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Cover Page Footnote

Eben would like to thank his parents (Bruce and Jan Allen) and his wife (Roxanne Allen) for all of their encouragement and patience during the writing process. Additionally, he extends a special thanks to the SJSJ Editorial Staff and Professor Heidi Bond for their valuable insight in improving his article.

Prosecution Benefits: A New HOPE for Bridging the Patent Law Access Gap

Eben Allen*

I. INTRODUCTION

In January 2010, a massive earthquake struck Haiti.¹ Months after the quake, although relief efforts continued in the impoverished nation, an epidemic of cholera suddenly broke out.² Thousands of people contracted the disease, and hospitals struggled to keep up with treatments as the death toll mounted.³ Humanitarian organizations worked with the government to rush massive quantities of aid supplies, including 10,000 boxes of water purification tablets and 2,500 jerricans, yet the disease continued to spread such that nearly a month later, one United Nations plan was still calling for \$89 million for clean water and sanitation and hygiene supplies.⁴

Cholera's spread in the aftermath of the quake is significant because cholera is not easily communicable between people and is almost entirely transmitted by contaminated water and food.⁵ Yet, due to the extreme poverty and natural disaster fallout in Haiti, the disease continued to spread

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¹ Press Conference, Deputy Emergency Relief Coordinator on Humanitarian Efforts in Haiti, United Nations (Oct. 22, 2010), http://www.un.org/News/briefings/docs/2010/101022_Bragg.doc.htm [hereinafter Bragg].

² *Id.*

³ Randal C. Archibold, *Cholera Deaths Up in Haiti, With Worst to Come*, N.Y. TIMES, Nov. 15, 2010, at A4.

⁴ *Id.*; Bragg, *supra* note 1.

⁵ 2010 Haiti Cholera Outbreak, CENTER FOR DISEASE CONTROL, <http://www.cdc.gov/haiticholera/preventionandcontrol.htm> (last updated Nov. 4, 2010).

as Haitians were unable to access clean water.⁶ The aid provided was still insufficient to meet the needs of the Haitian people—insufficient to fully and quickly quell the plague.⁷ But what if the resources available had more purchasing power: what if the dollars channeled through humanitarian organizations were able to purchase more aid supplies for the same price? What if the cost of water purification technology was cheaper and more readily available to this stricken nation?

Intellectual property regimes foster the innovation of new technologies, including water purification. However, these regimes also often raise the price of that technology. This hinders people's ability to access the technology due to the increased expenditure required to acquire the technology. Scholars have suggested various approaches for leveraging exclusive intellectual property rights (such as patents) to alleviate this access problem.⁸ However, very few consider utilizing the process known as patent prosecution, which is the application process used to acquire these patents in the first place. Nevertheless, simple adjustments in the patent prosecution process could be implemented to both alleviate the access problem and resolve issues inherent in patent prosecution.⁹

⁶ Archibold, *supra* note 3.

⁷ Compare Bragg, *supra* note 1 (138 deaths as of October 22, 2010), with Archibold, *supra* note 3 (917 deaths as of November 14, 2010).

⁸ Several such proposals are discussed *infra* Part II, Section B.

⁹ The primary concerns with the current patent prosecution process are its speed, cost, and high degree of complexity, as discussed *infra* Part II, Section C.

While many of the proposed solutions to the access problem are not based on prosecution, these approaches still provide valuable lessons about the components necessary for an effective access solution. This article explores those lessons and forms them into a prosecution-based approach to the access problem. This approach is to implement a new patent classification—a specialized set of rules for lifesaving technology—that offers prosecution benefits in exchange for minimal restrictions that both improve access and protect an innovator’s ability to charge a premium in the primary market. Such a classification provides a compromise between the socially just desire to make new technology affordable for humanitarian purposes and the economic need to make innovation profitable.

In Part II, this article explores the background of the access problem inherent in intellectual property law. Section A explores the competing aims that give rise to the access problem. Section B reviews some access-improving approaches suggested by scholarship and implemented via legislation. Finally, Section C outlines a new approach that focuses on prosecution benefits. This approach is to establish a new patent classification that will simultaneously benefit both society (by improving access) and businesses (by alleviating onerous aspects of the patent prosecution process). Because the new classification would have a strong humanitarian dimension and would address the most drastic instances of the access problem, the new classification proposed by this article is called the Humanitarian-Objective Patent Endorsement, or “HOPE” Certification. Such an approach engages the access issue in a preemptive instead of a reactionary manner, and the HOPE Certification can be modeled after the special classifications for plant and design patents. Since both plant and design classifications define (1) the particular subject matter covered by the classifications and (2) the rules that apply specifically to the classifications, Part III discusses the subject matter definition necessary for the HOPE classification. Part IV covers the rationale and mechanics behind the suggested rules for the implementation of the HOPE Certification.

II. UNDERSTANDING THE ACCESS PROBLEM

A. Defining the Access Problem

The purpose of patent law is to “advance the public welfare through the talents of authors and inventors in ‘Science and useful Arts.’”¹⁰ Patent law accomplishes this through a simple exchange: full disclosure of how to make and utilize an invention¹¹ in exchange for a limited monopoly on the invention’s implementation in any form.¹² Reflected in this exchange are the two principal values of patent law: providing incentives for invention and providing access to technology.¹³ This “need for access/need for incentive dichotomy”¹⁴ is at the heart of patent law, and this article will refer to it as the “innovation dichotomy.”

1. Providing Incentives for Invention

The “economic philosophy behind the clause [in the US Constitution] empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in

¹⁰ Charles Allen Black, *The Cure for Deadly Patent Practices: Preventing Technology Suppression and Patent Shelving in the Life Sciences*, 14 ALB. L.J. SCI. & TECH. 397, 401–02 (2004) (quoting *Mazer v. Stein*, 347 U.S. 201, 219 (1954)).

¹¹ The standard of disclosure mandated by US patent statutes is a written description that sets forth “the manner and process of making and using [the invention] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.” 35 U.S.C. § 112 (2006), *amended by Leahy-Smith America Invents Act*, Pub. L. No. 112-129, 125 Stat. 284 (2011).

¹² Patent statutes give a patent holder the right to exclude others from making, using, selling, offering to sell, or importing the invention. 35 U.S.C. § 271(a) (2006). In the United States, the duration of this exclusionary right lasts twenty years from the application date of the patent. 35 U.S.C. § 154(a)(2) (2006).

¹³ Wesley A. Cann, Jr., *On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism*, 25 U. PA. J. INT’L ECON. L. 755, 757 (2004).

¹⁴ *Id.*

‘Science and useful Arts.’”¹⁵ “In a world of limited resources and easily shared knowledge, there is little incentive for anyone to undertake the substantial costs and risks of research when the reward is shared by any who wish to mimic the advance.”¹⁶ For this reason, in US patent law, the inventor of a new technology is guaranteed a monopoly on the new technology for a limited time, specifically the “power to prevent [others] from making, using, selling, offering to sell, or importing the patented invention.”¹⁷ This right to exclude all other competitors from independently utilizing the invention has two benefits. First, it provides the inventor with sufficient time to recover the expenditures made in developing the invention. Second, it serves as an opportunity to make a profit, providing the personal gain that the Founding Fathers deemed may serve as the best way to motivate and foster technological advances.

2. Providing Access to Technology

The disclosure part of the exchange is intended to ensure that the invention will be available to the public at large once the patent has run its course—that people beyond the initial inventor will understand how the invention works. Such understanding ensures that the public can maximize the use of the invention in three ways. First, disclosure ensures that the technology will not be lost should the initial producer be unable to continue supplying the market with the product of his or her invention (e.g., in the case of an inventor dying without explaining his invention or a company going out of business without ever revealing its processes). Second, the public is better able to implement technology that is already well-explained in publicly available patent paperwork. Third, subsequent individuals will be better able to improve upon the design if they understand the

¹⁵ Black, *supra* note 10, at 402 (quoting *Mazer v. Stein*, 347 U.S. 201, 219 (1954)).

¹⁶ Michael Ilg, *Market Competition in Aid of Humanitarian Concern: Reconsidering Pharmaceutical Drug Patents*, 9 CHI.-KENT J. INTELL. PROP. 149–50 (2010).

¹⁷ Black, *supra* note 10, at 401–02.

fundamentals of how it works in the first place. The public thus avoids the risk of losing inventions, expands the value of the immediate implementation, and gains the value of subsequent improvements.¹⁸

3. The Difficult Balance Between Access and Incentive

Patent laws accordingly attempt to balance “two competing goals: giving adequate economic incentives to pioneering inventors while ensuring that the improvers who follow—and the public as a whole—[can] make effective use of inventions.”¹⁹ While the goal is to organize patent law in such a manner as to maximize gain in both categories (incentives and access), sometimes the values are mutually exclusive instead of mutually beneficial.

The tension between the two interests is often most easily visible in the context of lifesaving technology when access would seem to deserve more weight in the balancing test than incentive. A greater emphasis on the incentive of personal gain can result in a substantial portion of the public never receiving the benefit of the innovation; the people that most desperately need the innovation die before the innovation becomes accessible to them. This can happen either by the nefarious refusal to use patented technology or by the less suspect—but also problematic—pricing considerations in implementing patented technology.

a) Nefarious Refusal to Use Patented Technology

A troubling side effect of a patent holder’s right to exclude others from utilizing an invention is that the right to exclude applies equally to lifesaving technology.²⁰ Should a patent holder so choose, he or she may

¹⁸ A goal of patent law is “ensuring that *the improvers* who followed [*the pioneering inventors*—and *the public as a whole*—could make effective use of inventions.” *Id.* at 401 (quoting Matthew J. Conigliaro et al., *Foreseeability in Patent Law*, 16 BERKELEY TECH. L.J. 1045–1046 (2001)) (emphasis added). The focus on these three distinct classes suggests three ways that disclosure maximizes use of innovation.

¹⁹ *Id.*

²⁰ *Id.* at 408.

“legitimately” exert the exclusionary right to outright block consumer access to lifesaving technology.²¹ The two most common approaches are: “inventing and patenting new technology with the intent that it never be used” (‘sleeping patents’), and “acquiring patents from others with the intent not to develop the technology” (‘patent shelving’).²² While the solution suggested in this article could apply to the sleeping patents issue, this article focuses instead on the non-malicious price considerations that follow. As such, the very real and disturbing problem of nefarious refusal to use patented technology is beyond the scope of this article.²³

b) Problematic Pricing Considerations

A slightly different result of these competing goals of incentive and access is that some individuals may become unable to afford lifesaving technology because the premium put in place by intellectual property protections raises the price of the technology beyond the individual’s means.²⁴ This problem is commonly referred to as “deadweight loss.”²⁵

In his article regarding pharmaceutical drug patents, Michael Ilg explains deadweight loss and the amplification of its significance in the context of lifesaving technology:

A core difficulty of the patent approach, inherent since its inception, has been the loss of willing consumers due to monopoly pricing, identified as deadweight loss in economic terms. So as monopoly pricing extracts a lucrative price premium, it is inefficient, in that many willing consumers who would be able to purchase at a price lower than the monopoly price are excluded, and there is a block of lost purchasers due to the artificially-high price floor of the monopoly patent protection. While the loss of efficient pricing because of monopoly protection is an abstract

²¹ *Id.*

²² *Id.*

²³ However, for a fascinating look at this issue, see *id.*

²⁴ Ilg, *supra* note 16, at 156–57.

²⁵ *Id.*

issue of access which concentrates upon lost potential consumers, the question of access has gone far beyond deadweight loss and optimal purchase price. The issue of access has shifted perceptibly from abstract shades of grey into stark relief; from concerns over lost consumer purchasers at a monopoly price point to pointed humanitarian concerns over receipt of needed relief.²⁶

As Ilg points out, deadweight loss is often simply an economic consideration: a way of calculating the number of customers excluded by the high monopoly price. However, his comment prompts an important question: if society decides that deadweight loss is an acceptable price to pay for innovation when it simply excludes some customers from a convenient technology, then is society still willing to accept the price when technology is potentially lifesaving, and deadweight loss begins to literally refer to the dead?

The two cogent examples that follow, both of which have been extensively documented in scholarship, show that this is not simply a philosophical rumination, but a weighty social concern.

(1) AIDS Medication

“According to the World Health Organization, 95 percent of those infected with HIV live in developing countries.”²⁷ “Despite the existence of treatments, the vast majority of those infected with HIV do not have access to the pharmaceutical products that are available in many developed countries (e.g., Canada and the United States).”²⁸ “The result is an access gap, whereby patients in low- and middle-income countries cannot afford

²⁶ *Id.*

²⁷ Mark D. Penner & Prakash Narayanan, *Amendments to the Canadian Patent Act to Address Drug Access: Is Help on the Way?*, 60 FOOD DRUG L.J. 459, 460 (2005).

²⁸ *Id.*

expensive patented drugs, while patients in wealthy countries can afford and do have access to such treatments.”²⁹

In certain instances, the gap does narrow when patents finally expire. For example, “the average worldwide price for antiretroviral combination therapies (ARVs) that treat HIV/AIDS decreased from \$10,000 to as little as \$168 per patient upon expiration of key patents. This price reduction significantly enhanced access to critical treatments for millions who desperately need them.”³⁰ However, two questions still remain. How many lives were priced out of the market while waiting for the cost of this particular treatment to drop to an affordable level? How many more people will die before the currently available medications eventually become economically feasible for those most in need of them?

(2) Agricultural Advances

Agriculture is arguably “the key to global food security and economic development in the world’s poorest countries.”³¹ With the advent of genetically modified crops that can produce higher yields or greater resistance to pests, one might expect that starvation should no longer be an issue in poor areas of the world.³² However, major corporations such as Monsanto hold many of the patents on these technologies and vigorously deny general access to them.³³ In poverty-stricken locations, the premiums charged for the seeds are often so high that poor, rural farmers find themselves with no choice but to incur massive debts just to purchase the

²⁹ Beirne Roose-Snyder & Megan K. Doyle, *The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level*, 35 AM. J. L. & MED. 281, 281–82 (2009).

³⁰ Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 919 (2009).

³¹ See Ronald L. Phillips, *Introduction: Intellectual Property Rights for the Public Good: Obligations of U.S. Universities to Developing Countries*, 6 MINN. J.L. SCI. & TECH. 177, 180 (2004).

³² Jeffrey J. Mindrup, *Transgenic Crops in the Age of Human Rights: Moral Uncertainty and Rational Risk Policy*, 11 CHAP. L. REV. 213, 226 (2007).

³³ *Id.* at 227.

only seed with sufficient yield to sustain and feed their families.³⁴ The resulting question is similar to that of medications: how many lives were priced out of the market simply because the newest and most promising agricultural technology was unavailable to those most in need of it, and the unavailability was not due to the expense of production, but rather to the expense of intellectual property markups?

c) Addressing the Innovation Dichotomy Balance

Even advocating for placing the highest priority on the preservation of human life, always choosing access in favor of incentive would be self-defeating. On the one hand, without incentives many lifesaving technologies would not exist, and many people would die who could otherwise have been saved by new technologies. On the other hand, if technology pricing is so inflated by the monopoly incentive that the technologies are inaccessible to all but the inventors and those able to pay absolute top dollar, then those same people will still die. Thus, the incentive's utility is negated or diminished. While in an ideal world, any incentive for innovation would provide a reciprocal gain to access, achieving a perfect balance that will work for every given situation in reality is likely impossible. Yet, when people with the greatest need have the least access to the solutions, the system requires revision.

However, patents clearly do not cause this disparity between need and access in every situation. Thus, a comprehensive overhaul of the system is not necessary; instead, creative solutions are needed to specifically target the greatest disparities and add incentives to provide access where it is most crucial. The section that follows surveys various approaches suggested in scholarship to address the innovation dichotomy, after which this article

³⁴ See, e.g., Somini Sengupta, *On India's Despairing Farms, a Plague of Suicide*, N.Y. TIMES, Sept. 19, 2006, at A1 ("The modified seeds can cost nearly twice as much as ordinary ones, and they have nudged many farmers toward taking on ever larger loans, often from moneylenders charging exorbitant interest rates.").

will discuss a new potential tool in alleviating the access gap and balancing the innovation dichotomy: a new classification within patent prosecution.

B. Approaches to Address the Access Problem

Action taken to address the access problem falls into two main camps: scholarship and legislation. Many authors contribute to the scholarship by proposing theories in journals and other publications in an effort to improve understanding of the issue. At the same time, a few of the proposals have been the subject of government response, and government bodies around the world have introduced legislation to address the access problem.³⁵

1. Scholarship

Much ink has been spilled regarding this innovation dichotomy, and scholars have sought and suggested solutions, particularly in the access to medication discussion.³⁶ At some level, any proposed solution affects the basic exchange of patent law, either by adjusting the rights conferred by a patent or by modifying the conditions imposed to receive the patent rights. Changing the rights or the conditions in turn affects access to lifesaving technology as well as incentives to invent. The challenge is to find a set of adjustments to both patent conditions and patent rights such that an increase is realized not only in access to lifesaving technology, but also in incentives to invent. The varied scholarly solutions provide useful insight into what modifications to rights and conditions are available, and the recommendations suggest components that can be incorporated in future approaches to ensure that newly proposed solutions are effective.

a) Adjustments to Term Length

Currently, the basic exchange of conditions for rights in patent law is relatively straightforward. The condition is that an inventor must fully

³⁵ *E.g.*, TRIPS and the Bayh-Dole Act, discussed *infra* Part II, Section B(3)(a).

³⁶ Cann, *supra* note 13, at 757.

disclose an invention by sufficiently explaining in a patent application how the invention works and how to make it.³⁷ In return, the inventor receives the right to exclude any other person from utilizing³⁸ the invention for twenty years.³⁹

The exact proportions of this exchange have been modified over the years, most notably with the length of the term of the patent's validity.⁴⁰ Accordingly, one solution that scholars have proposed is to shorten the term of patents for humanitarian contexts so that humanitarian technology escapes exclusionary control sooner.⁴¹ However, simply shortening the term is likely to be an ineffective long-term solution that simply falls prey to the perpetual debate about what precisely is the optimum term length to balance public access against inventive incentive. However, this option is helpful in that it suggests creating a solution that is narrowly tailored to a specific subject matter to achieve a more specialized and nuanced approach instead of attempting to use a one-size-fits-all approach.⁴²

³⁷ 35 U.S.C. § 112 (2006) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”).

³⁸ “Utilizing” includes making, using, selling, offering to sell, or importing the invention. 35 U.S.C. § 271(a) (2006).

³⁹ 35 U.S.C. § 154(a)(2) (2006).

⁴⁰ For a discussion of the historical progression of term length from fourteen to seventeen to twenty years, see ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 132 (5th ed. 2010).

⁴¹ See Roose-Snyder & Doyle, *supra* note 29, at 301 (noting that some humanitarian licensing schemes “propose shortening the life of an exclusive license to less than the life of a patent” to protect against underperforming developers through the option to find another). While the article suggests making a context-specific limitation (in this case a humanitarian context) on the duration of the term of a license, the concept applies equally well to suggest a context-specific limitation on the duration of the term of a patent.

⁴² In fact, patent law already implements subject-matter-specific solutions: the USPTO has developed special procedural rules for distinct subject matter such as plant patents and design patents. Manual of Patent Examination and Procedure, §§ 1500, 1600 (8th ed., Rev. 4, Oct. 2005) [hereinafter MPEP].

Another term-adjusting solution proposed by scholars is the implementation of severable or transferrable patent terms.⁴³ Also called “wild card patent extensions” in other scholarship,⁴⁴ this suggested mechanism addresses the access disparity by rewarding an inventor and developer of humanitarian technology with an award of additional monopoly time on other patented and profitable technology.⁴⁵ An example of the implementation of this system could be “allowing a company developing a new agent targeting a disease or drug-resistant pathogen that would otherwise not have a high-profit margin to extend the patent term on a high-profit-making drug already within their active portfolio.”⁴⁶ This would motivate development of—and access to—lifesaving technology, not by focusing on the profitability of that technology, but instead by focusing on the gain from a greater exploitation of an unrelated profitable technology.⁴⁷

In the United States, the scholarly concept of wildcard patent extensions has reached proposed federal legislation, but no such legislation has ever passed Congress and been enacted into law.⁴⁸ In 2005, Congress proposed the “Project Bioshield II Act of 2005,” which included provisions to allow companies receiving Food and Drug Administration approval for certain new high priority drugs to extend the patent on company-selected profitable drugs already within their active portfolio.⁴⁹ Congress ultimately rejected

⁴³ See, e.g., Ilg, *supra* note 16, at 152–53 (proposing a system that grants transferrable patent terms for significant humanitarian drug developments and their donation).

⁴⁴ Ann Weibaecher, *Diseases Endemic in Developing Countries: How to Incentivize Innovation*, 18 ANNALS HEALTH L. 281, 304 (2009) (“The term ‘wild card’ is used because the drug company can choose the particular drug to which the patent extension is applied.”).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ Ilg, *supra* note 16, at 153 (suggesting that this strategy could accordingly equate “the humanitarian advance at an economic reward level very near to that of the current and most lucrative blockbuster drug in the marketable segment of patent reward.”).

⁴⁸ Weibaecher, *supra* note 44, at 306.

⁴⁹ *Id.*

the controversial bill in the face of the uncertainty that it could inject into the patent system.⁵⁰ While shifting extra patent term length to other products would cause problems with certainty, the notion of granting a patent term extension for a qualifying type of patent could be a useful patent right or an inventive incentive to offer in return for a potentially more burdensome, yet access-improving condition.

b) Licensing Approaches

Several of the access-improving methods suggested by scholars in the context of licensing provisions could also be implemented into a statutory scheme to modify rights and conditions in patent law. Patent holders often make trades of rights for alternate incentives in the context of transferring partial rights through licensing agreements. When granting a license, a patent holder gives up some of his right to exclude by effectively promising not to exercise the exclusionary right against another entity when that entity utilizes the patented invention in some specific and agreed upon way.⁵¹ Two considerations affect the impact of licensing: voluntariness and exclusivity. Usually, a patent holder provides a voluntary license: he or she voluntarily gives up exclusionary rights, often in exchange for a negotiated payment by the entity seeking the license.⁵² However, on occasion, patent holders are subject to compulsory licenses: they are forced to give up exclusionary rights, either in exchange for a government-determined payment or without

⁵⁰ *Id.* at 306–07 (quoting Kathleen Jaeger, president of the Generic Pharmaceutical Association) (“The wildcard would destroy the generic industry. We would never know which products might be protected by the branded maker, and so we would lose the predictability we need to do our own research and development into drugs coming off patent.”) (citing Marc Kaufman, *Bioterrorism Response Hampered by Problem of Profit*, WASH. POST., Aug. 7, 2005, <http://www.washingtonpost.com/wp-dyn/content/article/2005/08/06/AR2005080601164.html>).

⁵¹ RAYMOND T. NIMMER, LICENSING OF INTELLECTUAL PROPERTY AND OTHER INFORMATION ASSETS 3 (2d ed. 2007).

⁵² *Id.* (“Most licenses are part of a commercial transaction where the person transferring the . . . rights places limitations . . . and retains rights”). Nimmer’s use of the word “transaction” signals the voluntary nature of most licenses.

compensation because the government mandates that the entity be allowed to use the invention, effectively eliminating the patent holder's exclusionary right against that entity.⁵³ A patent holder can also grant exclusive licenses—granting one particular licensee immunity from the exclusionary rights and promising not to grant any other entity such immunity (or nonexclusive licenses granting a licensee immunity) without promising that another licensee might receive a similar immunity.⁵⁴

Just as modifying the exclusivity of a license changes its impact, changing the degree of exclusivity in the patent system could also have beneficial effects. For example, “some humanitarian licensing proposals have called for a movement toward utilizing non-exclusive licenses as the norm” in licensing technology to profit-driven production companies.⁵⁵ This same logic could be applied to statutory patent schemes; instead of having a uniform set of rights across all markets, patent laws could be modified so that they motivate disclosure in lifesaving technologies (by offering a monopoly in settings where consumers can likely afford it) while maintaining a humanitarian exception to the monopoly (for humanitarian contexts where the consumer is not likely to be able to afford it). Creating a distinction between the profit and humanitarian markets is a potentially useful alternative to making all humanitarian technology unprofitable by eliminating any profit-driven market for it.

Many nations utilize compulsory license provisions domestically to avoid nonuse of domestically patented inventions; after a reasonable time of nonuse has passed, a competitor may ask the government for permission to

⁵³ George Tsai, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes Under the WTO Doha Declaration*, 49 VA. J. INT'L L. 1063, 1064 (2009) (defining compulsory licensing) (“[A]uthorization granted by a government to a party other than the holder of a patent on an invention to use that invention without the consent of the patent holder.”).

⁵⁴ NIMMER, *supra* note 51, at 4.

⁵⁵ Roose-Snyder & Doyle, *supra* note 29, at 301.

use the invention.⁵⁶ Internationally, compulsory licensing has only been used to date “in emergency situations where patent-protected pharmaceuticals were seen as prohibitively expensive.”⁵⁷ In the United States, Congress has introduced bills that would adopt a compulsory licensing exception to current patent laws, but none have passed.⁵⁸ Given the setup of the US patent regime, were such a bill to pass, it would not give an access-deprived individual a private right of action⁵⁹ against the patent holder for either shelving the patent or setting the price beyond a given threshold of access—it would only give the right to another to use the technology.⁶⁰

Such immunity from infringement claims would provide a greater boost to access than what is currently imposed by international treaty obligations. The United States is subject to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an international patent treaty.⁶¹ As the TRIPS regime currently stands, a manufacturer could produce medication for use in another country that meets certain specifications, even though a

⁵⁶ Black, *supra* note 10, at 433.

⁵⁷ *China, India Push for ‘Patent Free’ Green Tech*, EURACTIV, (Nov. 23, 2009), <http://www.euractiv.com/en/innovation/china-india-push-patent-free-green-tech/article-187567> (“The Thai government used the mechanism to allow local medicines factories [to] produce HIV drugs at a fraction of the cost.”).

⁵⁸ Black, *supra* note 10, at 433–34.

⁵⁹ For a viewpoint suggesting that such suits might already be an option due to international treaty obligations, see Cann, *supra* note 13, at 877 (“This Article takes the position that treaty duties—including the duty to provide the highest attainable standard of health—are enforceable by means of a number of individual and interstate complaint systems at the domestic, regional, and international levels.”). See also Peter Straub, *Farmers in the IP Wrench—How Patents on Gene-Modified Crops Violate the Right to Food in Developing Countries*, 29 HASTINGS INT’L & COMP. L. REV. 187, 189 n.6, 195, 205, 211 (2006) (asserting that various treaties place an obligation on member States to realize socioeconomic rights “including the right to food” and proposing the utilization of treaty interpretation canons to resolve the “conflicting obligations” in favor of bypassing intellectual property regimes on humanitarian grounds).

⁶⁰ Black, *supra* note 10, at 433–34.

⁶¹ See discussion *infra* Part II, section B(2)(b).

different entity holds the patent in the United States.⁶² However, while compulsory licenses may improve access, they may also generate a problem with predictability; in doing a cost-benefit analysis of developing a specific technology, the losses imposed by a compulsory license added after the patent is issued will not be known and thus cannot be factored into the initial profitability evaluation that will drive most innovation.

On the opposite end of the spectrum from licensing solutions is the use of patent pools, which rely on voluntary instead of compulsory licensing. A patent pool is “an agreement between two or more patent owners to aggregate (pool) their patents and to license them to one another or to third parties.”⁶³ This entails a partial giving up of exclusionary rights using an incentive of receiving reciprocal immunity from the exclusionary rights of others. Through the collaborative effort between various patent holders, each individual patent holder or third party is better able to produce and improve access to lifesaving technology because the net result is that each party participating in the pool is less restricted in what it is allowed to do.⁶⁴

An interesting subset of the successful use of patent pools to improve access to lifesaving technology is the use of one agency as a broker between profit-motivated private companies and access-motivated humanitarian organizations. The International Rice Research Institute (IRRI) is a particularly inspiring example of this approach.⁶⁵ IRRI is an institute with the goal of providing access to agricultural advances and has been substantially involved with genetically engineered rice and the germplasms

⁶² See discussion *infra* Part II, section B(2)(b).

⁶³ Weilbaeher, *supra* note 44, at 292 (quoting *IGWG Briefing Paper on Patent Pools: Collective Management of Intellectual Property—The Use of Patent Pools to Expand Access Essential Medical Technologies*, KNOWLEDGE ECOLOGY INT’L (Jan. 23, 2007), <http://keionline.org/content/view/65/1>).

⁶⁴ *Id.* at 293 (“Patent pools can accelerate innovation by removing problems associated with ‘blocking’ patents, reducing transaction costs, and streamlining and centralizing licensing procedures, thereby making it quicker and simpler to obtain licenses.”).

⁶⁵ *Id.* at 295.

that contain the genetic information on these advances.⁶⁶ IRRI works by acquiring licenses in conjunction with private companies, essentially compiling a collection of the permissions necessary to implement agricultural advances in humanitarian contexts without infringing patents.⁶⁷ As part of the licensing agreements, IRRI implements material transfer agreements (MTAs) as a compliance or record-keeping measure, ensuring that the intellectual property utilized in the humanitarian context does not begin to compete or impinge upon other markets.⁶⁸ This allows IRRI to continue to provide these sorts of technologies to their clients, which are primarily national agricultural research and extension systems (NARES), national organizations that distribute the crop technology to the individuals most in need of it in their countries.⁶⁹

Such a brokering arrangement is valuable in that it brings together many entities that might otherwise be at odds or unwilling to negotiate on an individual basis. By representing a large group of humanitarian end-users, such arrangements can provide organizations with more bargaining power and better, more uniform, and more reliable intellectual property protection protocols. Through a brokering agency's efforts in seeking permission to use the technology in humanitarian contexts, profit-driven companies granting the license may stand to gain the ability to reach markets. This is due to the fact that brokered agreements may also include a simultaneous compact resolving licensing conflicts with other companies that would

⁶⁶ Ronald P. Cantrell et al., *The Impact of Intellectual Property on Nonprofit Research Institutions and the Developing Countries They Serve*, 6 MINN. J.L. SCI. & TECH. 253, 257 ("Historically, IRRI's intellectual property policy for germplasm was simple, driven by its mission to 'improve the well-being of present and future generations of rice farmers and consumers, particularly those with low incomes.' As part of this mission, IRRI produced and disseminated rice germplasm and knowledge without restraint as global public goods, in a manner readily accessible to the poor.").

⁶⁷ *Id.* at 258, 260 ("The Institute does not own this germplasm, but rather holds it in trust with the responsibility to conserve, maintain, improve, and distribute it for the benefit of global agricultural research.").

⁶⁸ *Id.* at 258.

⁶⁹ *Id.* at 257.

otherwise block exploitation in profitable markets.⁷⁰ IRRI's use of existing distribution organizations that function in the context of their specific circumstances is also a savvy way to achieve a more specialized and nuanced solution to the context-specific access disparity problem.

Another solution arising partially out of licensing considerations is the approach of "leveraging public scientific capital."⁷¹ This approach focuses on the fact that many patented health technologies depend extensively on "public scientific capital," that is, contributions of money, research labor, and bodily materials from public institutions such as federal and state scientific funding agencies, nonprofit foundations, universities, disease advocacy groups, and population-based biobanks.⁷² Essentially, the "leveraging" consists of withholding health technologies from those that would only consider the possible profits to be derived from it, effectively adding a new condition to the basic patent exchange and adding more weight to the access side of the innovation dichotomy balance. The access-motivated public entity would disclose and grant a monopoly in a profitable lifesaving technology in exchange for production of the technology on the condition that the licensee or monopolist provides access to those that need it most.⁷³ This notion of encouraging actors toward front-end commitments is a useful construct for access-improving methods, and it potentially addresses the predictability problem raised by the after-the-fact nature of compulsory licenses. While leveraging public scientific capital may in this way viably assure that access problems do not arise in the context of technologies that originate in public science, it offers no solution for those cases where private, profit-driven entities have developed lifesaving technologies independent of public science sources and thus independent of

⁷⁰ *Id.* at 270 ("In exchange for facilitating the availability of GoldenRice(R) for small farmers in developing countries, Syngenta secured rights to the rice for exploitation in developed countries.").

⁷¹ Lee, *supra* note 30, at 944.

⁷² *Id.* at 921–22.

⁷³ *Id.*

any ties or obligations that may accompany that origin or be imposed upon it. However, it is a partial solution, and it has gained recognition in legislation such as the Bayh-Dole Act.⁷⁴

A similar—but potentially broader—way of imposing additional conditions that ensure improved access to lifesaving technology is through working requirements. Working requirements oblige a patent holder to meet certain requirements or milestones after the patent is issued, or risk some sort of forfeiture such as compulsory licensing or statutory invalidity.⁷⁵

For example, the patent statutes could be modified to impose a working requirement of a commercial development plan, wherein the patent applicant would have to lay out a proposal by which it planned to develop and provide access to a technology that was clearly lifesaving.⁷⁶ This would

⁷⁴ See discussion *infra* Part II, Section B(2)(a). Additionally, the method has gained sufficient prominence such that other scholars have detailed several different types of licensing suggestions, approaches, mechanisms, or options that are useful to consider for publicly funded research entities. See, e.g., Roose-Snyder & Doyle, *supra* note 29.

⁷⁵ Black, *supra* note 10, at 434 (“[W]orking requirements are similar to compulsory licensing and statutory invalidity. Under these schemes, a patentee must make reasonable efforts to bring a technology to market or face compulsory licensing or statutory invalidity.”). Statutory invalidity in this case refers to having the patent protections voided by declaring the patent invalid as a matter of law for failure to meet specified criteria. While working requirements are discussed in this article in the context of licensing agreements, the practice could just as easily be included as part of the patent statutes, and the same conditions could be imposed because the subject matter is of a certain classification.

⁷⁶ This idea also comes primarily from an article on possible changes to patent licensing procedures that would improve access. Benton C. Martin, *The American Models of Technology Transfer: Contextualized Emulation by Developing Countries?*, 6 BUFF. INTELL. PROP. L.J. 104, 129 (2009) (“[L]egislation could even require that Commercial Development Plans for technology that may have a potential lifesaving effect include a provision for how the licensee is going to make the technology available to the low-income population.”). In fact, the article goes on to note that statutorily imposed Commercial Development plans already exist in patent licensing contexts. *Id.* at 129 n.159 (citing 35 U.S.C. § 209(a)(3)) (“A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention . . . only if . . . the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant’s request and the applicant’s demonstration that the refusal of such extension would be unreasonable.”).

grant a typical patent monopoly but would provide a mechanism for holding corporations accountable to proposed plans that provide improved humanitarian access. If the patent holder failed to make reasonable efforts to see this plan through, the patent office, court, or other appointed government entity would have the power to void the patent, thereby allowing other parties to provide access.⁷⁷ Such plans have the added benefit of both the patent holder and the patent grantor being involved in setting the terms; having negotiated ahead of time, both sides are more likely to honor the agreement instead of litigating the validity of the authorization, as is likely to happen in compulsory licensing contexts.⁷⁸

c) Non-Patent Law Alternatives

A completely different approach to improving access by modifying the basic exchange of patent law is to change the underlying incentives by either partially obviating the need for existing patent rights or outright eliminating them. A prize-based model can do either,⁷⁹ while an open-source model only performs the latter function.⁸⁰ Prizes can be either implemented in tandem with or in place of standard patent regimes because they offer a distinct incentive to invent: the prize-based model provides a one-time economic reward payment for the donation of knowledge to the public realm.⁸¹ The first entity to achieve a certain advance or develop and

⁷⁷ This example is based on a licensing example of a working requirement. *Id.* at 129 (“Requiring Commercial Development Plans . . . would grant a licensee full rights to the technology, but would provide research institutions a mechanism for holding corporations accountable to proposed access plans. . . . Under a Commercial Development Plan approach, if the licensee failed to take reasonable efforts to see this plan through, the research institution is not left . . . with media and public pressure as its enforcement mechanism. Instead, the research institution would have the power to void the license and issue a new license to [a] party who would provide access.”).

⁷⁸ *Id.* at 129–30 (“This approach would also require upfront honesty about provisions for access to low-income populations during the licensing process, which may address the transparency concerns raised by scholars.”).

⁷⁹ See generally Ilg, *supra* note 16; see generally Weilbaecher, *supra* note 44, at 302–04.

⁸⁰ Weilbaecher, *supra* note 44, at 302–04.

⁸¹ Ilg, *supra* note 16, at 151.

donate a particular lifesaving technology is thus rewarded by a lump sum for completing the technology instead of having to rely solely on recuperating development costs through selling the advance at the highest price during the monopoly patent protection period.⁸² Accordingly, the technology becomes more affordable on the market, and access to it is improved. Although securing sufficient sources of prize money to actually motivate the development or donation of lifesaving technology could be problematic, prizes are useful in that they provide predictability; developers can be sure that the technology is actually desired by the public because a specified amount has been set aside for it.⁸³ Thus, even if prizes are not ultimately implemented as a solution to the access problem, they provide a helpful lesson: before rewarding an entity for developing a technology for a humanitarian context, ideally some method should be used to verify that the public sector has a need for it.

An open-source model, on the other hand, completely eliminates exclusionary patent rights. An open-source response refers to “collaborative, community-based initiatives where the components of the project are made available to all and can be modified by all, such that individual members re-contribute to the larger project.”⁸⁴ This approach relies on an entirely different set of incentives than the usual profit incentive of monopolies: participants are mostly unpaid volunteers who “donate their time and expertise for the satisfaction of contributing to the solution of a large, complex problem and peer-recognition for having done so.”⁸⁵ As such, open-source models often operate as alternatives outside of the typical framework of patent law regulations; open-source initiatives are often not

⁸² *Id.*

⁸³ *Id.*

⁸⁴ Weilbaecher, *supra* note 44, at 286.

⁸⁵ *Id.* at 287.

patented after the fact, but enter directly into the public domain.⁸⁶ While specific examples like the Human Genome Project have certainly been successful,⁸⁷ the open-source approach is likely to only help promote access in two non-patent areas: non-patentable compounds and rare diseases.⁸⁸ However, open-source models do demonstrate the importance of promoting collaboration when trying to develop new solutions to the access-innovation dichotomy.

2. Legislation

Several of the above-mentioned approaches to remedying the access gap have actually been implemented to some degree through legislation. The following examples have found a significant discussion base in scholarship, and are important background for the access discussion.

a) *Bayh-Dole Act*

In 1980, Congress passed the Bayh-Dole Act.⁸⁹ To avoid or minimize the occurrence of government-funded technologies sitting on a shelf and not finding practical application, the Act granted research institutions

⁸⁶ *Id.* at 290 (“Open source drugs would not be patented; rather, the drug itself would enter the public domain for generic manufacturers to produce. This helps achieve the goal of bringing new medicines to people who need them, at the lowest possible price.”).

⁸⁷ *Id.* at 288 (“The international effort to sequence the human genome, known as the Human Genome Project, resembled an open source initiative by placing all of the resulting data in the public domain rather than allowing any individual researcher to patent the results.”).

⁸⁸ *Id.* at 288 (“Open source . . . may be effective in two areas. One is in the development of non-patentable compounds or drugs whose patents have expired. Since discovery involving these drugs and compounds cannot be protected, nor can they garner large profits, developers generally are less interested in pursuing research in these areas. The second is in the area of neglected diseases because there is not a large enough market of paying customers to justify the expense involved in developing a new drug.”).

⁸⁹ Bayh-Dole Act of 1980, Pub L. No. 96-517, 94 Stat. 3015-28 (1980) (codified as amended at 35 U.S.C. §§ 200-211, 301-307 (1994)). The Stevenson-Wydler Technology Innovation Act (passed in the same year as the Bayh-Dole Act) also deals with government-funded research. For a more detailed review of that legislation, see Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1705–09 (1996).

permission to take title and sell technologies to private industry, with a mandate to bring the invention to practical application.⁹⁰ Regarding the access gap, this Act corresponds most closely to the “Leveraging Public Scientific Capital” approach described *supra* in Part II, Section B(1)(b).

Before the passage of the Act, “previous legislation had typically encouraged or required that federal agencies sponsoring research make the results widely available to the public through government ownership or dedication to the public domain.”⁹¹ However, the Act authorized “universities and government agencies to patent and capitalize on their own research,” and “[u]niversities now own significant intellectual property rights that are licensed to pharmaceutical and biotech companies and are developed into lifesaving health innovations.”⁹² Additionally, the Act “allowed and encouraged small businesses and nonprofit organizations to patent the results of government-sponsored research, provided that they satisfy certain statutorily defined conditions.”⁹³

Regarding the mechanisms available to the government agencies to direct the use of the inventions after they are licensed to commercializing entities, Peter Lee explains:

First, under 35 U.S.C. § 202(a), a funding agency can prohibit a grantee from patenting an invention in “exceptional circumstances” when the agency determines that such action “will better promote the policy and objectives” of the Act. Second, the federal government retains a “paid-up license to practice, or have practiced” on its behalf, any invention subject to the Act. Third, agencies may exercise so-called “march-in rights” to compulsorily license subject inventions if certain statutorily defined factors are met. Notably, the second of these criteria explicitly permits march-in rights when “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor,

⁹⁰ Martin, *supra* note 76, at 105.

⁹¹ Eisenberg, *supra* note 89, at 1663.

⁹² Roose-Snyder & Doyle, *supra* note 29, at 283.

⁹³ Lee, *supra* note 30, at 951.

assignee, or their licensees.” . . . [B]y regulation, patents covered by the Act must state that “this invention was made with government support. . . . The government has certain rights in the invention.”⁹⁴

The Act has also been praised for bringing about significant change. “The number of patents filed and licensing agreements signed by universities nearly doubled between 1993 and 2003.”⁹⁵ “Prior to legislation, less than 4 percent of the tens of thousands of government-funded inventions were licensed to industry, resulting in many technologies failing to reach practical application.”⁹⁶ However, “currently, multiple types of research institutions in the United States negotiate an increasing number of licenses every year, resulting in the issuance of more patents and the disclosure of more inventions to technology transfer offices.”⁹⁷ Furthermore, “[e]ven scholars who believe this growth would have occurred eventually without the . . . Act agree that the legislation was important because it “accelerated this growth by clarifying ownership rules, by making these activities bureaucratically easier to administer, and by changing norms toward patenting and licensing at universities.”⁹⁸

b) TRIPS

Among the most prominent governmental actions taken that addresses the access problem is the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS). Regarding the access gap, this agreement corresponds to the “compulsory licensing” approach described *supra* p. 420. In short, TRIPS “allows for the grant of compulsory licenses to combat national health emergencies or other circumstances of extreme urgency.”⁹⁹ Much scholarship has been produced on the intricacies of TRIPS and the

⁹⁴ *Id.* at 954.

⁹⁵ Roose-Snyder & Doyle, *supra* note 29, at 283.

⁹⁶ Martin, *supra* note 76, at 104.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Tsai, *supra* note 53, at 1064.

subsequent legislation it has prompted. As such, it is worth summarizing that history here.

In 1994, the World Trade Organization (WTO) agreements were signed at the end of the Uruguay Round of Trade Negotiations.¹⁰⁰ Included in the Final Act of the new WTO Agreement was the TRIPS Agreement.¹⁰¹ Effective January 1, 1995, TRIPS required all WTO member-nations to meet minimum intellectual property protection standards in their laws and practices.¹⁰² Representing the need-for-incentive side of the innovation dichotomy, the United States, the European Union, and Japan pushed for the passage of TRIPS as a means of strengthening patent law protection, reflecting the increasing importance of their knowledge-based industries in the global economy.¹⁰³ Characterizing the need-for-access side of the innovation dichotomy, developing and least-developed nations accepted the passage of TRIPS, seeking freer access to agricultural markets and participation in the WTO trade system.¹⁰⁴ Accordingly, TRIPS not only strengthened international intellectual property protection and established new patterns of patent protection, but also provided some mechanisms of exception to patent protection to help developing countries adjust to the new intellectual property regime.¹⁰⁵

Article 31 of TRIPS outlines one such mechanism: the compulsory license.¹⁰⁶ The license is intended to allow generic versions of patented drugs to be manufactured without a patent owner's authorization.¹⁰⁷ Subject to the requirements found in Article 31 of the TRIPS Agreement,

¹⁰⁰ Fanni (Faina) Weitsman, *Eliminating Barriers to the Export of Generic Versions of Patented Drugs to Developing Countries—From Doha to Bill C-9*, 6 ASPER REV. INT'L BUS. & TRADE L. 103, 105 (2006).

¹⁰¹ *Id.* at 103.

¹⁰² Tsai, *supra* note 53, at 1064.

¹⁰³ *Id.* at 1067.

¹⁰⁴ *Id.*

¹⁰⁵ Weitsman, *supra* note 100, at 103.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

governments have the right to issue compulsory licenses to allow companies to produce a patented product, or to use a patented process, without the permission of the patent owner.¹⁰⁸ However, Article 31(f) restricts licenses to those that are “predominantly for the supply of the *domestic* market of the Member authorizing such use,” thus limiting the amount of the product that can be exported to a needy country under the license.¹⁰⁹ As a result, less-developed countries lacking the actual capacity to manufacture pharmaceuticals domestically were effectively unable to import any significant quantity of cheaper generics from drug-producing nations where pharmaceuticals were under patent.¹¹⁰

In March 2001, tensions over this restrictive mechanism came to a head when forty-one global pharmaceutical companies filed a lawsuit against South Africa, contesting a South African law that provided for enhanced access to patented drugs.¹¹¹ The South African Medicines Act authorized the South African health minister to issue compulsory licenses in addition to his preexisting authority to allow parallel imports of pharmaceutical products when public health was at stake.¹¹² While the pharmaceutical companies eventually dropped the lawsuit amidst intense criticism, the case generated significant public focus on the issue of compulsory licensing and access to essential medicines.¹¹³ “Developed countries . . . maintained that high levels of IP protection are the best means of increasing access to medicines by promoting investment in research and development, whereas

¹⁰⁸ Cann, *supra* note 13, at 817.

¹⁰⁹ *Id.* (emphasis added).

¹¹⁰ *Id.*

¹¹¹ Tsai, *supra* note 53, at 1068–69; Lee, *supra* note 30, at 932 n.73 (citing Pharm. Mfrs. Ass’n v. President of the Republic of S. Africa, Case No. 4183/98 (High Court of South Africa, Transvaal Provincial Division)).

¹¹² Tsai, *supra* note 53, at 1068–69; Lee, *supra* note 30, at 932 n.73 (citing Pharm. Mfrs. Ass’n v. President of the Republic of S. Africa, Case No. 4183/98 (High Court of South Africa, Transvaal Provincial Division)).

¹¹³ Tsai, *supra* note 53, at 1068–69; Lee, *supra* note 30, at 932 n.73 (citing Pharm. Mfrs. Ass’n v. President of the Republic of S. Africa, Case No. 4183/98 (High Court of South Africa, Transvaal Provincial Division)).

lesser developed countries . . . argued that the strict limitations of the TRIPS Agreement . . . overly restricted users' interests in pharmaceutical technology, especially in the context of health crises."¹¹⁴

In November 2001, shortly after the suit against South Africa, the WTO held its Fourth Ministerial Conference in Doha, Qatar, to clarify issues related to the implementation of TRIPS.¹¹⁵ At the conclusion of the conference, the ministers signed the "Declaration on the TRIPS Agreement and Public Health" (hereinafter "the Doha Declaration").¹¹⁶ The first three paragraphs of the Doha Declaration specifically cite the gravity of public health problems in the least-developed countries, the importance of TRIPS, and the tension between incentives to develop and corresponding product prices. The fourth paragraph proceeds to affirm that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."¹¹⁷ In the sixth paragraph, the ministers recognized that

¹¹⁴ Tsai, *supra* note 53, at 1067.

¹¹⁵ Weitsman, *supra* note 100, at 103–05; *The Doha Declaration Explained*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm (last visited Apr. 2, 2011); *The Fourth WTO Ministerial Conference*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm (last visited Apr. 2, 2011).

¹¹⁶ World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Pub. Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755, 755 (Nov. 14, 2001), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm#declarations [hereinafter WTO Ministerial Declaration on TRIPS]. The "Declaration on the TRIPS Agreement and Public Health" (referred to as "the Doha Declaration" in this article) should not be confused with the Doha Ministerial Declaration. Both declarations were signed November 14, 2001, as products of the Ministerial Conference. However, the Doha Ministerial Declaration was the overarching declaration summarizing the entire work of the conference, while the Doha Declaration was a more specific declaration targeting the access problem, couched in terms of public health. While the Doha Declaration provides the basis for subsequent enactments, some access-related scholarship does reference the Doha Ministerial Declaration as a source for more detail concerning the objectives and policy surrounding the Doha Declaration. *See, e.g.*, Weitsman, *supra* note 100, at 103–05.

¹¹⁷ WTO Ministerial Declaration on TRIPS, *supra* note 116.

“WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”¹¹⁸ The Doha Declaration called for the Council for TRIPS to find and report to the General Council on a solution no later than the end of 2002.¹¹⁹

On August 30, 2003, the WTO General Council issued a decision adopting the solution that the Council for TRIPS had reported.¹²⁰ Referred to as “the 30 August Decision,”¹²¹ the WTO decision “waived members’ obligations under Article 31(f) of TRIPS and allowed generic versions of patented drugs to be exported, under certain conditions, to developing countries that had insufficient manufacturing capacities.”¹²² This interim waiver is applicable until the TRIPS Agreement is formally amended.¹²³ The accompanying statement by the General Council’s chairperson mandates that such a waiver system should be used “in good faith to protect public health” and not as an “instrument to pursue industrial or commercial policy objectives.”¹²⁴

In a very thorough review of TRIPS and its implementation,¹²⁵ Wesley A. Cann, Jr. describes the formalities required by the waiver:

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr.1 (Aug. 30, 2003), available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

¹²¹ This article uses the terminology of Tsai, *supra* note 53, at 1066. Other scholarship employs other titles.

¹²² Weitsman, *supra* note 100, at 104.

¹²³ Cann, *supra* note 13, at 817–18.

¹²⁴ *Id.*

¹²⁵ For Mr. Cann’s extensive and detailed look at wiggle room, imprecision, vague definitions, particularly pertinent clauses (including an analysis of the language “necessary” in Article 73’s security exception to obligations under the treaty), and specific strategies to use the language of the TRIPS agreement and reliance on health reasons to justify a country’s evasion, breach, or ignoring of common IP protocol, see Cann, *supra* note 13.

The [30 August] Decision requires an eligible importing Member to make a notification to the Council for TRIPS that specifies the names and expected quantities of the products to be imported and confirms (if not a “least-developed” country) that the importing Member “has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector” for those products. The compulsory license issued by the exporting Member must indicate that only the amount necessary to meet the needs of the importing country will be manufactured under the license and that the entirety of this production will be exported to the eligible Member. Additionally, “adequate remuneration” shall be paid in the exporting Member to the patent holder taking into account the “economic value to the importing Member of the use that has been authorized.” All Members are directed to take reasonable measures to prevent the re-exportation of the products produced under these licenses, and to ensure effective legal means for the prevention of diversion.¹²⁶

To determine the royalty to be paid as “adequate remuneration,” the Use of Patented Products for International Humanitarian Purposes Regulations provides a formulation based on the Scheduled Country’s ranking on the United Nations Human Development Index (UNHDI); the lower the scheduled country’s rank, the lower the royalty to be paid.¹²⁷

With this waiver system in place, several countries implemented domestic legislation to allow the export of patented drugs to developing countries. For example, in May 2004, Canada became one of the first WTO member nations to enact legislation reflecting the 30 August Decision by amending its patent laws with the passage of Canada’s Access to Medicines Regime (CAMR).¹²⁸ CAMR provisions are codified as part of the Patent Act in Section 21 of the Consolidated Statutes of Canada and also references Part C of the Canadian Food and Drug Regulations.¹²⁹ A

¹²⁶ *Id.* at 818.

¹²⁷ Penner & Narayanan, *supra* note 27, at 464–65.

¹²⁸ Tsai, *supra* note 53, at 1076.

¹²⁹ *Id.*

manufacturer seeking to apply for an export authorization under CAMR must apply to the therapeutic products directorate of Health Canada, the agency that governs CAMR compliance.¹³⁰

Specifically, such an authorized manufacturer is approved to:

[M]ake, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it or export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.¹³¹

The granted authorization is valid for a period of two years, and is nonexclusive, nontransferable, and renewable for a further two-year period.¹³² In their overview of the CAMR¹³³ legislation, Penner and Narayanan summarize Schedules 2 to 4 as setting out three sets of enumerated countries (“Scheduled Countries”) as follows:

- a. any country recognized by the United Nations as being a “least-developed country,” whether or not it is a WTO Member country (a Schedule 2 Country);
- b. a WTO Member country that has indicated that it intends to import drugs needed only in a national or other extreme emergency (a Schedule 3 Country); and
- c. any WTO Member or non-WTO Member not listed in either Schedule 2 or 3 and which is identified by the Organisation [*sic*] for Economic Co-operation and Development (OECD) as eligible for development assistance, has provided notice of a national emergency and lack of capacity, agrees that the drug will not be used for commercial purposes, and undertakes to adopt the

¹³⁰ *Id.*

¹³¹ Penner & Narayanan, *supra* note 27, at 461–62.

¹³² *Id.*

¹³³ Penner and Narayanan refer to the legislation as “the Pledge to Africa Act,” reflecting the legislation’s working title from when it was still a bill, “An Act to Amend the Patent Act and the Food & Drugs Act” (The Jean Chretien Pledge to Africa). *Id.* at 461.

measures referred to in the General Council Decision (a Schedule 4 Country).¹³⁴

One important distinction not readily discernable from the schedules is that “when an importing country is not a WTO member and is not listed in the Schedules of eligible importing countries,” the country is subject to an additional requirement before being allowed to invoke CAMR: the country must declare “a national emergency or other circumstances of extreme urgency.”¹³⁵

The remuneration formula prescribed by CAMR to compensate patent holders is “related to the UN Human Development Index (UNHDI) and sets the highest rate of remuneration at 4 percent and the lowest at 0.02 percent.”¹³⁶ However, an exception to this scheme is available in Section 21.08 (4)–(7), wherein the patent holder can request a royalty payment increase from a Canadian Federal Court if the royalty “‘is not an adequate remuneration for the use of invention,’ taking into account humanitarian and non-commercial grounds for issuing a license and economic value of the use of invention to the importing country.”¹³⁷ To later terminate a compulsory license granted under CAMR, a patent holder must apply to the Canadian Federal Court on the grounds that the prospective compulsive licensee has failed to provide the necessary information, that the exported product has been used improperly, or that the exported product has become “commercial in nature.”¹³⁸ Authorization may also terminate automatically “when certain conditions have been met” or if “the Commissioner notifies the applicant that the exported products do not meet the requirements of the Food & Drugs Act and its regulations.”¹³⁹

¹³⁴ *Id.* at 462–463.

¹³⁵ Weitsman, *supra* note 100, at 120.

¹³⁶ *Id.* at 130.

¹³⁷ *Id.*

¹³⁸ Penner & Narayanan, *supra* note 27, at 465.

¹³⁹ *Id.*

Near the same time that Canada enacted CAMR, Norway enacted legislation in response to the 30 August Decision and amended its Patent Regulations on May 14, 2004.¹⁴⁰ “Norwegian regulations do not require that an importing non-WTO member country declare a health emergency situation in order to be eligible to import generic drugs under a compulsory license.”¹⁴¹ The Norwegian legislation “does not provide any clear way of assessing the appropriate remuneration[,] . . . [but instead merely] follows the vague language of the WTO General Council’s decision on the matter.”¹⁴²

India also has legislation implementing the 30 August Decision. However, it is vague and “gave only a general permit to export patented pharmaceutical products to countries with inadequate production capacities and in order to cope with public health emergencies.”¹⁴³

The European Union’s response to the 30 August Decision coalesced in July 2005 when the European Union Committee on International Trade published a final report regarding regulations proposed by the European Parliament and Council.¹⁴⁴ The proposal specifically dealt with regulations for “compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.”¹⁴⁵ These draft regulations only apply to WTO member countries.¹⁴⁶ Regarding adequate remuneration, the draft also mirrors the nonspecific language of the 30 August Decision, much like the Norwegian legislation.¹⁴⁷

¹⁴⁰ Weitsman, *supra* note 100, at 133.

¹⁴¹ *Id.*

¹⁴² *Id.* at 133–34.

¹⁴³ *Id.* at 134.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 135.

In December 2004, the Netherlands responded to the 30 August Decision by enacting “[p]olicy rules on issuing compulsory licenses.”¹⁴⁸ “An interesting and distinguishing feature of this legislation is that for the first time, [nongovernmental organizations] are considered potential applicants, if acting for one state or for a group of states.”¹⁴⁹

Even though various countries have implemented legislation to improve access to medication within the framework established by TRIPS and subsequent modifications, the TRIPS framework still suffers from several problems. The framework is plagued by confusion and a lack of clarity: an exporter that tries to provide generics under this framework would likely be unsure of its legal obligations due to the variation from country to country in definitions, royalty rates, and preliminary conditions that must be met before distribution may be made to a given country. Additionally, the framework suffers from a fundamental fairness problem. The compulsory licenses have been introduced long after the patents were issued; this introduction changes the rules and modifies the meaning of patent protection while the patent is still in force, which unfairly changes the legal ramifications of an action already taken.

One way to resolve these issues is to adjust the process for receiving new patents and to root the access improvements in those adjustments instead of in compulsory licenses. This approach would provide one standardized set of procedures in lieu of several international interpretations, thereby resolving clarity issues. It would also provide a clear method of determining rights and obligations *prior* to patent issuance, thereby resolving the fairness issue. The primary potential challenge in capturing these benefits is simply determining how exactly to implement such an approach.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

C. A Call for a New HOPE: Humanitarian-Objective Patent Endorsement Classification

Most of the above-proposed solutions offer ways to address the access problem by adjusting the innovation dichotomy balance with a way around the current patent system (for instance, by limiting otherwise expected rights or imposing requirements after the patent is already issued). Other proposed solutions seek to develop an alternate approach independent of the system. Most are taking an after-the-fact approach, modifying incentives or access by adjusting what patent protection provides for already-granted patents. By taking an opposite, before-the-fact approach and looking at options that could be implemented before a patent is granted, another useful tool to address the access disparity could be developed.

This tool could encourage innovation and improve access by affecting the issuance of the patent in the first place, therefore addressing the pre-issuance prosecution of patents (application process) instead of focusing on post-issuance patent litigation (the enforcement of patent rights in court).¹⁵⁰ A new subset of rules in the patent prosecution process that offers prosecution benefits in exchange for partial restrictions that do not completely destroy an innovator's ability to charge a premium in the primary market could provide a compromise between the socially just desire to make new technology affordable for humanitarian purposes and the economic need to make innovation profitable. Such a tool would simultaneously provide substantial benefits for society and for businesses. Society would receive the benefit of faster and more extensive access to

¹⁵⁰ This prosecution and litigation distinction merits further explanation. Patent prosecution is the process by which a patent is initially issued. It involves correspondence between the representatives of the inventor and the patent office and often lasts between two and five years before a patent is issued or finally denied. GARY MYERS, *PRINCIPLES OF INTELLECTUAL PROPERTY LAW: A CONCISE HORNBOOK* 7 (2008). Litigation generally refers to lawsuits filed after the patent has finally issued in which the patent holder exerts the right given by the patent by filing infringement suits against others that are using the invention.

humanitarian technology for those that most desperately need it, and businesses that are developing the humanitarian technology would receive a means to avoid the primary problems encountered in the patent system.

The primary problems with the patent prosecution process are that it is tedious, slow, and expensive. The process is tedious due to its extensive correspondence between a patent agent and a patent examiner. It begins when, on behalf of an inventor, a patent agent (an individual who has passed a qualifying test administered by the US Patent and Trademark Office (USPTO)) files an application with the USPTO.¹⁵¹ An examiner responds for the USPTO and evaluates whether or not the invention merits a patent.¹⁵² The examiner sends “office actions” detailing problems with the application to the agent.¹⁵³ The agent replies with a “response to office action” detailing answers to the examiner’s objections.¹⁵⁴ This cyclical correspondence between the patent examiner and the patent agent often lasts between two and five years before a patent is issued or finally denied.¹⁵⁵ Additionally, the USPTO also has an extensive list of fees,¹⁵⁶ which quickly add up.¹⁵⁷

A new subset of rules providing prosecution benefits—such as improved speed, cost, and simplicity—in exchange for improved access could easily be accomplished through an already-existing patent law mechanism, the patent classification. A patent classification is a specialized subset of rules within the patent prosecution framework that can be added to the Manual of

¹⁵¹ *Id.* at 256–57.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ See 35 U.S.C. § 41 (2006) amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

¹⁵⁷ See, e.g., World Intellectual Prop. Org. [WIPO], *World Patent Report: A Statistical Review*, 51 (2008), available at http://www.wipo.int/freepublications/en/patents/931/wipo_pub_931_2008.pdf.

Patent Examination and Procedure (MPEP)¹⁵⁸ when the nature of a particular subject matter necessitates an individualized set of procedures or treatment of the subject matter. For example, in response to the special nature of plant patents and design patents, the USPTO included a distinct chapter of requirements for each of the two subjects in the MPEP.¹⁵⁹ Each classification must specify the subject matter involved and the rules governing that area. For example, MPEP 1502 conveys the “Definition of Design”¹⁶⁰ while other sections specify rules regarding required application elements,¹⁶¹ examination protocol,¹⁶² term length,¹⁶³ review,¹⁶⁴ etc. Similarly, MPEP 1601 specifies “Type of Plants Covered,”¹⁶⁵ while subsequent sections specify rules regarding application elements,¹⁶⁶ examination protocol,¹⁶⁷ special reports guidelines,¹⁶⁸ etc.

Given the otherwise poor access to lifesaving technology in poverty and disaster situations, a new classification is warranted. The classification would be aimed at humanitarian contexts, and as such would be called the Humanitarian-Objective Patent Endorsement, or HOPE Certification.

¹⁵⁸ MPEP, *supra* note 42, at Foreword (“This Manual is published to provide US Patent and Trademark Office (USPTO) patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the USPTO. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application. The Manual does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.”).

¹⁵⁹ *Id.* §§ 1500, 1600 (Design Patents and Plant Patents, respectively).

¹⁶⁰ *Id.* § 1502.

¹⁶¹ *Id.* § 1503.

¹⁶² *Id.* § 1504.

¹⁶³ *Id.* § 1505.

¹⁶⁴ *Id.* §§ 1510, 1511.

¹⁶⁵ *Id.* § 1601.

¹⁶⁶ *Id.* § 1603.

¹⁶⁷ *Id.* § 1608.

¹⁶⁸ *Id.* § 1609.

Reflecting the patterns and requirements of plant and design patents, Part III of this article explores the task of determining an adequate definition for Humanitarian Objective in HOPE applications, while Part IV explores the guarantees to access (subsection A) and incentives (subsection B) that would be implemented by rules for a HOPE Certification.

III. DEFINING HUMANITARIAN SUBJECT MATTER

The nature of the access disparity necessitates a new classification. People die without lifesaving technology, especially in disaster- and poverty-stricken areas. However, the subject matter of a new classification should be narrowly tailored to meet only the greatest and most extreme of disparities; otherwise, more technologies might be included for special treatment that do not carry the heavy weight of the highest need for access, and the classification could be abused. Humanitarian organizations have traditionally filled the role of identifying and remedying the life-threatening situations from which affected individuals have the least opportunity to escape. Accordingly, defining such a classification as having a humanitarian objective is a good starting point. However, many definitions exist regarding the extent of humanitarian work. This section briefly discusses two definitions (from among many available): one from the United States Code and one from humanitarian relief organizations.¹⁶⁹ This section then

¹⁶⁹ Definitions from other potential sources (such as dictionaries, case law, patent law manuals, and law review articles) are not discussed at length in this article because they are not particularly helpful.

For example, the dictionary definition of “humanitarian” as “having concern for or helping to improve the welfare and happiness of people” is not helpful because it is far too broad; all patents could arguably be included within it, considering the close parallel to the fundamental statement of purpose of intellectual property rights set forth in the Intellectual Property Clause of the United States Constitution: “to Promote the Progress of Science and the Useful Arts.” THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE, 931 (Stuart Berg Flexner ed., 2d ed. 1987); Myers, *supra* note 150, at 7; US CONST. art. I, § 8, cl. 8.

At least two cases make tangential references to the definition of “humanitarian” in the immigration context. *Mounkam v. Way*, 2007 WL 974102, at *10 (D.Ariz., Mar. 30, 2007) (stating that humanitarian reasons to allow an exception to deportation include

suggests a definition for the subject matter of a new patent classification that is broad enough to accomplish the goal of improving access to lifesaving technology while being sufficiently narrow to guard against abuse.

Several portions of the United States Code refer to humanitarian aid and give examples in an attempt to define it.¹⁷⁰ In the context of US assistance to promote reconciliation and recovery from regional conflicts, humanitarian assistance “means assistance to meet humanitarian needs, including needs for food, medicine, medical supplies and equipment, education, and clothing.”¹⁷¹ Similarly, in a foreign relations statute, humanitarian assistance “means assistance to meet humanitarian needs, including needs for food, medicine, medical supplies, clothing, and

“past persecution, suffering, or other inhumane treatment,” yet ultimately leaving to a jury as a question of fact the decision of whether something was humanitarian or not); *Humanitarian Law Project v. U.S. Dep’t of Justice*, 352 F.3d 382, 385 (9th Cir. 2003) (implying that “humanitarian” means “securing the basic necessities for human life”).

Patent law prosecution guidelines include an international classification system to catalog the subject matter of inventions. MPEP, *supra* note 42, § 903.09. The International Classification of Patents for Inventions has eight principle sections, one of which is “Human Necessities.” *Id.* This definition was deemed unhelpful because it might overly constrict the reach of a new classification to the traditional “human necessities” of agriculture or pharmaceutical innovations instead of extending benefits to any technology with lifesaving implications in extreme lack-of-access situations.

One law review article surveyed licensing agreements employed by universities trying to ensure access for their technologies, and clauses in some of these agreements either defined “humanitarian” or otherwise attempted to delineate what organizations would be trusted as access providers. *Roose-Snyder & Doyle*, *supra* note 29, at 287, 290 (quoting a University of California at Davis license agreement that defines “Humanitarian Purposes” as developing or using a technology for the benefit of an “Economically Disadvantaged Country,” and quoting a Boston University agreement that defined Public Sector as the sovereign government of a country and other specific organizations). While this article was useful in modeling the inclusion of specific examples of organizations that would qualify as “humanitarian,” the definition was not discussed at length because it is overbroad; it does not include the specific purpose served by the technology.

¹⁷⁰ *See, e.g.*, 10 U.S.C. § 401 (2006); 22 U.S.C. § 2296 (2006); 22 U.S.C. § 7803 (2006).

¹⁷¹ 22 U.S.C. § 2296 (2006).

shelter.”¹⁷² There are more specific definitions provided in the context of humanitarian and civic assistance in conjunction with military operations, where the term “humanitarian and civic assistance” means any of the following:

- 1) Medical, surgical, dental, and veterinary care provided in areas of a country that are rural or are underserved by medical, surgical, dental, and veterinary professionals, respectively, including education, training, and technical assistance related to the care provided;
- 2) Construction of rudimentary surface transportation systems;
- 3) Well drilling and construction of basic sanitation facilities;
- 4) Rudimentary construction and repair of public facilities.¹⁷³

While several good examples of lifesaving technology are included in this definition, it does not include any sort of temporal aspect. If this definition were implemented in a patent classification, many technologies could arguably be lifesaving by extension, and—contrary to its intended purpose—the classification would no longer reach only technologies that are likely to have an immediate lifesaving effect for those that would otherwise be deprived access to the technology. The relationship between a particular technology and the preservation of a life might be too tenuous under this definition to justify its verbatim adoption for the HOPE classification.

The United States Code also articulates how the Internal Revenue Service defines humanitarian donations that result in tax deductibility.¹⁷⁴ However, the tax law focuses on the nonprofit nature of the organizations receiving such donations, not on the lifesaving effect of what the organization does.¹⁷⁵

¹⁷² 22 U.S.C. § 7803 (2006).

¹⁷³ 10 U.S.C. § 401 (2006).

¹⁷⁴ See 26 U.S.C. § 501(c)(3) (2006).

¹⁷⁵ 26 U.S.C. § 501(e) (2006).

As such, under section 501(c)(3) of the US Internal Revenue Code, “humanitarian” is defined too broadly within the context of nonprofit organizations. Thus, while the United States Code may be helpful for providing examples of humanitarian efforts, a particular definition should not be drawn straight from these statutes.¹⁷⁶

The other particularly helpful sources for an adequate humanitarian definition are humanitarian relief organizations themselves. The United Nations organizes its humanitarian efforts through the Office for Coordinated Humanitarian Affairs (OCHA).¹⁷⁷ Several definitions and purpose statements appear throughout OCHA materials, touching on the fundamental principles of humanitarian organizations. For example, “[t]he purpose of humanitarian action is to *protect life and health* and ensure

List of [tax-]exempt corporations . . . (3): Corporations, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation (except as otherwise provided in subsection (h)), and which does not participate in, or intervene in (including the publishing or distributing of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.

¹⁷⁶ In the Food and Drug Administration context, the Code also provides an unconventional definition—humanitarian means treating less than 4,000 individuals. “Devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States,” qualifying under this definition means getting certain exemptions from the stricture of the performance requirements (360d) & premarket approval (360e). 21 U.S.C. § 360j(m) (2006).

¹⁷⁷ UNITED NATIONS OFF. FOR COORDINATED HUMANITARIAN AFF., <http://www.unocha.org> (last visited Dec. 13, 2011).

respect for human beings,”¹⁷⁸ and “[h]umanitarian aid workers strive to *provide life-saving assistance* to the increasing number of people affected by man-made and *natural disasters* every year,”¹⁷⁹ These statements help ground the word “humanitarian” in addressing the most disparate access gap contexts. OCHA establishes that humanitarian aid is based on a “respect for human beings” that should focus on “protect[ing] life and health” by “provid[ing] life-saving assistance” in the context of poverty and “natural disasters.”

Combining principles from these various definitions, the definition for a new patent classification should be:

Humanitarian technology means technology likely to preserve human life by meeting basic needs that if unmet due to poverty or disaster would likely ultimately result in death within six months or be the direct cause of death. Such needs include food, medicine, medical supplies, sanitation, healthcare, and the like.

Humanitarian agencies are entities situated to best identify the poverty- or disaster-based need and disseminate corresponding humanitarian technology accordingly.

Such agencies shall include:

- a. The sovereign government of a country;
- b. Agencies of the United Nations, the World Health Organization, and the World Bank;
- c. Organizations which are members of the International Committee of the Red Cross and Red Crescent;
- d. International charitable agencies (also known as nongovernmental organizations or NGOs), including but

¹⁷⁸ *World Humanitarian Day*, UNITED NATIONS OFF. FOR THE COORDINATION OF HUMANITARIAN AFF., <http://ochaonline.un.org/whd/> (last visited Dec. 13, 2011) (emphasis added).

¹⁷⁹ *World Humanitarian Day Background*, UNITED NATIONS, <http://www.un.org/en/events/humanitarianday/background.shtml> (last visited Dec. 13, 2011) (emphasis added).

not limited to Oxfam, Médecins sans Frontières (Doctors Without Borders), and so forth.

The above definition addresses the concern that the targeted access gap is generally due to poverty or disaster. Additionally, it sets a timeline to ensure that technology too distantly related to saving lives is excluded, while allowing an exception for technology that combats direct but slower killers, such as HIV/AIDS and deadly illnesses specifically related to immune systems weakened by HIV/AIDS. It gives examples of what technology might specifically provide and details organizations that would be potential consumers and partners in the technology.

IV. RULES FOR A NEW CLASSIFICATION

The rules for the new classification should improve access to the group of individuals most affected by the access gap: those who have the least ability to obtain access to the technology and who also are most likely to die without it. To accomplish this increase in access, the rules governing the certification should make certain impositions. However, imposing access improvements without also offering incentive modifications may chill innovation. As such, incentives must also be granted through the operation of the rules. Part A below discusses proposed improvements to access while Part B discusses possible additional incentives that could reestablish the balance needed in the innovation dichotomy.

A. Guarantees to Access

1. Require Collaboration with Humanitarian Organizations

If the goal of a new certification is to improve access for those experiencing the greatest access disparity, a mechanism is necessary to identify those that are in the greatest need with the least access. Humanitarian organizations have well-established methods of not only recognizing needs, but also of addressing them with appropriate resources.

Since humanitarian organizations already have the infrastructure in place to both identify needs and disseminate responsive resources, requiring partnership between them and potential patent holders of humanitarian technology is an efficient mechanism to distribute the technology.

a) *Evidence of Agreement*

The most appropriate way to ensure such a partnership would be by contract. The HOPE application rules could require a copy of a contract showing the applicant's partnership with a humanitarian organization. Such a contract would require the patent holder to provide the humanitarian organization with the technology at cost or at a minimal profit.¹⁸⁰ The contract could also be of an output or requirement variety, obligating the patent holder to provide the humanitarian organization with a certain percentage of the patent holder's production or certain amounts reflecting the quantity that the humanitarian organization expects to be able to distribute or utilize. Of course, this contractual obligation would be contingent upon actual issuance of the patent to protect the inventor from an unfair obligation should the patent not be issued. However, it could provide valuable assurance that access to the new technology will be made available through humanitarian agencies to those who most desperately need it.

b) *Affidavit Certifying Humanitarian Use*

An additional partnership dynamic would be to require the humanitarian organization to submit an affidavit explaining the expected humanitarian use of the technology. This would assist the examiner in verifying that the technology meets the subject matter definition and would provide a safeguard against potential distribution abuse by humanitarian organizations.

¹⁸⁰ Examples of anywhere from 0.5 to 4 percent profit exist from compulsory licensing under TRIPS. Peter Maybardule & Sarah Rimmingto, *Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine?*, 35 AM. J. L. & MED. 323, 347 (2009).

2. Accountability

To ensure that humanitarian organizations can continue to receive the benefit of such an agreement, sufficient measures for accountability would need to be included to guard against potential breach of the agreement by the inventor before the access improvements could be realized.

a) *Adjustment of Fee Schedule*

One such accountability measure would be to adjust the fee schedule required to maintain a patent. A patent holder must pay a fee at 3.5 years, 7.5 years, and 11.5 years after the issuance of a patent or lose his or her patent monopoly and exclusionary rights.¹⁸¹ If a HOPE patent holder showed evidence of honoring the agreement, the fee could be reduced or waived. On the other hand, if a HOPE patent holder willfully breached the patent, the fee schedule could impose a penalty increase.

b) *Modify Patent Rights*

Another potential accountability measure would be to make patent exclusivity contingent on good faith performance of the agreement. For example, if a humanitarian organization can show that the patent holder has neglected the agreement, the resulting punishment can be to allow the organization to engage in compulsory licensing against the patent holder or to revoke the patent all together.

B. Incentives

To balance the access provisions, incentives are necessary for the inventor to agree¹⁸² to restrict what would otherwise be a complete

¹⁸¹ 37 C.F.R. § 1.20(e)–(g) (2011).

¹⁸² The choice to engage in this exchange is important. While a new classification could be imposed in such a manner that any humanitarian technology must comport with HOPE requirements to receive a patent (akin to any plant matter being subject to the specific plant patent rules), the better option is to allow patent applicants to opt in to the certification (akin to making a patent “special,” which only occurs when a patent

monopoly over the technology. While most of the proposed incentives provide advantages in the patent prosecution process, other incentives include tax write-offs, continued market monopoly, and public relations.

1. Benefits Within the Patent Prosecution Process

As is the case with many administrative processes, the principal complaints of patent prosecution are that the process is too slow, difficult, and/or expensive. As such, the primary advantages that would appeal to an applicant engaging in the patent prosecution process would be to make the process faster, easier, and less expensive. These three advantages are easily and justifiably includable in the current patent prosecution process for the HOPE Certification.

a) Expediting the Process (Making it Faster)

“New patent applications are normally taken up for examination in the order of their United States filing date.”¹⁸³ However, the USPTO has a procedure for requesting accelerated examination called a “petition to make special.”¹⁸⁴ If the USPTO grants a request to make an application “special,” that application will be processed out of turn and examined in advance of other applications.¹⁸⁵ The “appropriate showing” necessary for the USPTO to grant a request to make an application “special” requires an applicant to establish that the application fits within a select number of exception categories.¹⁸⁶ “The exceptions are created to expedite business or to serve

applicant elects to pursue that course). The extra level of choice is likely to increase the likelihood that the HOPE patent recipients would actually honor the agreement, generating an effect much like the pre-negotiated terms discussed in the context of leveraging public scientific capital.

¹⁸³ Changes to Practice for Petitions in Patent Applications to Make Special and for Accelerated Examination, 71 Fed. Reg 36323-01 (June 26, 2006).

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

an important purpose for public service.”¹⁸⁷ The decision to include a new exception rests with the director of the USPTO, although the president or other department heads can also request a new exception.¹⁸⁸

The existing exception categories found in the MPEP are:

- 1) Manufacture (invention is ready for manufacture);
- 2) Infringement (invention is being infringed);
- 3) Applicant’s Health (is poor and in danger of death before finishing application);
- 4) Applicant’s Age (is 65 or over, similar reasoning to 3);
- 5) Environmental Quality (significantly contributes to restoration or maintenance of the basic life-sustaining natural elements, e.g., air, water, and soil);
- 6) Energy (contributes to the discovery or development of energy resources or more efficient utilization of energy);
- 7) Recombinant DNA (developments in the area of recombinant deoxyribonucleic acid, which “[appear] to have extraordinary potential benefit for mankind”);¹⁸⁹

¹⁸⁷

(a) Applications will not be advanced out of turn for examination or for further action except as provided by this part, or upon order of the Director to expedite the business of the Office, or upon filing of a request under paragraph (b) of this section or upon filing a petition under paragraphs (c) or (d) of this section with a showing which, in the opinion of the Director, will justify so advancing it.

(b) Applications wherein the inventions are deemed of peculiar importance to some branch of the public service and the head of some department of the Government requests immediate action for that reason, may be advanced for examination.

37 C.F.R. § 1.102(a)–(b) (2011).

¹⁸⁸ For example, President Ronald Reagan directed the USPTO to permit accelerated examination of applications relating to superconductivity. Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(E) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q.J. 457, 478 n.70 (1989) (citing MPEP § 708.02(VII) (5th ed., Rev. 6, Oct. 1987)).

- 8) New Applications—Accelerated Examination (requiring a more onerous application process, discussed *infra* p. 455;
- 9) Superconductivity;
- 10) Inventions relating to HIV/AIDS and Cancer;
- 11) Countering Terrorism;¹⁹⁰ and
- 12) Applications Relating to Biotechnology Filed by Applicants who are Small Entities.¹⁹¹

Humanitarian technology would fit reasonably within this list. It fits squarely within the mandate that exceptions must “expedite business or . . . serve an important purpose for public service”¹⁹² because it would expedite the business interactions between inventors and humanitarian organizations and serve an important purpose for public service by saving lives through improved access. Furthermore, just as countering terrorism would seem to have as its primary goal preserving human life, so too would a humanitarian technology exception. While it could be argued that the exception for “[i]nventions relating to HIV/AIDS and cancer”¹⁹³ makes the proposed

¹⁸⁹ MPEP, *supra* note 42, at § 708.02(VII) (“This field might lead to ways of controlling or treating cancer and hereditary defects . . . [and] has possible applications in agriculture and industry.”).

¹⁹⁰ MPEP, *supra* note 42, at § 708.02. International terrorism is defined as including

activities that[:] (A) involve violent acts or acts dangerous to human life that are a violation of the criminal laws of the United States or of any State, or that would be a criminal violation if committed within the jurisdiction of the United States or of any State; [and] (B) appear to be intended[:] (i) to intimidate or coerce a civilian population; (ii) to influence the policy of a government by intimidation or coercion; or (iii) to affect the conduct of a government by assassination or kidnapping.

18 U.S.C. § 2331 (2006).

¹⁹¹ All of the exceptions listed in this paragraph are found in MPEP, *supra* note 42, § 708.02.

¹⁹² 37 C.F.R. § 1.102(a)–(b) (2011) (“(b) Applications wherein the inventions are deemed of peculiar importance to some branch of the public service and the head of some department of the Government requests immediate action for that reason, may be advanced for examination.”).

¹⁹³ MPEP, *supra* note 42, § 708.02.

humanitarian technology exception moot, the humanitarian technology exception would capture a substantially larger field. The humanitarian technology exception could either subsume the HIV/AIDS and cancer exception, or it could stand alongside it, thereby giving an applicant the option to pursue only an expedited application or an expedited application with the other attendant advantages of a HOPE Certification.

b) Simplifying the Process (Making it Easier)

At first, the accelerated examination exception for new applications looks like it may obviate the use for a HOPE acceleration exception. However, a closer inspection shows that a HOPE application would provide a simpler expediting process than the exception for new applications.

The exception for new applications requires a more onerous application process than a standard application.¹⁹⁴ Dirk Thomas, Chandran Iyer, and Aziz Burgy explain the requirements and process for applying for accelerated examination under the new application exception:

- 1) File the application, petition, and required fees electronically using the USPTO's electronic filing system (EFS);
- 2) File a complete, nonreissue utility or design application with three or fewer independent claims and twenty or fewer total claims directed to a single invention;
- 3) Agree to an interview (including an interview before a first Office action) whenever requested by the Examiner to discuss the prior art and rejections or objections;

¹⁹⁴ See Elizabeth Peters, *Are We Living in a Material World?: An Analysis of the Federal Circuit's Materiality Standard Under the Patent Doctrine of Inequitable Conduct*, 93 IOWA L. REV. 1519, 1550 (2008) ("Unlike the normal PTO application procedure, where applicants must disclose only information they knew about at the time of application, an applicant under the new procedure must conduct a thorough prior-art search and affirmatively state a good-faith belief that the prior-art search was completed properly.").

- 4) Provide a statement that a pre-examination search¹⁹⁵ was conducted of US patents and patent application publications, foreign patent documents, and nonpatent literature;
- 5) Agree not to separately argue the patentability of any dependent claim during any appeal of the application; and
- 6) Provide, at the time of filing, an accelerated examination support document with
 - a. an information disclosure statement (IDS) in compliance with 37 C.F.R. § 1.98 citing each reference deemed most closely related to the subject matter of each of the claims;
 - b. an identification of all the limitations in the claims that are disclosed by the reference, specifying where the limitation is disclosed in the cited reference;
 - c. a detailed explanation of how each of the claims is patentable over the references cited with the particularity required by 37 C.F.R. § 1.111(b) and (c);
 - d. a concise statement of the utility of the invention as defined in each of the independent claims (unless the application is a design application);

¹⁹⁵ See Shashank Upadhye, *Liar Liar Pants On Fire: Towards A Narrow Construction For Inequitable Conduct As Applied to the Prosecution of Medical Device and Drug Patent Applications*, 72 UMKC L. REV. 669, 713–714 (2004)

In effect, by so certifying, the applicant is ‘helping’ the Examiner find the prior art. The Federal Circuit in [*General Electric Music Corp. v. Samick Music Corp.*], stated that the required search must be more than just a casual search, more than just looking in one’s files, more than just talking to one’s colleagues, and more than just staying within one’s internal sources.

Id. (referencing *Gen. Electric Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1409–1410 (1994)).

- e. a showing of where each limitation of the claims finds support under the first paragraph of 35 U.S.C. § 112 in the written description of the specification; and
- f. identification of any cited references that may be disqualified as prior art under 35 U.S.C. § 103(c).¹⁹⁶

In contrast, under a HOPE application, the applicant would need only to provide a copy of the contract negotiated with the humanitarian organization and an affidavit from the humanitarian organization detailing the expected use. Creating the HOPE acceleration option would allow for expediting the process without the extra burdens of developing a more complete record and additional restrictions on prosecution.

c) Fee Adjustment (Making it Less Expensive)

To make the application cheaper, the fees could be adjusted or waived for a HOPE application. Fees are routinely waived for petitions for expedited patent prosecution when certain specific conditions are met.¹⁹⁷ Fees are also routinely adjusted for small entity status.¹⁹⁸ Considering that the five

¹⁹⁶ Dirk Thomas, Chandran Iyer & Aziz Burgy, *Slow Down Before Accelerating: Litigation Ramifications of Accelerated Examination Procedure on Nanotechnology*, 4 No. 1 A.B.A. SCITECH LAW. 4, 5 (2007).

¹⁹⁷ 37 C.F.R. § 1.102(e) (2011):

A [request to expedite an application] may be filed without a fee if the basis for the petition is:

- (1) The applicant’s age or health; or
- (2) That the invention will materially:
 - (i) Enhance the quality of the environment;
 - (ii) Contribute to the development or conservation of energy resources; or
 - (iii) Contribute to countering terrorism.

¹⁹⁸ 37 C.F.R. § 1.27(b)

bases¹⁹⁹ for waiving fees of petitions to make applications “special” are circumstances that are particularly in the public interest, the fee associated with requesting an application be made “special” on a HOPE basis should also be waived.²⁰⁰ By a similar rationale, subsequent filing and maintenance fees could also be reduced in a manner similar to the small entity status. However, since the HOPE certification would not be granted until the patent is granted, these fee reductions should be accomplished on a retroactive basis, refunding the applicant the overpayment only once the certification is granted.

2. Other Incentives

Various other incentives besides prosecution benefits could also be included in the adjusted exchange of a new classification. For example, tax write-offs could provide another incentive for an inventor or company to pursue a HOPE certification. Most humanitarian organizations are tax-exempt entities under 26 U.S.C. § 501(c), and therefore any charitable contributions made to them could count as tax deductible under 26 U.S.C § 170.²⁰¹ The precise amount that would be considered a charitable

Establishment of small entity status permits payment of reduced fees. (1) A small entity, as defined in paragraph (a) of this section, who has properly asserted entitlement to small entity status pursuant to paragraph (c) of this section will be accorded small entity status by the Office in the particular application or patent in which entitlement to small entity status was asserted. Establishment of small entity status allows the payment of certain reduced patent fees pursuant to 35 U.S.C. § 41(h)(1) [50 percent reduction of most fees].

Id.

¹⁹⁹ The five feeless bases are (1) the applicant’s age, (2) the applicant’s health, (3) that the invention will materially enhance the quality of the environment, (4) that the invention will materially contribute to the development or conservation of energy resources, or (5) that the invention will materially contribute to countering terrorism. 37 C.F.R. § 1.102(c).

²⁰⁰ Marc Verzani, *The Orphan Patent Act*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 5, 11 (1995).

²⁰¹ 26 U.S.C. §§ 501(c), 170 (2006).

contribution would need to be determined between the patent holder and the humanitarian organizations. Potential regimes range from the outright donation of technology (with a claim for a deduction or credit corresponding to the cost of the production) to the claim of a portion of the difference between the market price and the price charged to humanitarian organizations. If people fear abuse in tax deductions, Congress could enact new legislation regulating exactly what could be claimed.

Another incentive is the opportunity to develop new revenue streams. With the HOPE classification aimed at only the greatest access disparity, the innovator can still charge a premium in the market as usual. Those unaffected by poverty or disaster that are still able to afford the premium on intellectual property will continue to do so; the innovator can continue to count on that profit as an incentive for registering his/her intellectual property. In addition, the HOPE classification effectively develops a revenue stream that did not exist before. In the standard market, all consumers are in the same sphere of supply and demand. Of those who cannot afford a particular technology, the lack of access to the technology is only life-threatening to the specific subset of those people that do not have the means to even afford alternative remedies (i.e., those particularly affected by disaster or poverty). The HOPE classification would thus not rob the original market of any customers or profit because those reached through HOPE processes would never have been able to afford access to that market. With the introduction of a third-party humanitarian organization that would not usually be a customer at the market price—but that is willing to pay a reduced price to subsidize the cost for the small subset of the unreached market consisting of disaster- and poverty-stricken people—the company can actually capture an untapped source of revenue. In this way, the company could still exploit the very profitable private market, but add the small profit of the new humanitarian market to it as well.

An additional possibility would be to allow or provide term extensions exclusively for HOPE patents. At a conceptual level, this would give the patent holder more time to exploit the private market in exchange for the generation of a humanitarian market. A specific term extension granted exclusively to HOPE patents would implement the incentives suggested by wildcard patent terms (as discussed *supra* p. 417), but solve the predictability problem for generics. Additionally, by limiting the extension to a specific type of subject matter and restricting the incentive to the same technology that receives the improved access, the balance of the innovation dichotomy is narrowly tailored to a specific innovation instead of applying a rigid general rule to a specific situation.

Finally, the new classification could also provide a public relations incentive. An applicant will have a public relations incentive to get a HOPE patent because it is a certification of contribution to the public good, and it serves the underprivileged. The opportunity to publicize a company's acquisition of a new HOPE patent for a particular technology could allow a company to improve its public image due to the favorable contribution to the public good reflected in the certification's requirements. Going beyond a mere announcement of its acquisition of a HOPE patent, a company could further utilize the certification for public relations by boasting about the number of HOPE patents it holds in its portfolio.

V. CONCLUSION

Implementing the HOPE classification could provide another tool to address the greater issue of closing the gap of the access disparity that results from the innovation dichotomy and the current intellectual property regime. In light of the devastating tsunami in Japan in the spring of 2011, the continuing aftermath of the catastrophic 2010 earthquake in Haiti, and the lingering effects of Hurricane Katrina in the United States, incentives to improve the cost-efficiency of humanitarian aid in disaster situations are more needed than ever. With the ongoing massive death counts from health

epidemics such as AIDS or starvation, access to lifesaving technology is hugely needed in poverty-stricken regions. Even the USPTO has recognized the pressing current need to provide incentives to pursue humanitarian activity.²⁰² By implementing a new patent classification that offers new incentives—such as expediting applications, providing fee adjustments, employing tax deductions or credits, capturing additional profits, and establishing goodwill in public relations—the USPTO could inspire a whole host of businesses to commit to working with humanitarian organizations to reach poverty- and disaster-stricken people with lifesaving technology. The result would be something long missing from the patent system: HOPE.

²⁰² Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57261 (Sept. 20, 2010), *available at* <http://edocket.access.gpo.gov/2010/pdf/2010-23395.pdf> (“The USPTO is also exploring ideas for other strategies that would use the patent system to incentivize activity addressing humanitarian needs.”).