funded research or the healthcare system.<sup>7</sup> In contrast, the developing world lacks the infrastructure or system to spread the financial burden across beneficiaries. Furthermore, there is no coordination between countries concerning the reward for innovation and the ability of each country to pay. This uncoordinated system of international patent rights leads countries to take unilateral action to the detriment of patent holders and the TRIPS agreement as a whole. For example, in 1997, Brazil passed legislation authorizing a local company to produce a specific medicine without the consent of the patent holder.<sup>8</sup> In this example, Brazil took unilateral action to remedy insufficient access to that medication in its country without negotiating with the patent holder’s country of origin.

Without an International Panel, it is impossible to fairly determine whether pharmaceutical companies are being over or undercompensated for their innovations. Further, there is no way to resolve the distributive issue — “the determination of which . . . countries should bear the burden of providing the incentive”—without a coordination system.<sup>9</sup> In fact, even with a presiding International Panel, the distributive issue would be difficult to resolve given the concentration of pharmaceutical companies in only a handful of countries.

### III. THE CURRENT SYSTEM

TRIPS was enacted to promote the transfer and dissemination of technology through the protection and enforcement of intellectual

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6. Peter Gerhart, *The Tragedy of TRIPS*, 2007 MICH. ST. L. REV. 143, 155 (2007).
  7. *Cutting American Health Research Will Harm the World*, ECONOMIST (Mar. 2, 2013), <http://www.economist.com/news/science-and-technology/21572735-cutting-american-health-research-will-harm-world-bad-medicine> [https://perma.cc/MK2M-PYZG].
  8. Christie Mount, *Brazil’s Defiant AIDS Program: A Model for the Developing World*, COUNCIL HEMISPHERIC AFF. (July 30, 2013), <http://www.coha.org/brazils-defiant-aids-program-a-model-for-the-developing-world/> [https://perma.cc/9ZV7-BJ6E].
  9. Gerhart, *supra* note 6, at 158.

property rights<sup>10</sup> by establishing “minimum levels of protection that each government has to give to the intellectual property of fellow WTO members.”<sup>11</sup> When a member government determines its citizens cannot pay the market price for a drug, they are first encouraged to seek voluntary licenses from the patent holder. Under a voluntary license, the petitioning country is authorized to use patented material by the patent holder under “reasonable commercial terms.”<sup>12</sup> Additionally, Article 31 of TRIPS creates an exception to the exclusive right of the patent holder to determine the drug supplier and manufacturer. Under Article 31, a member government may allow “someone else to produce the patented product or process without the consent of the patent owner,” therefore issuing a compulsory license.<sup>13</sup> Before a government may issue a compulsory license, the proposed user must show proof of unsuccessful attempts to obtain a voluntary license over a “reasonable period of time.”<sup>14</sup> Further, the agreement provides an additional exception in cases of “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” where the issuing government need not demonstrate an initial attempt to obtain the patent holder’s authorization before issuing a compulsory license.<sup>15</sup>

Despite the exception to strong intellectual property protection, the compulsory license issuer must pay “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”<sup>16</sup> The language of TRIPS fails to delineate a process for determining adequate remuneration and therefore gives the issuing government wide discretion in determining appropriate royalty rates. As such, the issuing country may unilaterally decide to issue a compulsory license once favorable negotiations cannot be met and set the royalty rate according to their own measures of adequacy. Access to drugs is an important consideration for TRIPS and by demanding

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10. See Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 1, Annex 1C, Legal Instruments-Results of the Uruguay Round 33 I.L.M. 81 (1994) [hereinafter TRIPS].
  11. *Intellectual Property: Protection and Enforcement*, WHO, available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) [https://perma.cc/HZP3-UHQ3] (last visited Mar. 15, 2015).
  12. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm) [https://perma.cc/5J66-8WU3] (last visited Jan. 24, 2015).
  13. *Id.*
  14. *Id.*
  15. TRIPS *supra* note 10, at art. 31(b).
  16. TRIPS, *supra* note 10, at art 31(h).

royalty rates, no matter how minimal, it ensures pharmaceutical companies will at least obtain some profit from developing nations, which they would not otherwise receive because citizens of developing countries could never purchase the drugs at market value.

Further complicating the paradox created by the ambiguity of “adequate remuneration,” the agreement provides that the judiciary branch or some higher authority from the issuing country shall review determinations about remuneration for compulsory licenses.<sup>17</sup> A pharmaceutical company dissatisfied with the compulsory license or the issuing country’s determination of what constitutes adequate remuneration must seek relief through that nation’s judicial system. In order for that clause to be carried out successfully, the countries issuing compulsory licenses would need to provide a mechanism for impartial review.

Pharmaceutical companies that have attempted to challenge compulsory licenses using the issuing nation’s laws failed and significantly damaged their public image in the process.<sup>18</sup> In November of 2001, WTO members met in Doha, Qatar to clarify ambiguities in the TRIPS agreement and to pacify the developing nations unsatisfied with the current interpretation of TRIPS so that new negotiation rounds could be commenced.<sup>19</sup> The Doha Declaration provided an authoritative interpretation of TRIPS so that members would recognize another member’s right to take measures to protect public health and promote drug access.<sup>20</sup> The Doha Declaration changed the provision in the TRIPS Agreement that restricted compulsory licenses to mainly supply the domestic market.<sup>21</sup> The new understanding of the Article 31 exception allows countries unable to manufacture drugs domestically to obtain cheaper versions from other countries.<sup>22</sup> Additionally, the least developed countries may delay conformity to the TRIPS minimum standards of protection for pharmaceutical

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17. TRIPS, *supra* note 10, at art 31(j).
  18. See Ellen F. M.’T Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 3 CHI. J. INT’L L. 27, 30-31 (2003) (discussing the backlash that drug companies faced for challenging the South African legal framework).
  19. Carlo Trojan, *The Developing Countries Came of Age in Doha*, EUR. AFF. (2002), available at <http://www.europeaninstitute.org/index.php/component/content/article?id=389:the-developing-countries-came-of-age-in-doha> [https://perma.cc/K43R-XVLV] (last visited Mar. 14, 2015).
  20. James Love, *Measures to Enhance Access to Medical Technologies and New Methods of Stimulating R&D*, 40 U.C. DAVIS L. REV. 679, 682 (2007).
  21. *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 12.
  22. *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 12.

patents until 2016.<sup>23</sup> Therefore, the least-developed countries, not yet required to meet the minimum standards of protections, should not benefit from the compulsory license exception until after 2016. As a result, developing countries will be the most active players on the compulsory licensing agenda.

#### IV. DISEQUILIBRIUM IN THE CURRENT SYSTEM

The existing framework for global intellectual property protection of pharmaceuticals compensates pharmaceutical companies for research and development costs at the expense of global access to life saving drugs. Not only does the framework give inadequate attention to access, but the inadequacies lead to: (1) insufficient royalty payments under compulsory licenses and no proper judicial oversight; (2) damaging public relations incidents; (3) neglect of orphan diseases; and (4) a rise in the counterfeit drug market. The shortcomings of the existing framework are the result of uncoordinated distribution costs leaving pharmaceutical companies and developing countries alike dissatisfied with the status quo. Imposing impartial oversight for compulsory licenses would result in overall greater global access to drugs and the emergence of untapped markets.

##### *A. Insufficient Royalty Payments under Compulsory Licensing*

The patent system rewards innovators for assuming the risk and cost of research and development by giving patent owners the right to exclude others from using or producing their product for a certain amount of time so that they may recoup their expenses. Under the premise of recovering the cost of research and development, pharmaceutical companies are free to set inaccessibly high market prices for their drugs. This means, that some countries, those with citizens that can't afford market prices and where government subsidies are not enough to make the drugs affordable, are effectively forced to request a voluntary license or unilaterally issue a compulsory license to provide their citizens with access to certain drugs. Because voluntary licensing involves negotiations between two highly interested parties, the government seeking a voluntary license and the patent holder, negotiations are unlikely to result in terms agreeable to both. Thus, voluntary licenses are usually issued as a result of public pressure or legal action.<sup>24</sup> And even though the WTO imposes an

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23. *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 12.

24. TAHIR AMIN, VOLUNTARY LICENSING PRACTICES IN THE PHARMACEUTICAL SECTOR: AN ACCEPTABLE SOLUTION TO IMPROVING ACCESS TO AFFORDABLE MEDICINES? 13 (2007), *available at* <http://static1.1.sqspcdn.com/static/f/129694/1099999/1192729231567/Oxfam+-+Voluntary+Licensing+Research+IMAK+Website.pdf?token=WmNw>



unwritten obligation on members to bargain in good faith, governments seeking a voluntary license bargain with the knowledge that if agreeable terms cannot be established they may unilaterally issue a compulsory license. This system imposes high bargaining costs for pharmaceutical companies faced with the possibility of compulsory licenses and the notion that there is no widely accepted international standard for reasonable return rates.

Allowing each country issuing a compulsory license to set its own royalty rate effectively deprives pharmaceutical companies of any control over the return rate for their inventions. In such a system, there is no guarantee to the patent owner that a royalty rate will not be disproportionately low or high to the country's actual ability to pay. Countries issuing compulsory licenses are encouraged to adopt the Remuneration Guidelines for Non-Voluntary use of a Patent on Medical Technologies (Remuneration Guidelines) created by WHO and the Bureau for Development Policy of the United Nations Development Programme (UNDP) because they are the simplest, but countries can choose any of the existing guidelines or even develop their own.<sup>25</sup>

Most guidelines use a base rate of 4 percent that can be adjusted for special circumstances including the country's rank in the Human Development Index, utilization factor, and therapeutic value.<sup>26</sup> WHO Remuneration Guidelines adjust the 4 percent base rate by plus or minus 2 percent for the product's therapeutic value or the government's role in financing research and development.<sup>27</sup> A trifle two-percent plus-or-minus difference cannot be expected to account for the wide range of varying circumstances affecting each applicant. Moreover, with each country being free to choose with guidelines to use there can be no consistency among countries. Using these guidelines, pharmaceutical companies cannot expect to obtain a fair return on their innovations.

India's negotiations with the pharmaceutical company Bayer are a recent example of an ineffective license agreement under the current system. In 2012, India issued its first compulsory license for Nexavar, a compound used to treat advanced stages of kidney and liver

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25. Love, *supra* note 20, at 688-689.

26. Love, *supra* note 20, at 688-689.

27. JAMES LOVE, WORLD HEALTH ORG., REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT 7 (Robert Weissman ed., 2005), <http://www.undp.org/content/dam/aplaws/publication/en/publications/hiv-aids/access-to-drugs-via-compulsory-licensing-guidelines--non-voluntary-patent-use/22.pdf> [https://perma.cc/QE59-HCNK].

cancer.<sup>28</sup> Bayer obtained a license to import Nexavar into India in 2007, but did not import Nexavar in 2008 and only imported the drug in small quantities in 2009 and 2010.<sup>29</sup> Under Indian intellectual property law, failing to work a patent domestically is cause for forfeiture of the patent, which has gradually turned into a system of compulsory licensing instead.<sup>30</sup> In response, Natco Pharmaceutical, a national drug manufacturing company, applied for a compulsory license and was granted authorization to produce Bayer's patented cancer drug for domestic sale with a 6 percent royalty rate on net sales of the drug payable to Bayer on a quarterly basis.<sup>31</sup>

During negotiations for a voluntary license, the initial step in this process, Bayer requested royalty payments of 15 percent of net sales, but negotiations failed and India granted Natco Pharmaceutical a compulsory license.<sup>32</sup> Bayer appealed the grant of the compulsory license to the Intellectual Property Appellate Board ("IPAB") who upheld the order, but raised the royalty rate to 7 percent.<sup>33</sup> In their considerations, the board dismissed Bayer's argument for remuneration noting "expenditure incurred by the appellant is not the criterion, nor does this chapter intend[] that the patentee be enabled to recoup the amount spent."<sup>34</sup> Bayer then brought the issue to the Mumbai High Court, which dismissed the issue noting: "we don't see a reason to interfere with the order passed by IPAB, and therefore, the case is dismissed."<sup>35</sup> Lastly, Bayer filed a petition with the

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28. Marciel Estavillo, *India Grants First Compulsory License, for Bayer Cancer Drug at Intel*, I.P. WATCH (Dec. 3, 2012), available at <http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/> [https://perma.cc/DJ9H-52ST].
  29. *Id.*
  30. Jerome H. Reichman, *Non-Voluntary Licensing of Patented Inventions*, UNCTAD-ICTSD 1 (2003), [http://www.ictsd.org/downloads/2008/06/cs\\_reichman\\_hasenzahl.pdf](http://www.ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf) [https://perma.cc/WXF8-XKWW].
  31. Natco Pharm. Ltd. v. Bayer Corp., (2011) C.L.A.No.1 (India), available at [http://www.ipindia.nic.in/ipoNew/compulsory\\_License\\_12032012.pdf](http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf) [https://perma.cc/CW8Y-5FAS].
  32. Estavillo, *supra* note 28.
  33. Bayer Corp. v. Union of India, et. al., Order No. 45/2013 (India).
  34. Bayer Corp. v. Union of India, et al. (*Bayer Corp. v. India*), Order No. 223/2012 (India), available at <http://www.ipabindia.in/Pdfs/Order-223-2012-OA-35-2012-PT-MUM.pdf> [http://perma.cc/BDT3-PY32].
  35. *Bombay High Court Refused to Interfere with IPAB Order in Nexavar Compulsory License Case*, LEXORBITIS (July 16, 2014), <http://www.lexorbis.com/bombay-high-court-refused-to-interfere-with-ipab-order-in-nexavar-compulsory-license-case/#acceptLicense> [https://perma.cc/D7A7-G67T].

Supreme Court of India, which refused to entertain Bayer's Special Leave Petition against the Mumbai High Court's decision.<sup>36</sup>

This recent sequence of events illustrates the inevitable dilemma created by an international agreement restricting a pharmaceutical company's remedies to the judicial system of the compulsory license-issuing nation. Bayer diligently appealed to the adequate courts in India and followed protocol, but was denied actual appellate review. India's high court and Supreme Court refused to entertain the appeal and gave deference to the decision of the IPAB. Simultaneously, Bayer was forced to engage in a public relations battle against a nation that seemingly afforded the pharmaceutical company appellate review but in fact dismissed the matter.

*B. Public Relations Battles are a Waste of Resources*

When pharmaceutical companies like Bayer must use financial resources to defend their intellectual property, they divest funds from research and development. On average, pharmaceutical companies spend one-third of all sales revenue on marketing their products,<sup>37</sup> and an average of \$4 billion on research and development for a single drug.<sup>38</sup> Arguably, pharmaceutical companies also enjoy the highest profit margins on the market. For example, Pfizer, the world's largest pharmaceutical company, ended 2013 with a 42 percent profit margin.<sup>39</sup> While the amounts spent on advertising seem excessive and irrational, the public fails to consider the reasons why pharmaceutical companies must invest such large sums in marketing. In addition to the standard cost of maintaining public interest, pharmaceutical companies are constantly fighting a public relations battle.<sup>40</sup> In today's

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36. *Supreme Court Says No to Bayer, Upholds Compulsory License on Nexavar*, INFO JUSTICE (Dec. 15, 2014), <http://infojustice.org/archives/33690> [<https://perma.cc/7D8N-JZ5K>] (last visited Mar. 13, 2015).
37. *Pharmaceutical Industry*, WHO, available at <http://www.who.int/trade/glossary/story073/en/> [<https://perma.cc/5RBP-WU94>] (last visited Jan. 25, 2015).
38. Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 2, 2012), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/> [<https://perma.cc/HK38-KMA4>].
39. Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), <http://www.bbc.com/news/business-28212223> [<https://perma.cc/AB8U-P6DF>].
40. Marcia Angell, *The Truth About the Drug Companies*, N.Y. BOOKS (July 15, 2004), available at <http://www.nybooks.com/articles/archives/2004/jul/15/the-truth-about-the-drug-companies/> [<https://perma.cc/R7L7-UHKD>].

age, pharmaceutical companies are both revered and hated by the public for their innovations and unsightly escalating drug costs.

In 1998, thirty-nine multinational pharmaceutical companies sued Nelson Mandela and the South African government challenging legislation that would allow the South African government to “purchase brand-name drugs at the lowest rates available anywhere in the world,” without prior approval.<sup>41</sup> Pharmaceutical companies alleged the legislation violated the South African constitution and the TRIPS agreement.<sup>42</sup> During the three-year legal dispute, pharmaceutical companies closed factories and canceled investments in South Africa.<sup>43</sup> Initially, the United States government supported the pharmaceutical industry’s claim by withholding trade benefits and threatening trade sanctions against South Africa.<sup>44</sup> International public outrage at the pharmaceutical companies’ seemingly insensitive actions forced the United States to withdraw support, and prompted the eventual negotiations between pharmaceutical companies and the South African government.<sup>45</sup> In the end, the pharmaceutical companies conceded that South African law could be implemented as it was, and agreed to pay the South African government’s legal costs.<sup>46</sup>

This case demonstrates the futility of raging a political war against nations attempting to increase access to lifesaving drugs. Pharmaceutical companies failed to overturn the legislation, severely damaged their public image and lost an estimated \$286,000 in court costs.<sup>47</sup> J.P. Garnier, chief executive of GlaxoSmithKlein, said in

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41. Rachel L. Swarns, *Drug Maker Drop South Africa Suit Over AIDS Medicine at Intel*, N.Y. TIMES (Apr. 20, 2001), available at <http://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html> [https://perma.cc/C5WK-HX2W].
  42. Joel Lexchin, *Canada and access to medicines in developing countries: intellectual property rights first*, Globalization and Health (2013), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3844468/pdf/1744-8603-9-42.pdf> [https://perma.cc/A4NV-YZYH].
  43. Swarns, *supra* note 41.
  44. *1998: Big Pharma Versus Nelson Mandela*, M.S.F. ACCESS (Jan. 2009), <http://www.msfacecess.org/content/1998-big-pharma-versus-nelson-mandela> [https://perma.cc/Z7UE-G96G].
  45. Swarns, *supra* note 41.
  46. WILLIAM W. FISHER III & CYRILL P. RIGAMONTI, *THE SOUTH AFRICA AIDS CONTROVERSY: A CASE STUDY IN PATENT LAW AND POLICY 9* (2005), available at <http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf> [https://perma.cc/LJC7-2CFG].
  47. Ann M. Simmons, *Suit Against Cheap AIDS Drugs Ends in S. Africa at Intel*, L.A. TIMES (Apr. 20, 2001), available at

response to the decision to withdraw the lawsuit, “[w]e have never been opposed to wider access. We have discounted our drugs. We’ve done everything we could. Frankly, the legislation was the worst distraction. It did not allow us to communicate our message effectively.”<sup>48</sup> When pharmaceutical companies feel apprehensive over the degree of patent protection awarded in a given country, they will respond defensively. Such defensive actions contribute to the high marketing costs spent by pharmaceutical companies to maintain customer loyalty in light of bad public presence and to obtain new customers.

Despite the disappointing outcome of the South African legislation challenge, pharmaceutical companies launched a similar attack on the Brazilian government in 2001.<sup>49</sup> Brazil’s 1997 legislation reserved the “right to authorize a local company to produce ARVs<sup>50</sup> without the permission of the patent holder, regardless of the pharmaceutical company’s country of origin.”<sup>51</sup> Pharmaceutical companies felt threatened by the implications of such legislation and urged the United States to challenge the legislation at the WTO conference in Qatar.<sup>52</sup> In January 2001, the U.S. Trade Representative filed a complaint with the WTO Dispute Settlement Body against Brazil’s patent laws authorizing compulsory licensing.<sup>53</sup> As a result of heavy international criticism, the U.S. Trade Representative withdrew the complaint on June 25, 2001.<sup>54</sup> Brazil, however, privately agreed to give the United States advanced notice of any future plans to issue compulsory licenses.<sup>55</sup>

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<http://articles.latimes.com/2001/apr/20/news/mn-53295>  
[<https://perma.cc/WE8H-HVPY>].

48. Swarns, *supra* note 41.

49. Mount, *supra* note 8.

50. Standard antiretroviral therapy (ART) consists of a combination of at least three antiretroviral (ARV) drugs to suppress HIV. As explanation, see *Use of Antiretrovirals for Treatment and Prevention of HIV Infection*, WHO, available at <http://www.who.int/hiv/topics/treatment/en/> [<https://perma.cc/687Y-VZAR>] (last visited Mar. 14, 2015).

51. Mount, *supra* note 8.

52. Mount, *supra* note 8.

53. Jennryn Wetzler & Ana Ayala, *Timeline on Brazil’s Compulsory Licensing*, PROGRAM INFO. JUST. & INTELL. PROP. WASH. C. L. AM. U. (2008), available at <https://www.wcl.american.edu/pijip/download.cfm?downloadfile=9C0107B5-DE2F-4E48-6CE8D03F4933FCD4> [<https://perma.cc/3TXW-U3VC>].

54. *Id.*

55. *Id.*

Ineffective intellectual protection drives pharmaceutical companies to respond defensively to national efforts to increase access. This aggressive behavior, and the public relations nightmare it creates, feeds into the vicious cycle of increasing pharmaceutical costs. The pharmaceutical industry, like all other industries, must bear the cost of market competition and particularly the cost of generic drug alternatives. Amending public image problems should not be added to the steep marketing costs.

### *C. Orphan Diseases*

The top ten largest pharmaceutical companies in the world, controlling one-third of the pharmaceutical industry, are all located in first-world countries and mainly supported by the private sector.<sup>56</sup> In first-world countries, both private and public funding supports research and development for the sake of innovation and much of the funding benefits the medical field. In the U.S., the National Institute of Health's research underpinned five of America's twenty best selling drugs.<sup>57</sup> Unfortunately, developing nations do not enjoy the same type of financial support available to research organizations in the first world. Under this framework, pharmaceutical companies lack the incentive to invest in the research and development necessary to create treatments for orphan diseases, rare diseases affecting a small number of individuals, because they would prefer to allow government funded institutions to bear that risk.

In the United States, an orphan disease is one that affects fewer than 200,000 people nationwide, but in Japan it's fewer than 50,000 individuals, and fewer than 2,000 in Australia.<sup>58</sup> The different thresholds are proportional to the nation's population size, and indicate the baseline of affected individuals necessary to spike pharmaceutical interest. The difference, however, is that first-world countries spend billions of dollars on research across all fields.<sup>59</sup> Given the high cost of research and development, pharmaceutical companies lack the incentive to research these rare diseases because the return rate is unlikely to cover the expense of the research or produce profit.

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56. *Pharmaceutical Industry*, *supra* note 37.

57. *Cutting American Health Research Will Harm the World*, *supra* note 7.

58. J.K. Aronson, *Rare Diseases and Orphan Drugs*, 61 BRIT. J CLINICAL PHARMACOLOGY 243, 243-45 (2006), *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1885017/> [<https://perma.cc/4C92-L2X6>]; *Orphan Products: Hope for People with Rare Diseases*, FDA (2012), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143563.htm> [<https://perma.cc/Y5TS-RHKZ>].

59. *Cutting American Health Research Will Harm the World*, *supra* note 7 (indicating that in 2011 the U.S. and the E.U. countries spent a combined \$641 billion on research, while China spent \$160 billion).

Developed nations address the orphan disease problem by inducing research and development through subsidies. A subsidy system for pharmaceutical research and development functions like insurance coverage: the risk is spread amongst all taxpayers who may or may not benefit from the results of the innovation.<sup>60</sup> Countries like the United States, Japan, Australia, and the European Community mitigate the problem of orphan diseases by passing legislation encouraging research through “tax credits and research aids, simplification of marketing authorization procedures, and extended market exclusivity.”<sup>61</sup> Orphan disease issues are more prominent in developing countries where government funds cannot be allocated to treat rare diseases.

Developing drugs for orphan diseases is not cost-effective according to market standards; so pharmaceutical giants with the resources to tackle the problem but largely driven by profit margins remain apathetic to the needs of those afflicted by orphan diseases. Drugs that benefit the industrialized nations are prioritized over drugs that can benefit countries with individuals that are unable to pay the price of innovation.<sup>62</sup> Under a framework of international laws securing a fair return on medical innovation, pharmaceutical companies could be enticed to fund research for orphan diseases. While the projects would not be categorized as lucrative, the eventual payoff of the initial investment and improved public image would suffice to incentivize pharmaceutical companies to undertake the research. Moreover, once return rates are globally coordinated, pharmaceutical companies can offset the cost of research for orphan diseases from their more successful products.

#### *D. Rise in the Counterfeit Drug Market*

Disproportionately high prices and limited access to name brand medicines exacerbate the counterfeit drug market problem. The WHO explains, “[w]hen prices of medicines are high and price differentials between identical products exists there is a greater incentive to supply cheap counterfeit medicines.”<sup>63</sup> The counterfeit drug market functions by supplying counterfeit drugs through traditional distribution

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60. See Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents - Prizes Debate*, 92 TEX. L. REV. 303, 314-15 (2013).

61. Aronson, *supra* note 58, at 244.

62. *Pharmaceutical Industry*, *supra* note 37.

63. *General Information on Counterfeit Medicines*, WHO (Feb. 2006), available at <http://www.who.int/medicines/services/counterfeit/overview/en/index1.html> [https://perma.cc/4QHC-PPVV].



channels or directly to consumers.<sup>64</sup> A counterfeit drug is “one which is deliberately and fraudulently mislabeled with respect to identity and/or source.”<sup>65</sup>

The inability to regulate the creation or distribution of counterfeit drugs creates a number of risks to public health. While some individuals might consciously purchase counterfeit drugs, the majority are inadvertent recipients of subpar medications.<sup>66</sup> Counterfeit drugs “may include [products with the] correct ingredients but with fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.”<sup>67</sup> The most dangerous counterfeit drugs are those with incorrect compositions because of their potential health effects. For example, more than 500 people, mostly children, died from consuming medications “fraudulently or [] mistake[nly]” containing diethylene glycol, a poisonous solvent.<sup>68</sup>

In addition to the health risk associated with counterfeit drugs, the healthcare industry must worry about the public’s lost sense of faith in the healthcare system. Many individuals with access to regular pharmaceutical treatments are skeptical of the system’s ability to produce positive results. Counterfeit drugs on the market only serve to reinforce apprehension against modern medicine.

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64. *Growing Threat from Counterfeit Medicines*, WHO (Apr. 2010), available at <https://www.who.int/bulletin/volumes/88/4/10-020410/en/> [<https://perma.cc/LX5Z-6FFY>] (asserting that “international trade presents easy opportunities for counterfeiters to insert their products into the supply chain of legitimate pharmaceuticals and to disguise the source.”).
65. *General Information on Counterfeit Medicines*, *supra* note 63.
66. See THE REAL DANGERS OF COUNTERFEIT DRUGS, PHARMA, available at <http://pharma.webpackaging.com/issue1/healthcare/anti-counterfeiting/the-real-dangers-of-counterfeit-drugs/> [<https://perma.cc/JK5W-BMRU>] (last visited Mar. 14, 2015) (observing that easy access to popular drugs on the Internet since the late 1990s has led some unsuspecting buyers to purchase counterfeit drugs, while other consumers deliberately buy counterfeit drugs to avoid high treatment costs).
67. Anna Gu, *The Fight Against Counterfeit and Substandard Pharmaceuticals by Governments, International Agencies, and Professional Societies*, in 1 COUNTERFEIT MEDICINES: POLICY, ECONOMICS, AND COUNTERMEASURES 53, 53-54 (Albert I. Wertheimer & Perry G. Wang, eds., 2012).
68. *Counterfeit Drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs*, WHO 13 (1999), available at <http://apps.who.int/medicinedocs/en/d/Jh1456e/4.html> [<https://perma.cc/L4DA-PJ48>]; see generally L. J. Schep et al., *Diethylene Glycol Poisoning*, 47 CLINICAL TOXICOLOGY 525, 525-35 (2009).



V. PROPOSAL: AN INTERNATIONAL PANEL OF NEUTRAL  
INDIVIDUALS

A potential solution to the problems that arise from having an uncoordinated, decentralized system is to establish an International Panel that will review national decisions to ensure that pharmaceutical companies receive adequate return on investments while ensuring that market prices reflect the ability of countries to pay for drugs. This body's impartial nature will allow the members to determine the common interests between the issuing country and the pharmaceutical company that transcend beyond national interests.

*A. Special Board*

Disputes arising out of TRIPS are governed by the dispute settlement system instituted by the WTO and subject to the general rules and procedures for management of disputes.<sup>69</sup> This system seeks to maintain a balance between the obligations and rights of members by addressing instances of unfair outcomes as a result of measures taken by other members.<sup>70</sup> The dispute settlement mechanism instituted by the WTO is inadequate for resolving compulsory license disputes for pharmaceutical patents because pharmaceutical companies cannot appeal compulsory license decisions directly to a designated board. Further, the international health crisis distinguishes itself from all other intellectual property conflicts by its indisputable effect on human existence. Moreover, the effectiveness of the dispute settlement system continues to face criticism especially in regards to the developing nations' ability to access the system and devote financial and legal resources to make it effective.<sup>71</sup> Here, the International Panel will specifically focus on coordinating payments by countries to achieve a global system that induces the right amount of investment and distributes costs among countries based on their ability to pay.

International support for the institution of an International Panel specifically created to address compulsory license disputes will remove the stigma associated with challenging compulsory licenses. A compulsory license is not intrinsically unfair, but may be unfair as applied/ in practice due to inadequate royalty rates. Marked economic differences and bargaining power disparities between Brazil and South

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69. Viviana Muñoz Tellez, *Dispute Settlement Under the TRIPS Agreement: The United States-Brazil (2000) and United States-Argentina (2002) Patent Disputes*, in RESEARCH HANDBOOK ON THE INTERPRETATION AND ENFORCEMENT OF INTELLECTUAL PROPERTY UNDER WTO RULES 215, 215 (Carlos M. Correa ed., 2010).

70. *Id.*

71. *Id.* at 216.

Africa depict a perfect illustration of how a neutral board could sanction each government's respective compulsory license, but under different terms. Shedding the stigma and allowing transparent review of compulsory licensing applications will benefit pharmaceutical companies, governments, and consumers.

### *B. Board Composition*

The International Panel will be composed of seven standing members and closely resemble the Appellate Body of the WTO. Like the Appellate Body of the WTO, the Dispute Settlement Body (DSB) will appoint each member of the International Panel.<sup>72</sup> The DSB is "made up of all member governments, usually represented by ambassadors," thus, assuring uniform international representation.<sup>73</sup> Members of the WTO Appellate Body must be "individuals with recognized authority . . . demonstrated expertise in law, international trade and the subject-matter of the covered agreements generally."<sup>74</sup> Following this example, the International Panel members must meet the same qualification with additional expertise in patent law and the pharmaceutical industry. Further, a staff of experts on investment in risk and innovation will support the members. Additionally, the members must be unaffiliated with any government, and be "broadly representative of the Membership of the WTO."<sup>75</sup> Each member will be elected for a four-year term, with the possibility of being reappointed once.<sup>76</sup> Board members will be subject to the Rules of Conduct for the Understanding of Rules and Procedures Governing the Settlement of Disputes.<sup>77</sup> Using this method for selecting board members will ensure each compulsory license is subject to the same review process and free of national bias.

### *C. Review Process*

The International Panel will have appellate review over the remuneration established by the government issuing a compulsory license and will only entertain cases of compulsory licenses for pharmaceutical patents. The board can juxtapose the pharmaceutical

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72. *Appellate Body*, WTO, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/appellate\\_body\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/appellate_body_e.htm) [https://perma.cc/9NU6-8T8X] (last visited Jan 25, 2015) [*Appellate Body Members*, WTO].

73. *Dispute Settlement*, WTO, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm) [https://perma.cc/NP62-X4CL] (last visited Jan. 26, 2015).

74. *Appellate Body Members*, WTO, *supra* note 72.

75. *Appellate Body Members*, WTO, *supra* note 72.

76. *Appellate Body Members*, WTO, *supra* note 72.

77. *Appellate Body Members*, WTO, *supra* note 72.

company's research and development costs and other factors it sees fit with the nation's need and accessibility concerns, taking into account the revenue that the pharmaceutical company earns from domestic sales and in other countries. Parties to a dispute will be expected to meet evidence thresholds to support their positions. Pharmaceutical companies challenging a compulsory license will have the burden of producing records that illustrate the cost to the pharmaceutical company for the specific drug and the issuing country must produce evidence of the country's need for the drug and ability to pay. The board shall have absolute discretion to construe a party's failure to cooperate as evidence of bad faith.

As described earlier, when responding to inadequate royalty payments, WHO in collaboration with UNDP published an extensive set of guidelines for establishing "adequate" remuneration that countries issuing a compulsory license can use to determine adequate remuneration for a specific drug.<sup>78</sup> But these guidelines still produce unsatisfactory results for pharmaceutical companies. In 2012, India determined the royalty rate for Bayer's cancer drug using WHO's Remuneration Guidelines but Bayer still appealed the rate.<sup>79</sup> The existing guidelines, including WHO's Remuneration Guidelines, impose a rigid equation for establishing adequate remuneration and tend to focus on concerns specific to the country of origin. So long as countries are free to choose which guidelines to follow and how to discount factors, pharmaceutical companies will continue to receive disagreeable and inconsistent royalty rates. The International Panel shall make use of the different formulas for remuneration and introduce flexibility into the calculation process while maintaining consistency across countries. For example, the board must have authority to retroactively entertain a dispute for a compulsory license issued for an emergency situation and design a payment plan so that the pharmaceutical company can be compensated.

The International Panel will build on the formulas devised by WHO and other countries without committing to a single mechanism. The most notable difference between existing considerations and factors the neutral board will consider will be the capital investment spent on the specific drug by the pharmaceutical company. In *Bayer v. Natco*, Bayer's challenge to the compulsory license was dismissed because Bayer's inability to recover its investment did not pertain to the issue at hand. The Intellectual Property Appellate Board, Chennai reasoned that the "expenditure incurred by the appellant is not the criterion, nor does this chapter intend[] that the patentee be

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78. LOVE, *supra* note 27.

79. Bayer Corp. v. Union of India, et al. (*Bayer Corp. v. India*), Order No. 223/2012 (India), available at <http://www.ipabindia.in/Pdfs/Order-223-2012-OA-35-2012-PT-MUM.pdf> [<http://perma.cc/BDT3-PY32>].

enabled to recoup the amount spent.”<sup>80</sup> India, like each government making the same argument, assumes the pharmaceutical company recovered its investment from market sales in the developed world. The fault in that reasoning is that without global coordination and parallel importation concerns pharmaceutical companies stand to lose the ability to actually recover their investment.<sup>81</sup>

In order to secure a fair return for the labor and money-intensive investments, the International Panel must factor a pharmaceutical company’s investment costs into their decisions and cannot assume that the pharmaceutical company will recover the costs exclusively from the developed countries. Companies will not be awarded higher royalty rates to meet the company’s marketing needs or surplus profits but can expect to receive a fair return rate consistent with the monetary investments on research and development. Because not all drugs are successful and the incentive of pharmaceutical companies to invest in research and development depends on their ability to offset losses from some drugs with profits from their more successful drugs, pharmaceutical companies must be permitted to recover the cost of successful drugs. Pharmaceutical companies will need to provide extensive records of spending costs over the years and detailed accounts of the labor in order to fairly assess royalty rates. Although pharmaceutical companies will be reluctant to produce these documents, they will be incentivized by the higher likelihood of obtaining fair compensation if they comply.

Litigation costs before the International Panel can replace the cost of futile challenges to the issuing country’s judicial system, and the public relations costs of protecting public image. The establishment of the International Panel should cause a sizable redistribution of spending that should reduce marketing costs in the long run. Eventually, the decision of the International Panel shall serve as precedent for future compulsory licenses, but it is crucial that countries and pharmaceutical companies alike continue to have access to this impartial review.

#### *D. Authority*

The Panel will be given authority to make final decisions on all compulsory matters under the supervision of WTO members. In accordance with WTO ideals, the decision to institute the board and the determination of its powers will be a product of a majority member decision. A declaration amending the original TRIPS agreement must therefore be brought into effect so that the board can

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80. *Bayer Corp. v. India*, Order No. 223/2012.

81. Parallel Imports occur when a country imports a drug from another country where a lower price is charged for the drug. See Sykes, *supra* note 3, at 57.

function with the support of the international community. The United Nations has designated forty-eight countries as least-developed countries, thirty-four of which are currently members of the WTO.<sup>82</sup> The WTO's process for making collective decisions involving all member nations<sup>83</sup> and its broad international representation render the WTO the appropriate international organization to empower the International Panel to preside over compulsory license issues.

The International Panel's decisions will be appealable to the WTO Appellate Body, which shall be the only entity with authority to overturn the International Panel's decision. Once the International Panel reaches a decision, the decision will be binding on both parties unless appealed to the WTO Appellate Body. Given the International Panel's flexibility and impartial interest in the subject matter, the number of appeals to the WTO Appellate Body should be minimal. The neutral board shall have full authority to impose trade sanctions against any country refusing to comply with its resolutions. The Panel's decisions must preempt national law and thus reinforce the notion of fairness for both parties involved.

If a dispute arises between a country that is not a member of the WTO and a member-country, the board may extend temporary member status to the country for that proceeding. This temporary member status will be contingent on a contractual obligation to be bound by the International Panel's final decision. Failure to adhere to the stipulations of the International Panel will result in trade sanctions. Additionally, the non-member country will be added to the WTO observer status country list, where the country will have the ability to follow discussions on subjects that pertain to them.<sup>84</sup> If the non-member country abstains from WTO jurisdiction, the pharmaceutical company must resort to resolving the dispute through the WTO's dispute settlement system or the issuing country's judicial system.

## VI. CONCLUSION

This Note has reviewed the shortcomings of compulsory licensing under the current framework of TRIPS and proposed the institution

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82. *Least Developed Countries*, WTO, available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm) [https://perma.cc/47RT-7JQX] (last visited Jan. 25, 2015).
83. *Whose WTO is it Anyway*, WTO, available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org1\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm) [https://perma.cc/LAL9-QUGZ] (last visited Jan. 25, 2015).
84. *International Intergovernmental Organizations Granted Observer Status to WTO Bodies*, WTO, available at [http://www.wto.org/english/thewto\\_e/igo\\_obs\\_e.htm](http://www.wto.org/english/thewto_e/igo_obs_e.htm) [https://perma.cc/67U5-6B5S] (last visited Jan. 25, 2015).

of an International Panel with appellate review to exclusively entertain cases of compulsory licensing for pharmaceutical innovations. This Note does not suggest countries should forego initial attempts to obtain voluntary licenses, but instead provides patent holders a greater opportunity to obtain a fair return on their inventions even under compulsory licenses. Ultimately, the goal is to increase universal access to lifesaving drugs, but monetary constraints create a conflict of interest between investing in research and development and fair returns. The conflict of interest must be resolved by a third party, a neutral body of individuals, tasked with equalizing costs across national borders.