

U.S. PATENT REFORM AND INTERNATIONAL PUBLIC HEALTH: ISSUES OF LAW AND POLICY

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Abstract

While technology continues to advance in many countries, the developing countries of the world are still playing catch-up. Technological progress is a key element of economic development, but only when adapted properly and affordably to meet the needs of the recipient country and population. However, development plans involving technology transfers to developing countries often encounter difficulties in the form of conflicting private sector patent¹ interests, inter-governmental bureaucratic inertia and misplaced or minimal technological investment.² Of primary concern is the lack of access to affordable pharmaceuticals and medical treatments created by a mixture of expensive medical/pharmaceutical research, overreaching profit-seeking, and diminishing global property rights. Unfortunately for the well-meaning development professionals already struggling with the tensions between the need for both medicinal technology transfers and intellectual property protection, greater barricades to disease treatment and access to medicine loom on the horizon. A way out of this dilemma is presented.

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¹ See *infra* note 3.

² Rodrigo Santos, *IPRs and the Transfer of Technology: Brazilian Case Study*, in WIPO-WTO Joint Workshop on Intellectual Property Rights and Transfer of Technology, November 17, 2003, http://www.wipo.int/documents/en/meetings/2003/wipo_wto/presentations/doc/santos.doc (last accessed on Mar. 10, 2008). In his case study, Santos assessed patent reform in Brazil and its relationship to the international patent regime under the World Trade Organization.

*Delimitation of the Problem**A. Patents in General*

Patent law is a highly complicated area of the law due to the intricacies of most of the scientific and engineering achievements it protects. There are many different types of patents to cover the multitude of natures of the discoveries sought to be protected. Medicinal/pharmaceutical patents, the subjects of our discussion, generally fall under the category of a “process patent,” particularly under the American patent system. Black’s Law Dictionary defines a “process patent” as:

A patent for a method of treating specified materials to produce a certain result; a patent outlining a means of producing a physical result independently of the producing mechanism. The result might be brought about by chemical action, by applying some element or power of nature, by mixing certain substances together, or by heating a substance to a certain temperature.³

The most common type of patent is the “utility patent,” which generally covers new machines, chemicals or manufactures.⁴ A “cyber,” or “Internet,” patent is a utility patent specifically issued for “an invention that combines business methods and software programs for Internet applications.”⁵ Most patents follow these forms with some minor variations in the European and international patent system under WIPO. For international patent law harmonization and efficiency reasons, patents under the U.S., European, WIPO and WTO/TRIPS systems have a life span of twenty years.⁶

³ Black’s Law Dictionary, Patent (8th ed. 2004) (Westlaw).

⁴ *Id.*

⁵ *Id.*

⁶ In order to be a member of the WTO, members must accept the TRIPS Agreement which adopted portions of the WIPO administered Paris Convention, both of which recognize a 20 year patent protection term. *See infra* note 69.

B. Patent Reform

Following several unsuccessful attempts at revising the American patent system,⁷ the Patent Reform Act of 2007 has fared better than its predecessor, but at what cost? On September 7th, 2007, the United States House of Representatives passed the Patent Reform Act of 2007 (the “PRA07”) by a vote of 220 to 175.⁸ Now, all that remains is for the United States Senate to pass the PRA07 in the same form in order for the proposal to be presented to the President to be signed into law.⁹ Although American patent reform is a commendable goal, several of the broad, sweeping proposals on infringement damage award limitations and patent administration could have severe indirect, but substantial, international consequences. In this paper, I intend to show how adoption of the PRA07 in its current form will stifle high-capital vested research-intensive innovation (*e.g.*, pharmaceutical/medical development) and force firms that engage in such research to practice loss-shifting behavior from the market disincentives that will result from the passage of the PRA07.

Under the PRA07, global patent property rights could be weakened domestically (and, consequently, internationally) to allegedly encourage innovation. This has created a great division domestically between the biomedical/pharmaceutical/life sciences and the information technology sectors in the U.S. economy. This paper focuses on two primary areas of concern regarding the PRA07: the modification of patent damage awards to effectively decrease the amount an infringer of a patent would have to pay and the switch

⁷ Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005), *Summary*, in THOMAS (Library of Congress), <http://thomas.loc.gov/cgi-bin/bdquery/z?d109:HR02795:@@L&summ2=m&> (last accessed on Mar. 10, 2008). The Patent Reform Act of 2005’s inquiry subcommittee requested a substitute proposal after holding hearings on the issue and dismissing the PRA2005.

⁸ Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007), *Major Actions*, in THOMAS (Library of Congress), <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR01908:@@R> (last accessed on Mar. 10, 2008).

⁹ U.S. House of Representatives, *Tying it All Together: Learn about the Legislative Process*, http://www.house.gov/house/Tying_it_all.shtml (last accessed Mar. 10, 2008).

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from the first-to-invent system to first-to-file to promote international patent harmonization. Generally, the proposed damage reforms would lower the amount that could be recovered when a person infringes on a patent. For example, reasonable royalties for infringement would be determined based only on the value of what is added to the infringed device and not the economic value of the entire device.¹⁰ Put more specifically, owners of infringed products/processes would have their reasonable royalty damages based on the “economic value of the infringer’s use of the features of the product or process that were novel and non-obvious at the time of infringement.”¹¹ This will have the effect of decreasing liability for patent infringement because it will result in little to no damage awards unless the new product is astoundingly innovative (since damages will be based on new features added). Less substantial of an issue than damages, but still a concern (for small inventors) is the switch from first-to-invent to first-to-file.¹²

As a consequence of the proposed reforms, passage of the PRA07 could result in negative externalities¹³ that will impact developing countries in relation to international intellectual property patent agreements and medicinal technology transfers. Also, the benefits of the positive externality generation of patent property protection for medical/pharmaceutical inventions will be considered in light of international public health. Specifically, I will compare

¹⁰ See H.R. 1908, 110th Cong. Sec. 5(a)(1)(b)(2) (2007).

¹¹ Coalition for 21st Century Patent Reform, Patent Damages: A Proposed Compromise (2008), http://www.patentsmatter.com/issue/leg_proposals/Coalition%20Damages%20Proposal.pdf (last accessed Apr. 16, 2008) [hereinafter *Patent Damages*].

¹² Patent rights would go to the “first inventor to file”, which could really harm small inventors who are competing against research firms with large wallets. H.R. 1908, 110th Cong. Sec. 3 (2007).

¹³ An externality arises from behavior in the market and can be either positive (conferring a benefit) or negative (conferring a detriment). A good example of a negative externality would be pollution generated from the production of industrial goods. An example of a positive externality could be an invention, such as the transistor, which advanced productivity levels worldwide through increasing communicative and output efficiency. Organization for Economic Cooperation and Development, *Externalities*, in GLOSSARY OF STATISTICAL TERMS <http://stats.oecd.org/glossary/detail.asp?ID=3215> (last accessed Mar. 18, 2008).

economic utilitarian arguments with human rights deontological concerns posed both in support of and against the passage of the PRA07 and how these relate to and impact international access to medicines.

Part I briefly addresses the parties involved in the conflict over the PRA07, the international patent rights affected and the current state of the global pharmaceutical industry. Part II summarizes a brief history of intellectual property law and patent law in the United States and the most recent attempts at patent law revision. Part III addresses the key components of international patent systems, including the European Patent System, the General Agreement on Tariffs and Trade (the “GATT”), the World Trade Organization (the “WTO”), and World Intellectual Property Organization (the “WIPO”) patent agreements to better understand the how domestic legislation has international impact. Part IV analyzes and assesses some of the problems with the PRA07 domestically and internationally in light of developing country access to medicines using basic economic concepts applied to utilitarian and human rights models. Part V concludes by proposing the adoption of a two-tiered American patent system, potential changes to patent life spans and options to pursue internationally in consideration of potentially severe global consequences resulting from the suggested patent reforms and subsequent adoption of PRA07.

I. *Opponents, Proponents, and the Forgotten Third Parties of the PRA07*

A. *The IT Industry: Weaker Patent Protection to Encourage Innovation*

Most firms in the IT industry would like to see a loosening of patent protections to allow for greater innovation and prevent patent abuse by patent troll firms¹⁴ or the building of patent thickets¹⁵ to please Wall Street.¹⁶ Recently, USPTO Director commented on the problems currently facing the domestic patent system by pointing out an example of an out of control patent: IBM's attempt to patent a number system for using the restroom on airplanes; such a patent literally and figuratively is a junk patent.¹⁷ Junk patents tend to serve no purpose other than to fortify a monopoly on any idea no matter how absurd or impractical it is, unlikely to achieve real life implementation.¹⁸ Technically, U.S. Patent Examiners are supposed to screen out such patents and disallow them, but over the last forty years 62-72% of all patents applied for were granted.¹⁹ The IT Industry points to things such as the great Blackberry near-blackout of 2006, where a patent holding company (occasionally a formalized

¹⁴ Patent Troll firms are companies that collect junk patents in the hopes of one day extorting money out of the owner of a truly valid invention/idea by claiming that the true owner infringed on their junk patent. JoAnn Mangione, *Junk Patent Extortion*, IP Frontline, Jan. 21, 2004, <http://www.ipfrontline.com/depts/article.asp?id=1432&deptid=4> (last accessed Apr. 4, 2008).

¹⁵ Patent thickets generally occur when patent standards are lower than they should be, thus allowing firms in developed industries to abuse economies of scale and patent any/every potential facet of a discovery, thus creating significant unnatural monopolistic barriers to trade in that industry. For more information on patent thickets, see generally James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies*, available at <http://www.researchoninnovation.org/thicket.pdf> (last accessed Apr. 17, 2008).

¹⁶ Nate Anderson, *USPTO Boss: IBM Bathroom Patent Symbolic of U.S. Patent Ills*, Ars Technica, Mar. 27, 2008 <http://arstechnica.com/news.ars/post/20080327-uspto-boss-ibm-bathroom-patent-symbolic-of-us-patent-ills.html> (last accessed Apr. 18, 2008).

¹⁷ IBM's patent stated it was "an apparatus, system, and method for providing reservations for restroom use." *Id.*

¹⁸ See Mangione, *supra* note 14.

¹⁹ *Id.*

term for a patent troll firm) sued for infringement of one of their many collected patents and threatened to get an injunction to prohibit the sale and operation of Blackberry phones in the United States.²⁰ Aside from this, the U.S. is one of the only countries in the world that permits patenting of software applications;²¹ this explains why some companies such as Sun Microsystems have made the switch to open source software distributions as complimentary distributions to their primary hardware components (*i.e.* servers).²² Other firms that are primarily software product-oriented, such as the Microsoft Corporation, have faced numerous patent problems. Microsoft specifically has been the target of a multitude of lawsuits for software patent infringement suffering large damages and thus, like Blackberry has an interest in minimizing future damage payouts.²³ The IT Industry is coordinated through the “Coalition for Patent Fairness”²⁴ comprised of primarily information technology industries that support the bill.

²⁰ Eric Bangeman, *It's Over: RIM and NTP Settle Blackberry Dispute*, Ars Technica, March 3, 2006, <http://arstechnica.com/news.ars/post/20060303-6314.html> (last accessed Apr. 18, 2008).

²¹ The U.S. permits software patents while the European Patent Office rarely grants patents for computer programs except under very strict circumstances. European Patent Office, Computer-Implemented Inventions, <http://www.epo.org/topics/issues/computer-implemented-inventions.html> (last accessed Apr. 2, 2008).

²² Sun Microsystems, *Open Platforms, Open Standards, Open Source*, in Sun Executive Boardroom Newsletter (February 2008), <http://www.sun.com/emrkt/boardroom/newsletter/0208/grantham.html> (last accessed Apr. 2, 2008).

²³ Eric Bangeman, *Eolas, Microsoft and the Patent Process*, Ars Technica, Nov. 3, 2003 <http://arstechnica.com/news.ars/post/20031103-3061.html> (last accessed Apr. 18, 2008). Microsoft also got slammed with patent damages ironically for stealing a software methodology for preventing others from stealing Microsoft software. *See also* Gregg Keizer, *Microsoft Loses 'Product Activation' Patent Suit, Owes \$142 Million*, Information Week, Aug. 22, 2006 http://www.informationweek.com/news/windows/microsoft_news/showArticle.jhtml;jsessionid=UZQSUAUYQ4VTAQSNDLRSKH0CJUNN2JVN?articleID=192203157&_requestid=414120 (last accessed Apr. 18, 2008).

²⁴ Coalition for Patent Fairness, About the Coalition, http://www.patentfairness.org/about_the_coalition/ (last accessed Mar. 21, 2008).

B. The Medical-Pharmaceutical Industries: Stronger Patent Protection v. Developing Countries: Human Rights over Property Rights and Hypocrisy in Light of Past Indigenous Plunder

The pharmaceutical and biomedical industries are represented by a host of industry groups, most visibly so by the “Coalition for 21st Century Patent Reform”²⁵ along with numerous academic research organizations and individual inventor groups who also oppose the PRA07. These industries are concerned about the PRA07’s provisions to weaken patent rights domestically through limited damage award provisions in infringement suits and the large amount of discretionary power granted to the USPTO in assessing the validity of patents.²⁶ Contrary to their IT opponents, these industries believe that opening up the patent system by weakening rights will discourage innovation by undermining economic incentives to pursue medical research.²⁷ Consequently, it follows that the international community has a strong interest in protecting those economic incentives to promote continued research in the health sciences. The following example illustrates the biotech/pharmaceutical industry concerns with the proposed damages:

Consider the invention of the first protease inhibitor to treat AIDS, invented in year one, first marketed in year 10, and first infringed in year 15. Between years one and 15, having learned that such a protease inhibition strategy may be useful in combating AIDS, many other protease inhibitors will have been developed. To judge the technical merits of the first protease inhibitor to see if it is novel and unobvious as compared to other, subsequently developed protease inhibitors, would be illogical. Later developments in the field have nothing to do with the technical merits of the original invention, or the inventor’s right to be able to

²⁵ Coalition for 21st Century Patent Reform, About Us, <http://www.patentsmatter.com/about/coalition.php> (last accessed Mar. 21, 2008).

²⁶ Coalition for 21st Century Patent Reform, About Us: What We Stand For, http://www.patentsmatter.com/about/what_we_stand_for.php (last accessed Mar. 21, 2008).

²⁷ *Id.*

recover the fair economic value for his original invention's unauthorized use. Instead, any infringement of a patent on the original protease inhibitor should be based upon the *economic* value of using the patented invention at the time of the infringement, even if by then such a use is considered technically ordinary.²⁸

The grievances of the life sciences/pharmaceutical coalition regarding the PRA07 are linked to continuing concerns over international access to disease treatment and future medical discoveries. Pharmaceutical firms have a spotty history of interactions with developing countries mainly because of the unfortunate inability of poor countries to pay for certain life-saving pharmaceutical products and the counterproductive measures taken on both sides of the issue. Developing countries argue that they are entitled to provide for the health and well-being of their citizens even if it means disregarding pharmaceutical property rights.²⁹ Related to developing country arguments is the U.N. Covenant on Civil and Political Rights which states that "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life."³⁰ Conversely, there are arguments stating that without property rights, human rights appear convoluted and incongruous; therefore, human rights require property rights to sustain them.³¹ When placed within the context of access to medicines in developing countries, pharmaceutical firms essentially argue that without adequate patent protections (property rights) they cannot continue to develop new medicines (indirectly protect the inherent right to life human right). Meanwhile, developing countries cry hypocrisy of apparent developed country dual-standards of enforcing intellectual property rights selectively

²⁸ See *Patent Damages*, *supra* note 11, at 4.

²⁹ See *infra*, at 26-29.

³⁰ United Nations International Covenant on Civil and Political Rights art.6(1), Dec. 16, 1966, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, *available at* <http://www2.ohchr.org/english/law/pdf/ccpr.pdf>.

³¹ Murray N. Rothbard, "*Human Rights*" *As Property Rights*, in *THE ETHICS OF LIBERTY* (New York University Press) (2003), *available at* <http://www.mises.org/story/2569> (last accessed Apr. 1, 2008).

when it serves their best interests.³² Some additional concerns, particularly in the realm of pharmaceutical property rights, include past abuse by developed country firms regarding traditional indigenous medicines. While pharmaceutical firms fight for what they claim as their intellectual property, in some instances 'their intellectual property' was not actually 'theirs' in the first place, but was outright stolen from indigenous populations in developing countries.³³ Needless to say, such encounters have generated a certain degree of animosity. As one leading indigenous rights scholar, Professor Siegfried Wiessner pointed out:

The indigenous view of the world, generally speaking, is the antithesis to the Western paradigm: communitarian, not individual, focused on sharing rather than shielding things, respect for land and all living things as sacred rather than as objects ripe for exploitation and consumption. This view arguably set them up for defeat. They were not prepared for the onslaught of Western conquerors who took advantage of this sharing philosophy.³⁴

On both sides of the coin, intellectual property rights arguments are strong; however, the pleas for protection of indigenous traditional medicines have long been stifled in favor of a 'modern' (or

³² An example of this can be seen in the WTO Dispute case regarding Antigua and Barbuda regarding online gambling controls where the US made Antiguan gambling sites illegal but permitted US race horsing sites to operate. The WTO ruled against the US who has failed to comply and in response Antigua has been granted permission to allow piracy of U.S. intellectual property until the U.S. complies with the WTO ruling. Nate Anderson, *IP Hypocrisy: US Likes WTO Rulings Only When it Wins*, ARS TECHNICA, Mar. 25, 2008 <http://arstechnica.com/news.ars/post/20080325-ip-hypocrisy-us-likes-wto-rulings-only-when-it-wins.html> (last accessed Apr. 18, 2008).

³³ Many developing countries, such as Brazil, have pushed for a *sui generis* system of IPR protection for traditional indigenous medicinal knowledge because it would allow for greater protection of such knowledge which is based in a communal or unique property system. See generally Richard Wilder, *Protection of Traditional Medicine*, in CMH Working Paper Series, World Health Organization: Commission on Macroeconomics and Health Working Paper Series, WG4:4 July 2001, available at <http://www.emro.who.int/cbi/PDF/TraditionalMedicine.pdf>.

³⁴ Siegfried Wiessner, *Defending Indigenous Peoples' Heritage: An Introduction*, 14 ST. THOMAS L. REV. 271, 272 (2001).

euphemism for 'Western') intellectual property system, inflaming tensions on all sides.

C. Conditioning Factors: An Ailing Pharmaceutical Industry and Disease Proliferation

When referencing the 'global' pharmaceutical industry, it may be more appropriate to use such a title in the context of product distribution as opposed to product manufacture. The reason for this is that although pharmaceutical products can be found everywhere, very few countries account for the market in an economic sense; the global pharmaceutical market is currently valued at ~US\$518 billion dollars of which 79% is derived from the G7 countries (US, Canada, UK, France, Germany, Japan and Italy).³⁵ Current industry market forecasts place a value of US\$1.3 trillion on the global pharmaceuticals market by the year 2020, of which almost 20% will be accounted for by the emerging economies³⁶ also known as the E7 countries.³⁷ Despite this forecast of large market growth, the industry is facing a multitude of internal and external problems. As industry analysts point out:

The current pharmaceutical industry business model is both economically unsustainable and operationally incapable of acting quickly enough to produce the types of innovative treatments that will be demanded by global markets. Pharmaceutical companies are facing a dearth of new compounds in the pipeline, poor share value performance(1), rising sales and marketing expenditures,

³⁵ PricewaterhouseCoopers, *Pharma 2020: The Vision, Which Path Will You Take* at 4 (2007), available at http://www.biovalley.ch/downloads/downloads_files/PHARMA%202020%20FINAL.pdf (last accessed Apr. 13, 2008) [hereinafter *Pharma 2020*].

³⁶ *Id.* at 5.

³⁷ The E7 or emerging economies constitute China, India, Indonesia, Brazil, Russia, Turkey and Mexico. Maureen Martino, *Press Release: Global Pharmaceutical Market to Double in Value to \$1.3 Trillion by 2020*, Fierce Biotech: The Biotechnology Industry's Daily Monitor, June 13, 2007, <http://www.fiercebiotech.com/node/7238> (last visited Apr. 13, 2008) [hereinafter *Global Pharma*].

increased legal and regulatory constraints and tarnished reputations.³⁸

Currently, U.S. firms account for 75% of all biopharmaceutical research expenditures globally and in 2006 alone spent US\$55.2 billion on research and development.³⁹ In terms of product development, the global industry has invested double the amount of R&D expenditure in 2006 as it did in 1996, but with an outcome of 60% fewer viable products.⁴⁰ For example, in 1996, the U.S. Food and Drug Administration approved fifty-three new discoveries, while only approving twenty-two in 2006.⁴¹ As of June 2007, there were 245 pure (*e.g.*, Hepatitis C) vaccines and 11 combination vaccines (*e.g.*, Measles, Mumps, Rubella or MMR) in clinical development; vaccines benefit the global community by preventing disease, but are costly to produce because of the higher risks during clinical trials associated with the attempt at immunizing otherwise healthy people.⁴² Compounding all of these problems, the products responsible for 90% of the industry's total revenues have approximately less than fifteen years on average left on their patent lifespans "exposing [US]\$157 billion worth of sales (measured in 2005 terms[dollars]) to generic erosion."⁴³ Generic erosion generates concerns over generic dumping or the flooding of markets with generic versions of off-patent drugs the day of patent expiration; such fears may be warranted as highlighted in a case brought before the WTO against Canada.⁴⁴

³⁸ The editor's note (1) refers to this: "In the six years to March 30, 2007, the FTSE Global Pharmaceuticals Index rose 1.3% while the Dow Jones World Index rose by 34.9%", further illustrating the problems facing the industry. *Id.*

³⁹ *See Pharma 2020, supra* note 35 at 5.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.* at 20-21.

⁴³ *Id.* at 6.

⁴⁴ Canada was letting generics firms manufacture and stockpile massive amounts of generic equivalents so they could be released the day of the expiration of the retail version's patent. The WTO Dispute panel found this to be a violation of Canada's obligations under TRIPS. Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (March 17, 2000), available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

With globalization come global health concerns. Increased multicultural interactions generate increased transfer of and exposure to disease pathogens, such as the world community witnessed with the SARS virus.⁴⁵ International environmental degradation and global warming have also been pointed to as aggravating factors adding to the global disease burden as “cases of malaria have now been reported in Azerbaijan, Corsica, Georgia and Turkey, where the disease was eradicated after World War II.”⁴⁶ Also, more traditional diseases caused by a combination of lifestyle choices and genetics (heart disease, diabetes, etc.) are emerging in some of the leading developing countries. As of 2004, it was estimated that over 600 million people in the developing world had hypertension and by 2025 it would increase to around 1 billion.⁴⁷ Overall, the populations of developing countries are subject to growing rates of chronic illnesses, and will continue to be in the future, with earlier disease onsets (than in developed countries); developing country populations currently account for approximately 80% of global deaths from chronic diseases.⁴⁸

⁴⁵ It only took the SARS Virus several days to disperse from Asia into other areas of the world, including the United States and Europe. *See Pharma 2020, supra* note 35 at 2.

⁴⁶ In addition to this, scientists also believe that global warming could spread diseases traditionally linked to lack of development (e.g. dengue fever, cholera and diphtheria) to developed countries. Specifically, they point to replication rates for key bacteria, such as salmonella, campylobacter and E.coli, which increase in some instances up to 6% per degree above -10 Celsius. *Id.* at 2-3.

⁴⁷ *Id.* at 3.

⁴⁸ *Id.* at 11.

*II. American Growing Pains and Revisiting 21st Century**U.S. Patent Reform*

The 19th Century French economist and law maker, Frederic Bastiat⁴⁹ said: “There is in all of us a strong disposition to regard what is lawful as legitimate, so much so that many falsely derive all justice from law. It is sufficient, then, for the law to order and sanction plunder, that it may appear to many consciences just and sacred.”⁵⁰ Undoubtedly the founding fathers of the American Revolution and the colonists themselves had a similar message spurring them to cast off the reins of a domineering British empire. This particularly rings true when placed in context of the American patent system. The American patent system is an economic system founded on principles supporting innovation, invention and the promotion of scientific progress for the betterment of both society and the individual. The U.S. Constitution explicitly states: “Congress shall have power to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”⁵¹ The Patent Act of 1790 was initially established as the first law governing patents in the United States, but this act faced an early demise.⁵² Three years later, the Patent Act of 1793 firmly established the concept of ‘first-to-invent’ in the American patent system in section three of the act.⁵³ More specifically, section three states: “[E]very

⁴⁹ Frederic Bastiat is considered to be an originator of modern Libertarian legal and economic philosophy who championed economic and social liberty as well as limited government. Bastiat’s works also contributed to the emergence of the Austrian School of economic thought, which among other things promoted a competitive free- market economic system. Thomas J. DiLorenzo, *Biography of Frederic Bastiat (1801-1850): Between the French and Marginalist Revolutions*, The Ludwig von Mises Inst., 2008, <http://www.mises.org/about/3227> (site last accessed on Mar. 15, 2008).

⁵⁰ Frederic Bastiat, *The Law*, 5 available at The Ludwig von Mises Institute. December 1991. <http://mises.org/books/thelaw.pdf> (site last accessed on Mar. 15, 2008).

⁵¹ U.S. CONST. art. I § 8, cl. 8.

⁵² Patent Act of 1790, Ch.7, 1 Stat. 109-12 (1790), *repealed by* Patent Act of 1793, Ch.11, 1 Stat. 318-23 (1793).

⁵³ Patent Act of 1793, Ch. 11, 1 Stat. 318-23 (1793), *repealed by* Patent Act of

inventor, before he can receive a patent shall swear or affirm that he does verily believe that he is the true inventor.”⁵⁴ The early American intellectual property system or, more appropriately, a lack thereof, suffered growing pains during the newly formed nation’s economic and political infancy.

Early into independence, Americans actively stole protected works from Europe; cheap knock-offs flooded U.S markets and the price of books dropped making them affordable to some of the poorest members of society.⁵⁵ Thus, a majority of members in American society benefited from this piracy in the nation’s early years. This proliferation of literature undoubtedly increased the literacy rate, which in turn generated economic growth.⁵⁶ However, as American ‘entrepreneurs’ plundered the intellectual wealth of European publishing houses and others, domestic legislators soon realized the need for an intellectual property and patent system based on reciprocity and joined the international patent agreement known as the Paris Convention for the Protection of Industrial Property in 1887⁵⁷ and the International Copyright Act of 1891.⁵⁸ Fortunately for both American and European inventors, patent infringement/invention theft was not quite as attractive as copyright piracy due to greater protections afforded by earlier patent reform in 1836. Although the Patent Reform Act of 1836 led to the foundation of the first U.S. Patent and Trademark Office,⁵⁹ the most significant

1836, Ch. 357, 5 Stat. 117 (1836).

⁵⁴ *Id.*

⁵⁵ John Gantz & Jack Rochester, *Pirates of the Digital Millennium: How the Intellectual Property Wars Damage Our Personal Freedoms, Our Jobs, and the World Economy* 37 (Financial Times Prentice Hall) (2004).

⁵⁶ Economic growth refers to a positive change in a country’s Gross Domestic Product or Gross National Product. Dr. Paul M. Johnson, *Growth Theory*, in *A Glossary of Political Economy Terms*, 2005, http://www.auburn.edu/~johnspm/gloss/growth_theory (site last accessed on Mar. 17, 2008).

⁵⁷ The Paris Convention will be discussed in greater detail in Section III of the paper addressing the international patent system. World Intellectual Property Organization, Contracting Parties: Paris Convention, http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2 (last accessed Mar. 23, 2008).

⁵⁸ The Copyright Act of 1790 did not protect foreign works, only domestic. See, Gantz & Rochester, *supra* note 55, at 36-9.

⁵⁹ Patent Act of 1836, Ch. 357, 5 Stat. 117 §a (1836), *amended by* Patent Act

modern overhaul of the American patent system occurred with the passage of the Patent Act of 1952.

On July 19, 1952 Title 35 of the United States Code entered into force and codified several significant recognitions and changes in the law.⁶⁰ One of the most significant features found in Title 35 relevant to the present day PRA07 addresses application of the first-to-invent principle to patents outside the U.S.⁶¹ On June 8, 2005, Texas Representative Lamar Smith introduced a bill, known as the Patent Reform Act of 2005 (“PRA05”), with the intent to strengthen Title 35 and the United States patent system; however, the bill did not progress very far.⁶² The current damage structure in the U.S. for patent infringement reasonable royalties is determined by a fifteen factor test established by the *Georgia-Pacific* case, which will be assessed in comparison to the new damage system under Part IV.⁶³ The PRA07 is the legislative successor to the PRA05 and is supported and opposed by two very diverse coalitions.⁶⁴ The “Coalition for Patent Fairness”⁶⁵ comprised of primarily information technology industries supports the bill and the “Coalition for 21st Century Patent Reform” comprised of mostly pharmaceutical, biotechnological and chemical firms⁶⁶ along with numerous academic research organizations oppose the PRA07. In addition to these organizations, the Association of American Universities (the “AAU”)⁶⁷ and the Intellectual Property Law Section of the

of 1839, Ch. 88, 5 Stat. 353-355 (1839).

⁶⁰ The Patent Act, 35 U.S.C. (1953).

⁶¹ 35 U.S.C. § 102(b) (2007). “A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.”

⁶² See H.R. 2795, *supra* note 7.

⁶³ The fifteen factor test first surfaced in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp 1116, 1120 (S.D.N.Y. 1970).

⁶⁴ See *supra* notes 24 and 25.

⁶⁵ See Coalition for Patent Fairness, *supra* note 24.

⁶⁶ See Coalition for 21st Century Patent Reform, *supra* note 25.

⁶⁷ The AAU is particularly concerned about the “expansion of prior user rights” and the modification of the damage awards system. Association of American Universities, PRA07 Response Letter (2007), <http://www.aau.edu/>

American Bar Association (the “IPABA”)⁶⁸ both expressed their concerns regarding the PRA07.

III. European and International Patent Law

Since many of the PRA07 coalition (both for and against) firms established headquarters in the U.S. and Europe, it is necessary to briefly provide a background of the European patent systems. Additionally, in order to better understand the interaction of these systems in relation to the overall international patent system, an overview of the GATT/WTO TRIPS patent system⁶⁹ and the WIPO patent system is essential.

A. Old World Intellectual Property Law Origins and the European Patent System

One of the earliest incidents of intellectual property theft occurred in 6th century Ireland, when a Catholic monk copied another Catholic Abbott’s Book of Psalms.⁷⁰ The case went to the king who ruled in favor of St. Finnian, only to have St. Columba refuse to return the copied work.⁷¹ The legal ruling passed by King Diarmait follows as: “Le gach bain a bainin, le gach leabhar a leabhrán,” which, translated from Celtic, means “To every cow its calf, to every book, its copy.”⁷² Although this today deals with copyright, the

intellect/Ltr_Vaughn_Judiciary_HR1908%20_9-6-07.pdf (site last accessed Mar. 21, 2008).

⁶⁸ The IPABA recently expressed some concerns with the PRA07 and stated that in its current form they oppose passage of the bill. American Bar Association Section on Intellectual Property Law, IPL Section Letter to Senate Opposing PRA07 (2007), <http://www.abanet.org/intelprop/LeahySpecterltrPatentbills.pdf> (site last accessed Mar. 21, 2008).

⁶⁹ TRIPS article 33 expressly covers a 20 year term of patent protection required. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197, 1210 (1994) [hereinafter TRIPS].

⁷⁰ See Gantz & Rochester, *supra* note 55, at 32.

⁷¹ *Id.*

⁷² *Id.*

general idea behind King Diarmait's ruling is very relevant today to all forms of IPR protections, including patent protection. Many years later (hundreds of years before the U.S. came into the picture), the Venetian government enacted one of the earliest patent laws in 1474.⁷³ Much like the objectives behind the American patent system, the Venetian system protected "works and devices discovered (by) men of great genius, apt to invent and discover ingenious devices."⁷⁴ Although each European country enacted a set of individualized patent laws, efforts towards creating a unified patent system shortly followed the general trend of European integration.

The European Patent Convention (the "EPC") initially entered into force on October 7, 1977.⁷⁵ By 1980, the first European patents were granted and by 1983 the European Patent Office (the "EPO") received the one hundred thousandth European patent application.⁷⁶ The initial four articles of the EPC granted formal legal recognition to patents filed with the EPO by all EPC participant countries.⁷⁷ In December of 2007, the revised version of the EPC entered into force, bringing the EPC into full alignment with all WTO/TRIPS obligations.⁷⁸ In current practice, the concept of a "European patent" more truly refers to a batch of national patents – one from each country party to the EPC at the time of the patent

⁷³ Francois Dessemontet, *The Role of IPRs in the Transfer of Technology*, 5 in WIPO-WTO Joint Workshop on Intellectual Property Rights and Transfer of Technology, November 17, 2003 http://www.wipo.int/documents/en/meetings/2003/wipo_wto/presentations/doc/dessemontet.doc (last accessed on Mar. 22, 2008).

⁷⁴ *Id.*

⁷⁵ European Patent Office, About US, <http://www.epo.org/about-us/office/history.html> (last accessed Mar. 22, 2008).

⁷⁶ *Id.*

⁷⁷ Convention for the European Patent for the Common Market, 76/76/EEC, 1976 O.J. (L 017) (Jan. 26, 1976) (European Patent Convention) arts. 1-4 (as in effect Dec. 13, 2007), April 2006. More specifically, article two, clause one states that filings under the EPC will then forth be recognized as "European Patents."

⁷⁸ European Patent Office, The EPC 2000, <http://www.epo.org/topics/patent/system/epc2000.html> (last accessed Apr. 18, 2008).

grant by the EPO.⁷⁹ Thus, under the present structure of Europe's patent system the owner of an infringed patent must seek recognition of the infringement from the court system of each country participant to the EPC in which the patent infringement occurred.⁸⁰ However, some disputes that arise directly from the framework of the EPC can be brought before the Boards of Appeal, which operate independently of the EPO and only address concerns strictly related to the EPC.⁸¹ Additionally, the EPC clearly delineates a patent system procedure in which the first person to file for a patent receives the patent rights to the invention.⁸²

B. International Patent Agreements within the World Intellectual Property Organization

1. The World Intellectual Property Organization ("WIPO") System

The WIPO is an agency that is part of the United Nations System established in 1967 to deal with growing concerns over inequities and inconsistencies with IPR administration around the world.⁸³ Currently, there are 184 States that participate in the WIPO system to some degree, as criteria for membership is highly inclusive to represent the broad range of concerns on IPR issues.⁸⁴ The WIPO

⁷⁹ European Patent Office, Topics: The European Patent Litigation Agreement, <http://www.epo.org/focus/issues/epl.html> (site last accessed Mar. 22, 2008).

⁸⁰ *Id.*

⁸¹ European Patent Office, Boards of Appeal, <http://www.epo.org/about-us/boards-of-appeal.html> (last accessed Apr. 18, 2008).

⁸² European Patent Convention art. 60 (as in effect 2007). Naturally, there are some procedural stipulations to the European first-to-file system as outlined in the rule. The general provisions of clause two in article sixty applies only if the first person to file fulfills the publication requirements under article ninety-three. *Id.*

⁸³ World Intellectual Property Organization, What is WIPO?, http://www.wipo.int/about-wipo/en/what_is_wipo.html (last accessed Mar. 26, 2008).

⁸⁴ Any State is allowed membership to WIPO if they meet the following criteria: "(i) is a member of the Paris Union for the Protection of Industrial Property, or of the Berne Union for the Protection of Literary and Artistic Works; (ii) or is a member of the United Nations, or of any of the United Nations' Specialized Agencies, or of the International Atomic Energy Agency, or that is a party to the Statute of the International Court of Justice;

is governed by a General Assembly comprised of one delegate (with one vote) from each country party to the WIPO Convention and an International Bureau that acts as Secretariat.⁸⁵ The WIPO governs numerous treaties comprising the international intellectual property rights system, including trademarks, copyrights and patents. Only the patent portion of the WIPO IPR system will be addressed for the purposes of this paper.

WIPO, like many UN-affiliates and other IGOs, has implemented programs to address the concerns of developing countries. The WIPO Development Agenda was officially established following a proposal by Brazil and Argentina during the thirty-first session of the WIPO General Assembly.⁸⁶ The Development Agenda brought to the forefront developing country grievances regarding technology transfer, anticompetitive measures and protecting public interest concerns unique to situations found in developing countries.⁸⁷ Somewhat similar to other development proposals, the Development Agenda calls for greater convergence and specific interfacing between multiple U.N. and non-U.N. bodies, denoting specific areas of concern within the WTO-TRIPS system⁸⁸ and the U.N. system.⁸⁹ However, WIPO has been actively involved in IP for development projects for several years prior to the implementation of the Development Agenda; therefore, it seemed logical to formalize these efforts for greater efficiency. Examples of prior activity can be seen in a WIPO publication highlighting country-by-country reports covering all of the organization's IP for

(iii) or is invited by the WIPO General Assembly to become a Member State of the Organization." WIPO, Member States, <http://www.wipo.int/members/en/> (last accessed Mar. 26, 2008).

⁸⁵ WIPO, Convention Establishing the World Intellectual Property Organization, Arts. 6-9, as amended Sept. 28, 1979, 21 U.S.T. 1749, 828 U.N.T.S. 3, available at http://www.wipo.int/export/sites/www/treaties/en/convention/pdf/trtdocs_wo029.pdf.

⁸⁶ WIPO, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WO/GA/31/11, Aug. 27, 2004.

⁸⁷ *Id.*

⁸⁸ *See infra*, at 323-329.

⁸⁹ *Id.*

development activities over a five-year period from 2000 to 2005.⁹⁰

2. *WIPO Patent Law: From the Paris Convention to the Patent Law Treaty*

The Paris Convention of 1883 established the first international rules system to address concerns regarding industrial property rights, particularly patent rights and ownership, through the creation of a Union.⁹¹ The agreement requires States Parties to the Union to implement the provisions of the agreement on a domestic level upon ratification of the agreement and therefore is not self-executing.⁹² Articles four and five of the Paris Convention laid down the ground rules for international patents. As the initial international agreement on patents, the Paris Convention arguably established the first-to-file standard as the international standard for patent ownership recognition. Patents are granted an initial period of priority protection of twelve months following the filing of the application with the appropriate domestic governmental agency, which allows the inventor twelve months of priority filing for patent protection in the other Union countries.⁹³ The provisions of the agreement also take into consideration inventor's certificates, effectively granting them equal footing as patent applications for the purposes of priority filing status.⁹⁴ Since its initial passage, the Paris Convention has evolved to become a foundational pillar of the international intellectual property system.

Currently, thirty-five least-developed countries ("LDCs") are party to the Paris Convention.⁹⁵ Of some relevance to LDCs are the

⁹⁰ WIPO, *Information on WIPO's Development Cooperation Activities*, WIPO/EDS/INF/1 Rev., Sept. 23, 2005.

⁹¹ The patents recognized were those as recognized under the legal systems of the parties to the Union. Paris Convention for the Protection of Industrial Property art. 1, (as amended Sept. 28, 1979) 21 U.S.T. 1583, 828 U.N.T.S. 305.

⁹² *Id.* at art. 25(2).

⁹³ *Id.* at art. 4(C)(1).

⁹⁴ *Id.* at art. 4(I).

⁹⁵ WIPO, *Accession of the Least Developed Countries to the WIPO Convention and Conventions Administered by WIPO*, <http://www.wipo.int/lcds/>

provisions covering compulsory licensing, but are subject to several limitations, such as a wait of four years from filing or three years from the grant of the patent, whichever is the longest period.⁹⁶ In addition to the compulsory licensing provisions, patent protection provisions prevent indirect theft of a patented product/process through the importation of a counterfeit product made by a process patented in a Union country.⁹⁷ These two provisions taken together do not provide much benefit to developing countries seeking to circumvent patents, whether legitimately or not. The Paris Convention was last amended in 1979 and has since had aspects integrated into more recent international patent agreements.⁹⁸

A glaring problem with the Paris Convention when initially established was that it relied upon individual inventors to assert their rights in each country of the Union. This situation was finally remedied by the Patent Cooperation Treaty of 1970, which created a true 'international patent' and an international body to administer related patent rules known as the International Patent Cooperation Union (the "IPCU").⁹⁹ International patent applications are published globally upon acceptance by the International Bureau (composed of patent examiners from mostly highly developed countries)¹⁰⁰ of the IPCU providing notice of the patented

en/accession/wipo_convention.html (last accessed Mar. 28, 2008).

⁹⁶ Article five of the Paris Convention states: "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." Paris Convention, art. 5(A)(2). Additionally, paragraph three covers potential forfeiture of a patent for abuse if compulsory licenses would not remedy the situation, but limitations are established under paragraph four. *Id.* at art. 5(A)(3-4).

⁹⁷ *Id.* at art. 5*quater*.

⁹⁸ See generally Paris Convention, *supra* note 57.

⁹⁹ WIPO, Patent Cooperation Treaty, art. 1, (as in force April 1, 2002), 28 U.S.T. 7645, 9 I.L.M. 978, available at <http://www.wipo.int/pct/en/texts/pdf/pct.pdf>.

¹⁰⁰ Upon filing of an international patent application, an international search and examination of the product/process to be patented is conducted by "the Patent Offices of Australia, Austria, Canada, China, Finland, Japan, the Republic of Korea, the Russian Federation, Sweden, the United States of America, and the European Patent Office." WIPO, Summary of the Patent Cooperation Treaty,

invention.¹⁰¹ The PCT provides for an additional eighteen months of protection for international patenting and prevents against protectionist behavior, by guaranteeing acceptance at the national level by another party of an international patent filed appropriately.¹⁰² The PCT also provides for settlement of disputes by granting the International Court of Justice jurisdiction, subject to allowable reservations under PCT article sixty-four, over conflicts arising out of country obligations.¹⁰³ Lastly, the PCT grants certain privileges to the nationals of countries with per capita incomes below \$3000 and least-developed countries (“LDCs”)¹⁰⁴ as defined by the United Nations.¹⁰⁵ By applying cost reduction measures for LDCs and reduced income applicants, the PCT effectively encourages property right recognition and protection in otherwise unprotected markets.

Subsequent international patent agreements were created to protect specialized areas of patent concern, such as microbial organisms¹⁰⁶ and International Patent Classification (“IPC”)¹⁰⁷, within the framework of the Paris Convention and PCT. The current eight edition of the IPC entered into force January 1, 2006 and contains over seventy-thousand patent classification groups

http://www.wipo.int/treaties/en/registration/pct/summary_pct.html (last accessed Mar. 29, 2008).

¹⁰¹ Patent Cooperation Treaty, article 21 and article 55, *available at* <http://www.wipo.int/pct/en/texts/pdf/pct.pdf>.

¹⁰² Summary of the Patent Cooperation Treaty, *supra* note 100.

¹⁰³ Patent Cooperation Treaty, article 59, *available at* <http://www.wipo.int/pct/en/texts/pdf/pct.pdf>.

¹⁰⁴ For a current list of UN recognized LDCs please see: <http://www.un.org/special-rep/ohrlls/ldc/list.htm>.

¹⁰⁵ Summary of the Patent Cooperation Treaty, *supra* note 100.

¹⁰⁶ WIPO, Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, April 28, 1977, 32 U.S.T. 1241, T.I.A.S. No. 9768, *available at* http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/pdf/trtdocs_wo002.pdf (last accessed Mar. 29, 2008).

¹⁰⁷ WIPO, Strasbourg Agreement Concerning the International Patent Classification, March 24, 1971, 26 U.S.T. 1793, T.I.A.S. No. 8140, *available at* http://www.wipo.int/export/sites/www/treaties/en/classification/strasbourg/pdf/trtdocs_wo026.pdf (last accessed Mar. 29, 2008).

categorized within eight sections.¹⁰⁸ Section A of the IPC contains classifications for “Human Necessities” and Section C covers “Chemistry; Metallurgy.”¹⁰⁹ More specifically, Article A61 addressing classifications for “Medical or Veterinarian Science; Hygiene” and article C12 handling “Biochemistry. . . Microbiology; Enzymology; Mutation or Genetic Engineering,” pertain to classifications relevant for medicinal research and development.¹¹⁰

The most recent agreement administered under the WIPO System, the Patent Law Treaty (the “PLT”), adopted on June 1, 2000 in Geneva, Switzerland and entered into force on April 28, 2005, expanded upon the previous international patent agreements without undermining any of the existing obligations of States Parties.¹¹¹ The PLT set out to harmonize and streamline the international patent process by creating more specific standardized procedures for participant States’ patent offices.¹¹² For the first time, on June 2, 2005, electronic patent filing procedures were implemented bringing the WIPO international patent system into the digital millennium (however, paper documents are still required to be kept on-file).¹¹³ Generally, the PCT is less draconian in terms of strict compliance with formalities, recognizing the inherent complexities of patent law and providing appropriate remedies to avoid loss of substantive rights from failure to comply with procedures or meet time limits.¹¹⁴ Lastly, standardized ‘Model International Forms’ were also adopted to simplify recognition of international patent submissions, thus streamlining the international patent process and easing burdens for

¹⁰⁸ WIPO, Introduction to the IPC on The Internet, <http://www.wipo.int/classifications/ipc/en/general/intro.html> (last accessed Mar. 29, 2008).

¹⁰⁹ WIPO, Reformed IPC: Internet Publication, <http://www.wipo.int/classifications/ipc/ipc8/?lang=en> (last accessed Mar. 29, 2008).

¹¹⁰ *Id.*

¹¹¹ WIPO, Basic Features of the Patent Law Treaty, at 3 http://www.wipo.int/export/sites/www/patent-law/en/pdf/plt_features.pdf (last accessed Mar. 28, 2008).

¹¹² *Id.*

¹¹³ WIPO, Summary of the Patent Law Treaty, http://www.wipo.int/treaties/en/ip/plt/summary_plt.html (last accessed Apr. 1, 2008).

¹¹⁴ *Id.*

participating country patent offices.¹¹⁵

C. The WTO Patent System and TRIPS to Developing Countries with a DOHA Agenda

In 1994, the World Trade Organization standardized recognition of international intellectual property rights when the treaty on the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) entered into force.¹¹⁶ This agreement resulted from nearly a decades worth of debate between multinational firms in wealthier nations and state-sponsored industries in the developing and transitional economies.¹¹⁷ The TRIPS agreement is quite significant because it is an official treaty of the World Trade Organization (the “WTO”), thus making adoption of the agreement a requirement for continued membership in the organization. The government of China, as the most economically powerful of the developing country coalition, fought and struggled with western concepts of IP protection even when admitted as a member of the WTO.

As part of its obligations under the WTO, the Chinese government began a revision of their domestic laws to harmonize the domestic legal system with international intellectual property obligations.¹¹⁸ The US Patent Office assisted in this matter through the sponsorship of an ‘Intellectual Property Rights Working Group’ during the 2004 U.S.-China Joint Commission on Commerce and Trade; institutional bureaucracy has been a major obstacle to

¹¹⁵ *Id.*

¹¹⁶ See TRIPS, *supra* note 69.

¹¹⁷ The term ‘transitional economy’ used in this context refers to former Soviet-bloc countries and other economies, primarily in Asia, making a transition from a centralized command economy to a market-based economy. For a case study example see, Asian Development Bank Institute, *Transition Economies, in The Indonesian Economy in Transition: The International Context* (Feb. 24, 2004), available at <http://www.adbi.org/files/2004.02.25.spc002.mccawley.jakarta.pdf>.

¹¹⁸ United States Patent and Trademark Office, Intellectual Property Policy and Leadership Performance, http://www.uspto.gov/web/offices/com/annual/2004/040204_intel_policy.html (last accessed Mar. 26, 2008).

securing intellectual property protection in China.¹¹⁹ Although China is a now member of the WTO and must offer such protections, there exists the problem of bureaucratic red tape that multinational firms must cross before they *might* be granted some protection.¹²⁰ Also, China's use of administrative, as opposed to criminal punishments for IP theft, gives violators of such protections minimal incentive to curb their behavior.¹²¹

Earlier efforts by China to accommodate the WTO included the adoption of a share-holding structure, which opened doorways for cleaner operations, management responsibility and less liability for losses on behalf of the government of China.¹²² The wave of semi-privatization that took place following adoption of corporatization principles resulted in state-owned enterprises accounting for only 28% of industrial output in 1998, down from approximately 75% pre-reform.¹²³ Without supporting assignment of property rights in the form of shareholder ownership this probably would not have happened. While the issue of tangible property rights fell closer into alignment with rights granted in most market economies, intellectual property rights still posed to be quite problematic both in China and other developing countries. Importation of foreign knowledge through foreign direct investment and the subsequent re-exportation of goods manufactured from stolen/inappropriately used intellectual property set off alarms regarding the current level of adherence to international property protection laws.¹²⁴

¹¹⁹ *Id.*

¹²⁰ United States Government Export Office, Protecting Your Intellectual Property Rights in China, <http://www.mac.doc.gov/China/Docs/BusinessGuides/IntellectualPropertyRights.htm> (last accessed Mar. 26, 2008).

¹²¹ *Id.*

¹²² See Zhiyuan Cui, *Whither China? The Discourse on Property Rights in the Chinese Reform Context*, Social Text, No. 55, Summer 1998, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=70948.

¹²³ John Child & David Tse, *China's Transition and Its Implications for International Business*, 32 J. INT'L BUS. STUD. 5-8 (2001).

¹²⁴ Andrzej Zwaniacki, *Chinese Intellectual Property Theft Could Spur U.S. Protectionism*, in U.S. Department of State: Telling America's Story, Nov. 15, 2006. <http://www.america.gov/st/washfile-english/2006/November/20061115165>

The primary on-going obstacle to intellectual property protections in developing countries is the use of piracy and misguided economic protectionism to stave off foreign firms and promote what is seen as the local economy.¹²⁵ A great area of concern for developing countries centers on access to pharmaceuticals to ensure appropriate treatment for their citizens. Prior to the DOHA round of negotiations, numerous cases were brought against developing countries by the U.S. and E.C. for pharmaceutical patent protection/infringement problems. The U.S. and the E.C. brought subsequent cases against India in 1996¹²⁶ and 1997¹²⁷ respectively for failure to provide adequate patent protection in that country. A case was also brought against Brazil by the U.S. because Brazil forced compulsory licensing of all drugs brought into the country; this case in a way represented a precursor to future developments in WTO/TRIPS law.¹²⁸ During the WTO Doha Ministerial Conference in 2001, developing countries reached an agreement with developed nations allowing them to continue to manufacture cost-effective generic drugs patented prior to 1995 and

615saikceinawz0.3555109.html (last accessed Mar. 26, 2008).

¹²⁵ Some developing countries use an economic policy based in the Infant Industry Argument, which basically states that countries should be allowed to protect newly developing industries from international markets to allow them a chance to survive infancy and later compete on their own. WILLIAM EASTERLY, *THE ELUSIVE QUEST FOR GROWTH: ECONOMIST'S ADVENTURES AND MISADVENTURES IN THE TROPICS* 230 (MIT Press Cambridge, Massachusetts, 2002).

¹²⁶ In the *U.S. v. India* dispute, the Appellate Body found India in breach of TRIPS art. 70(8) general patent protection provisions and 70(9) exclusive marketing rights for patented products (*Protection of Existing Subject Matter*) and recommended India bring its laws into compliance. WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, Dec. 19, 1997.

¹²⁷ In the *E.C. v. India* dispute, the Dispute Panel once again found India in breach of the same articles as in the U.S. case from t and recommended India bring its patent system into compliance. WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS79/R, Aug. 24, 1998.

¹²⁸ The *U.S. v. Brazil* dispute was settled mutually with the U.S. asking Brazil to inform the U.S. prior to it taking unilateral measures to engage in compulsory licensing of pharmaceuticals. WTO, *Brazil - Measures Affecting Patent Protection*, WT/DS199/4, July 19, 2001.

introduced the compulsory licensing system.¹²⁹ However, this agreement did not crystallize obligations of developing countries and patent holders under the emergency provisions, nor did it clearly delineate a threshold for when it is acceptable under TRIPS to break patent obligations.¹³⁰ Shortly after the initial Doha Ministerial, participants in the conference attempted to clarify the rights and obligations under the compulsory license system with the Declaration on the TRIPS Agreement and Public Health (the “DTPH”).¹³¹ In paragraph four of the DTPH it states:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.¹³²

The DTPH generated controversy because it appeared to patent holders that the allowances granted contradicted the provisions of the TRIPS Agreement. More specifically, the DTPH modified article sixty-six in the TRIPS Agreement, which targeted the initial concerns of developing country members prior to the

¹²⁹ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002). Compulsory licensing occurs when a government grants permission to break a patent protection obligation and allows a company (usually a domestic generic pharmaceutical firm) to duplicate a patented process or product without permission from the patent holder. *See*, World Trade Organization, *Fact Sheet: TRIPS and Pharmaceutical Patents*, at http://www.wto.org/english/tratop_e/TRIPS_e/factsheet_pharm02_e.htm#compulsorylicensing (last accessed on Mar. 27, 2008).

¹³⁰ The TRIPS article addressing use of patented processes or products without permission from the patent holder allows countries to break patents in “the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” *See* TRIPS art. 31(b).

¹³¹ World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 20 November 2001, WT/MIN(01)/DEC/2.

¹³² *Id.*

implementation of TRIPS.¹³³

The international system of intellectual property protection still left much to be desired. Developed nations concerned about the security of their intellectual property dragged their feet in fulfilling their TRIPS obligations under Article 66 paragraph two, to engage in technology transfers.¹³⁴ This prompted the Council for TRIPS to issue a decision specifically on the obligation of developed nations under Article 66 paragraph two requiring developed countries to submit reports accounting for their technology transfer activities with developing countries.¹³⁵ The Council for TRIPS decided, “[d]eveloped country Members shall submit annually reports on actions taken or planned in pursuance of their commitments under Article 66.2.”¹³⁶ The Council sought information on the incentive structures adopted to promote technology transfers to developing countries and the companies and/or organizations involved.¹³⁷

Aside from generic pharmaceuticals manufactured by developing countries engaged in now-legitimized patent-breaking behavior, developed country pharmaceutical firms encountered problems with target-market adaptive pricing schemes.¹³⁸ The provisions under the DTPH along with unaffordable domestic drug alternatives generated gray markets and parallel importing

¹³³ This article provided for an extended timetable for implementation of the TRIPS Agreement by least-developed country members and created an obligation for developed country members to engage in technology transfers to promote technological advancement in developing countries. *See* TRIPS art. 66.

¹³⁴ Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Article 66.2 of the TRIPS Agreement*, IP/C/28 (February 20, 2003).

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ Global pharmaceutical pricing schemes differ according to the economies of distribution, particularly in regard to pharmaceutical distribution in developing countries. For more information on the economics of pharmaceutical pricing, *See* Patricia M. Danzon, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents* (2001), available at <http://hc.wharton.upenn.edu/danzon/PDF%20Files/Differential%20pricing%20of%20Pharmaceuticals%202002%20WHO%20paper%2012.15.01.pdf> (last accessed Mar. 18, 2008).

scenarios.¹³⁹ In addition, the lack of effective regulation in most developing country pharmaceutical markets that create weariness among developed country firms have led to the proliferation of counterfeit pharmaceuticals marketed as an actual patented drug.¹⁴⁰ Despite these difficulties, additional measures were taken to ensure access to medicines in developing countries. A decision on the implementation of the DOHA Declaration opened up the possibility of compulsory licensing for export, effectively allowing developing countries without any pharmaceutical manufacturing capacity to legitimately obtain pharmaceuticals made elsewhere.¹⁴¹ Canada became the first country to use compulsory licensing for export, having a domestic firm manufacture the AIDS drug TriAvir for Rwanda.¹⁴² An amendment was proposed in 2005 that would incorporate the grant of export and import compulsory licensing procedures into the main TRIPS Agreement as article 31*bis*, thus further legitimizing such compulsory licensing activities.¹⁴³ As of May 2008, seventeen countries (including the U.S.) and the E.C. have accepted the proposed amendment to the TRIPS Agreement.¹⁴⁴ Collectively, the changing landscape of international patent protection contributes to philosophical divisions that generate stalemates which diminish the ability of developing countries to

¹³⁹ Parallel importing is the practice of exporting goods priced and manufactured only for a specific market to other markets where the same good may exist, but at prices that are generally higher due to the lack of a special arrangement for the country where the good is parallel imported. *See* World Trade Organization, Fact Sheet: TRIPS and Pharmaceutical Patents, http://www.wto.org/english/tratop_e/TRIPS_e/factsheet_pharm02_e.htm#compulsorylicensing (last accessed on Mar. 27, 2008).

¹⁴⁰ Tope Akinwande, *Lethal 'cures' plague Africa*, in *WORLD PRESS REV.* (Feb. 2004), <http://www.worldpress.org/Africa/1749.cfm> (last accessed on Mar. 29, 2008).

¹⁴¹ WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540, Sept. 1, 2003.

¹⁴² WTO, *Canada is First to Notify Compulsory Licence to Export Generic Drug*, Oct. 4, 2007, http://www.wto.org/english/news_e/news07_e/TRIPS_health_notif_oct07_e.htm (last accessed Apr. 18, 2008).

¹⁴³ WTO, *Amendment of the TRIPS Agreement*, WT/L/641, Dec. 6, 2005.

¹⁴⁴ WTO, *Members Accepting Amendment of the TRIPS Agreement*, http://www.wto.org/english/tratop_e/TRIPS_e/amendment_e.htm (last accessed May 23, 2008).

address the growing health concerns among their populations.

IV. Projection of Future Trends

A. Global Conformity and Domestic Property Concerns on the First-to-File Standard

One of the primary arguments for the adoption of the Patent Reform Act of 2007 is that it will bring the United States into alignment with international standards by implementing the “first-to-file rule.”¹⁴⁵ Yet, the efficiency gains of replacing the current regime based on first-to-invent with the international standard of first-to-file are suspect. Domestic legislators are under assault by lobby interests from two very large industry coalitions: the pro-adoption information technology industries (e.g. Apple and Sun Microsystems) and the anti-adoption medical tech industries (e.g. biotech and pharmaceutical firms); legislators have not fully considered the implicit/explicit costs and benefits of the proposed reforms when weighed against the current domestic and international patent standards.

Misperception of various standards in the international legal community appears to be (whether intentional or not) a common trend in recent U.S. domestic legislation. The policy standards stated by the European Patent Office (the “EPO”) provide insight into the debate over American patent reform: “The EPO is convinced that patents could have ‘an even stronger impact on economic growth’ once the patent system is better known in Europe and a patent culture develops similar to that of the United States.”¹⁴⁶ The EPO specifically addresses how one of their primary goals is to develop a patent culture similar to United States, meanwhile the United States is busy trying to conform to a global (which would include

¹⁴⁵ The PRA07 proposed change is technically titled “first-inventor-to-file”, but operates to reward the person who filed for the specific invention first. See H.R. 1908, 110th Cong. Sec. 3 (2007).

¹⁴⁶ European Patent Office, The Economic Importance of Patents, <http://www.epo.org/focus/innovation-and-economy/economic-impact.html> (last accessed on Mar. 30, 2008).

European) patent culture with the proposed adoption of first-to-file.¹⁴⁷ Related to the arguments on the domestic adoption of the first-to-file standard, the rise in low-quality patents is not a problem unique to the U.S. and is currently at the forefront of European patent reform negotiations; thus showing that low-quality patents are common problems irrespective of which filing standard is used.¹⁴⁸

Although the EPO acknowledges patent inflation issues in the United States, when economies of scale and natural law are considered, a first-to-file policy change in the U.S. may only exacerbate the United States Patent Office backlog and undermine patent property rights. If individuals are forced to protect their property rights by engaging in unending vigilance of technological developments in their fields and amongst their competitors they may feel less inclined to pursue costly product research.¹⁴⁹ Additionally, there is something to say for the natural law concept of protecting the property derived from the fruits of one's own labor.¹⁵⁰

The issue of economies of scale is one of concern for

¹⁴⁷ This is the case as can be seen by a strive towards the adoption of a first-to-file patent system along with the explicit language in the PRA07 which requires a report of findings on and recommendations of the Director "on the operation of prior user rights" which must include "a comparison between the patent laws of the United States and the laws of other industrialized countries, including the European Union, Japan, Canada, and Australia." H.R. 1908, Sec. 5(a)(1)(b)(1) (2007).

¹⁴⁸ Charlie McCreevy, European Commissioner for Internal Market and Services, Closing Remarks at Public Discussion on Future Patent Policy in Europe (July 12, 2006), *available at* <http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/06/453&format=PDF&aged=1&language=EN&guiLanguage=en> (last accessed on Mar. 19, 2008).

¹⁴⁹ This concern ties directly in with the modified damage awards system under the PRA07, which sets arbitrary limitations on infringement damages essentially encouraging infringement by minimizing the costs associated with intellectual property theft. *See* H.R. 1908 sec. 5 (2007).

¹⁵⁰ The concept of protecting an individual's work product as his individual property is one which is stressed by a cross-section of legal, economic and political theorists, including the well-known political economist Adam Smith. For a domestic example, the Libertarian Party supports such a belief. *See* Libertarian Party, National Platform of the Libertarian Party, http://www.lp.org/issues/platform_all.shtml#ii (last accessed on Mar. 19, 2008).

individual inventors in the United States who oppose the PRA07.¹⁵¹ Although generally placed in the context of manufacturing goods, the concept of economies of scale is very much applicable to the manufacture of patentable ideas and processes. Traditionally, the argument has focused on costs of ‘racing to the patent office’ to file first and how this negatively impacts individual inventors with minimal investment capital versus the benefits of international patent law harmonization and efficiency.¹⁵² One commentator in favor of the first-to-file standard argues that the efficiency gains from the ‘you snooze you lose’ philosophy of the proposed standard are significant when placed in a utilitarian context.¹⁵³ However, as utilitarianism is a broad concept with multiple levels of interpretation, the utilitarian consequences of a first-to-file system may differ on a domestic and international level.

The previous attempt at domestic patent reform, the PRA05, proposed the adoption of the first-to-file procedure and failed.¹⁵⁴ As one commentator on the H.R. 2795 pointed out then, the concept of the term “inventor” refers to someone “who produces something new”, not someone or some firm who has the financial resources to outrun an ‘inventor’ to the patent office.¹⁵⁵ Oddly, the PRA07 addresses this by defining an inventor for the purposes of the act

¹⁵¹ Economies of scale, in simplified terms, refer to the concept where the larger producers of goods can take advantage of their larger size to produce cheaper goods. Basically, as each additional unit of a good is produced the cost of production for each additional unit becomes cheaper until a production threshold point is reached. See Webfinance Inc., *Economy of Scale Definition*, http://www.investorwords.com/1653/economy_of_scale.html (last accessed Mar. 19, 2008).

¹⁵² Professional Inventors Alliance, Patent Reform Issues: First-to-File, http://www.piausa.org/patent_reform_issues/first_to_file/ (last accessed Mar. 20, 2008).

¹⁵³ Ryan Dickey, Notes, *The First-To-Invent Patent Priority System: An Embarrassment to the International Community*, 24 B.U. Int'l L.J. 283, 300-01 (2006).

¹⁵⁴ See H.R. 2795, 109th Cong. (2005), *supra* note 7.

¹⁵⁵ Greg Mayer, *Parts of Patent Reform Bill Could Hurt Independent Inventors, Startups*, Small Times, Oct. 3, 2005, http://stm.dev.pennnet.com/articles/article_display.cfm?Section=ARCHI&C=Legal&ARTICLE_ID=270296&p=109 (last accessed Apr. 1, 2008).

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before going on to seemingly contradict this definition within the language proposing an American version of the first-to-file standard.¹⁵⁶ From an international standpoint, harmonizing American patent standards with its international trading partners will generate positive results internationally; however, the domestic costs may be too high if not implemented appropriately.¹⁵⁷ As another commentator points out, when you factor in fees from patent searches, attorneys and the USPTO procedures, it costs upwards of \$6,000 to get a patent for a simple invention and around \$25,000 or more for a complex invention.¹⁵⁸ Under the PRA07, when the proposed procedures for patent searches combine with the unclear “first-inventor-to-file” standard, economies of scale kick in to the disadvantage of individual entrepreneurial inventors.

The PRA07 contains a provision that requires all applicants, except “micro entities”, as noted in the next clause, to submit a search report that can be performed only by United States citizens.¹⁵⁹ On the surface, the micro entity exception seems to be carved out specifically to address the concerns of inventors or organizations with limited capital. However, if supporting non-wealthy inventors was truly the goal of the micro entity clause, it would seem more appropriate not to punish the industrious small inventor (e.g. one that files greater than four patent applications) by burdening him with a

¹⁵⁶ In section 3 of the PRA07 the bill defines an ‘inventor’ as: “the individual or, if a joint invention, the individuals collectively *who invented or discovered the subject matter of an invention.*” The bill goes onto to explain how the patent right goes to the first ‘inventor’ to file the application. H.R. 1908, 110th Cong. Sec. 3 (2007).

¹⁵⁷ See Dickey, *supra* note 153.

¹⁵⁸ Bethaney Halford, *First to File*, PRISM: American Society for Engineering Education, November 2005, http://www.prism-magazine.org/nov05/feature_first.cfm (last accessed Apr. 1, 2008).

¹⁵⁹ Under §123(a), the Director has the discretion to require individuals to perform patent searches on their own, even though the Patent Office is required to still perform patent searches when an application is filed. Also, an inventor who fails to perform the Director-commanded patent search, “shall [have his patent application] be regarded as abandoned.” A micro entity excepted under §124 from this requirement is an inventor that has not been named on more than four filed patent applications and whose income does not exceed 2.5 times the median household income of the United States. H.R. 1908, Sec. 12 §123-4 (2007).

Director-imposed patent search process.¹⁶⁰ This adds to the concerns of economies of scale because it essentially limits the number of financially feasible patents that a lower-income entrepreneurial inventor can pursue. Additionally, when put in the context of a race to the patent office under the first-to-file system, an inventor's right to the fruits of his labor and thus, the inviolability of his property, are undermined. Under these conditions and the significant ambiguities surrounding the proposed first-to-file standard under PRA07, it seems highly doubtful that the provision will suffice for Senate approval unless the provisions are clarified and the concerns of lower income inventors are appropriately addressed.

B. PRA07 Damage Externality Concerns and Medicine Access in Developing Countries

Foreign Direct Investment ("FDI") is the primary vehicle for technology transfer in developing countries.¹⁶¹ However, given the questionable state of, and benefits derived from intellectual property protection in developing countries, the future of technology transfer remains a continual concern. Multinational firms, particularly those aligned with one of the pro or anti PRA07 coalitions, show concern for their property in light of the resurgence of New International Economic Order (the "NIEO") approaches to international trade law.¹⁶² Many development economists point out that copying the

¹⁶⁰ The IPABA briefly mentioned the patent searches in their opposition letter to the PRA07 and also stated concerns regarding the imposition of tremendous responsibilities on the Director of the U.S. Patent Office under the proposed legislation. See IPABA, *supra* note 68.

¹⁶¹ United States Department of State. *Financial Resources and Technology Transfer*, in Fourth Climate Action Report to the UN Framework Convention on Climate Change. <http://www.state.gov/g/oes/rls/rpts/car/90326.htm> (last accessed Apr. 3, 2008).

¹⁶² The NIEO originated in the 1970s as a coalition of developing countries seeking what they perceived as fair and balanced international trade and property laws. NIEO views consider intellectual property not as private property, but as a sort of common heritage of mankind. For more information on NIEO views in relation to the growth of developing country IP protection, see generally Susan K. Sell, *Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice*, in 49 INT'L ORG. 315 (1995).

intellectual property of others appears to be the only way to catch up and that historically this has proven true on several occasions.¹⁶³ These individuals argue that when viewed retrospectively, the development of many of today's top economies required a certain degree of intellectual property flexibility to permit rapid innovation, but that this benefit eventually turns into a detriment as the economy becomes more developed.¹⁶⁴ On the other hand, it is unacceptable to suggest that large technology firms turn a blind-eye to large scale intellectual property theft given international agreements under the WTO. Due to conflicting ideologies of intellectual property protection, developing countries and technology firms are locked in a constant struggle to find common ground for technology transfer agreements. Enter TRIPS, the Doha Development Agenda and now the PRA07.

Different cultures around the world have all developed unique approaches to medicine, varying from traditional cures to modern pharmaceuticals or a combination of both. The debate over which practice is superior is one that will undoubtedly never see an end. Regardless, one thing is certain: the value placed on pharmaceutical drugs in the global economy has led to the creation of an expansive industry of medicines meant to treat everything from cancer to hair loss. The continual growth of the industry has brought several practices into question both on the pharmaceutical firms' side and the consumer side. With the advent of globalization and strengthened concepts of intellectual property rights, a property rights war has ensued between several leading generic drug manufacturers of the developing world and the formidable coalition of retail pharmaceutical firms.¹⁶⁵ The arguments supporting each

¹⁶³ Lester C. Thurow, *Needed: A New System of Intellectual Property Rights*, HARV. BUS. REV., Sept. 1, 1997.

¹⁶⁴ *Id.*

¹⁶⁵ India has one of the largest generic drug industries and has also been a major source of intellectual property theft for pharmaceutical products until recent domestic legislation changed the laws. Brook K. Baker, *India's 2005 Patent Act: Death by Patent or Universal Access to Second- and Future-Generation ARVs?*, in Health Gap Global Access Project Background Paper, Sept. 19, 2005, http://www.healthgap.org/press_releases/05/091905_HGAP_BP_India_patent_baker.html (last accessed Apr. 18, 2008).

side are compelling and provide a new social and scientific frontier for lawmakers, business managers, and consumers to balance ethics, humanism, and profits.

The WTO has strived in recent years to accommodate developing country concerns regarding unbalanced technology transfer relationships between themselves and the developed world.¹⁶⁶ The TRIPS agreement protects the intellectual property, including the technological patents of firms, but offers little in return for developing country acquiescence.¹⁶⁷ Naturally, developing countries feel snubbed to say the least. When the WTO implemented the Doha Development Agenda, the TRIPS agreement started to balance out in terms of fairness to developed and developing nations.¹⁶⁸ However, the current problems center on the obligation of developed countries to engage in technology transfer, who is entitled to property rights from technology transfers and the extent of these rights.

The largest opposition to the PRA07 is primarily composed of firms that develop the technologies essential to a higher quality of life.¹⁶⁹ The economic argument against adoption of the PRA07 is that it will take away financial incentives for these firms to pursue high-risk (and potentially high-monetary and international social gain) investments. Since advances in high technology, particularly medical technology, is beneficial to all members of society, it is thus arguable that passage of the PRA07 would generate anti-utilitarian consequences. The impact of removing economic incentives from technological research will result in a shift of the associated losses and place upward pressure on product costs to compensate, thereby burdening consumers.¹⁷⁰ Of more severe consequence is the negative externality effect this incentive alteration will have on

¹⁶⁶ World Trade Organization, The Doha Development Agenda: Negotiations, Implementation and Development, http://www.wto.org/english/tratop_e/dda_e/dda_e.htm (last accessed Apr. 5, 2008).

¹⁶⁷ See TRIPS art. 66.

¹⁶⁸ See *supra* notes 129 and 131.

¹⁶⁹ See Coalition for 21st Century Patent Reform, *supra* note 25.

¹⁷⁰ To fully understand this concept please review the current state of the global pharmaceutical industry as discussed earlier *supra*, at 306-311.

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developing countries who receive cost subsidies for medicines under the already fragile international patent laws.¹⁷¹

Specifically, the proposed damage provision under the PRA07 limits 'reasonable royalties' to a point where the economic incentives to invent are severely diminished if the development is being pursued by a private entity that relies on monetary gain to support R&D.¹⁷² The problem with such a proposal is that the PRA07 burdens the courts by setting an arbitrary damage award calculation that must be employed by the courts and does not truly take into account the consequences of a patent infringement.¹⁷³ The existing legal standard for a reasonable royalty calculation for patent infringement is more likely to award appropriate compensatory damages.¹⁷⁴ The courts have defined a 'reasonable royalty' as "the amount that a willing licensor and licensee would bargain for at an arm's length hypothetical negotiation occurring on the date the infringement began."¹⁷⁵ Ironically, one of the main agenda items for reform is to clarify and reduce wayward damage awards. Contrary to the vague damage measure for reasonable royalty proposed under PRA07, the courts have established a less arbitrary fifteen factor test to ensure appropriate reasonable royalty calculation.¹⁷⁶ This test has been expanded in a recent case, *University of Pittsburgh v. Townsend*, to protect the intellectual property of universities, the sale

¹⁷¹ Associated Press, *Brazil to break Merck AIDS-drug patent*, May 4, 2007, <http://www.msnbc.msn.com/id/18490388/> (last accessed Apr. 5, 2008).

¹⁷² In terms of reasonable royalties, the PRA07 states that the calculation rate only applies to the "economic value properly attributable to the patent's specific contribution over the prior art" and the "court shall exclude from the analysis the economic value properly attributable to the prior art, and other features or improvements, whether or not themselves patented, that contribute economic value to the infringing product or process." H.R. 1908, 110th Cong. Sec. 5(a)(1)(b)(2) (2007).

¹⁷³ *Id.*

¹⁷⁴ Currently, a reasonable royalty is based on adequate compensation for the infringement for the use made by the infringer. See 35 U.S.C. §284 (2007).

¹⁷⁵ *Proctor & Gamble, Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 606 (D. Del. 1997).

¹⁷⁶ The *Georgia-Pacific* factors have consistently been applied as the methodology to calculate reasonable royalty damages since that decision was made in 1970. *Id.* at 606-07.

of which tends to be restricted by legislation known as the Bayh-Doyle Act.¹⁷⁷ In the *Pittsburgh* case, the court held that “the Georgia-Pacific factors and the assessment of a reasonable royalty rate ‘fit’ within the facts of this case. . . and that the Georgia-Pacific factors are a reasonable and reliable way to assess such a royalty.”¹⁷⁸ Yet, proponents of the PRA07 point to other alleged flaws in the current patent system, such as awarding the entire market value of an infringed patent.¹⁷⁹

Under the current patent system, courts have the discretion to award the entire market value of a product containing an infringed patent to the owner of the patent.¹⁸⁰ In his testimony, law professor John Thomas emphasized the \$1.52 billion damage award granted to Alcatel-Lucent for patent infringement committed by Microsoft.¹⁸¹ However, since his testimony, the court system has corrected this inequity on appeal. The court on appeal held “there was insufficient evidence to establish the required nexus between the patented features and the value of the entire computer and therefore, the jury’s application of the entire market value rule to the computer was unsupported as a matter of law.”¹⁸² Furthermore, the appellate court reinforced the proper application of the *Georgia-Pacific* fifteen factor test for calculating reasonable royalties and granted Microsoft a new trial on that matter since “the jury’s verdict was against the clear weight of the evidence.”¹⁸³ Essentially, the court system

¹⁷⁷ One such case involved the licensing of a medical scanning device developed by the University of Pittsburgh. Generally, universities cannot sell or assign intellectual property developed with federal grant funds because the Bayh-Doyle Act prohibits this behavior, but allows licensing of the property for a fee. *University of Pittsburgh v. Townsend*, 2007 WL 1002317 (E.D. Tenn. 2007).

¹⁷⁸ *Id.* at 24.

¹⁷⁹ Testimony of Law Professor John R. Thomas, *Hearing on the Patent Reform Act of 2007*, April 26, 2007, available at <http://judiciary.house.gov/media/pdfs/Thomas070426.pdf> (last accessed Apr. 6, 2008).

¹⁸⁰ *Id.*

¹⁸¹ *Id.* at 3.

¹⁸² *Lucent Technologies, Inc. v. Gateway, Inc.*, 509 F. Supp. 912, 937-38 (S.D. Cal. Aug. 6, 2007). Although Gateway is listed in the case title, Microsoft was a co-plaintiff.

¹⁸³ *Id.* at 940.

worked effectively, despite all those who cried wolf before the case had fully processed through the legal system. The PRA07 has not completely overhauled the potential for awarding the entire market value of a patent infringement like it has with the reasonable royalty system.¹⁸⁴ Although the entire market value rule still exists, the PRA07 has eviscerated its effectiveness and application by requiring a stringent standard. Specifically, the PRA07 states that the entire market value rule may only be applied when “the patent’s specific contribution over the prior art is the predominant basis for market demand for an infringing product or process.”¹⁸⁵ This rule, like the reasonable royalty damage award system proposed, could permit an astute patent infringer to subtract prior art from the damage award by arguing to limit his infringing product or process down to a minuscule shell of the patent allegedly being infringed and thus benefit from being an intelligent thief. In heavy science/research intensive fields this could be very threatening to companies that wish to protect their intellectual property patent rights. The proposed damage reform measures taken together with the unclear proposed first-to-file standards place much doubt on the viability of PRA07 adoption in its current form and express the potential dangers of a hasty solution.

V. Alternatives and Recommendations in the Global Common Interest

The abandonment of a mostly functional patent system for the constrained, arbitrary and abstract damage system and filing standards proposed under the PRA07 simply for the sake of reform is a rash and dangerous action. However, this is not to say the entire spirit of the PRA07 should be discarded and forgotten. Domestic patent reform should be actively pursued, but more considerations need to be made for the multitude of actors, domestically and internationally affected by U.S. legislative externalities. Clearly, the

¹⁸⁴ Under the proposed PRA07, a court is permitted to award damages “based upon the entire market value of products or processes involved that satisfy that demand” when certain qualifications are met. H.R. 1908, Sec. 5(a)(1)(b)(3) (2007).

¹⁸⁵ *Id.*

American patent system has a number of problems relating to over monopolization through patent abuse. Despite these problems, rushing to patch up a leaking Hoover Dam with bubble gum will only result in tremendous future heartache -- literally, given the potential dangers to medical innovation. Companies in the pharmaceutical industry that have massive vested financial interests in the development of a single new drug could see their works stolen and themselves facing tremendous losses. This danger is aggravated by the already existent problems that pharmaceutical companies face in developing countries regarding the protection of their products. Due to international patent protection problems, developed countries (particularly within the U.S. and E.U.) have long been the vanguard of profits for the pharmaceutical/medical research industries because of high disposable incomes.¹⁸⁶ Thus, assaulting this last stronghold of profits could severely debilitate future disease research efforts.

In the U.S., it would seem that a better solution across the board would be to adopt a two-tiered approach to domestic patent reform. It would not be very impractical to give both coalitions (IT and pharmaceutical/biomedical) most of what they want and thus indirectly protect international public health by maintaining the economic incentives that lead to new medical/pharmaceutical research while minimizing the impact from patent trolling on the IT side. Exceptions for pharmaceuticals under U.S. patent law are not new and therefore it is not odd to consider adding an additional exception if the benefit conferred outweighs the additional burdens imposed.¹⁸⁷ To begin with, if the U.S. wants to truly harmonize with the international patent community, the problematic issue of software patents would need to be addressed. Alleged and actual 'outlandish' damage awards for patent infringement can be avoided by increasing the standards of patentability, starting with software patents. As opposed to implementing broad reforms, such as suggested by the PRA07, such measures should filter out pharmaceutical and chemical

¹⁸⁶ See *Pharma 2020*, *supra* note 35.

¹⁸⁷ For example, the U.S. grants extra time for pharmaceutical patents awaiting FDA approval. WIPO, *United States of America*, in WIPO Index of Patent Systems (May 2005), available at http://www.wipo.int/export/sites/www/ipstats/en/resources/pdf/united_states.pdf.

process patents. This exception for life sciences research will protect innovation in that sector (thus protecting live saving research) and still allow for addressing the concerns of the IT industry over junk patents and patent trolls.

Internationally, preserving domestic patent rights will help ensure continued innovation in the life sciences based on current R&D figures and capital investments mentioned earlier. However, developing countries should press for greater technology transfer while respecting patent property rights to prove that they can be responsible with technology that is transferred. In other words, if tech transfer continues to stall a dispute should be filed with the WTO DSM for developed country violations of article sixty-six and it is best that developing countries come with clean hands to augment their moral and legal arguments. To further protect developing country interests, the TRIPS Amendment should be adopted to fully legitimize export as well as import compulsory licensing for use by severely impoverished countries. Additionally, developed nations should recognize that *international health concerns are domestic health concerns too* and consider shortening patent lengths for revisited formulations of drugs by five years (*i.e.* subsequent protease inhibitor variants or alternative uses/repositioning; Viagra) while lengthening patents for completely new discoveries by five years or so (*i.e.* completely new AIDS treatment strategy).¹⁸⁸ It is estimated that an increase of five years for new discoveries can still result in decent gains (conservatively ~50%) despite a decrease in protection for reformulations.¹⁸⁹

Additionally, the first-to-invent standard should only be replaced if costs for patent filings were increased proportional or progressively to prevent firms from engaging in aggressive over-filing for inefficient monopolization purposes.¹⁹⁰ This could be done through an income measurement device, as opposed to a flat rate fee

¹⁸⁸ This concept of patent shortening and lengthening for certain categories of pharmaceuticals has been suggested by external industry analysts. See *Pharma 2020*, *supra* note 35, at 8.

¹⁸⁹ *Id.*

¹⁹⁰ See Nate Anderson, *supra* notes 16 and 17.

of \$500 per patent application.¹⁹¹ The PRA07 considers income sensitivity issues somewhat in terms of patent search and review for applications.¹⁹² Five hundred dollars (more with the additional burden just mentioned) to a research behemoth such as IBM is little, but could be a lot to a creative individual who lacks the institutional capacity to become a patenting machine. The option of adopting first-to-file to harmonize with the international community while still protecting the natural law right to the fruits of one's labor is feasible if executed appropriately. Innovation can be promoted by drafting a domestic patent reform bill that takes into account the very diverse industries that engage in patenting behavior. International patent protections can best be served by a balanced incentive structure for developing countries and global pharmaceutical firms. Global patent reform is on the horizon, but one cannot become so blinded by a goal so as to recklessly pursue it for the sake of achieving the goal without considering the externality effects of their actions.

¹⁹¹ *Id.*

¹⁹² Inventors with incomes less than 2.5 times the national median income are not required to conduct their own search report and patent analysis when submitting a patent applicant. H.R. 1908, Sec. 12 (2007).