

# BREAKING PATENTS

*Daniel R. Cahoy\**

## ABSTRACT

*Patent breaking to eliminate market exclusivity has occurred in a surprisingly large number of contexts. There are examples in a variety of technologies, ranging from medicine to military, and the countries that break patents include least-developed nations like Rwanda as well as developed, intellectual-property-centric nations like the United States. It is a useful legal mechanism that can provide an essential relief valve to intellectual property control. Unfortunately, evidence suggests that current international rules regarding patent breaking are ad hoc, rife with exploitation opportunities, and generally incapable of responding when the public good is truly in danger. In part, the sorry state of the law is due to the narrow political and academic focus on a single context, namely access to medicines. While extraordinarily important, this is only part of the picture and has led to an effort to shoehorn a useful tool into a setting where it does not fully fit, while ignoring its optimization in contexts where it could be more important. Three recent stories highlight the incoherence: the current failure of “access to medicines” legislation to deliver on its promise; the opportunistic patent breaking of developed and middle-developed countries; and the inability to secure licensed goods in emergency contexts. This paper uses the threads of these lessons to weave a coherent fabric of future compulsory license policy. It looks to the essence of compulsory license policy and proposes a revised analytical framework centered on human rights norms that would constitute an improvement over the current rules.*

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\* Associate Professor of Business Law, Smeal College of Business, and Affiliate Professor of Law, Dickinson School of Law, the Pennsylvania State University. This research was conducted in part at the University of Ottawa, Canada under a scholarship from the U.S.-Canada Fulbright Scholars program. Thanks to the following individuals for feedback and advice in the course of my research: Amir Attaran, Richard Gold, Chantal Blouin, Penelope Simons, Teresa Scassa, Lucie LaMarche, Sonya Nygam, Jeremy deBeer, Robert Bird, Ron Bouchard. Thanks also to the participants of the Canadian Intellectual Property Academy Conference in November 2009, the Mid-Atlantic Academy of Legal Studies in Business in March 2010 and the Academy of Legal Studies in Business in August 2010 for valuable questions and comments.

## TABLE OF CONTENTS

Introduction.....	1
I. Three Stories of Policy Failure.....	4
A. The Access to Medicines Conundrum.....	6
1. Canada’s Access to Medicines Regime Leads the Way.....	8
2. Shifting NGO Priorities.....	10
B. Politics and Opportunism.....	12
C. The Future Disasters.....	17
II. Takeaway Lessons to Guide Future Reform.....	20
A. Compulsory Licenses will be Underutilized as Long-Term Humanitarian Relief.....	20
B. If Licenses Provide Significant Advantages Over Bargaining, They Will be Disruptive.....	28
C. A Lack of Predictable Structure Delays Emergency Response.....	32
III. A Way Forward through <i>Ex Post</i> Balancing of Stakeholder Interests.....	35
A. Bringing All the Parties to the Table: Licensing vs. Breaking.....	36
B. The Utility of a Human Rights Framework in Categorizing and Valuing Interests.....	39
C. Future Revision: Streamlining the Rules with Open Licensing.....	47
Conclusion.....	49

## INTRODUCTION

In the 1970s and 1980s, the Boeing aircraft company worked to address the rising cost of jet fuel by inventing lighter metal alloys for use in aerospace materials.<sup>1</sup> Among its discoveries was a method of producing aluminum-lithium alloys with high “fracture toughness,”<sup>2</sup> and in 1989, Boeing received a patent for the process.<sup>3</sup> Five years later, another aerospace company working as a National Aeronautics and Space Administration (NASA) contractor, Lockheed Martin, was attempting to solve a similar problem related to materials used in the space shuttle. Lighter materials were necessary for future shuttle missions to transport components of the International Space Station.<sup>4</sup> Lockheed Martin

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<sup>1</sup> Boeing Co. v. United States, 86 Fed. Cl. 303, 307 (2009).

<sup>2</sup> *Id.*

<sup>3</sup> U.S. Patent No. 4,840,682 (filed Nov. 21, 1985).

<sup>4</sup> *Boeing*, 86 Fed. Cl. at 308-09.

independently discovered the same method that Boeing had patented, and Lockheed used it to lighten the shuttle's external fuel tank. When Boeing discovered the unauthorized use of its patented method, it sued the U.S. government and won a judgment of patent infringement in 2006.<sup>5</sup> Because U.S. law does will not allow a patent injunction against the government,<sup>6</sup> Boeing must settle for damages, which will likely be a reasonable royalty.

Boeing's legal dispute with the U.S. government may seem uncontroversial – even mundane – but it is an example of one of the most contentious legal mechanisms in international law: a patent compulsory license, which is colloquially referred to as “breaking a patent.”<sup>7</sup> True, Boeing's case does not involve humanitarian suffering or pit an international conglomerate against a developing nation. It's just business. But that is exactly the point. The case demonstrates that the mechanism can have relatively common applications, and its imposition by the U.S. government is evidence that intellectual property-centric, developed nations are willing participants in the system. Such a case requires a cogent legal structure to ensure the government does not inequitably diminish Boeing's established rights. However, in most academic and political debate, examples like the Boeing case are ignored. The analysis has primarily focused on a few (albeit important) contexts, particularly access to medicines.<sup>8</sup> The problem with this approach is that it has left us with a

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<sup>5</sup> Boeing Co. v. United States, 69 Fed. Cl. 397 (2006).

<sup>6</sup> See 28 U.S.C. § 1498 (2006) (reasonable and entire compensation available for use of patentee's invention by United States without license). Section 1498 is the exclusive remedy for unauthorized use of a patent by the U.S. government. Zoltek Corp. v. United States, 442 F.3d 1345, 1349-50 (Fed. Cir. 2006).

<sup>7</sup> The definition of patent breaking or compulsory licensing is somewhat flexible. One could include only explicit *ex ante* compulsory licenses, or throw in infringement-like after-the-fact compensation mechanisms as well as antitrust remedies. See Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1093-94 (2009) (describing the complexity in counting compulsory licenses due to differencing definitions); Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions*, UNCTAD-ICTSD Issue Paper No. 5, at p. 10 (2004), available at [http://www.ictsd.org/pubs/ictsd\\_series/iprs/CS\\_reichman\\_hasenzahl.pdf](http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf); United States v. Besser Mfg. Co., 343 U.S. 444, 447 (1952) (compulsory licensing is “a well-recognized remedy where patent abuses are proved in antitrust actions and it is required for effective relief.”). It certainly includes the Boeing example, as such U.S. licenses were known when the relevant international rules were negotiated, and specific language was added to address the practice. See UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT (“UNCTAD”) & INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (“ICTSD”), RESOURCE BOOK ON TRIPS AND DEVELOPMENT 466, 468 (2005) [hereinafter UNCTAD-ICTSD RESOURCE BOOK].

<sup>8</sup> For recent examples, see Ho, *supra* note 7; Robert C. Bird, *Developing Nations and the Compulsory license: Maximizing Access to Essential Medicines While minimizing Investment Side Effects*, 37 J. L. MED. & ETHICS 209 (2009); Frederick M Abbott & Jerome

broader international regime that is understudied, vague, unpredictable, and not useful when it really counts. A more comprehensive assessment is necessary to understand how the mechanism of patent breaking should be applied efficiently across all of its possible non-remedial contexts.<sup>9</sup>

Significantly, such an assessment is very timely. There is growing interest in the use of compulsory licensing to address access problems in emerging crises, such as climate change.<sup>10</sup> Moreover, as a result of current discontent over recent initiatives to streamline the patent breaking system,<sup>11</sup> the members of the World Trade Organization appear open to discussing how it might be revised.<sup>12</sup> Determining how to improve patent breaking in a comprehensive sense has never been more important.

This article departs from the narrow focus of the existing patent compulsory license literature by considering the mechanism more broadly, as a general intellectual property tool. This approach presents unique challenges because compulsory licensing can encompass so many different types of problems and actors, and general recommendations are difficult to conceive in the abstract. Indeed, one must look only to the original negotiations underlying the current system to see how hard it is to find consensus.<sup>13</sup> To address the complexity, this article employs a unique experiential approach, looking to real-world failures to frame the issues for

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H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921 (2007); Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131 (2007); F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. INT'L ECON. L. 913, 925 (2002); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47, 57 (2002).

<sup>9</sup> Going forward, this article excludes consideration of compulsory licenses as antitrust remedies, as they stem from an entirely different legal theory (remediation for illegal activity), and thus do not have the same market impact as the other forms. Cahoy, *supra* note 8, at 169-72.

<sup>10</sup> See generally Robert Fair, *Does Climate Change Justify Compulsory Licensing of Green Technology?* 6 BYU INT'L L. & MGT. REV. 21 (2009).

<sup>11</sup> Even WTO Director-General Pascal Lamy remarked on the "debate . . . over whether the [doha] solution really works, or whether it continues to throw up obstacles." Pascal Lamy, *Strengthening Multilateral Cooperation on IP and Public Health* (July 14, 2009), [http://www.wipo.int/meetings/en/2009/ip\\_gc\\_ge/presentations/lamy.html](http://www.wipo.int/meetings/en/2009/ip_gc_ge/presentations/lamy.html).

<sup>12</sup> Kaitlin Mara, *Efficacy of TRIPS Public Health Amendment in Question at WTO*, INTEL. PROP. WATCH, Mar. 1, 2010, <http://www.ip-watch.org/2010/03/01/efficacy-of-TRIPS-public-health-amendment-in-question-at-wto/>; Catherine Saez, *Health Waiver, IP Enforcement Discussed at Lively WTO TRIPS Council Meeting*, INTEL. PROP. WATCH, June 10, 2010, <http://www.ip-watch.org/weblog/2010/06/10/health-waiver-ip-enforcement-discussed-at-lively-wto-trips-council-meeting/>

<sup>13</sup> See UNCTAD-ICTSD RESOURCE BOOK, *supra* note 7, at 463-67 (describing various drafts of TRIPS article 31, and the differing positions of developed and developing countries).

reform. In particular, it considers three recent stories: (1) the failure of “access to medicines” legislation to deliver on its promise; (2) the opportunistic or political patent breaking of developed and middle-developed countries; and (3) the inability to secure licensed goods in emergency contexts in the face of confusing rules. This article finds that each provides an important lesson that can be incorporated into international law to create a truly effective patent breaking rule. It uses the threads of the three lessons to weave a coherent fabric of compulsory license policy.

In Part I, the article recounts three stories of policy failure. In Part II, the article extrapolates the takeaway lessons from the stories that must be incorporated into a functional patent breaking system. In Part III, the article provides the structure of a functional system that provides the best incentives to encourage innovation and respect basic human rights. Importantly, it neither discourages nor encourages the use of compulsory licensing, but rather suggests that more intelligent policy can benefit all stakeholders.

### I. THREE STORIES OF POLICY FAILURE

Hailed as a means of promoting public health, demonized as a barrier to trade, and scrutinized as a loophole in intellectual property regimes, the legal ability to break patents has garnered a significant amount of curiosity. Such license gives the government the ability to practice the patented invention, or permit another to do so, without the authority of the patentee.<sup>14</sup> In fact, the patent is not destroyed — it is otherwise still enforceable — but what is “broken”<sup>15</sup> is the patentee’s right to exclude all others.<sup>16</sup>

While many (if not most) countries have some means of relaxing patent enforcement when necessary,<sup>17</sup> it is relatively rare for such measures to be

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<sup>14</sup> Reichman & Hasenzahl, *supra* note 7, at 10.

<sup>15</sup> The phrase “patent breaking” is often used for hyperbolic effect in order to place compulsory licenses in a more negative light. This article has no such intent. Rather, it simply uses the “breaking” terminology as a convenient means of conveying the business community’s perception of the impact of the mechanism.

<sup>16</sup> This is often referred to as the *sine qua non* of property. See *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979) (“In this case, we hold that the ‘right to exclude,’ so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation.”)

<sup>17</sup> See Reichman & Hasenzahl, *supra* note 18, at 1 (noting that “[a]bout one hundred countries recognized some form of non-voluntary licensing in their patent laws by the early 1990s”). Examples of other industrialized nations with compulsory licensing regimes

employed.<sup>18</sup> Still, the academic and international policy communities have focused a great deal of attention on compulsory licensing as a relief valve.<sup>19</sup> In part, this may be due to the fact that patents are often viewed as tools of multinational corporations, and compelled licensing can be viewed as a way for economically disadvantaged persons to gain a foothold.<sup>20</sup> Additionally, in response to those who object to the application of a strong property rights regime to information, patent breaking may provide a welcome limitation.<sup>21</sup> Despite these commendable intentions, there is little to applaud in the policy realm; the actual implementation of compulsory licensing for the public good has been disappointing and its true potential is largely unrealized.

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include the UK, Canada, Germany and Japan. Joseph A. Yosick, *Compulsory Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275,1289-90 (2001).

<sup>18</sup> Exactly what constitutes compulsory licensing is a somewhat unclear question. One could include only explicit *ex ante* compulsory licenses, or throw in infringement-like after-the-fact compensation mechanisms as well as antitrust remedies. See Ho, *supra* note 7, at 1093-94; Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions*, UNCTAD-ICTSD Issue Paper No. 5, at p. 10 (2004), available at [http://www.ictsd.org/pubs/ictsd\\_series/iprs/CS\\_reichman\\_hasenzahl.pdf](http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf); *United States v. Besser Mfg. Co.*, 343 U.S. 444, 447 (1952) (compulsory licensing is “a well-recognized remedy where patent abuses are proved in antitrust actions and it is required for effective relief.”), an *ex ante* IP limitation such as the copyright phonorecord compulsory license (17 U.S.C. § 115 (2006); Jessica E. Vascellaro, *Vonage Can Sign Up Users During Appeal*, WALL ST. J., Apr. 11, 2007, at A11. Regardless of the definition, the amount of compulsory licensing certainly pales in comparison to actual licensing or infringement compensation, so it can be fairly called rare. With no international reporting mechanism, there is no way to know the actual amount of global compulsory licensing.

<sup>19</sup> See *supra* note 8. Other examples include Fair, *supra* note 10; Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853 (2003); F.M. SCHERER, *THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSES* (1977). Such relief valves are an essential part of property systems in general. See generally Gregory S. Alexander, *The Social-Obligation Norm in American Property Law*, 94 CORNELL L. REV. 745 (2009) (noting that there are times when property rights should give way to a greater social good).

<sup>20</sup> See, e.g., Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1579-86 (2009) (describing, primarily in the context of India, the transition to stronger patent rights in the developing world and strategies such as compulsory licensing used to counter it); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 888 (2007) (arguing that “there is no denial that the TRIPS agreement is biased against developing countries”).

<sup>21</sup> See, e.g., Ann Bartow, *Open Access, Law, Knowledge, Copyrights, Dominance and Subordination*, 10 LEWIS & CLARK L. REV. 869, 872-74 (2006) (“Developed nations that enforce patent rights . . . are preventing people who are unwilling or unable to pay surcharges from reaping the benefits of knowledge that in and of itself is freely available.”); Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1699-1700 (2008) (“[I]ntellectual property rights circumscribe the use of knowledge and thus, almost necessarily, cause inefficiency.”).

The following three stories help explain current international compulsory licensing failures. One can see how the regime, as currently designed, is unable to satisfy positive policy goals while at the same time it remains open for exploitation.

#### A. *The Access to Medicines Conundrum*

At first glance, compulsory licensing seems like a natural component of the ongoing effort to increase access to medicines. The covered articles are well defined and clearly important: pharmaceutical intervention is a key weapon in the battle against diseases that disproportionately affect the developing world, namely HIV/AIDS, tuberculosis and malaria.<sup>22</sup> And because patents on pharmaceuticals can permit companies to raise prices,<sup>23</sup> it is logical to assume that access in poor nations might be unduly restricted.<sup>24</sup> Indeed, one can find evidence of significant price differences in examples of branded and generic versions of identical pharmaceutical products.<sup>25</sup> Moreover, the prevalence of patents has been greatly increased through the adoption of international trade agreements that require reasonably strong patent systems, with the Trade-Related Aspects of Intellectual Property (TRIPS) agreement serving as the

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<sup>22</sup> In 2010, the United Nations reported decreases in the death attributed to HIV/AIDS and malaria, crediting in part pharmaceutical intervention. UNITED NATIONS, THE MILLENNIUM DEVELOPMENT GOALS REPORT 41, 48 (2010) (referring to AIDS, stating “the number of people living with the virus is still rising, largely due to the life-sustaining impact of antiretroviral therapy.”). The report also noted that incidents of tuberculosis prevalence is decreasing, but attributed the reason to “control efforts” as opposed to pharmaceutical treatment specifically. *Id.* at 51.

<sup>23</sup> The ability to raise prices is related to the market in addition to the scope of the patent grant. Tun-Jen Chiang, *Fixing Patent Boundaries*, 108 MICH. L. REV. 523, 545-46 (2010).

<sup>24</sup> See, e.g., WORLD HEALTH ORGANIZATION (WHO), COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 20 (2008) [hereinafter “CIPIPH REPORT”]:

But where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding.

See also Amy Kapczynski, et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1047-49 (2005) (patent rights can render treatments unavailable for impoverished populations).

<sup>25</sup> WHO, THE WORLD MEDICINES SITUATION 68-70 (2004) [hereinafter “WHO MEDICINES SITUATION”] (noting that generic medicines are usually much less expensive than patented medicines and providing examples from several countries).

most prominent.<sup>26</sup> Thus, developing country governments and members of civil society have focused on breaking patents through the TRIPS framework as an important means of increasing the delivery of low-cost medicines.

As noted earlier, the literature on access to medicines and TRIPS is massive, to say the least, and it is unnecessary to recount the entire history here.<sup>27</sup> A few summary highlights can provide the necessary context. Immediately following the GATT rounds that produced both the WTO and TRIPS, the global aid community viewed this intellectual property agreement as unduly restrictive when it came to essential medicines.<sup>28</sup> The agreement required members to provide patent protection to all inventions without prejudice.<sup>29</sup> Various countries that had excluded pharmaceutical compounds from protection would now be required to permit patents, cutting off important sources of generic pharmaceuticals.<sup>30</sup> In addition, the relatively detailed provisions in TRIPS that allowed for use of patented inventions without the authorization of the patent owner were restricted to primarily supplying the domestic market.<sup>31</sup> This meant that nations unable to manufacture generic pharmaceuticals were unable to make much use of TRIPS flexibilities. During the Doha round of trade negotiations, WTO members agreed that changes to TRIPS that would permit the export of licensed, low-cost pharmaceuticals to developing nationals was a moral necessity.<sup>32</sup> This produced the so-called Doha Declaration and its

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<sup>26</sup> See Yu, *supra* note 20, at 858-62 (describing the enclosure of developing country technology space by the TRIPS regime).

<sup>27</sup> For a very nice overview of the issues and a comprehensive compilation of academic resources, consider Holger Hestermeyer's recent text published by Oxford University Press: HOLGER HESTERMAYER, *HUMAN RIGHTS AND THE WTO* (2008).

<sup>28</sup> Frederick M. Abbott & Rudolf V. Van Puymbroeck, *Compulsory Licensing For Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No. 61, at pp. 8-9 (2005).

<sup>29</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1994) [hereinafter TRIPS], at art. 27 (declaring that, with the exception of certain treatment and biologic subject matters, patents shall be available “in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”). See also

<sup>30</sup> Kapczynski, *supra* note 20, at 1579-80.

<sup>31</sup> Richard Elliott, *Delivering on the Pledge: Global Access to Medicines, WTO Rules, and Reforming Canada's Law on Compulsory Licensing for Export*, 3 MCGILL INT'L J. SUSTAINABLE DEVELOPMENT L & POL'Y 23, 36 (Abbott & Van Puymbroeck, *supra* note 28, at 8-9).

<sup>32</sup> Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 354-57 (2005); Carlos Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO/EDM/PAR/2004.4 (2004),

“Paragraph 6 implementation” that permitted countries to make exceptions in the compulsory license export rules.<sup>33</sup>

In the aftermath of the adoption of the Paragraph 6 declaration, several countries rushed to enact compulsory licensing legislation.<sup>34</sup> None was more pronounced and proud than Canada. This country’s regime serves as an excellent encapsulation of the issues in patent breaking that resulted in system’s current underutilization in the public health context.

### 1. Canada’s Access to Medicines Regime Leads the Way

Prime Minister Jean Chretien’s government began work on legislation that would enact the TRIPS exception into Canadian law in 2003.<sup>35</sup> Part of a broader social agenda, the compulsory licensing legislation was cast as a form of aid to the developing world.<sup>36</sup> When the following government picked up the bill, it was christened the “Jean Chretien Pledge to Africa Act,” in recognition of the Prime Minister’s tenure when the bill was introduced.<sup>37</sup> After much negotiation that included input from industry, the government and non-governmental organizations (NGOs), the bill was passed into law in 2004 as Canada’s Access to Medicines Regime (CAMR).<sup>38</sup>

The Regime is restricted to a specific list of drugs (that could be amended) and a small list of least developed countries.<sup>39</sup> Countries wishing to use the regime must partner with a Canadian pharmaceutical company that is prepared to manufacture the requested drug, and a request must be

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[http://www.who.int/medicines/areas/policy/WTO\\_DOHA\\_DecisionPara6final.pdf](http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf).

<sup>33</sup> Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, ¶ 1(b) n.3 (Aug. 30, 2003), Doc. WT/L/540 (Sept. 1, 2003) [hereinafter Paragraph 6 Decision], *available at* [http://www.wto.org/English/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm).

<sup>34</sup> See Amir Attaran, *Why Canada’s Access to Medicines Regime Can Never Succeed*, 60 U. NEW BRUNSWICK L.J. 150, 156-57 (2009) (noting that thirty-two countries have enacted legislation to enable the Paragraph 6 decision)

<sup>35</sup> See Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 J.L. MED. & ETHICS 222, 226-27 (2009) (describing the legislative history of the act); Elliott, *supra* note 31, at 41 (describing the push by Canadian NGOs and the UN for Canada to implement the decision).

<sup>36</sup> Lybecker & Fowler, *supra* note 35, at 226 (“It is one part of the Government of Canada’s broader strategy to assist countries in their struggle against HIV/AIDS, tuberculosis, malaria and other diseases.”) (quoting Government of Canada, *Canada’s Access to Medicines Regime*, [http://www.camr-rcam.gc.ca/index\\_e.html](http://www.camr-rcam.gc.ca/index_e.html) (last visited June 25, 2010); Amir Attaran, *A Tragically Naïve Canadian Law For Tragically Neglected Global Health*, 176 CAN. MED. ASSOC. J. 1726, 1726 (2007).

<sup>37</sup> Elliott, *supra* note 31, at 41.

<sup>38</sup> Lybecker & Fowler, *supra* note 35, at 222.

<sup>39</sup> *Id.* at 226.

formally filed with the government.<sup>40</sup> The approval of Health Canada is also necessary before any generic drug can be shipped.<sup>41</sup> Although somewhat bureaucratic, the detailed and structured regime was at the time of its passage perceived to be an important step in fulfilling the promise of the Paragraph 6 negotiation.

Following Canada's lead, several other industrialized countries and regions, including the European Union, enacted similar provisions.<sup>42</sup> They have the same basic structure requiring a specific country to make a licensing request before generic manufacture can commence, as mandated by TRIPS.<sup>43</sup> Some specific provisions, such as a list of approved drugs or licensees may differ, but the functionality should be essentially equivalent.

Unfortunately, CAMR and the related international enactments have fallen dramatically short of expectations. Canada's legislation has been used only once, for a combination HIV/AIDS therapy to be exported to Rwanda.<sup>44</sup> And no other country's Paragraph 6 legislation has been used at all.<sup>45</sup> Moreover, the participants in Canada's one transaction have indicated that they have no intent to engage in the process again.<sup>46</sup> The arguments have centered on the complex nature of the process,<sup>47</sup> though it is unclear whether this is truly the problem.<sup>48</sup>

As a result of Canada's experiences, disappointment with the arrangement has grown<sup>49</sup> and many policy advocates have all but abandoned the process as a development focal point. They appear to have turned their attention to other initiatives, leaving the access to medicines regimes fallow.

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<sup>40</sup> Government of Canada, *Canada's Access to Medicines Regime: Requirements for Companies*, [http://www.camr-rcam.gc.ca/compan-entrepris/req-exig/index\\_e.html](http://www.camr-rcam.gc.ca/compan-entrepris/req-exig/index_e.html) (last updated July 28, 2006).

<sup>41</sup> *Id.*

<sup>42</sup> Attaran, *supra* note 34, at 156-57.

<sup>43</sup> TRIPS, *supra* note 29, at art. 31(a) (licenses must be considered on individual merits).

<sup>44</sup> Abbott & Reichman, *supra* note 8, at 933.

<sup>45</sup> Attaran, *supra* note 34, at 6; Lybecker & Fowler, *supra* note 35, at 227.

<sup>46</sup> See Apotex, *CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to Be Developed* (May 14, 2009) (press release), <http://www.apotex.com/global/about/press/20090514.asp> ("For Apotex, the time and costs involved were high and the company stated it was reluctant to do it again if changes are not made to streamline CAMR.").

<sup>47</sup> GOVERNMENT OF CANADA, REPORT ON THE STATUTORY REVIEW OF SECTIONS 21.01 TO 21.19 OF THE PATENT ACT 29 (2007) [hereinafter "CAMR REVIEW"] (noting that stakeholders indicate that more permissive regimes are necessary to encourage licensing).

<sup>48</sup> Attaran, *supra* note 34, at 7-8.

<sup>49</sup> See Lamy, *supra* note 11.

## 2. Shifting NGO Priorities

Without a doubt, one of the most important forces behind the Paragraph 6 amendment to TRIPS and the various national enactments has been the NGO community.<sup>50</sup> Its support is critical, and a shift in the collective focus of the community can have a great impact. So it is particularly interesting that, very close to the time that Canada passed its Access to Medicines Regime, a migration appears to have occurred in the NGO movement. More organizations began touting alternative mechanisms for delivering low-cost medicines and improving health, and compulsory licensing was pushed to the relative background.<sup>51</sup> First, there were the patent prize proposals, systems in which government would pay to buy out important patented inventions and remove them from private control.<sup>52</sup> This was quickly followed by patent pool proposals, which would utilize a well-established mechanism for non-exclusive licensing of technology, usually owned by more than one company.<sup>53</sup> Additional ideas include the Health Impact Fund,<sup>54</sup> a variation on the patent prize idea that requires government to acquire, pool and license inventions based on their health care impact, and the Medical Research and Development Treaty,<sup>55</sup> which structures government investment in innovation. None of these alternative

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<sup>50</sup> See Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 835-36 (2008) (describing the substantial impact of activist organizations on IP law).

<sup>51</sup> This movement tends to be cast in terms of dissatisfaction with the existing patent regime and the need to find alternatives to provide the same research and development output. See, e.g., James Love, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D*, 40 U.C. DAVIS L. REV. 679, 699-710 (2007) (describing various options for innovation in the context of medicine that do not rely on traditional patent protection).

<sup>52</sup> See, e.g., James Love & Tim Hubbard, *Prizes for Innovation in New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155 (2009). But see Michael Abramowicz, *Patent Prizes*, 56 VAND. L. REV. 115, 170-71 (2003) (introducing a detailed discussion as to why such “patent prize” systems are inherently flawed).

<sup>53</sup> See, e.g., UNITAID, *The Medicines Patent Pool Initiative*, <http://www.unitaid.eu/en/The-Medicines-Patent-Pool-Initiative.html> (last visited June 25, 2010) (describing the 2008 decision of the UNITAID Executive Board to establish a voluntary patent pool for medicines). For a more detailed evaluation of UNITAID’s Patent Pool Initiative, see THE INNOVATION PARTNERSHIP (TIP), PRELIMINARY LEGAL REVIEW OF PROPOSED MEDICINES PATENT POOL (2007), available at <http://www.theinnovationpartnership.org/data/documents/00000003-1.pdf>.

<sup>54</sup> AIDAN HOLLIS & THOMAS POGGE, *THE HEALTH IMPACT FUND: MAKING NEW MEDICINES AVAILABLE FOR ALL* (2008), available at [www.yale.edu/macmillan/igh/hif\\_book.pdf](http://www.yale.edu/macmillan/igh/hif_book.pdf)

<sup>55</sup> See Laurence R. Helfer, *Toward a Human Rights Framework for Intellectual Property*, 40 U.C. DAVIS L. REV. 971, 1007-09 (2007) (describing a proposal for a Medical Research and Development Treaty forwarded by “a coalition of more than 150 NGS, public health experts, economics and legal scholars.”).

mechanisms has been employed,<sup>56</sup> and it is therefore not clear that any are viable. They may turn out to be significantly more viable than compulsory licensing. Importantly, they have diverted a great deal of academic and civil society attention away from the existing compulsory license regimes.

Why has the NGO community begun to shift away from compulsory license initiatives? One reason may be the lack of prominent impact. With almost no compulsory licensing activity, and as noted above, very little to see in the future, continued association with these mechanisms has the stench of failure. In a related vein, it has been argued that the compulsory license regimes in place were constructed as the result of consensus negotiation, and are so fatally flawed that they cannot be pursued any further.<sup>57</sup> Another reason may be that the legal process has been taken as far as it possibly can. There is no real reason for advocacy related to the access to medicines regimes. They are fundamentally market tools, and if there is a need, they are arranged to function right now. Finally, the supporting academic community, which was highly concerned about empowering compulsory licensing a decade ago, seems to have shifted its focus to new treaty initiatives like the Anti-Counterfeiting Trade Agreement.<sup>58</sup> Such initiative can impact compulsory licensing,<sup>59</sup> but are not directly related to encouraging its use.

Interestingly, Canada remains one area where NGOs are focused on compulsory licenses. Recent initiatives to amend the CAMR regime have been strongly supported by groups such as the Canadian HIV/AIDS Legal Network and Oxfam Canada.<sup>60</sup> But these groups generally declare that the current system is unworkable and advocate for a less narrow and regulated system.<sup>61</sup> To the extent that their ideal regime exceeds that currently

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<sup>56</sup> Although one could argue that these various mechanisms have moved forward some interesting policy debates, very few concrete changes have been effected. See E. Richard Gold & Jean-Frédéric Morin, *The Missing Ingredient in Medicine Patent Pools*, 374 LANCET 1329, 1330 (2009).

<sup>57</sup> See generally Jean-Frédéric Morin & Edward Richard Gold, *Consensus-Seeking, Distrust, and Rhetorical Entrapment: The WTO Decision on Access to Medicines* (July 18, 2009), <http://ssrn.com/abstract=1435747>.

<sup>58</sup> Anti-Counterfeiting Trade Agreement, Public Predecisional/Deliberative Draft (April 2010), available at [http://www.ustr.gov/webfm\\_send/1883](http://www.ustr.gov/webfm_send/1883).

<sup>59</sup> See generally Margot Kaminski, *Recent Development, The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement (ACTA)*, 34 YALE J. INT'L L. 247 (2009).

<sup>60</sup> See, e.g. Judy Wasylycia-Leis, *Hansard-2<sup>nd</sup> Reading of Bill C-393* (June 12, 2009) (comments of Canadian MP describing her bill to amend the Access to Medicines Regime and noting "I want to particularly thank the Canadian HIV/AIDS Legal Network, Results Canada, Stephen Lewis Foundation and Oxfam Canada" for support).

<sup>61</sup> See, e.g., Canadian HIV/AIDS Legal Network, *Making CAMR Work: Streamlining Canada's Access to Medicines Regime*, Brief to Senate Banking Trade and

allowed under TRIPS,<sup>62</sup> the Canadian NGO community could be viewed as attempting to encourage expansive national approaches to TRIPS. Perhaps they see an opening in the Canadian political environment for change that could compulsory licensing a more relevant market actor. In any case, it is unclear that these revisions will be adopted, and in the present state, Canadian compulsory licensing to provide access to essential medicines is — along with the rest of the world — stalled.

In the end, most would conclude that, to date, breaking patents as a means for addressing shortfalls has not been as effective as imagined. If the world were simply left with an unused mechanism having only narrow, theoretical utility, it might be acceptable. But some actors have found ways to take advantage of the flexibilities to serve other purposes.

### *B. Politics and Opportunism*

The next story is essentially the opposite of the access to medicines conundrum. It primarily involves countries that may be described as developing,<sup>63</sup> but are not dramatically economically disadvantaged. They

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Commerce Committee Regarding Bill-S-232, at pp. 3-4 (Oct. 21, 2009), *available at* <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1563> (declaring that the CAMR cannot be declared a success and advocating amendment to make it workable).

<sup>62</sup> See CAMR REVIEW, *supra* note 47, at 34-35 (discussing the so-called “one license” plan advocated by activists that would eliminate the need for a particular country to come forward before a generic producer created a medicine, and why such a plan likely conflicts with Canada’s TRIPS obligations).

<sup>63</sup> The term “developing country” is actually self-designated under the WTO regime. See WTO, *Who are the Developing Countries in the WTO?*, [http://www.wto.org/english/tratop\\_e/devel\\_e/d1who\\_e.htm](http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm) (last visited June 26, 2010). As of 2001, the following countries indicated their intent to claim developing status: The WTO refers to this category “developing countries.” Inclusion in this group is self-regulated under the WTO. See WTO, *Who are the Developing Countries in the WTO?*, [http://www.wto.org/english/tratop\\_e/devel\\_e/d1who\\_e.htm](http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm) (last visited Dec. 10, 2007). Members indicating developing status include: Antigua and Barbuda, Argentina, Bahrain, Barbados, Belize, Bolivia, Botswana, Brazil, Brunei Darussalam, Cameroon, Chile, Colombia, Congo, Costa Rica, Côte d’Ivoire, Cuba, Cyprus, Dominica, Dominican Republic, Egypt, El Salvador, Estonia, Fiji, Gabon, Ghana, Grenada, Guatemala, Guyana, Honduras, Hong Kong, China, India, Indonesia, Israel, Jamaica, Kenya, Korea, Kuwait, Macau, Malaysia, Malta, Mauritius, Mexico, Morocco, Namibia, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Qatar, Saint Lucia, Singapore, Sri Lanka, St. Kitts and Nevis, St. Vincent and Grenadines, Suriname, Swaziland, Thailand, Trinidad and Tobago, Tunisia, Turkey, United Arab Emirates, Uruguay, Venezuela, Zimbabwe. See WTO, *Frequently Asked Questions About TRIPS*, [http://www.wto.org/english/tratop\\_e/trips\\_e/tripfq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm) (last visited June 28, 2010). However, the list is not necessarily exhaustive or binding. Developing status in the WTO is distinct from “least-developed countries,” a designation rendered by the United Nations and recognized by the WTO for countries that are disadvantaged in their development and in need of international assistance. WTO, *Least-Developed Countries*,

have serious economic issues, but may also have budgets that could permit the purchase of essential goods.<sup>64</sup> For example, China is now the world's second largest economy, yet it considers itself "developing" due to relatively low per capita GDP.<sup>65</sup> Almost every year, one of these middle-developed countries publicly threatens to "break" the patent rights of a large multinational company. These rights are often related to medical products like pharmaceuticals, and the rationale is almost always to obtain lower prices. Recently joining the club — which includes Egypt,<sup>66</sup> Thailand<sup>67</sup> and Brazil<sup>68</sup> among its members — was Ecuador, which in October 2009 declared its intent to issue a compulsory license, in part to produce generic versions of several unnamed patented drugs.<sup>69</sup> The first license was actually issued in April 2010.<sup>70</sup>

While Ecuador's compulsory licensing of pharmaceuticals received the most press, perhaps the more interesting but often overlooked aspect of the initiative is that it was explicitly broader and intended to serve a more general political agenda. For example, president, Rafael Correa, has

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[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) (last visited June 28, 2010). The current list of least developed countries includes: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Gambia,, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, Zambia. *Id.*

<sup>64</sup> One way to assess a country's specific level of development with respect to economic ability is to consult the United Nations' Human Development Index. *See* UN, Human Development Report 2009, *available at* [http://hdr.undp.org/en/media/HDR\\_2009\\_EN\\_Indicators.pdf](http://hdr.undp.org/en/media/HDR_2009_EN_Indicators.pdf) [hereinafter "2009 UN-HDR"]. Poverty levels and income are listed. *See id.* at tbl. I. In addition, health care spending is also listed. *Id.* at tbl. N.

<sup>65</sup> Embassy of the People's Republic of China in the United States of America, *China's Developing Country Identity Remains Unchanged* (Aug. 13, 2010), <http://www.china-embassy.org/eng/gdxw/t723893.htm>.

<sup>66</sup> Richard A. Castellano, Note, *Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent*, 46 IDEA 283, 289 (2006); Abeer Allam, *Seeking Investment, Egypt Tries Patent Laws*, N.Y. TIMES, Oct. 4, 2002, at W1.

<sup>67</sup> Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public Use of Patent for Pharmaceutical Products (Nov. 29, 2006) [hereinafter *Thail. Efavirenz CL.*], *available at* [www.wcl.american.edu/pijip/documents/ThailandCLAnnouncement.doc](http://www.wcl.american.edu/pijip/documents/ThailandCLAnnouncement.doc); Nicholas Zaminska, *Thai Move to Trim Drug Costs Highlights Growing Patent Rift*, WALL ST. J., Jan. 30, 2007, at A.8

<sup>68</sup> Abbott & Reichman, *supra* note 8, at 950-52 (describing the conditions related to Brazil's compulsory licensing of Efavirenz in 2007).

<sup>69</sup> Jeannetch Valdivieso, *Ecuador to Make Cheap Versions of Patented Drugs*, ASSOC. PRESS, Oct. 28, 2009.

<sup>70</sup> Catherine Saez, *Ecuador Grants First Compulsory License for HIV/AIDS Drug*, INTEL. PROP. WATCH (Apr. 22, 2010), <http://www.ip-watch.org/weblog/2010/04/22/ecuador-grants-first-compulsory-licence-for-hivaids-drug/>

stressed that the licenses would be extended to agrochemicals next.<sup>71</sup> This declaration is prominently linked from the front page of Ecuador's government office for intellectual property, the Instituto Ecuatoriano de la Propiedad Intelectual (IEPI).<sup>72</sup> A translation of one of President Correa's speeches, posted by the website essentialaction.org goes farther, noting Correa's interest in extending the licenses to "everything possible," and that:

Intellectual property is a mechanism for development for the people. This is our vision of intellectual property. It's not a mechanism to enrich the pharmaceutical or agrochemical companies. It's a mechanism for development for the people.<sup>73</sup>

While such an informal translation lay not perfectly capture the Ecuadorian government's intent, in other documents, Correa has expressed the belief that "knowledge is a public good that cannot be privatized."<sup>74</sup> It seems clear that Ecuador's goals in licensing are more extensive than increasing access to medicines.

To avoid barriers from patent owners, Ecuador was able to use article 31 of the standard text of TRIPS.<sup>75</sup> This section permits public non-commercial use of patented products without any prior negotiation with the patent owner.<sup>76</sup> Additionally, Ecuador has pledged to pay royalties for any patent it licenses.<sup>77</sup> Despite the fact that Ecuador's move is not clearly for an emergency purpose, it appears to be entirely TRIPS-compliant.<sup>78</sup>

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<sup>71</sup> Republica del Ecuador, Instituto Ecuatoriano de la Propiedad Intelectual, *Licencias Obligatorias*, [http://www.iepi.gov.ec/index.php?option=com\\_content&view=article&id=59](http://www.iepi.gov.ec/index.php?option=com_content&view=article&id=59) (last visited Aug. 24, 2010) (translation on file with author).

<sup>72</sup> Instituto Ecuatoriano de la Propiedad Intelectual, <http://www.iepi.gov.ec/> (last visited Aug. 24, 2010).

<sup>73</sup> Essential Action, *Ecuador's Compulsory Licensing Plan and Alternate Vision for IP* (Oct. 5, 2009), <http://www.essentialaction.org/access/index.php?/archives/224-Ecuadors-compulsory-licensing-plan-and-alternate-vision-for-IP.html>.

<sup>74</sup> The government's press release can be found here: [http://www.elciudadano.gov.ec/index.php?option=com\\_content&view=article&id=7035:la-produccion-de-medicamentos-mas-baratos-se-hace-posible&catid=1:actualidad](http://www.elciudadano.gov.ec/index.php?option=com_content&view=article&id=7035:la-produccion-de-medicamentos-mas-baratos-se-hace-posible&catid=1:actualidad) (translation on file with author).

<sup>75</sup> TRIPS, *supra* note 29, at art. 31.

<sup>76</sup> *Id.*

<sup>77</sup> Saez, *supra* note 70.

<sup>78</sup> Compulsory licensing under TRIPS requires neither prior negotiation with the patent holder or a declared emergency. *See id.* *See also* Essential Action, *Backgrounder, Ecuador's Presidential Declaration on Access to Medicines and Compulsory Licensing* (Oct. 27, 2009), <http://www.essentialaction.org/access/index.php?/archives/226-Backgrounder-about-Ecuadors-Presidential-Declaration-on-Access-to-Medicines-and->

Interestingly, although the immediate reaction to Ecuador's statement was predictably dichotomous, it was not as contentious as the reaction that greeted Brazil and Thailand. Not surprisingly, members of the NGO community touted Ecuador's move as a positive event (but rarely mentioned the licensing of agrochemicals).<sup>79</sup> However, the business community was uncharacteristically restrained. In fact, an early report of President Correa's announcement, the local pharmaceutical industry trade association representing GSK, Pfizer and Bayer stated "We accept the democratic decision ... to use this extraordinary legal measure, observing the rights and responsibilities" as described in international law."<sup>80</sup>

Regardless of the business community's acceptance, one might view Ecuador's move with skepticism.<sup>81</sup> A strict property rights advocate might argue that such economically stable nations could pay *developing* country market prices for patented pharmaceuticals or agrochemicals (as they do for other goods), and the TRIPS mechanism simply provides a legal procedure for discounting (albeit in a socially important areas). For reference, Ecuador is designated as a "high human development" country on the United Nations' (UN) Human Development Index, ranking 80 out of 177 countries, and ranks 38 out of the 135 countries on the UN Human Poverty Index, two rankings below China and two above Turkey.<sup>82</sup> However, the UN Human Development Index indicates that its health care spending is comparatively low, listed at only \$130 per capita, below some countries designated least-developed such as Rwanda (\$134 per capita).<sup>83</sup>

In addition, though public good is likely the primary motivator in Ecuador's decision, it is possible that there are other influences. For

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Compulsory-Licensing.html.

<sup>79</sup> See, e.g., People's Health Movement, *Praise for Ecuador's Grant of Compulsory License for AIDS Drug* (May 4, 2010), <http://www.phmovement.org/en/node/2883> ("Civil society organizations have praised a recent decision by the Ecuadorian government to issue its first compulsory license . . .").

<sup>80</sup> *Bayer, GSK, Pfizer and other MNCs Agree to Bypass Drug Patents in Ecuador* (Oct. 30, 2001), <http://www.dancewithshadows.com/pillscribe/bayer-gsk-and-other-mncs-agree-to-bypass-drug-patents-in-ecuador/>

<sup>81</sup> The United States elected to keep Ecuador on its watch list for 2010 as a result of various concerns regarding its enforcement of intellectual property. U.S. TRADE REP., 2010 SPECIAL 301 REPORT 31 [hereinafter "2010 SPECIAL 301"], *available at* [http://www.ustr.gov/webfm\\_send/1906](http://www.ustr.gov/webfm_send/1906). Regarding the compulsory license, it states:

The United States will continue to monitor recent developments concerning compulsory licensing of pharmaceutical and agricultural chemical products in Ecuador, bearing in mind the discussion of the Doha Declaration on TRIPS and Public Health in Section I of this report

*Id.*

<sup>82</sup> 2009 UN-HDR, *supra* note 64, at tbl. I<sup>1</sup>. The Human Development Index ranking is carried through on each of the tables.

<sup>83</sup> *Id.* at tbl. N.

example, the U.S. State Department notes that Ecuador announced in December of 2009 its intent to establish a national pharmaceutical company (“ENFARMA”) that will produce generic drugs, which may imply a desire to develop a stronger domestic industry.<sup>84</sup> The pursuit of a broader social/political agenda in concert with other regional powers could be gleaned from the government’s public statements as well.<sup>85</sup>

In the end, if Ecuador’s decision has been essentially accepted by the relevant business communities, and it is TRIPS-compliant, is there a problem? Isolated to an individual country, the effects may be small, and certainly there is global interest in seeing the Ecuadorian people increase their standard of living and health. But more broadly applied, Ecuador’s actions introduce an element of unpredictability into the patent system that could undermine innovation. The reason is that, under current international law, the actual obligations to fairly license are so vague as to be non-existent.<sup>86</sup> While the TRIPS agreement does require “adequate remuneration,” this has been interpreted to be as low as 0.5% of sales in the case of Thailand,<sup>87</sup> a decision that was not disputed at the WTO. It is hard to imagine that there is actually a lower limit as long as the royalty is above zero. Any investment incentive that patent holders believed they could derive from their Ecuadorian patents has been eliminated and substituted with something akin to largess.

The issue is not about Ecuador, per se, but the misaligned incentives in the current TRIPS framework. In essence, countries are able to circumvent the market and revise the bargaining rules as they see fit. Instead of a uniform and equitable system, power and insulation from the withdrawal of foreign direct investment give advantages to some countries over others.<sup>88</sup> It is antithetical to the notion of an international system of

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<sup>84</sup> U.S. Department of State, *2010 Investment Climate Statement – Ecuador* (Mar. 2010), <http://www.state.gov/e/eeb/rls/othr/ics/2010/138060.htm>.

<sup>85</sup> See, e.g., Mercedes Alvaro, *Ecuador Demands Oil Revenue – Venezuela Ally Threatens to Expropriate Companies’ Holdings if They Don’t Agree*, WALL ST. J., Apr. 19, 2010, at A.10 (linking the Ecuadorian government to Venezuela and suggesting a pattern of nationalization to shore up a populist image).

<sup>86</sup> See Cahoy, *supra* note 8, at 173-77 (describing a “unitary system” of compulsory license remuneration that permits both developed and developing countries to license at discount rates in their own interests rather than equity).

<sup>87</sup> Announcement of the Dep’t of Disease Control, Ministry of Pub. Health, Thail. on the Pub. Use of Patent for Pharmaceutical Products (Nov. 29, 2006) [hereinafter Thail. Efavirenz C.L.], available at <http://www.wcl.american.edu/pjip/documents/ThailandCLAnnouncement.doc> (announcing government use of patented anti-retroviral medicine used to treat HIV/AIDS, efavirenz).

<sup>88</sup> See Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 309-17(2008) (describing Brazil’s resistance to foreign direct investment retribution as a shield

rules. Arguably, countries that don't take advantage of the TRIPS flexibilities are missing out on a financial goldmine.

Going forward, there are risks for developing world innovation investment. The message sent to multinational corporations that there is an inherent risk in marketing important technologies in middle-developed countries. Efforts may be better focused on inventions less critical to the survival of humanity or marketing may ideally be restricted to more secure environments. In either case, the world loses.

As a final point, consider that even if one were inclined to give all developing nations a pass on the TRIPS remuneration ambiguities due to their real economic difficulties and the existence of a broader global market, the same remuneration discount could be applied by developed nations like the United States. Referring back to the Boeing example at the outset of this article,<sup>89</sup> suppose the United States decided to use its patent compensation statute as a discount mechanism. There is evidence that the United States specifically reserved the ability to use article 31 under its traditional government infringement compensation scheme.<sup>90</sup> While most would not argue for the U.S. government's right to discount patented goods through compulsory licensing, it used exactly this type of leverage when it found itself in need of a large amount of ciprofloxacin pills and was reluctant to pay patent owner Bayer AG's market price.<sup>91</sup> The lack of neutral control over the remuneration structure – and the rise political power as a factor – could lead to substantial inequity and unintended externalities.

### C. The Future Disasters

If the above stories depict patent breaking mechanism in a negative light, perhaps one could defend the mechanism by focusing on the circumstances wherein compulsory licensing is the most necessary and useful. While it can be fairly observed that breaking patents serves many uses, including maintenance of competitive markets<sup>92</sup> and efficient government procurement,<sup>93</sup> it appears that an important consideration in

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to its compulsory licensing strategy).

<sup>89</sup> See *supra* notes 1-6.

<sup>90</sup> 28 U.S.C. § 1498 (2006).

<sup>91</sup> Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro®: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 127 (2002).

<sup>92</sup> See, e.g., Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* 10-22 (Ctr. for Advanced Studies at the Univ. of Buenos Aires, Arg., Working Paper No. 5, 1999), <http://www.southcentre.org/publications/workingpapers/wp05.pdf>.

<sup>93</sup> Thomas F. Mullin, Note, *AIDS, Anthrax, and Compulsory Licensing: Has the*

drafting the detailed compulsory license rules in the TRIPS text and the Paragraph 6 Implementation was to permit governments to respond to emergencies.<sup>94</sup> The notion that a patent could prevent a government from coming to the aid of its citizens is odious, to be sure, and there is much in the negotiation record to suggest that this was well-recognized.<sup>95</sup> The final story is therefore somewhat shocking in that it establishes that current procedures are so ambiguous, unclear and disdained that we are in no position to respond to a worldwide crisis.

In 2009, it became almost impossible to escape talk of a global pandemic of swine flu. Technically, the pandemic actually happened by the fall (using the WHO definition<sup>96</sup>), but it did not appear to be as deadly as some had feared.<sup>97</sup> Still, there was much demand for flu-related goods such as vaccine<sup>98</sup> and hand sanitizer.<sup>99</sup> If events were to take a substantial turn for the worse, there was great concern that certain flu treatments would be in short supply or even unavailable. One of the most prominent medicines was *Tamiflu*, an antiviral pharmaceutical created and patented by Roche pharmaceuticals.<sup>100</sup> In October 2009, American officials noted that *Tamiflu* could be a very important treatment<sup>101</sup> and that they could supply the drug

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*United States Learned Anything? A Comment on Recent Decisions on the International Intellectual Property Rights of Pharmaceutical Patents*, 9 ILSA J. INT'L & COMP. L. 185, 192 (2002) (describing various advantages to a government that uses or even threatens compulsory licensing).

<sup>94</sup> The text of the TRIPS agreement does not enumerate all possible reasons for compulsory licenses, but it does clearly highlight the “case of a national emergency or other circumstances of extreme urgency.” TRIPS, *supra* note 29, at art. 31(b). Note that a common misinterpretation of article 31 is that an emergency is required before licensing. The enumeration of several other justifications for licensing demonstrate that this is clearly not the case.

<sup>95</sup> UNCTAD-ICTSD RESOURCE BOOK, *supra* note 7, at 464 (noting that an early draft limited the grounds for licensing to “public interest concerning national security, or critical peril to life fo the general public or body thereof.”).

<sup>96</sup> WHO, *The International Response to the Influenza Pandemic* (June 10, 2010), [http://www.who.int/csr/disease/swineflu/notes/briefing\\_20100610/en/index.html](http://www.who.int/csr/disease/swineflu/notes/briefing_20100610/en/index.html) (responding to critics that the WHO definition of pandemic is too broad).

<sup>97</sup> See, e.g., Donald G. McNeil Jr., *Flu Death Estimate Spikes*, CHI. TRIB., Nov. 12, 2009, at 13 (stating that, even though estimates of the number of Americans that died from swine flu were approximately 4,000, it was far less than originally predicted).

<sup>98</sup> Thomas H. Maugh II, *H1N1 Spread Now Global*, CHI. TRIB., Nov. 6, 2009, at 27 (reporting on world-wide shortages of flu vaccine).

<sup>99</sup> Rob Varnon, *Sanitizer Demand Outpaces Supply at Local Colleges*, MCCLATCHY-TRIBUNE BUSINESS NEWS, Nov. 25, 2009.

<sup>100</sup> See Rob Stein, *Tamiflu Shortages Have Parents on Wild Dose Chase*, WASH POST, Oct. 29, 2009 (online), [http://www.washingtonpost.com/wp-dyn/content/article/2009/10/28/AR2009102803823\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2009/10/28/AR2009102803823_pf.html).

<sup>101</sup> CDC, *2009 H1N1 and Seasonal Flu: What You Should Know about Flu Antiviral Drugs* (Oct. 8, 2009), <http://www.cdc.gov/H1N1flu/antivirals/geninfo.htm> (noting that

in an emergency. To the extent that the need outstripped the capacity of Roche to supply the drug, such a measure could involve acquiring generic sources. However, in response to an inquiry about the potential emergency need, the only producer of generic *Tamiflu* (known as “*Antiflu*”), India’s Cipla Pharmaceuticals, explained that it would take time to gain approval for the drug through the U.S. Food and Drug Administration and noted that there was no interest in starting the process due to existing patents (and the lack of a license).<sup>102</sup> The reticence to enact a compulsory license by an industrialized nation like the US effectively put the entire process in some degree of jeopardy.

Disasters can be progressive as well. In contrast to flu, the exact dimensions of which arguably cannot be predicted from year to year, the world has been on notice of the potential effects of global climate change for quite some time. Some believe that climate change will create shortages of food or water, in addition to many other habitat related impacts. There is technology to ameliorate the impacts of global warming. For example, agricultural biotechnology companies like Monsanto and BASF are reportedly developing crops that are genetically engineered to grow in very dry climates.<sup>103</sup> It is reasonable to assume that much of the groundbreaking climate-change technology will be patented.<sup>104</sup> Leading up to the 2009 international climate talks in Copenhagen, a group of seventy-seven developing nations led by China forwarded the idea of making climate-change technology subject to compulsory licenses.<sup>105</sup> But very few countries have moved forward on any concrete plan to access such technology by breaking patents.<sup>106</sup>

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CDC recommends Tamiflu and Relenza as a second line defense against the flu).

<sup>102</sup> *Will Tamiflu Shortage Drive U.S. to India’s Version?*, Morning Edition (NPR), Nov. 10, 2009, transcript available at <http://www.npr.org/templates/transcript/transcript.php?storyId=120254536>.

<sup>103</sup> Rajesh Chhabara, *Climate Ready GM Crops: The Patent Race*, ClimateChangeCorp.com, Sep. 17, 2008, [http://www.climatechangeCorp.com/content\\_print.asp?ContentID=5644](http://www.climatechangeCorp.com/content_print.asp?ContentID=5644) (biotechnology companies are flooding patent offices with applications for “genetically engineered climate-resistant seeds [that] can withstand catastrophic effects of global warming, such as floods, drought, heat, cold and salinity.”).

<sup>104</sup> See Lisa Larrimore Ouellette, Comment, *Addressing the Green Patent Global Deadlock Through Bayh-Dole Reform*, 119 YALE L.J. 1727, 1727-28 (2010) (noting that developing countries have recognized that patents can limit access to green technologies).

<sup>105</sup> See *China, India Push for ‘Patent Fee’ Green Tech*, EURACTIV.COM, Nov. 23, 2009, <http://www.euractiv.com/en/innovation/china-india-push-patent-free-green-tech/article-187567>; Ouellette, *supra* note 104, at 1727.

<sup>106</sup> In fact, the U.S. House of Representatives has entertained legislation to thwart such compulsory licenses. See Matthew Rimmer, *The Road to Copenhagen: Intellectual Property and Climate Change*, 4 J. INTELL. PROP. & PRACTICE 784 (2009).

The reason to put off the patent breaking discussion is probably rooted in part in the ambiguity of the rules and the retribution countries may face for undertaking such a measure.<sup>107</sup> But this fear means that countries are not preparing for an emergent eventuality. While an opportunist's actions may be arguably inappropriate if a country is simply responding to the normal business environment with a cost-cutting venture, the failure to establish a system for responding to an emergency could have far worse consequences.

## II. TAKEAWAY LESSONS TO GUIDE FUTURE REFORM

The three stories discussed above expose three very different problems with the way compulsory licensing is conceptualized on an international scale. These issues end up fundamentally hobbling the system, frustrating civil society advocates and provoking disdain from patent owners. But rather than simply demonstrating that the current system is not functional, these stories actually highlight lessons or principles that can be used for reform. By understanding what does not work and why, we can make a healthier patent breaking regime and generate greater social utility.

The lessons all essentially relate to human behavior in one way or another. Even better explanations could be modeled with a more complex behavioral theory, but this short sketch is sufficient to begin the conversation. The lessons can be divided into (a) understanding market structure, (b) appreciating profit-seeking behavior, and (c) maximizing the certainty of a well-defined legal regime. If followed, the lessons should fundamentally transform the use of the compulsory licensing.

### *A. Compulsory Licenses will be Underutilized as Long-Term Humanitarian Relief*

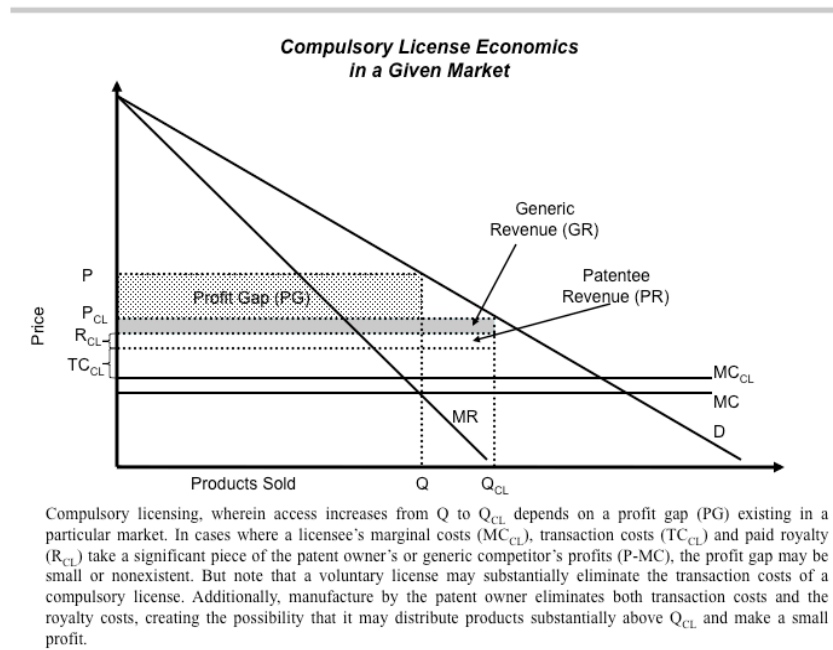
In order for a compulsory license to be an attractive option, there must be a substantial and sustained difference in the price of the patented good and the costs of manufacturing a licensed good. This is particularly true if a for-profit company will be manufacturing under the license (which would be the case unless a government-owned facility is involved<sup>108</sup>). Such a company must be able to pay a royalty, offer a price advantage, and still obtain a profit (see Figure 1).

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<sup>107</sup> See Fair, *supra* note 10, at 33-34 (describing the economic backlashes that might result from compulsory licenses on green technology).

<sup>108</sup> See, e.g., Lybecker & Fowler, *supra* note 35, at 229 (noting that the Thailand's compulsory licenses were handled by the Government Pharmaceutical Organization).

Figure 1



But the existence of such a “profit gap” depends on a patentee’s monopoly power in the relevant markets as well as its inability or unwillingness to take advantage of revenue opportunities by engaging in differential pricing. These conditions have not historically occurred in the context of least-developed countries. And, as described below there is good reason to believe that they may not occur in the future. The absence of such a profit gap will mean that compulsory licensing may have minimal utility as a humanitarian aid mechanism. Although the underutilization may cause many to conclude that the mechanism is a failure requiring radical reform, what is really going on is a simple misapplication of a specialized tool.

Consider as the prime example the access to medicines initiatives.<sup>109</sup> Advocates believed that drugs to treat conditions disproportionately impacting the developing world — especially HIV/AIDS, tuberculosis and malaria — were too expensive, and the reason was patent rights.<sup>110</sup> By

<sup>109</sup> Declaration on the TRIPS Agreement and Public Health, ¶ 4 (Nov. 14, 2001), Doc. WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].

<sup>110</sup> Susan Sell’s contemporaneous article provides an excellent account of the politics underlying the movement to utilize the TRIPS flexibilities. See Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT’L L.J. 481, 496-98 (2001).

reforming TRIPS to permit export of compulsorily licensed drugs, it was presumed that generic companies in industrialized nations would rise to not only fill the need, but actually develop a profitable business by exploiting the difference between branded sales prices and the marginal costs of manufacturing.<sup>111</sup> Advocates may have looked to industrialized pharmaceutical markets as a model, in which branded and generic drugs coexist.<sup>112</sup> Generic companies from developed countries could be let lose to fill the need for low cost drugs.

In fact, this “gap market” for industrialized-nation generics never emerged. The most important reason is that the pricing disparity in least developed countries was not as linked to patent rights as believed.<sup>113</sup> When it came to purchasing the pharmaceuticals on the WHO Essential Medicines List for treating HIV/AIDS, tuberculosis or malaria, it turns out that patent rights did not cover the drugs in the most important countries. Significantly, India, which instituted pharmaceutical product patent protection only in 2005,<sup>114</sup> housed several generic pharmaceutical companies that were prepared to produce low-cost medicines on demand.<sup>115</sup> Governments and NGO’s preferentially purchased from Indian companies, obviating any need for industrialized-country generics.<sup>116</sup> A second,

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<sup>111</sup> See Abbott & Reichman, *supra* note 8, at 970-71 (discussing the reasons why a branded pharmaceutical company may not adopt a generic pricing model in developing countries).

<sup>112</sup> See Puneet Manchanda et al., *Understanding Firm, Physician and Consumer Choice Behavior in the Pharmaceutical Industry*, 16 MKTG. LETTERS 293, 302 (2005) (noting that, although innovator sales drop sharply once a generic is on the market, prices for branded drugs actually rise as innovators focus on a small, price insensitive part of the market).

<sup>113</sup> Attaran and Gillespie-White conducted one of the most discussed initial investigations into this phenomenon, demonstrating that patents did not pose a substantial barrier in developing countries in Africa. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASSN. 1886, 1891 (Oct. 2001) (concluding that “the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa.”). While this did not address the important question of patents in exporting countries, it nevertheless involved an empirical look into a market that was presumed to operate differently.

<sup>114</sup> See Kapczynski, *supra* note 20, at 1586-88 (detailing the evolution of India’s current patent regime).

<sup>115</sup> See CIPIPH REPORT, *supra* note 24, at 83-85 (describing the development of India’s robust generic industry before pharmaceutical products were patentable); Lybecker & Fowler, *supra* note 35, at 229 (“India is currently the principle supplier of essential medicines for developing countries, exporting an estimated two-thirds of the drugs it produces.”).

<sup>116</sup> See Mark Schoofs, *Clinton Foundation Sets Up Malaria-Drug Price Plan*, WALL ST. J., July 17, 2008, at A.8 (detailing a pricing agreement to provide malaria drugs relying on Indian generic companies).

equally important reason that the gap market did not emerge is that branded companies have been increasingly willing to lower their prices to compete with generic alternatives (or simply to generate additional goodwill).<sup>117</sup> Together, these actions essentially caused the gap market to collapse over time.<sup>118</sup> Governments that suggested compulsory licensing would benefit the impoverished were left with little to show for their legislative efforts.

A review of the recent market environment for Canada's Access to Medicines Regime succinctly makes this point. The CAMR maintains a list of drugs that are, for the most part, listed as patented in Canada<sup>119</sup> and are also on the WHO Essential Medicines List (EML).<sup>120</sup> In comparing the drugs used to treat HIV/AIDS, malaria and tuberculosis against the WHO Global Price Reporting Mechanism, a database detailing reported prices paid for these drug combinations,<sup>121</sup> one finds that generic versions were sold in *every case but one*.<sup>122</sup> In other words, a generic market already exists, and there is no need for Canadian intervention.

In the one instance where an export was actually arranged, between Rwanda and the Canadian generic manufacturer, Apotex, there were apparently cheaper versions of the drug available on the open market.<sup>123</sup>

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<sup>117</sup> See, e.g., *id.* at A.8; Andrew Jack, *Pfizer Agrees to Cut Price of TB Drug*, FIN. TIMES, Aug. 7, 2009, at 16 (describing a growing willingness by research-based drug companies to cut prices in order to expand business as well as increase access to medicines); Andrew Jack, *GSK to Slash Drug Prices for Developing Countries*, FIN. TIMES, Nov. 30, 2009, at 19; Brenda Waning et al., *Temporal Trends in Generic and Brand Prices of Antiviral Medicines Procured with Donor Funds in Developing Countries*, 7 J. GENERIC MEDICINES 160, 168 (2010).

<sup>118</sup> Waning et al., *supra* note 117, at 166-68 (noting the dramatic fall in prices of branded antiretroviral drugs, particularly as compared to generic antiretroviral drugs).

<sup>119</sup> Canada's Access to Medicines Regime, R.S.C., ch. P-4, § 21.01 (1985) (Can.). Twenty-six of the drugs on the list are also listed in Canada's database of patented medicines, the Canadian version of the U.S. *Orange Book*. Health Canada, Patent Register Search Page, <http://www.patentregister.ca/> (modified Aug. 24, 2010).

<sup>120</sup> WHO, MODEL LIST OF ESSENTIAL MEDICINES (16th list, Mar. 2010), *available at* [http://www.who.int/entity/medicines/publications/essentialmedicines/Updated\\_sixteenth\\_adult\\_list\\_en.pdf](http://www.who.int/entity/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf).

<sup>121</sup> WHO, Global Price Reporting Mechanism, <http://apps.who.int/hiv/amds/price/hdd/index.aspx> (last visited Nov. 2009) [hereinafter "WHO-GPRM"].

<sup>122</sup> The one drug that had no reported generic equivalent sale was "amprenavir tablet, 150 mg; capsule, 50 mg or 150 mg; oral solution, 15 mg/mL." This is likely because the branded manufacturer, GlaxoSmithKline, discontinued production of the drug in 2007. U.S. Dept. of Health & Human Svs., AIDSinfo, *Amprenavir*, [http://www.aidsinfo.nih.gov/DrugsNew/DrugDetailT.aspx?int\\_id=258](http://www.aidsinfo.nih.gov/DrugsNew/DrugDetailT.aspx?int_id=258) (last updated Apr. 30, 2010).

<sup>123</sup> See CAMR REVIEW, *supra* note 47, at 34 ("[F]ive major Indian generic pharmaceutical companies are listed on the Clinton Foundation Website as having lower-priced versions of the same product available . . . the lowest of which is roughly half the

Looking back at this case, there was literally no reason for Rwanda to request a compulsory license from Canada.<sup>124</sup> Commentators have subsequently speculated that there were political motivations for pushing the license.<sup>125</sup> In any case, the fact that no license was requested subsequently from Canada (or any other country) by Rwanda (or any other country) certainly suggests that this is not a viable option for funding drug dissemination.

Stated broadly, the mistake made with essential medicines was to fundamentally misunderstand the least-developed-country market and the reason for technology access barriers. The significance of patents was overstated, and the utility of patent breaking mechanisms oversold. In the end, direct financial and other developmental aid has proven much more effective in addressing the ravages of poverty.<sup>126</sup>

However, a fair response to this point is that, although patent-generated price gaps have not been important to date, they could be in the future. In the context of essential medicines, many commentators have noted that countries like India have instituted patent protection over basic compounds.<sup>127</sup> And other instances in which patents could play a role, such as climate change, have not been tested. Perhaps patent breaking as a relief initiative will eventually prove its worth. But here again, there are reasons why this may not be the case.

When faced with a compulsory license in a least-developed country and the accompanying loss of market exclusivity, it is reasonable to assume that innovator companies would take advantage of their production efficiency and generally undercut generic efforts (see Figure 1). Only where generic companies possess greater efficiencies in terms of labor markets, access to materials or combinations of separately patented products<sup>128</sup> would a compulsory licensed pharmaceutical be expected to

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price specified by Apotex in its application . . .”).

<sup>124</sup> See Attaran, *supra* note 34, at 4.

<sup>125</sup> *Id.* at 9; Morin & Gold, *supra* note 57, at 22 (describing the reputational entrapment of NGOs).

<sup>126</sup> See, e.g., Eran Bendavid & Jayanta Bhattacharya, *The President's Plan for AIDS Relief in Africa: An Evaluation of Outcomes*, 150 ANNALS OF INTERNAL MED. 688, 691 (2009) (finding that the PEPFAR program was associated with a decrease in deaths due to HIV/AIDS).

<sup>127</sup> See, e.g., Brenda Waning et al, *Intervening in Global Markets to Improve Access to HIV/AIDS Treatment: An Analysis of International Policies and the Dynamics of Global Antiretroviral Medicines Markets*, 6 GLOBALIZATION & HEALTH 1, 13 (2010) (“[I]ncreasing implementation of the TRIPS Agreement in developing countries means that medicines patents are becoming more widespread,” eliminating generic competition to reduce prices).

<sup>128</sup> See CIPIPH REPORT, *supra* note 24, at 153, Box 5.4 (detailing the “Cost Advantages of Indian Firms,” including fixed asset costs, cheaper labor, chemistry or

have the lowest price. This would be the case even if existing drug export regimes were changed to remove restrictions; any advantage by developed countries would be mirrored by low cost producers and matched by branded companies.

As important, there is evidence that firms are seeing more opportunities in the developing country market.<sup>129</sup> This is particularly true for pharmaceutical companies.<sup>130</sup> It is not clear that developing countries will completely erase losses due to expiring blockbuster drug sales in developed countries,<sup>131</sup> but it is where the revenue focus lies in the future. It is reasonable to presume that firms will only be more willing to deliver essential goods to developing countries at moderate prices in order to continue developing these emerging markets. That is yet another factor obviating the need for compulsory licensing.

Still, significant pricing disparities can persist between branded and generic goods, even in the absence of patents.<sup>132</sup> And some countries pay significantly higher costs for the same goods than other similarly situated countries.<sup>133</sup> While this may be acceptable in middle-developed countries — even necessary for a tiered pricing scheme — if it occurs in least-developed countries a genuine access issue is raised. In fact, it does appear that companies may at times maintain high prices in the face of the economic incentives to serve a lower priced market.<sup>134</sup> For a number of reasons, including information asymmetry, specific business strategy, and fear of losing control over product distribution, a company may choose to maintain high prices and reduced access.<sup>135</sup> However, the extent to which a company can engage in such behavior appears to be much more limited currently, primarily as a result of NGO pressure.<sup>136</sup> Companies are publicly

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process costs, and clinical study costs, as well as noting that such costs are estimated to be as little as one-eighth of those confronted by developing country firms).

<sup>129</sup> See Don Lee, *A Rebalancing Act; U.S. Firms Sharpen Focus on Overseas Consumers*, CHI. TRIB, Oct. 6, 2009, at 19 (reporting on the increased focus on fast developing countries for new profits).

<sup>130</sup> Avery Johnson, *Drug Firms See Poorer Nations as Sales Cure*, WALL ST. J., July 7, 2009, at A.1.

<sup>131</sup> Hester Plumridge, *Rising Nations are no Remedy for Big Pharma*, WALL ST. J. (Online), May 25, 2010.

<sup>132</sup> See WHO MEDICINES SITUATION, *supra* note 25, at 69.

<sup>133</sup> *Id.* (“Clearly, big price differences exist not only between generic and innovator medicines, but also between prices for the same brand or generic in different countries.”).

<sup>134</sup> Abbott and Reichman provide some reasons as to why this condition could exist temporarily. Abbott & Reichman, *supra* note 8, at 970-71.

<sup>135</sup> *Id.*

<sup>136</sup> See Kapczynski, *supra* note 50, at 828-29 (relating the strategies of the “access-to-medicines” campaign and its perceived success in compelling pharmaceutical companies to lower prices).

derided for high prices, particularly upward adjustments. Published sales information provides additional bargaining power to essential medicine purchasers and levels the playing field.<sup>137</sup> Finally, increased anti-counterfeiting awareness has placed greater emphasis on the authorized sale of medicines and methods to manage it.<sup>138</sup> Although such measures can create problems for the legitimate international transport of generic medicines,<sup>139</sup> they also play a role in ensuring that access-promoting price discrimination schemes can function.<sup>140</sup>

Yet another licensing rationale that has recently been forwarded is that profit-motivated behavior may provide a barrier to lowering prices when it concerns developing countries with great internal income disparities. In that case, firms may choose to maintain high prices if they can render more profit from the extremely wealthy than they can from more sales at low prices to larger, impoverished citizens. Described as the “Convex Demand Curve Problem” in a fascinating article on essential medicines, Flynn, Hollis and Palmedo argue that it is one of the more important reasons that high prices persist for patented drugs.<sup>141</sup> However, there are reasons that it may not entirely characterize the economic environment underling prospective compulsory licenses. The analysis assumes uniform distribution of need, which may be less true in the case of essential goods that are more in demand by the poorer segments of society. And the comparison of medicine prices in more uniform, high-income countries does not address the existence of price controls or reference pricing schemes in those nations. But most important is the fact that the Convex Demand Curve Problem will probably only exist when a compulsory license has not issued. Once even the serious threat of such a license exists, the economic basis for the irrationally high prices disappears. While it is an interesting and important theory that should be integrated into the analysis, Flynn et al.’s framework may not describe many compulsory-licensing situations in established markets.

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<sup>137</sup> See, e.g., WHO-GPRM, *supra* note 121 (global prices of HIV/AIDS, tuberculosis and malarial medications); Medicines Sans Frontieres, Untangling the Web of Antiretroviral Price Reductions, <http://utw.msfaaccess.org/> (last visited June 29, 2010) (global prices of antiretroviral drugs).

<sup>138</sup> See Daniel R. Cahoy, *Addressing the North-South Divide in Pharmaceutical Counterfeiting*, 8 WAKE FOREST INTELL. PROP. L.J. 407, 416-23 (2007) (detailing measures used to combat counterfeiting, and noting how such measures influence incentives).

<sup>139</sup> See, e.g., Ho, *supra* note 7, at 1105-07 (describing the Dutch seizures of generic drugs in transit under the mistaken impression that they were counterfeit).

<sup>140</sup> The Paragraph 6 implementation provisions contain detailed requirements for pharmaceutical marking, which maintains price discrimination schemes as well as limiting counterfeiting. Paragraph 6 Decision, *supra* note 33, at ¶ 2(b)(ii).

<sup>141</sup> Sean Flynn et al., *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J. L. MED. & ETHICS 184, 187-88 (2009).

Finally, for those who consider developing country licensing for export to be the most likely source of future activity, the recent experiences of India are instructive. Although India has traditionally housed a robust generic drug industry fueled by a lack of composition patent protection, the country adopted such protection in 2005<sup>142</sup> to comply with TRIPS.<sup>143</sup> As a result, a small group of medicines have already been patented.<sup>144</sup> Contemporaneously, India has enacted a Paragraph 6-influenced compulsory license statute for the production of medicines for export.<sup>145</sup> To date, no such license has been granted.<sup>146</sup> The generic pharmaceutical company, Natco, applied for a license in 2007<sup>147</sup> but was unable to produce a request from an importing country.<sup>148</sup> In addition, the Indian Controller determined in the context of the application that patent owners have a right to a hearing to dispute such licenses, complicating the process.<sup>149</sup> Although one might presume that Natco's difficulties could be overcome, a 2010 report by the Indian Department of Industrial Policy and Promotion<sup>150</sup> suggests that the climate for compulsory licenses in India may be turning more hostile. It notes that Indian generic companies are increasingly partnering or merging with foreign pharmaceutical companies, reducing their incentive to compete through intellectual property limitations.<sup>151</sup> Although the report advocates future compulsory licensing, it suggests that efforts to reform focus on antitrust licensing and price controls.<sup>152</sup> All things considered, India does not appear poised to make substantive humanitarian use of patent breaking any time soon.<sup>153</sup>

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<sup>142</sup> Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

<sup>143</sup> TRIPS, *supra* note 29, at art. 64.5; *see also* Kapczynski, *supra* note 20, at 1576-1579.

<sup>144</sup> *See, e.g.,* Rupsa Gupta & Padmavati Manchikanti, *Analysis of Patenting Trends of Antifungal Drugs in the Product Patent Regime in India*, 32 WORLD PAT. INFORMATION 135 (2009) (describing product patent activity for antifungal drugs post 2005).

<sup>145</sup> Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India), at sect. 92A

<sup>146</sup> MINISTRY OF COMMERCE & INDUSTRY, DEPARTMENT OF INDUSTRIAL POLICY & PROMOTION, DISCUSSION PAPER ON COMPULSORY LICENSING 3 (Aug. 24, 2010) [hereinafter CL-DISCUSSION PAPER], *available at* <http://dipp.nic.in/CL-DraftDiscussion.doc>.

<sup>147</sup> *See* Swarup Kumar, *Compulsory Licensing Provision Under TRIPS: A Study of Roche vs. Natco Case in India Vis-à-vis the Applicability of the Principle of Audi Alteram Partem*, 7 SCRIPTED 135, 141 (2010).

<sup>148</sup> CL-DISCUSSION PAPER, *supra* note 146, at 16.

<sup>149</sup> Kumar, *supra* note 147, at 141-43.

<sup>150</sup> CL-DISCUSSION PAPER, *supra* note 146

<sup>151</sup> *Id.* at 8-9.

<sup>152</sup> *Id.* at 10-11.

<sup>153</sup> In addition to the procedural complexities, Indian companies face economic and political hurdles in licensing as well. Shamnad Basheer, *India's New Patent Regime:*

Therefore, the first lesson to learn from compulsory licensing to date is that, in an established market wherein the demand is relatively clear and predictable, true humanitarian compulsory licenses from least-developed countries directed at developed country manufacturers will probably not be used. The mechanisms will tend to sit fallow because developing countries will see no advantage in using them, particularly given the potential for some foreign direct investment backlash. Even in the face of the best intentions on the part of developed nations, with no requests, there will be no licensing. After the emergence of patents in generic producing countries like India, there may be limited compulsory licensing. But it will be countered by branded price cuts and authorized licensing, and will be limited by its procedural complexities.

Will compulsory licenses have any function in an established market? Most certainly, in the form of pressure on patent owners to maintain pricing that more closely conforms to Ramsey or tiered pricing ideals.<sup>154</sup> But that is a far cry from substituting for a country's foreign aid contribution. The power to break patents is a check on the system, rather than a future solution. And, as discussed below, there are many other instances where breaking patents is useful. The lesson is as much about the narrowness of the conclusions as it is about licensing ineffectiveness.

*B. If Licenses Provide Significant Advantages Over Bargaining, They Will be Disruptive*

What if the goal is not simply to gain access to important technology, but to take advantage of legal rules in order to obtain an advantage that would not be possible through bargaining? In some cases, accessing a product or service on a reasonable basis is not the objective, but rather the license is a means of simply getting lower prices. While a country's efforts to spend less to provide basic and essential services to its citizens is reasonable and laudable, if this is achieved through the unexpected use and unpredictable application of an *ex post* legal regime, economic disruption may occur.<sup>155</sup> This is particularly true if the regime is

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*Aiding "Access" or Abetting "Genericide"?*, 9 INT'L J. BIOTECHNOLOGY 122, 131-33 (2007).

<sup>154</sup> Ramsey pricing is price discrimination that yields the highest possible social welfare subject to ensuring a target level of profit for the producer. See Patricia M. Danzon & Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals*, in KEITH E. MASKUS & JEROME H. REICHMAN, INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY 431 (2005).

<sup>155</sup> Fair, *supra* note 10, at 34-36 (arguing in the context of climate change technology that compulsory licensing disrupts the profit flowing from IP that is necessary for long-term innovation and technology diffusion).

not available to all countries due to political and exogenous economic pressure.

In general, a firm with patent rights will expect to negotiate prices that will enable it to generate the most profit globally. It should be willing to make concessions in low-income countries so long as profits in higher-income countries are sufficient.<sup>156</sup> Conversely, it will resist rock-bottom pricing in larger, higher income countries, even if there is a public health use for the medicine. Still, negotiation can reduce information asymmetries and provide a pricing structure that is mutually acceptable for the firm and the purchasing entity. The predictable use of a Ramsey-like, tiered pricing scheme becomes very important to rolling out a global marketing strategy.<sup>157</sup> It is key to funding research and development through overall firm profits. When the patent expires, the firm can no longer depend on the ability to control pricing, so there is a limited window for action. Most economists agree that the potential for obtaining a profit structure like this is the basis for innovation through a patent system<sup>158</sup> (though alternative innovation incentive systems might exist<sup>159</sup>).

When the pricing scheme is circumvented by a legal mechanism that discourages negotiation, this can be disruptive. Such discouragement can occur if the legal mechanism simply permits a country to establish a rock-bottom pricing scheme regardless of need. In this case, assuming there is a manufacturer at the ready (particularly a domestic one), there is no reason to negotiate with a firm seeking some level of monopoly pricing.<sup>160</sup> The

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<sup>156</sup> See Jerome Reichman, *Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 251 (2009) (describing the conventional economic view as the “realists’ perspective,” but ultimately disagreeing that it characterizes existing behavior).

<sup>157</sup> See Danzon & Towse, *supra* note 154, at 431.

<sup>158</sup> See, e.g., Schreer & Watal, *supra* note 8, at 925-28 (2002) (explaining the concept of differentiated pricing or tiered pricing). *But see* Stiglitz, *supra* note 21, at 1706-09 (2008) (describing why patent incentives may not produce benefits exceeding costs).

<sup>159</sup> Many argue that a patent system is sub-optimal in certain contexts. See Love & Hubbard, *supra* note 52, at 162 (arguing that price and innovation incentives should be de-linked using an alternative to the patent system.); Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT’L L. & COM. REG. 371, 453-57 (2009) (no single system is likely to be ideal for all types of innovation).

<sup>160</sup> Although there is some disagreement, it has been alleged that Thailand did not negotiate with pharmaceutical companies before imposing several compulsory licenses in 2006 and 2007. Lybecker & Fowler, *supra* note 35, at 228-29. Some has described the circumstances as opportunistic. *Id.* (noting that the Thai government pharmaceutical company which operated under the compulsory license is increasingly viewed as a profitable player). The same allegation has been leveled against Brazil. Lawrence A. Kogan, *Brazil’s IP Opportunism Threatens U.S. Private Property Rights*, 38 U. MIAMI INTER-AM. L. REV. 1, 98-1-2 (2006) (arguing that Brazil issues compulsory licenses to gain trade

rational decision is to use the legal mechanism.

Certainly, opportunistic licensing can have the greatest effect on predictable profits when it occurs in high-income countries. For example, if the United States were to engage in licensing as a budget lowering initiative, the effect could be dramatic in fields such as pharmaceuticals in which it is the primary world market.<sup>161</sup> Interestingly, U.S. officials have occasionally voiced an interest in such opportunism.<sup>162</sup> But, such a use of intellectual property is considered analogous to a taking,<sup>163</sup> and compensation is generally provided at a market rate.<sup>164</sup> As such, there is literally no advantage to licensing. The same is true of any country that views patent compulsory licensing as a property “expropriation,” requiring market-based compensation.<sup>165</sup>

The more pressing problem is the middle-income country that guarantees no such protection for intellectual property compensation. For example, when countries such as Thailand, Brazil or even Ecuador license patents at a rate that has no connection to market expectations, any profits from those countries that were figured into a global marketing scheme are

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advantages and engage in protectionism).

<sup>161</sup> According to IMS Health, the total global pharmaceutical market was \$808.3 Billion. IMS Health, *Total Unaudited and Audited Global Pharmaceutical Market by Region* (Mar. 2010), available at [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/Global%20Pharmaceutical%20Market2009.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Global%20Pharmaceutical%20Market2009.pdf). Of that, the United States alone accounted for \$300.3 Billion in prescription sales, representing a full 37% of the world market. IMS Health, *Top Therapeutic Classes by U.S. Sales* (Apr. 2010), available at [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/Top%20Therapy%20Classes%20by%20U.S.Sales.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Top%20Therapy%20Classes%20by%20U.S.Sales.pdf)

<sup>162</sup> See Cahoy, *supra* note 91, at 127 (describing the United States’ threat to compulsorily license Cipro in response to Anthrax attacks).

<sup>163</sup> See *Boeing Co. v. U.S.*, 86 Fed. Cl. 303, 310 (2009) (“[T]he waiver of sovereign immunity in section 1498(a) differs from those provisions in that it does not sound in tort, but rather authorizes an action analogous to one for a non-exclusive taking of a license under the Fifth Amendment.”).

<sup>164</sup> *Id.* at 310 (patentee can recover “reasonable and entire” compensation from the United States); Richard J. McNeely, Comment, *Governmental Indirect Patent Infringement: The Need to Hold Uncle Sam Accountable Under 28 U.S.C. § 1498*, 36 CAP. U.L.REV. 1065, 1081 (2008) (lost profits included as well as a royalties in possible damages calculations).

<sup>165</sup> Many Bilateral Investment Treaties (BITs) require fair or market compensation for expropriations of property. Antony Taubman, *Rethinking TRIPS: “Adequate Remuneration” for Non-Voluntary Patent Licensing*, 11 J. INT’L ECON. L. 927, 963-64 (2008). But there is some ambiguity as to whether compulsory licenses could be considered expropriations, though some explicitly exclude TRIPS-compliant licenses. *Id.* See also Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT’L L. 331, 348-51 (2004). The WTO has not yet addressed the issue.

impacted.<sup>166</sup> In some cases, international pressure, particularly the loss of foreign direct investment, will dissuade such disruptive policies.<sup>167</sup> But some countries are relatively immune from such pressures due to their size and lack of dependence on foreign investment.<sup>168</sup> They can engage in opportunistic licensing as a reasonable alternative to bargaining without suffering economic effects.

Perhaps the more insidious effect of this disruption is that it may have negative externalities for countries with less power. A firm that has had its Ramsey pricing scheme scuttled may attempt to increase prices in countries that have less recourse. Rather than a punishment of patent owning monopolists, opportunistic licensing can devolve into a source of division between the powerful and the powerless, creating inequity and even decreasing access in some areas.

Equally as bad, firms may respond by changing marketing strategy to limit exposure to future patented technology in countries wherein it may be exploited. Although patents represent public information, there are often secret aspects of a product's manufacture that would hinder copying.<sup>169</sup> Even in the context of the relatively open drug approval process, these secrets may be disclosed in an application, but the contents are generally not public in their entirety.<sup>170</sup> A foreshadowing of this possibility can be seen in the recent actions of Thailand and pharmaceutical company, Abbott Labs. When Thailand issued a compulsory license for a patented drug Abbott sells under the name Kaletra, the company responded by refusing to register new medicines in the country.<sup>171</sup> One of the medicines held back was a version of Kaletra (called Aluvia) which was heat-stable, a characteristic that is extremely important in tropical environments like Thailand.<sup>172</sup> If Abbott

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<sup>166</sup> See Cahoy, *supra* note 8, at 166 (describing the impact of reduced profits on a global pharmaceutical innovation program). *But see* Flynn et al., *supra* note 141, at 192 (arguing that in many developing countries, patent incentives do not provide substantial motivation for innovation so lost profits are irrelevant).

<sup>167</sup> For an excellent review of many of the pressures faced by licensing countries, see Reichman, *supra* note 156, at 256-59.

<sup>168</sup> See, e.g., Bird & Cahoy, *supra* note 88, at 309-17 (describing Brazil's resistance to FDI retribution).

<sup>169</sup> See, e.g., Abbott & Reichman, *supra* note 8, at 979-80 (remarking on the difficulties in reverse engineering some drugs and suggesting that some companies may count on that in setting their prices high).

<sup>170</sup> For example, even after a drug is approved, much of the important information about how to manufacture and formulate a drug — information not in a compound patent — remains secret. DONALD O. BEERS, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS* § 5.01 (1999); 21 C.F.R. §§ 20.61, 314.430, 601.51 (2009).

<sup>171</sup> Ho, *supra* note 159, at 443-447.

<sup>172</sup> *Id.*

had maintained its position,<sup>173</sup> lives may have been unnecessarily lost. Although Abbott's move may have been more of punishment than an act to prevent copying, the same policy could be implemented to control information.

### C. A Lack of Predictable Structure Delays Emergency Response

Despite the fact that imposing a compulsory license may be an extremely important mechanism for managing a crisis, it does not appear to be central in the planning of developed nations. Even in developing nations, one rarely sees the phrase outside of the context of essential medicines. There are at least two, related reasons for this lack of consideration for compulsory licenses: it is difficult to predict how they should be addressed from a legal and financial standpoint, and (2) there is a perception that they are somehow illegitimate, particularly in a country with a strong system of support for property rights.<sup>174</sup>

The ambiguity surrounding compulsory licensing goes to the core of its purpose, as exemplified by the phrase (and title of this article), "breaking patents." In fact, such licenses do not actually break patents but merely relax them in a very limited context, and then only temporarily.<sup>175</sup> But when the patents can be relaxed, to what extent, and what the obligations on the licensing country are less than clear.

A review of the TRIPS agreement is useful in demonstrating that the power to issue compulsory licenses is actually quite broad. The agreement does not limit such licensing to emergencies, it does not require an initial negotiation (so long as the use is not commercial), and it is certainly not limited to medicines or other essential goods.<sup>176</sup> The paragraph 6 provision for increasing access to medicines is more limited in that it specifically applies to pharmaceuticals and provides some advantages for least developed nations.<sup>177</sup> But even here, specific disease conditions are not

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<sup>173</sup> Abbott relented and eventually agreed to sell Aluvia in Thailand. AIDS Healthcare Foundation, *AIDS Healthcare Foundation Says CalPERS to Question Abbott on Thailand Drug Blacklist* (Apr. 26, 2007), <http://www.aidshealth.org/news/press-releases/archive/aids-healthcare-foundationsays-calpers-to-question-abbott-on-thailand-drug-blacklist.html>.

<sup>174</sup> As noted earlier, the United States mentioned Ecuador's compulsory license in its Special 301 Report. 2010 SPECIAL 301, *supra* note 81, at 31. And when Thailand imposed its licenses, which were clearly within TRIPS legalities, Merck stated, "expropriation of intellectual property sends a chilling signal to research-based companies." Ho, *supra* note 159, at 451.

<sup>175</sup> The TRIPS agreement requires that "the scope and duration of [the license] be limited to the purpose for which it was authorized." TRIPS, *supra* note 29, at art. 31(c).

<sup>176</sup> *Id.* at art. 31.

<sup>177</sup> Paragraph 6 Decision, *supra* note 33, at ¶¶ 2, 6.

addressed and the procedure is still relatively undefined.<sup>178</sup>

Perhaps the most critical ambiguity is an economic flexibility that exists in both the general TRIPS agreement and the paragraph 6 revisions. Namely, it does not define compensation. The agreement merely states that compulsory licenses should provide “adequate remuneration . . . taking into account the economic value of the authorization.”<sup>179</sup> In practice, this has ranged as low as the 0.05% royalty imposed by Thailand<sup>180</sup> (even 0% if you count licenses imposed as antitrust remedies).<sup>181</sup> Graduated compensation scales have been proposed<sup>182</sup> and even incorporated into national laws like Canada’s Access to Medicines Regime,<sup>183</sup> but these are only recommendations. At the very least, most presume that compulsory licenses will represent a discount from the market rate, but there is no guarantee as to how much profit will be reduced.

Partially due to their ambiguous nature and ad hoc rules, compulsory licenses can be politically problematic. The United States has placed countries on its well-known Special 301-list in part because they have engaged in compulsory licensing without negotiation<sup>184</sup> (despite the fact that the U.S. essentially engages in such behavior itself<sup>185</sup>). Such a license is viewed by some as a failure of the market system and a measure of disrespect for intellectual property rights.<sup>186</sup> The ultimate issue of compensation probably underlies the generally negative attitude toward breaking patents among industrialized nations. In some contexts, like access to essential medicines, there is a general perception that compulsory

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<sup>178</sup> *Id.*

<sup>179</sup> TRIPS, *supra* note 29, at art. 31(h).

<sup>180</sup> Thail. Efavirenz C.L. *supra* note 87. Professor Reichman argues that Thailand would have been willing to renegotiate the royalty, though it is unclear what the motivation for doing so would have been given the unilateral nature of compulsory licensing. Reichman, *supra* note 156, at 256. Still, he concedes that it was a “low royalty.” *Id.*

<sup>181</sup> Makan Delrahim, *Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property Rights and Antitrust* (May 10, 2004), <http://www.usdoj.gov/atr/public/speeches/203627.htm> (noting that compulsory licenses can be issued without royalties attached).

<sup>182</sup> See, e.g., James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, Health Economics and Drugs TCM Series No. 18 (2005), [http://www.who.int/medicines/areas/technical\\_cooperation/WHOTCM2005.1\\_OMS.pdf](http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf)

<sup>183</sup> Canada’s Access to Medicine Regime, *Royalty Payment*, [http://camr-rcam.hc-sc.gc.ca/compan-entrepris/applic-demande/royal\\_pay-verse\\_redev\\_e.html](http://camr-rcam.hc-sc.gc.ca/compan-entrepris/applic-demande/royal_pay-verse_redev_e.html) (last updated Jul. 28, 2006) [hereinafter Canada Royalty Guidelines]

<sup>184</sup> See Kapczynski, *supra* note 20, at 1630.

<sup>185</sup> See UNCTAD-ICTSD RESOURCE BOOK, *supra* note 7, at 468 (noting common U.S. practice of issuing compulsory licenses without notification).

<sup>186</sup> See, e.g., Andrew Jack & Amy Kazmin, *Abbott Pulls HIV Drug in Thai Patents Protest*, FIN. TIMES, Mar. 14, 2007, at 5 (reporting on Abbott Labs’ criticism of Thailand for its “disrespect for western companies’ intellectual property.”).

licenses must represent a discount from the market price of the licensed good.<sup>187</sup>

But it does not follow that compulsory licenses are always disruptive. In fact, they are not always controversial. Handled the right way, with compensation guarantees in particular, they can fit within the broader goals of the intellectual property system, encouraging fair and intelligent pricing and supporting access. One might even argue that there is a shadow context for compulsory licensing that takes place relatively often, even in developed countries, and raises no hackles. A case in point is the United States. When it authorizes one company, like Lockheed Martin, to use another company's patent rights, like Boeing's, it ensures that the license will have little market effect. The U.S. government compensates for its own after-the-fact "infringement" of patents through a federal intellectual property takings statute.<sup>188</sup> It provides market-based compensation, and therefore creates no disruption in the U.S. marketplace.<sup>189</sup> This is not viewed as illegitimate or immoral. Other countries engage in similar actions.

Regardless of the apparent workability under the right conditions, the politics and uncertainty of breaking patents prevent most nations from integrating it into an emergency plan. That creates a danger that a bureaucratic hurdle will prevent a nation from acting as quickly as it otherwise could. The fact that few such instances have occurred in the past may blind policy-makers as to the need for compulsory licensing in emergency plans. But the industry's greater dependence in intellectual property as a core asset<sup>190</sup> suggests that the need is more important now than ever, and it will continue to grow.

The knowledge that access to life-saving goods, if necessary, could be obtained through a defined process would be very helpful in navigating uncharted waters. Consider the fact that this kind of planning is quite common in the context of real property. When governments have a need to obtain large amounts of land to support public projects like highways and stadiums, eminent domain is retained as an option.<sup>191</sup> And it is generally

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<sup>187</sup> Cahoy, *supra* note 8, at 155-62 (referring to the fact that compulsory licenses must represent a discount from market compensation as a legal myth).

<sup>188</sup> 28 U.S.C. § 1498 (2006). *See also* Boeing Co. v. U.S., 86 Fed. Cl. 303, 310 (2009) (characterizing § 1498).

<sup>189</sup> McNeely, *supra* note 164, at 1081. *See also* Cahoy, *supra* note 91, at 163-71 (providing rationale for market compensation)

<sup>190</sup> *See* Margo Reder, *CEO Postings — Leveraging the Internet's Communications Potential While Managing the Message to Maintain Corporate Governance Interests in Information Security, Reputation and Compliance*, 7 DEPAUL BUS. & COM. L.J. 179, 190 (2009) (value of IP accounts for two-thirds of the value of U.S. companies).

<sup>191</sup> *See, e.g.*, EMPIRE STATE DEVELOPMENT CORPORATION, ATLANTIC YARDS LAND

not considered to be economically disruptive (though it can still be politically contentious).<sup>192</sup> Conversely, the inability to consider such a notion paralyzes an aspect of emergency response and imperils the welfare of nations.

### III. A WAY FORWARD THROUGH *EX POST* BALANCING OF STAKEHOLDER INTERESTS

For patent breaking to continue to exist as a viable strategy, supported by both developed and developing nations, and accepted by both industry and activists, the three stories presented above must be coherently resolved. There must be a single system that can address all of the instances in which compulsory licensing is necessary. And yet, that system must be structured such that it does not primarily provide an end-run for those with sufficient power to thwart the market. This is a goal that has been present since compulsory licensing was first fully articulated, but the ascendance of developing nations and the existence of a truly global economy provide perspective that has not existed in the past. This new knowledge and experience should be integrated into a regime that preserves compulsory licensing as a respected and dependable legal tool.

One of the barriers to reform has always been that it is viewed as a compromise between diametrically opposed forces.<sup>193</sup> However, using the right structure, one might be able to envision a mechanism that is supported by all sides. If the incentives and dispute resolution system was properly aligned to global patent breaking goals, one can imagine that parties could participate in ways they deem unacceptable now. In some cases, activists would discourage compulsory licenses as counter productive, and in others, industry would favor the use of such licenses.

Importantly, an international solution is key. Although it is possible for national or regional legislation to ameliorate some of these issues, the trend toward harmonization is counter to local problem solving. The fact is

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USE IMPROVEMENT AND CIVIC PROJECT MODIFIED GENERAL PROJECT PLAN 22, 23, 30 (June 23, 2009), *available at* [http://www.empire.state.ny.us/Subsidiaries\\_Projects/Data/AtlanticYards/ModifiedGPP2009.pdf](http://www.empire.state.ny.us/Subsidiaries_Projects/Data/AtlanticYards/ModifiedGPP2009.pdf) (describing the retained option of using eminent domain power if necessary to acquire land for the Atlantic Yards development project in New York City).

<sup>192</sup> See, e.g., Julia Vitullo-Martin, *Columbia Gets a Lesson in Property Rights*, WALL ST. J., Jan. 2, 2010, at A.9 (reporting on the political and legal fight surrounding Columbia University's planned expansion into supposedly "blighted" private land).

<sup>193</sup> See Kapczynski, *supra* note 50, 827-36 (describing the confrontational tactics of the "access to knowledge" movement); Morin & Gold, *supra* note 57, at 14-16 (suggesting that NGOs and pharmaceutical companies argued to reach a consensus without trust in one another).

that international intellectual property rules are becoming more important in setting standards. In addition, it is equally important that the solution be simple and fit within the existing structure. The likelihood that TRIPS would be renegotiated in any substantial way in the near future is very small.

Just such a possibility may be at hand through a rather simple modification of the compulsory license remuneration mechanism.<sup>194</sup> As discussed below, an interpretive tweak could heal the existing rift significantly. Thankfully, the time is ripe for reform. International interest in the Paragraph 6 mechanism is an opportunity to consider overall reform that is equitable and predictable.

#### *A. Bringing All the Parties to the Table: Licensing vs. Breaking*

An important aspect of compulsory license reform is to re-imagine the mechanism as something that is positive for all sides. Traditionally, industry has viewed compulsory licensing as a rights exception and therefore something to be opposed at every turn.<sup>195</sup> Conversely, activists are skeptical that an attenuation of compulsory license rules will result in a windfall for industry, particularly in areas in which profits are perceived to be unnecessarily high.<sup>196</sup> If there were some way to bring all parties to the table as participants in a system that could actually have broad advantages all around, it would be a great improvement.

The problem with current practice is that it treats planned compulsory licensing as an *ex ante* exception to rights. Such a royalty discount is assumed, un-tethered to any actual market condition, and patent owners consider the payment to be a token as best.<sup>197</sup> This is clear in emergence of the phrase used throughout this paper and in the popular

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<sup>194</sup> TRIPS, *supra* note 29, at art. 31(h).

<sup>195</sup> Janice Mueller, *Public Access Versus Proprietary Rights in Genomic Information: What is the Proper Role of Intellectual Property Rights?*, 6 J. HEALTH CARE L. & POL'Y 222, 232 n. 68 (2003) (listing sources dating back to the 1950s that describe industry resistance to general compulsory licensing).

<sup>196</sup> Nevin M. Gewertz & Rivka Amado, *Intellectual Property and the Pharmaceutical Industry: A Moral Crossroads Between Health and Property*, 55 J. BUS. ETHICS 295, 298 (2004) (discussing the moral and ethical issues involved in a patent right's ability to provide a "windfall" to its owner).

<sup>197</sup> For example, Canada's former pharmaceutical compulsory license system, which was abandoned in 1987, arbitrarily applied a 4% royalty almost uniformly following an Exchequer Court decision involving Hoffman-LaRoche's Valium. Schreer & Watal, *supra* note 8, at 924. The current Canadian regime incorporates a 4% royalty as a ceiling because this is "is consistent with the humanitarian and non-commercial considerations that are the foundation of the Regime." Canada Royalty Guidelines, *supra* note 183. There is no pretense that the rate reflects real-world licensing for any of the scheduled pharmaceuticals.

media, “breaking patents.”<sup>198</sup> But perhaps there is another way to envision unauthorized use of patents. A system where patent owners can expect a reasonable return may encourage them to realign the private market. And with property owner participation, consuming countries can make use without fear of stigma or punishment. Such a system would likely be more limited in its boundaries than TRIPS is currently. It may not be useful in all of the contexts for which compulsory licensing has been imagined in the past. But as described above, in the most critical aspects like emergencies, it will serve its function of permitting access.

The idea of bringing patent owners into the system is not radical or new. Many commentators that have considered the legal regimes associated with the Paragraph 6 (essential medicines export) amendments suggest they are a fair realignment of property rules that permit all sides to come out ahead.<sup>199</sup> However, the execution of this goal has been poor. It is apparent that the negotiation of such legal regimes, at least in the patent context, has generally occurred without the enthusiastic participation of industry.<sup>200</sup> In some cases, where industry actually did participate, it could be argued that it was motivated primarily by public relations concerns.<sup>201</sup> Regardless, the participation of industry has not been helpful in finding a way forward.

Outside of Paragraph 6 licensing, the extent to which industry is a participant or given respect depends on the country. In many developed countries, the interests of industry are accounted for in the same way that general property rights are.<sup>202</sup> But in some developing countries, there is a lack of this level of accounting. The difference may be related to whether the affected industry has investment interests in the licensing country, rather than a deep ideological split on how to account for licensing.

But there is an interesting model for equitable patent licensing that

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<sup>198</sup> See, e.g., *Abbott in Thailand*, CHI. TRIB., May 10, 2007, at 26 (referring to Thailand’s “threat to break patents”).

<sup>199</sup> See, e.g., Flynn et al., *supra* note 141, at 191 (“Converting the property rule to a liability rule through a compulsory license allows a country to change most of the deadweight loss into consumer surplus . . . while providing a measured contribution to research and development expenses through a royalty payment.”).

<sup>200</sup> In many cases, industry stakeholders have their own solutions in mind and are reluctant to cede control to NGOs or developing country governments. See Gold & Morin, *supra* note 56, at 1330 (“NGOs and industry need to work together to achieve success.”).

<sup>201</sup> Morin & Gold, *supra* note 57, at 21-22 (“industry representatives described debates on access to medicines as a ‘political exercise,’ a ‘symbolic issue,’ the ‘easiest scapegoat,’ a ‘media-visible solution,’ or a ‘total political process.’”).

<sup>202</sup> See Laurence R. Helfer, *The New Innovation Frontier? Intellectual Property and the European Court of Human Rights*, 49 HARV. INT’L L.J. 1, 32-34 (2008) (describing the European Commission’s consideration of a compulsory license under the rubric of the human right to property in *Smith Kline & French Labs, Ltd. v. Netherlands*, App. No. 12633/87, 66 Eur. Comm’n H.R. Dec. & Rep. 70, 72-73 (1990)).

can be found in U.S. copyright law. Since the early part of the 20th century, U.S. law has provided for a compulsory license — referred to as a “mechanical license” — for the subsequent recording of musical works that have been distributed to the public on phonorecords.<sup>203</sup> Most people refer to the copies as “cover songs.”<sup>204</sup> The system has been widely criticized as unwieldy<sup>205</sup> and argued to be an inappropriate conversion of a property regime to one focused on liability.<sup>206</sup> But there are some positive lessons to be learned. First, the system does ensure that the rights are available for use without the problem of holdouts.<sup>207</sup> In addition, the existence of a defined licensing fee has enabled private negotiation to flourish.<sup>208</sup> The U.S. copyright office in consultation with interested parties determines the fee.<sup>209</sup> It is actually a functional system in many respects.

Most importantly, due to the existence of copyright compulsory licenses, there are very likely some cases wherein a copyright owner increases its profit because music is used and royalties are obtained that would not have been without the compulsory licenses. In other words, it is almost certain that, due to the mechanical license, some copyright owners increase their profits.

The greatest problem with the copyright mechanical licensing

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<sup>203</sup> 17 U.S.C. § 115 (2006). The copyright act actually has other compulsory license sections, including secondary transmission for cable television, 17 U.S.C. § 111 (2006).

<sup>204</sup> John Baldrica, *Cover Songs and Donkey Kong: The Rationale Behind Compulsory Licensing of Musical Composition Can Inform a Fairer Treatment of User-Modified Videogames*, 11 N.C. J. L. & TECH. 103, 104-05 (2009).

<sup>205</sup> Jeffrey A. Wakolbinger, *Compositions are Being Sold for a Song: Proposed Legislation and New Licensing Opportunities Demonstrate the Unfairness of Compulsory Licensing to Owners of Musical Compositions*, 2008 U. ILL. L. REV. 803, 815-16 (2008) (noting composer and publisher complaints about unnecessary middlemen for licensing)

<sup>206</sup> Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1308-1312 (1996) (arguing that the liability rules related to copyright compulsory licensing are clearly suboptimal, pointing to the market distortion effect of the rarely-revised royalty rate).

<sup>207</sup> This was apparently the primary motivation of the statute. *See id.* at 1308-09. In the patent context, there have been theoretical arguments as to how compulsory licensing could lead to greater efficiencies for all parties when hold-ups exist. *See, e.g.*, Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair Use Exception*, 76 N.Y.U. L. REV. 1623, 1679-84 (2001).

<sup>208</sup> Daniel A. Crane, *Intellectual Liability*, 88 TEX. L. REV. 253, 262-263 (2009) (describing the work of the Copyright royalty board in setting rates).

<sup>209</sup> *Id.* at 295-96 (compulsory licenses have been subject to bargaining in the shadow of copyright royalty judges). A list of participant in recent license rate determinations demonstrates the substantial participation of publishers, composers and distributors. U.S. Copyright Office, *Adjustment or Determination of Compulsory License Rates for Making and Distributing Phonorecords* (Oct. 15, 2008), <http://www.loc.gov/crb/proceedings/2006-3/index.html#participants>

system is that it is a blunt instrument that cannot take into account when a private market would be superior.<sup>210</sup> A license with a moderate, government-determined royalty exists in all cases, regardless of whether the owner of the work would be a rational negotiator and easily identifiable. Folding just a few these notions into the TRIPs patent rules might be a path toward a more reliable system. But a wholesale adoption would never be a realistic possibility, either in terms of efficiency or political viability.

In the end, the trick seems to be to design a system that provides for stability and reliability for property owners as well as reasonable access for those in need of the invention. Ideally, it would apply to any license of patented technology, whether related to pharmaceuticals or computer chips. And it would be simple and streamlined so as not to deter use through complex rules or bureaucracy.

Surprisingly, all of this could be accomplished with a relatively simple revision of TRIPs. One would focus on the interpretation of the remuneration aspects and incorporate a normative analytical framework that may not be formally accepted by all TRIPs members, but has seemingly provided the guiding principles for operations to date. A human rights framework and a simplification of the qualification rules is a promising path that should at least be considered by the TRIPs council going forward.

#### *B. The Utility of a Human Rights Framework in Categorizing and Valuing Interests*

Given that the primary issue in compulsory licensing is income, it makes sense to focus on the royalty aspects of TRIPs. Thankfully, this provides a great deal of flexibility. The section of TRIPs addressing remuneration is set forth in very vague terms, which means that a modification could be layered on top. No formal system need be disassembled, and no real expectations exist that must be revised.

TRIPs article 31 and 31*bis* both require only that remuneration be “adequate.”<sup>211</sup> In addition, TRIPs requires that the remuneration to be open to challenge within the licensing country.<sup>212</sup> Theoretically, one could bring a dispute before the TRIPs dispute settlement body on the amount of

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<sup>210</sup> See Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783, 831-33 (2007) (stating the compulsory licenses should encourage private bargaining).

<sup>211</sup> TRIPs, *supra* note 29, at art. 31(h); Paragraph 6 Decision, *supra* note 33, at ¶ 3 (referring back to TRIPs art. 31(h)).

<sup>212</sup> TRIPs, *supra* note 29, at art. 31(j). Since the Paragraph 6 Decision incorporates the remuneration provisions of TRIPs, one assumes that the appeal process is also included, though it is not explicitly referenced.

remuneration.<sup>213</sup> But to date, no country has.<sup>214</sup> Truthfully, using the current rules, it would be hard to imagine how one would clearly establish that any remuneration amount above zero is not adequate, particularly when the market remains intact across the rest of the globe.<sup>215</sup> Does adequate mean sufficient to cover lost sales, production and/or R&D costs, or simply a rule-of-thumb amount that has been allocated in other contexts? TRIPS is silent on this account. Moreover, although the negotiation history reveals that there were many perspectives forwarded during the negotiation of the final language,<sup>216</sup> the participants' intent on the final meaning is still open to question.

However, this silence provides an opportunity. The incorporation of some means of determining when remuneration is adequate would solve the inconsistencies noted above. It could distinguish between a circumstance in which there is no access in an emergency from that wherein a country engages in pure opportunistic licensing. Moreover, the involvement of the dispute resolution panel would ensure that there is some objectivity. On the other hand, it seems obvious that the licensing country would have a bias in determining whether the licensing rate is too low (it would be like having an arbitration system run entirely by a company at the center of a dispute<sup>217</sup>), yet that is the system that currently exists.

Of course, stating that a dispute body should be able to settle on reasonable royalty rates in necessary circumstances, and actually identifying that rate are different things. Climate change technology does not have the fungible properties of popular music that naturally lend themselves to government royalty setting. Drugs may have dramatically different therapeutic efficacies, production costs, and global price support. The same is certainly true for other inventions that do not lend themselves to a clear valuation. A royalty rate that might be fair for one might not be appropriate for another. But that does not necessarily mean that the process is completely without boundaries, knocking a reformation attempt back to square one. There are general principles that could be used to ground a royalty process.

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<sup>213</sup> See Taubman, *supra* note 165, at 941-43 (outlining how a dispute on compulsory license remuneration would proceed through the WTO Settlement Body).

<sup>214</sup> Of the twenty-nine cases that have been brought to date, none concern TRIPS art. 31. WTO, Disputes by Agreement, [http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_agreements\\_index\\_e.htm?id=A26#selected\\_agreement](http://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26#selected_agreement) (last visited June 30, 2010).

<sup>215</sup> See Taubman, *supra* note 165, at 951-57 (addressing various arguments that would be considered in determining whether a royalty rate is adequate, and noting that it is not equivalent to full compensation in all cases).

<sup>216</sup> See UNCTAD-ICTSD RESOURCE BOOK, *supra* note 7, at 462-67.

<sup>217</sup> See *id.*; Taubman, *supra* note 165, at 952-53.

A human rights assessment could provide some indication of when a less than market royalty payment is necessary. Although human rights obligations are not accepted by every nation — notably, the U.S. has refused to ratify the most important treaty relating to cultural and social rights<sup>218</sup> — there is more agreement here than meets the eye. The fundamental principles of human rights seem to underlie almost every nation's pronouncements regarding access to inventions, and all nations actually do accept some obligations.<sup>219</sup> The disagreement appears to be on when human rights are truly at stake and what mechanisms are necessary to “respect, protect and fulfill” them.<sup>220</sup> Still, given the absence of *any* measuring norm in the current regime, it seems likely that most nations would agree to a human rights analysis as a set of balancing principles if such an analysis were complete enough to consider all interests. In cases wherein there is a deep objection to the language of human rights, an argument that the relevant principles are part of customary international law may carry some weight in this particular context.<sup>221</sup>

The first step in the process would be to determine what human rights are implicated in a given compulsory licensing decision. Where patented inventions are concerned, the right to health is a primary candidate for remuneration consideration. According to article 25 of the Universal Declaration of Human Rights (UDHR) “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social service.”<sup>222</sup> That basic broad principle was ratified by many of the

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<sup>218</sup> International Covenant on Economic, Social & Cultural Rights (ICESCR) art.12, Dec, 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR]. The United States signed the treaty in 1977, but has never ratified it. See U.N. Treaty Collection, Status of International Covenant on Economic, Social and Cultural Rights, [http://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=IV-3&chapter=4&lang=en](http://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en) (last visited June 30, 2010).

<sup>219</sup> Even though the United States has resisted the notion of the right to health as it has been expressed in major treaties, it has shown support for aspects of such a right in its support of resolutions on international health care and trade policies. HESTERMEYER, *supra* note 27, at 131.

<sup>220</sup> Elizabeth M. Bruch, *Whose Law is it Anyway? The Cultural Legitimacy of International Human Rights in the United States*, 73 TENN. L. REV. 669, 687-90 (2006) (noting that current debates in the U.S. about human rights relate to the cultural legitimacy of the standards). Guidance for members of ICESCR is provided by a document known as General Comment 14, a binding interpretation of the Covenant. ECOSOC, COMM. ON ECON., SOC. & CULTURAL RIGHTS, GENERAL COMMENT 14, THE RIGHT TO THE HIGHEST ATTAINABLE STANDARD OF HEALTH, U.N. Doc. E/C.12/2000/4 (2000) [hereinafter CESCR COMMENT 14] at ¶ 31.

<sup>221</sup> See HESTERMEYER, *supra* note 27, at 122-23 (discussing the application of customary international law).

<sup>222</sup> Universal Declaration of Human Rights (UDHR) art. 25, G.A. Res. 217A, at 71,

developed-country members of the TRIPS agreement, including the United States.<sup>223</sup> However, it is not binding and is reasonably subject to interpretation.<sup>224</sup> More specific is the International Convention on Economic, Social and Cultural Rights (ICESCR), which acknowledges “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>225</sup> This agreement has binding obligations and is a bit more limited in its signatories, with the most important hold-out being the United States.<sup>226</sup> Regardless, the ICESCR has been subject to detailed interpretation in the context of compulsory licensing. According to the Commission on Economic, Social and Cultural Rights in its comment 14 issued in 2000, the right to health does not mean that convention members are obligated to provide full health care services, such as instituting a national insurance system.<sup>227</sup> Rather, the Committee announced several “core” obligations that include access to essential medicines, food, basic shelter, sanitation and safe, potable water.<sup>228</sup> As a starting point, a remuneration regime that stands as a barrier to these core obligations is problematic.

However, balancing this human right out, to some extent, is the right to profit from one’s invention. This right is often ignored or at least highly subjugated to other human rights. According to UDHR article 27, “Everyone has the right to the protection of the moral and material interests resulting from any scientific literary or artistic projection of which he or she is the author.”<sup>229</sup> Again, this is reflected in the ICESCR, article 15, which describes the “right of everyone . . . [t]o benefit from the protection of the moral and material interests resultant from any scientific literary or artistic production for which he is the author.”<sup>230</sup> This seemingly strong statement has been tamped down a bit by the Committee, which noted that the right to

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U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948) [hereinafter UDHR].

<sup>223</sup> The United States not only ratified the UDHR, but also was actually one of the primary drafters of the document. Scott L. Cummings & Loise G. Trubek, *Globalizing Public Interest Law*, 13 UCLA J. INT’L L. & FOREIGN AFF. 1, 12 (2008).

<sup>224</sup> See Mac Darrow & Louise Arbour, *The Pillar of Glass: Human Rights in the Development Operations of the United Nations*, 103 AM. J. INT’L L. 446, 470 (2009) (stating that the UDHR is not binding, but that substantial parts likely now qualify as customary international law).

<sup>225</sup> ICESCR, *supra* note 218.

<sup>226</sup> See U.N. Treaty Collection, *supra* note 218 (listing all signatures and ratifications).

<sup>227</sup> CESCR COMMENT 14, *supra* note 220, at ¶ 36 (stating a number of mechanisms for providing health care, including private insurance).

<sup>228</sup> *Id.* at ¶ 43.

<sup>229</sup> UDHR, *supra* note 222, at art. 27.

<sup>230</sup> ICESCR, *supra* note 218, at art. 15(c).

benefit from intellectual property is not coextensive with legal IP right.<sup>231</sup> Rather, it is tied into a personal right.<sup>232</sup> This is similar to the natural rights or Lockean perspective on intellectual property, which was prevalent earlier in common law jurisprudence and scholarship.<sup>233</sup> One aspect this perspective does make clear is the necessity for alienation of the property (as opposed the human right), which feeds into adequate remuneration.<sup>234</sup> The ability to be fairly compensated for a scientific production is highly related to its alienability.<sup>235</sup> In addition to ICESCR rights for IP specifically, there is a right to property accepted in non-binding human rights documents like the UDHR<sup>236</sup> and the Declaration on the Rights and Duties of Man.<sup>237</sup> These could be informative in providing some interpretative context to a compulsory licensing remuneration valuation.

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<sup>231</sup> ECOSOC, COMM. ON ECON., SOC. & CULTURAL RIGHTS, GENERAL COMMENT 14, THE RIGHT OF EVERYONE TO BENEFIT FROM THE PROTECTION OF THE MORAL AND MATERIAL INTERESTS RESULTING FROM ANY SCIENTIFIC, LITERARY OR ARTISTIC PRODUCTION OF WHICH HE OR SHE IS THE AUTHOR, U.N. Doc. E/C.12/GC/17 (2005) [hereinafter CESCR COMMENT 17] at ¶ 3.

<sup>232</sup> *Id.* at ¶ 2.

<sup>233</sup> See Adam Mossoff, *The Use and Abuse of IP at the Birth of the Administrative State*, 157 U. PA. L. REV. 2001, 2022-2044 (2008) (relating John Locke's labor theory of property as applied to intellectual property).

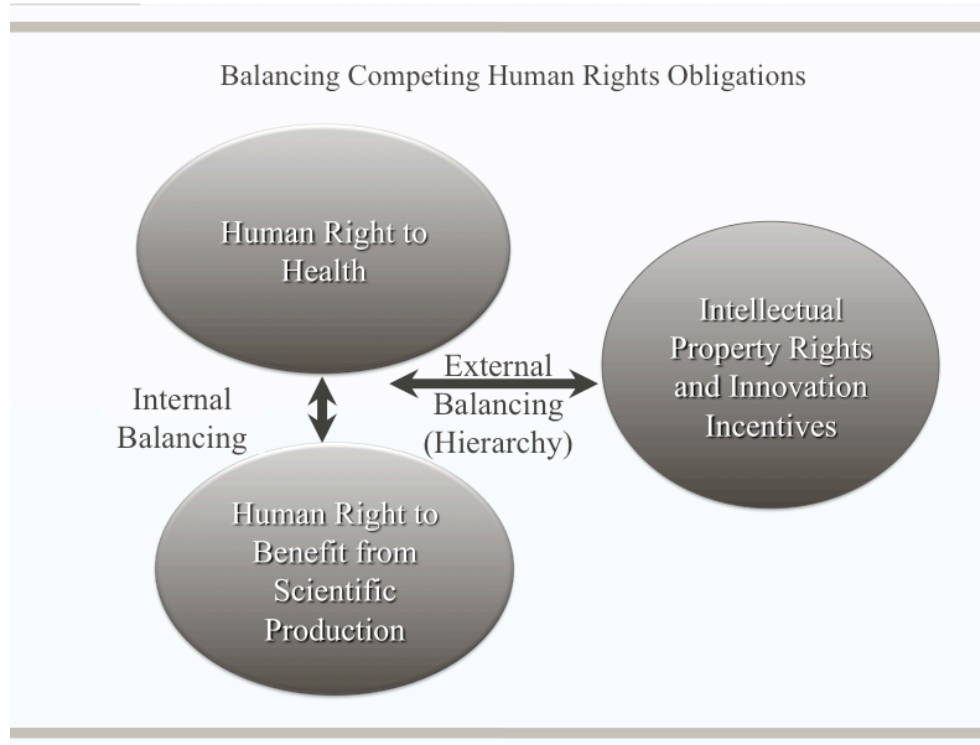
<sup>234</sup> CESCR COMMENT 17, *supra* note 231, at ¶ 3 (noting the economic dimension of the right).

<sup>235</sup> *Id.* at ¶ 31 ("States parties must ensure that third parties adequately compensate authors for any unreasonable prejudice suffered as a consequence of the unauthorized use of their productions.").

<sup>236</sup> UDHR, *supra* note 222, at art. 17 ("Everyone has the right to own property alone as well as in association with others" and "No one shall be arbitrarily deprived of his property.").

<sup>237</sup> Organization of American States, American Declaration of the Rights and Duties of Man, adopted by the Ninth International Conference of American States (1948), reprinted in Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L./V/II.71, doc. 6 rev. 1 (1988), at art. 23 ("Every person has a right to own such private property as meets the essential needs of decent living and helps to maintain the dignity of the individual and of the home.").

Figure 2



Considering these rights, what one can see evolving is a balancing test similar to one that exists in other areas of law, such as the U.S. conception of copyright fair use.<sup>238</sup> First, there is an internal human rights balancing test. One assesses the current state of access to the technology. Does pricing play a role in reducing access such that a core health obligation is impacted? Additionally, what impact would the remuneration discount have on the right to benefit from the invention? Second, there should be an external innovation incentive policy balancing. What impact would a royalty reduction have on the overall innovation environment? In some cases, where there is great need for access supported by human rights principles, and little impact on investment returns, the reduction in remuneration from market levels may be great.<sup>239</sup> In others, where access is not a problem and profit would be dramatically affected, remuneration

<sup>238</sup> 17 U.S.C. § 107 (2006).

<sup>239</sup> Alan Devlin et al., *Success, Dominance and Interoperability*, 84 IND. L.J. 1157, 1188 (2009) (noting that intellectual rights that are not economically important or “weak” in a particular market are excellent candidates for compulsory licensing).

reduction will be small. Essentially, this is little more than formalizing what advocates on all sides have been saying for years.

Clearly, using a broad system like this would not yield complete predictability, but it would compel actors to articulate a case for their plan and have some understanding of when rules will bend in their favor. For example, one could outline the three scenarios above and see how a human rights perspective provides significantly more guidance.

**Table 1**  
**Examples of Human Rights Balancing**  
**in Remuneration Calculation**

<b>Unauthorized Use</b>	<b>Impact on Health and Life Rights</b>	<b>Impact on Right to Benefit from IP</b>	<b>Impact on Innovation</b>	<b>Outcome</b>
Current AIDS, TB and Malaria treatments	Limited increase in access due to existence of generics	Small impacts due to profits in developed countries	Small impacts on innovation for developing country diseases	Compulsory licensing at a steep discount from developing country market not necessary
Agro Chemical licensing by middle-developed countries	Limited increase due to competitive pricing	Large impact due to size of agricultural market	Little impact due to developed country market	Compulsory licensing at a steep discount from developing country market not necessary
Emergency reaction to Pandemic	Significant increase in access due to volume purchasing and limited production by IP owner	Small impact due to expected profits in developed countries	Very little impact due to ex ante nature of emergency	Compulsory licensing at a steep discount from developing country market may be necessary

An understanding of what interests the law favors, in turn, fosters negotiation whenever possible. That is essentially the lesson of copyright compulsory licensing (and arguably Paragraph 6 licensing).<sup>240</sup> If you set the landscape completely enough, a private market will fill in the space unless impeded by some other barrier. In such a case, compulsory licensing

<sup>240</sup> See Crane, *supra* note 208, at 295-96.

can be used to address the deficiency.

Key to a human rights attenuated remuneration system is the participation of an international decision making body, namely the WTO's Dispute Settlement Body.<sup>241</sup> While this entity has been growing more active in recent years, deciding a number of issues related to TRIPS,<sup>242</sup> it has never commented on remuneration. It is reasonable to assume that additional expertise would be necessary. But such expertise is not unattainable, or even unusual in the field of intellectual property compensation. In every infringement case, courts and lay juries are required to make an *ex post* determination of damages in view of a number of complex factors.<sup>243</sup> There is no reason to assume that a WTO body would be unable to do the same, and perhaps issue some measure of guidance in the form of advisory opinions. In addition, it is likely that a political process could be included to ensure that royalty rules capture all of the relevant interests, as in the case of U.S. copyright royalty setting.<sup>244</sup> Though one could argue that such a process is already guaranteed by the WTO's own negotiation structure, the long and contentious debate leading up to the Paragraph 6 implementation suggests that there may be better alternatives.

Of course, functionally, an attenuated remuneration system must also be implemented in national laws. The WTO Dispute Settlement Body's power extends only to sanctions for countries that do not fulfill their obligations to under TRIPS and other aspects of the GATT. To comply, a country would be required to establish a process for ensuring the relevant human rights and innovation considerations are taken into account in setting royalties. Theoretically, any country that has a process for expropriating property already has the outline in place, and certain specifics relevant to patents would simply need to be incorporated.

What about countries such as the United States that do not adhere to the Covenant on Cultural, Economics and Social Rights<sup>245</sup> — wouldn't a remuneration attenuation regime based on such principles be subject to

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<sup>241</sup> See Taubman, *supra* note 165, at 951-52. See also Rochelle C. Dreyfuss, *Fostering Dynamic Innovation and Development: International IP as a Case Study in Global Administrative Law*, ACTA JURIDICA (forth coming 2008), available at <http://www.iilj.org/publications/documents/2008.4Dreyfuss.pdf>.

<sup>242</sup> Rochelle Dreyfuss, *TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis* 52 (Public Law and Legal Theory Working Paper No. 09-44, Aug. 2009), available at <http://ssrn.com/abstract=1443248>

<sup>243</sup> See David W. Opderbeck, *Patent Damages Reform and the Shape of Patent Law*, 89 B.U. L. REV. 127, 132-34 (2009) (describing the current process for determining lost profits and a reasonable royalty under U.S. patent law).

<sup>244</sup> See *supra* note 209 and accompanying text.

<sup>245</sup> See *supra* note 218.

serous objection? This would likely be the case if the regime was imposed on a given country, but such implementation is actually never required. The ability to attenuate remuneration is a voluntary relaxation of intellectual property obligations, and as with other flexible provisions in TRIPS, countries may impose stronger property standards. This is of course exactly what has occurred today with the Paragraph 6 implementations. Although many countries have revised their laws in response, other countries — e.g., the United States — have not.

### *C. Future Revision: Streamlining the Rules with Open Licensing*

While the above remuneration policy could be instituted with little revision to TRIPS, it is possible to imagine more significant changes that would increase the utility of a compulsory license regime. While this would present a greater challenge politically, the benefits would be significant. Specifically, consider that when an attenuated remuneration process is coupled with a complex set of criteria that limits when countries are even eligible to consider a license, the utility of the system is greatly reduced. The imposition of subject matter limitations, time limitations, or pre-negotiation requirements<sup>246</sup> has the effect of squeezing the utility of licensing for no real benefit to property owners. All such limitations can be eliminated under a human rights-based remuneration system without a negative impact on innovation incentives.

A more controversial but equally important streamlining measure would be to eliminate the general requirement that compulsory licensing be primarily for use in the licensing country.<sup>247</sup> From the perspective of the

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<sup>246</sup> The TRIPS agreement contains several procedural restrictions that limit the breadth of a compulsory license. Some are generally applicable to all compulsory licenses, such as the requirement that authorization be individual and limited in scope and duration, as opposed to a standing license. TRIPS, *supra* note 29, at art. 31(a), (c). Other limitations are specific to the license type, such as the requirement for prior negotiation with the patent holder except in cases of emergency, urgency or public non-commercial use, TRIPS, *supra* note 29, at art. 31(b), or the need to confirm a lack of manufacturing capacity in the Paragraph 6 amendments, Paragraph 6 Decision, *supra* note 33, at ¶ 2(a)(ii). In addition, national legislation often imposes additional constraints, such as Canada's requirement for Health Canada approval before exporting medicines. Government of Canada, Canada's Access to Medicines Regime, *Preparing to Submit an Application*, [http://www.camr-cam.gc.ca/compan-entrepris/applic-demande/prepar\\_e.html](http://www.camr-cam.gc.ca/compan-entrepris/applic-demande/prepar_e.html) (last updated July 28, 2006). Moreover, regional trade agreements (particularly those known as "TRIPS-plus", see Bird, *supra* note 8, at 211) or bilateral investment treaties (see generally Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT'L L. REV. 357 (2010)) may add additional procedural limitations.

<sup>247</sup> TRIPS, *supra* note 29, at art. 31(f).

property owner, if compensation is fairly attenuated as outlined above, such a license could actually result in more efficient pricing. As long as royalties are connected to specific sales, there should be no need (or advantage) to requiring specific licenses. In many ways, a streamlined process mimics the freedom of copyright fair use in the United States. Rather than define the eligibility for fair use or create an ex ante application process, people engage in good faith and prepare to argue for the benefits if infringement occurs.

However, for an open licensing regime to function, one limitation vaguely supported in TRIPS must be enhanced: national exhaustion.<sup>248</sup> National patent exhaustion is the principle that a sale in one country exhausts the patentee's right in only that country.<sup>249</sup> It is an essential component of limiting parallel importation between countries that in turn preserves tiered pricing.<sup>250</sup>

Of course, national exhaustion seems overly strict when it precludes parallel importation between countries at a similar development stage. This is the idea behind the Paragraph 6 implementation rule permitting trade of licensed pharmaceuticals between least-developed countries.<sup>251</sup> This principle could be extended to provide for economic regional exhaustion.<sup>252</sup>

In general, a streamlined, open licensing model would do much to enhance the efficiencies of attenuated remuneration without burdening property owners. However, this would constitute a fairly radical change to TRIPS, and it is difficult to imagine much progress soon. In contrast, much of the human rights framework articulated above could be instituted without a great deal of effort or negotiation. Therefore, remuneration attenuation provides a better starting point for developing a more rational, equitable and functional patent breaking system.

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<sup>248</sup> The TRIPS agreement specifically does not address the issue of intellectual property exhaustion. TRIPS, *supra* note 29, at art. 6.

<sup>249</sup> *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1376 (Fed. Cir. 2005) (articulating the doctrine in the context of an infringement case concerning disposable cameras); *see also* *Quanta Computer, Inc. v. LG Electronics Inc.*, 553 U.S. 617 (2008) (clarifying the doctrine in the context of licensees).

<sup>250</sup> *See Cahoy, supra* note 8, at 187-92 (describing the significance of exhaustion in the context of medicines).

<sup>251</sup> Paragraph 6 Decision, *supra* note 33, at ¶ 6(i).

<sup>252</sup> The European Union provides for regional exhaustion based on membership. Robert C. Bird & Peggy E. Chaudhry, *Pharmaceuticals and the European Union: Managing Gray Markets in an Uncertain Legal Environment*, 50 VA. J. INT'L L. 719, 732-33 (2010). Because this is not based on economic need, but rather trade policy, it would be better to provide for an economic-based regional exhaustion. For example, one could exhaust rights between all least developed countries. *See supra* note 63.

## CONCLUSION

The current dysfunction in compulsory licensing the TRIPS regime yields a system with all of the disadvantages of a reduction in intellectual property right, but none of the access advantages imagined. Populations truly in need lose, while the politically powerful gain unnecessary advantages. A consideration of the full scope of compulsory license use highlights these issues and also suggests a route for reform. Reform based on incorporating balancing human rights norms into the remuneration mechanism is a simple fix that is likely to make compulsory licensing useful and predictable in the future.