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Get the Balance Right!: Squaring Access with Patent Protection

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Get the Balance Right!: Squaring Access with Patent Protection

Kristen Osenga*

Presented in March 2011 at the University of the Pacific, McGeorge School of Law Symposium on The Global Impact and Implementation of Human Rights Norms.

*Be responsible, respectable,
Stable but gullible
Concerned and caring, help the helpless
But always remain ultimately selfish
Get the balance right, get the balance right!*

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I. INTRODUCTION

There is a typical story, summed up by the lyrics above, that is told when considering the impact of intellectual property rights on human rights. To achieve the human rights goal of access to health, medications must be accessible to those

* Associate Professor, University of Richmond School of Law. This Article is based, in part, on remarks made at “The Global Impact and Implementation of Human Rights Norms” symposium, held at University of the Pacific, McGeorge School of Law in March 2011.

1. DEPECHE MODE, *Get the Balance Right!*, on PEOPLE ARE PEOPLE (Sire Records 1984).

who cannot otherwise obtain them. Think antiretroviral therapies and other medications related to the treatment of HIV/AIDS, particularly in African nations.² Intellectual property rights that often cover these therapies make the drugs prohibitively expensive, especially in regions where the per capita annual healthcare expenditure is less than a couple of coffee shop lattes.³ The flip-side to this story is the one told by pharmaceutical companies, often in response to being portrayed as greedy. Pharmaceutical development, particularly to bring a new drug from discovery to United States Food and Drug Administration (“FDA”) approval, costs a lot of money.⁴ Intellectual property rights are simply necessary to recoup some of these costs and keep drug companies profitable and in business.

The conflict between intellectual property rights and human rights is longstanding. As a general rule, intellectual property rights award the grantee some powers of control or exclusion over the subject matter created or invented.⁵ Human rights norms, though, speak in terms of access, not restrictions. Consider, for example, documents such as the Universal Declaration of Human Rights (“UDHR”) and the International Covenant on Economic, Social, and Cultural Rights (“ICESCR”); both of these provide, among other things, that every person has the right to health, food, and education.⁶ Many commentators look at this bipolar system of exclusion and access and contend that one of the objectives

2. Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1140 (2007).

3. Lisa Anderson, *The Conflict Between Intellectual Property Rights of Pharmaceutical Companies and the Right to Health of AIDS Victims in South Africa*, GLOBAL POL. NETWORK, http://www.globalpolitics.net/essays/Lisa_Anderson.pdf (last visited Mar. 6, 2012); see, e.g., *Global Health Observatory Data Repository: Health Expenditure Ratios*, WORLD HEALTH ORG. (2011), <http://apps.who.int/ghodata/?vid=> (stating the annual per capita expenditure on health in 2009 at an average exchange rate of U.S. dollars in Ethiopia was \$15; in Niger, \$21; and in Liberia, \$29). Of course, it is not just African nations that report this level of health expenditures. For example, the annual per capita expenditure on health in Bangladesh in 2009 was \$18; in Pakistan, \$23; and in Haiti, \$40. *Id.* The United States, in comparison, spent an average of \$7,410 per person in health expenditures in 2009. *Id.*

4. See, e.g., HUGH B. WELLONS ET AL., *BIOTECHNOLOGY AND THE LAW* 204 (2007) (estimating that bringing a drug from development through regulatory approval and to market costs nearly \$900M).

5. See, e.g., HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 13.2 (2002) (“The purpose of intellectual property rights is to encourage innovation by granting their owner a reward better than it could obtain in a competitive market.”).

6. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc A/RES/217(III), art. 25-26 (Dec. 10, 1948) [hereinafter UDHR]; International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp No. 16, at 49, U.N. Doc. A/6316 (1966) [hereinafter ICESCR]. As if intellectual property rights and human rights were not already sufficiently in competition, human rights documents also call for every creator to have rights in her invention or work, although most commentators view this as a somewhat weaker obligation. See UDHR, *supra*, at art. 27(2) (“Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”); see ICESCR, *supra*, at art. 15(1)(c) (providing for an author to “benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”); see also Yu, *supra* note 2, at 1041-42.

must yield—some contend that the human rights goals can only be achieved by weakening intellectual property rights, while others assert that these goals can be accomplished only through increased innovation driven by heightened intellectual property rights.⁷ Although this conflict certainly supports the story being told, perhaps there is more to it. By looking at the rest of the story, it is possible to better square intellectual property rights with human rights.

This essay will proceed in three parts. Section II will discuss the two sides of the conflict—intellectual property rights, more specifically patents,⁸ and human rights. This section will also cover some of the aspects that have been left out of the familiar story. Section III will explain the current balance between patent rights and human rights, focusing mainly on compulsory licensing. This section will also describe how certain current events are tipping the balance toward human rights and away from intellectual property rights in a potentially detrimental fashion. Finally, Section IV will show that, in all the hoopla, a couple of key points are being missed. The essay concludes with some ideas about how to get the balance right.

II. COMPETING INTERESTS: PATENTS AND ACCESS

At least according to the traditional story, patent rights groups and human rights advocates are talking past each other or, perhaps worse, screaming at each other.⁹ Before looking into the interaction between the parties, however, it is helpful to consider each side's respective position.

A. *Patents to Promote Innovation and Disclosure*

A patent is basically a property right, granted by a government, that provides its holder with exclusive rights, including the ability to prevent other parties from making, using, selling, or offering the invented technology for sale in, or importing it into, the country that granted the patent.¹⁰ A patent, however, does

7. See, e.g., Sharon E. Foster, *Prelude to Compatibility Between Human Rights and Intellectual Property*, 9 CHI. J. INT'L L. 171, 171 (2008); see also David Weissbrodt & Kell Schoff, *Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7*, 5 MINN. INTELL. PROP. REV. 1, 26 (2003).

8. Although there is a similar conflict between intellectual property rights and access in the copyright realm, this Essay focuses on patents. For recent examples of copyright/human rights analysis, see Lea Shaver & Caterina Sganga, *The Right to Take Part in Cultural Life: On Copyright and Human Rights*, 27 WIS. INT'L L.J. 637 (2010); Mary W.S. Wong, *Toward an Alternative Normative Framework for Copyright: From Private Property to Human Rights*, 26 CARDOZO ARTS & ENT. L.J. 775 (2009).

9. See Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1049 (2009) ("Public discussions of compulsory licenses not only include quick dismissals of opposing views, but outright hostility and name calling.").

10. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 28, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS].

not grant any positive rights, nor are the rights absolute;¹¹ any rights granted by a patent can be restricted or subjected to other regulation.¹² Consider, for example, the pharmaceutical industry: a patent on a drug does not provide the patent holder the right to make or sell the drug, because that right may be determined by a governmental agency, such as the FDA in the United States.¹³ A patent only allows the patent holder to prevent other manufacturers from making and selling a product covered by the patent during its term.¹⁴ With this right of exclusion may come the ability to set monopoly pricing or otherwise restrict access to the patented invention.

While the human rights side is quick to point to the ability of the patent holder to set monopolistic prices or otherwise thwart ready availability, the positive aspects of patenting often go unnoticed.¹⁵ There are at least three common justifications for awarding patent rights that may have positive effects for human rights: incentive to invent, incentive to innovate, and incentive to disclose.

First, patents are granted to incentivize invention.¹⁶ Inventors generally have limited time and resources; choosing where to spend the time and resources will depend on where the inventor expects to get the most value.¹⁷ In the case of a user-inventor, his time and resources will be spent fixing a problem immediate to the inventor. An example of this would be a farmer who comes up with a spring mechanism for his plow because he is tired of breaking it when plowing over stones in his field.¹⁸ But where the inventor is not trying to solve his own problem, he will want to spend his resources on a project from which he is likely to benefit, most likely financially. The grant of a patent gives the inventor a period of exclusivity where he has the opportunity to recoup the costs associated with his inventing, and potentially even profit, before his competitors can exploit the fruits of his invention without having sunk the development costs themselves. The limited monopoly granted by a patent may be one reason that pharmaceutical companies endeavor to develop drugs specific to less-wealthy parts of the world.¹⁹

11. See Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact From Fiction Under TRIPS*, 34 N.C.J. INT'L L. & COM. REG. 371, 381 (2009).

12. See *id.*

13. The FDA administers the Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-399D (2006). Specifically, the FDCA prohibits the introduction of new drugs without FDA approval. 21 U.S.C. § 355.

14. See, e.g., 35 U.S.C. § 154 (2006).

15. See Yu, *supra* note 2, at 1076.

16. See David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMPLE L. REV. 181, 195-96 (2009).

17. See *id.*

18. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966); see also John F. Duffy & Robert P. Merges, *The Story of Graham v. John Deere Company: Patent Law's Evolving Standard of Creativity*, in INTELLECTUAL PROPERTY LAW STORIES 109 (Jane C. Ginsburg & Rochelle Cooper Dreyfuss eds., 2005).

19. Consider, for example, the heat-stable formulation of Kaletra®, a protease inhibitor used in the

Second, patents are granted to induce companies to invest in innovation.²⁰ Innovation is broader than invention, in that it includes activities such as developing and testing a commercial embodiment of the new technology, marketing and selling the new technology, and making improvements on the new technology.²¹ The limited monopoly granted by a patent allows the patent holder to spend resources to innovate in the space around the new technology, developing improvements or related technologies, again having the monopoly period to recoup his expenditures. Without the patent right, it is possible that fewer new technologies would be brought to market and thus be available and accessible to the public.

Third, patents are granted to encourage disclosure of new technologies.²² It is not merely enough that new technologies are discovered and honed; in order for science to advance, the knowledge must be made available for subsequent researchers to build upon. One of the better statements of this concept is the famous quote by Sir Isaac Newton: "If I have seen further it is only by standing on ye shoulders of Giants."²³ The patent system helps make this possible, because an inventor must make a sufficiently detailed disclosure of the technology to qualify for a patent.²⁴ Without receiving the benefit of a patent, an inventor may choose to keep knowledge of his new technology secret.²⁵ In keeping it secret, the inventor may have an advantage over his competition that may allow him to recoup his development costs. However, if he keeps it secret, another inventor may waste resources trying to discover the same technology, delaying and making more expensive the progress of additional technology—technology that may improve the lives of people around the world.²⁶

Thus, although the human rights side generally argues that patents decrease access to necessary technologies, there are a number of reasons why patents actually have a positive impact on availability and access.

treatment of HIV/AIDS. The particular formulation is especially useful in developing countries because the original formulation degrades rapidly in warm temperatures. *See, e.g.,* Keith Alcorn, *MSF Calls For Rapid Registration of Heat-Stable Kaletra in Low-Income Countries*, AIDS MAP (Mar. 16, 2006), <http://www.aidsmap.com/MSF-calls-for-rapid-registration-of-heat-stable-Kaletra-in-low-income-countries/page/1423332/>.

20. *See, e.g.,* Robert P. Merges & Jeffrey M. Kuhn, *An Estoppel Doctrine for Patented Standards*, 97 CAL. L. REV. 1, 24 (2009).

21. *See, e.g.,* Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 366 (2010).

22. *See, e.g.,* *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

23. *See* THE CORRESPONDENCE OF ISAAC NEWTON: VOLUME I, 1661-1675, at 416 (H.W. Turnbull ed., 1959).

24. *See* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1186 (2000) (stating that the "quid pro quo for the grant of a patent is the statutorily-mandated disclosure that adds to the store of public knowledge").

25. *See, e.g.,* *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) ("As a reward for inventions and to encourage their disclosure, the United States offers a [limited] monopoly to an inventor who refrains from keeping his invention a trade secret.").

26. *See, e.g.,* Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2009-10 (2005).

B. Access to the Fruits of Innovation and Disclosure

While the patent side of the conflict is focused on discovering, developing, and commercializing new technologies, the hallmark of human rights is access. The portions of the key human rights documents relevant to this discussion (the UDHR and the ICESCR) provide that every person should have access to certain “things”—food, clothes, shelter, and healthcare, among others.²⁷ These documents also call for all persons to have access to the benefits of scientific advancements.²⁸

Certainly, it is difficult to argue with these goals. And if these goals were the driving force behind much of the human rights side of the story, the tale may well be very different. Unfortunately, some human rights supporters are unabashedly “anti-property activists and patent hooligans.”²⁹ But even if patents were abolished, human rights concerns of access and availability would persist. As just one simple example, providing access also requires distribution. Distribution of pharmaceuticals or other technologies faces an uphill battle in some cases, far and above the barrier caused by the existence of patents.³⁰ At the very least, there must be management of the distribution process and infrastructure to effectuate it.³¹ Beyond that, there are cultural and historical issues that must be overcome in order for the medication or other technology to be accepted by those it is intended to help.³² To assert that only intellectual property rights are preventing people from accessing the “things” to which all people are entitled is naïve and only a small part of the story.

27. UDHR, *supra* note 6, at art. 25(1) (“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services”); ICESCR, *supra* note 6, at art. 11(1) (recognizing “the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing”).

28. UDHR, *supra* note 6, at art. 27(1) (“Everyone has the right freely . . . to share in scientific advancement and its benefit.”); ICESCR, *supra* note 6, at art. 15(1)(b) (recognizing the right “[t]o enjoy the benefits of scientific progress and its applications”).

29. See Ho, *supra* note 9, at 1049 (“Patent-owning pharmaceutical companies are called greedy corporations that place profits above life, whereas public health advocates are decried as anti-property activists and patent hooligans.” (internal citations omitted)); Ronald A. Cass, *Patent Remedy*, WALL ST. J. ASIA, Aug. 28, 2007, at 13 (noting that some human rights activists “oppose protection of all property rights”).

30. Clark A.D. Wilson, *The TRIPS Agreement: Is It Beneficial to the Developing World, or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers?*, 10 J. TECH. L. & POL’Y 243, 261-62 (2005).

31. See Kara M. Bombach, Note, *Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement*, 19 B.U. INT’L L.J. 273, 286-87 (2001).

32. See Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*, 37 J.L. MED. & ETHICS 209, 216 (2009).

III. THE CURRENT BALANCE: HEADING TO A TIPPING POINT

While there may be a small amount of truth to the story that intellectual property rights interfere with global access to food, shelter, healthcare and the like, by looking at the rest of the story it is clear that not all patents are bad, and not all that is bad is caused by patents.³³ Still, the existence of this conflict between patent holders and those seeking to provide access has compelled provisions in a number of international agreements involving intellectual property. The most important international document involving patent law and human rights is the World Trade Organization (“WTO”) Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), which sets forth, among other things, patent law minimums for all member nations of WTO.³⁴ Even developed and developing nations have agreed to the requirements of TRIPS to get the benefits of WTO membership.³⁵

TRIPS is generally considered to be a pro-patent agreement,³⁶ but its impact on human rights is less well-defined. Scholars have argued about whether TRIPS improves or hinders access to the fruits of invention.³⁷ Proponents of TRIPS argue that heightened patent protection is required to promote innovation, which will improve developing countries generally, thereby encouraging investment in these countries. Opponents suggest that requiring patents—worldwide and for all technologies—will necessarily increase the costs of goods and services and, ultimately, compromise access. In any case, countries are trying to work within the TRIPS agreement to effectuate human rights.³⁸

A. Access Under TRIPS

Prior to the implementation of TRIPS in 1995,³⁹ countries were only required to honor patents reciprocally.⁴⁰ Under this regime, countries could opt not to

33. The term “bad patents” typically refers to patents that should not have been granted by the Patent Office. However, in this context, I am referring colloquially to the fact that patents may, to a small extent, interfere with human rights goals.

34. See Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1473 (2007) (calling TRIPS the “cornerstone of global IP laws”).

35. *Id.* For a list of developing countries that have joined and are joining onto TRIPS, see *Frequently Asked Questions About TRIPS in the WTO: Which Countries Are Using the General Transition Periods?*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#Transition (last visited Mar. 6, 2012).

36. See Ho, *supra* note 34, at 1470.

37. See, e.g., Wilson, *supra* note 30.

38. *Id.* at 261-63.

39. TRIPS, *supra* note 10. Developing countries were granted an additional five-year grace period to phase in most of the TRIPS requirements, while least-developed countries received an eleven-year grace period. See *id.* at art. 65(2), 66(1).

40. See, e.g., Jamie Crook, *Balancing Intellectual Property Protection with the Human Right to Health*, 23 BERKELEY J. INT’L L. 524, 531 (2005).

provide patent protection to certain inventions, such as pharmaceuticals or software.⁴¹ Countries concerned about providing access to drug therapies, for example, could simply opt not to grant patents for them, thereby avoiding the restrictions and potentially higher prices that may come with the patent. One of the main consequences of TRIPS, however, is the imposition of minimum standards of intellectual property protection in member states;⁴² one provision specifically states that patents “shall be available for any inventions, whether products or processes, in *all fields of technology*.”⁴³ This means countries can no longer try to promote access by failing to recognize intellectual property rights of certain types of technologies.

Although TRIPS sets forth a minimum level of patent protection that must be provided (subject to patentability requirements), it also includes a couple of exceptions to patent rights, as well as a means for compulsory licensing of patent rights.⁴⁴ Human rights activists have attempted to use the flexibility provided by these exceptions and compulsory licensing systems to ease the conflict between intellectual property rights and human rights, with varying levels of success.⁴⁵

1. Exceptions to Patent Rights

TRIPS does provide for two exceptions to the requirement that exclusive rights be granted for any invention that meets patentability requirements: first, an exception may be made for inventions within certain limited subject matters, and second, an exception known as the “limited exception” provision.⁴⁶ The subject matter exception is covered by three paragraphs in TRIPS, specifically article 27(3)(a) and (b) and article 27(2).⁴⁷ Article 27(3)(a) permits nations to exclude methods of medical diagnosis and treatment from being granted exclusive patent rights.⁴⁸ This exception is limited to methods; it cannot be used to prohibit patenting of drug therapies or other “things.” Article 27(3)(b) allows for nations to prohibit granting patent rights for inventions of plants and animals other than microorganisms.⁴⁹ Although this provision cannot be used to except pharmaceuticals from coverage, this provision may be useful for ensuring access to genetically modified plants, which can aid in increasing access to food. Finally, Article 27(2) allows for nations to deny patent rights to inventions

41. See *id.*

42. See Ho, *supra* note 34, at 1470.

43. See TRIPS, *supra* note 10, at art. 27(1) (emphasis added).

44. See, e.g., Ho, *supra* note 34, at 1475-77, 1480-94 (demonstrating flexibilities in patentability requirements that are being exploited).

45. See, e.g., *id.* at 1485-89.

46. See TRIPS, *supra* note 10, at art. 27, 30.

47. See *id.* at art. 27.

48. See *id.* at art. 27(3)(a).

49. See *id.* at art. 27(3)(b).

against *ordre public*, or fundamental principles.⁵⁰ This exception is limited, with the exception itself providing guidance that it should be used in cases of “protect[ing] human, animal, or plant life, or health, or to avoid serious prejudice to the environment.”⁵¹

Second, Article 30 allows for “limited exceptions” to exclusive rights, subject to the following requirements: the “exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”⁵² This provision has been given a very narrow interpretation by the WTO.⁵³ One example of a WTO panel finding a limited exception to be appropriate is a Canadian safe harbor provision that allows for generic pharmaceutical companies to manufacture and test drugs while on patent so that they can hit the ground running when the drug goes off patent.⁵⁴

Both of these exceptions, while they appear to inject flexibility into the system that may help human rights concerns of access, are very narrow and have met little success. More often, human rights folks are taking aim at patent rights using the compulsory licensing provision of Article 31.

2. Compulsory Licensing of Patent Rights

The subject matter exception and the limited exceptions provision are very narrow and do not apply to most technologies that would be of greatest benefit to meeting human rights needs. However, TRIPS also contains a provision that permits compulsory licensing.⁵⁵ In short, if a nation invokes a compulsory license, the nation is permitted to use (or may authorize a third party to use) a patented invention without permission of the patent holder.⁵⁶ It is not a free taking; the invoking nation must pay a government-imposed royalty rate that is usually well below the rate a patent owner would have negotiated for.⁵⁷

All countries that are members of the WTO are expressly permitted to exercise this right, but political pressures and trade sanctions have kept compulsory licenses quite limited.⁵⁸ For example, a number of wealthier nations have publicly stated they do not wish to take advantage of the compulsory license

50. *See id.* at art. 27(2).

51. *See id.*

52. *See id.* at art. 30.

53. *See* Ho, *supra* note 34, at 1481.

54. *See id.* at 1481-83.

55. *See* TRIPS, *supra* note 10, at art. 31. *But see* Ho, *supra* note 34, at 1484.

56. *See, e.g.,* Carlos M. Correa, *Pro-Competitive Measures Under the TRIPS Agreement to Promote Technology Diffusion in Developing Countries*, 4 J. WORLD INTELL. PROP. 481, 489 (2001).

57. *See* Crook, *supra* note 40, at 531; Ho, *supra* note 11, at 407.

58. *See* Ho, *supra* note 11, at 443-50 (discussing industry retaliation and international trade sanctions).

provision, although they may find themselves hamstrung if some serious issue, such as the anthrax scare in 2001, were to arise.⁵⁹

For nations that choose to invoke compulsory licenses, each authorization must be considered on its individual merits, meaning that it must be limited to a specific technology, not an entire class or category.⁶⁰ For example, a government can authorize a compulsory licensing of Kaletra®, a specific HIV/AIDS therapy, but could not authorize a compulsory licensing of all anti-retroviral therapies. The scope and duration of the license shall also be limited “to the purpose for which it was authorized.”⁶¹ This provision has been interpreted to mean that there can be no modifications after the license is invoked; other interpretations require the duration and scope to be listed in the grant of license itself.⁶²

Article 31 lays out a set of procedural requirements for granting a compulsory license.⁶³ Paragraph (b) requires that “the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”⁶⁴ The default rule is prior negotiation, but there is no definition of “reasonable.” Even if reasonability were defined, there are broad exceptions to the negotiation requirement: in particular, prior negotiation may be waived in case of national emergency, extreme urgency, or in cases of public non-commercial use.⁶⁵ Again, there are no definitions of national emergency or extreme urgency, nor is a public non-commercial use explained. The Doha Declaration, an agreement made subsequent to TRIPS,⁶⁶ provides guidance on interpreting two of these exceptions to the prior negotiation requirement. The Doha Declaration provides “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics” as illustrative of national emergencies or circumstances of extreme urgency.⁶⁷ However, the Doha Declaration also affirms that it is within each member’s discretion to determine what it believes is a national emergency or circumstance of extreme urgency.⁶⁸

59. See Ho, *supra* note 34, at 1471.

60. See TRIPS, *supra* note 10, at art. 31(a).

61. See *id.* at art. 31(c).

62. See Ho, *supra* note 11, at 404-07.

63. See TRIPS, *supra* note 10, at art. 31.

64. See *id.* at art. 31(b).

65. See *id.*

66. See World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration]. The Doha Declaration is most well known for its waiver provision that allows for a country with manufacturing capabilities to export technology into a second country requiring a compulsory license. This waiver allows skirting of TRIPS Article 31(f) that required use to be authorized “predominately for the supply of the domestic market of the Member authorizing such use.” This provision made compulsory licensing almost an illusory answer, because the countries in most need of requiring compulsory licenses were in the worst position to manufacture the technology for their own use. See Ho, *supra* note 34, at 1489-90.

67. See Doha Declaration, *supra* note 66, at para. 5(c).

68. See *id.*

The government is also required to pay the patent holder “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”⁶⁹ However, the level of “adequacy” is not defined. Perhaps countries could use the compulsory licensing scheme to exact a price that they otherwise would not have obtained through voluntary negotiation with the patent holder.⁷⁰

B. Thailand—Tipping Too Far?

In cases where one party’s rights are subjugated to another party’s needs, it is nearly inevitable that the taking party will turn the inch into a mile. A recent example of this phenomenon took place in Thailand.

Thailand, via its National Health Security Act, has a mandate to provide access to essential medicine to all of its citizens.⁷¹ To achieve this mandate, Thailand invoked a number of compulsory licenses in 2006 and 2007.⁷² The initial licenses followed the traditional story. Thailand first issued a compulsory license on the patented HIV/AIDS therapy Stocrin® (efavirenz).⁷³ In obtaining this license, Thailand noted that it had a public interest in achieving its universal health mandate, that it was not seeking a compulsory license for commercial purposes, and that without a compulsory license, it simply could not cover the cost.⁷⁴ The following year, Thailand issued a compulsory license for Kaletra®, another HIV/AIDS drug.⁷⁵ Without the license, this medication would cost \$2,200 per patient, per year—the yearly income of an average Thai citizen.⁷⁶ At this price, the drug would have been inaccessible to most that needed it.⁷⁷

These licenses, however, are not the ones that made headlines. Thailand also issued a compulsory license for the drug Plavix®, used to treat heart disease.⁷⁸ Thailand reasoned that, because heart disease is one of the top three causes of death in the nation and because only twenty percent of patients could access the medicine in the absence of the compulsory licenses, issuing the license was consistent with Thailand’s mandate.⁷⁹ The country then announced it was

69. See TRIPS, *supra* note 10, at art. 31(h).

70. See Ho, *supra* note 11, at 410.

71. See *id.* at 411.

72. See *id.* at 413-14.

73. See *id.* at 413.

74. See *id.*

75. *Id.* at 413-14.

76. See *id.* at 414.

77. *Id.* at 413-14.

78. See *id.*

79. See *id.*

considering issuing (and eventually did issue) compulsory licenses on a number of cancer medications, again claiming that its mandate required it to do so.⁸⁰

These compulsory licenses drew much ire.⁸¹ First, they were not drugs to treat infectious diseases and prevent further outbreak.⁸² Second, the royalty rate set by Thailand was approximately one-half of one percent of the sale price of the medications.⁸³ Third, Thailand is considered to be nearing middle-income status.⁸⁴

Numerous trading partners of Thailand, such as members of the European Union, complained.⁸⁵ The United States moved Thailand up in its Special 301 report.⁸⁶ Patent holders retaliated by taking drugs off the market in Thailand.⁸⁷ Despite these repercussions, Thailand did not back down from its compulsory licenses.⁸⁸

IV. GETTING THE BALANCE RIGHT!

Both sides of this conflict between intellectual property rights and human rights have bought into the traditional tale, which is the starting point for a parade of horrors. The existence of patents will spell doom for access to medicine and other “things” that all people are entitled to. The compromise position of compulsory licenses will put patent holders out of business. Both sides of the conflict need to look beyond the traditional story and realize that their positions can be balanced. Here are some suggestions that may help to get the balance right.

First, patent holders need to realize that compulsory licensing will not necessarily be their ruin. With respect to pharmaceuticals, many nations did not even permit patent protection on these technologies prior to TRIPS—drugs simply could not be patented.⁸⁹ And yet, these companies continued to invent and innovate drugs, recouping their costs through differentiated pricing in other markets.⁹⁰ Further, patent holders need to stop claiming that they will be unable to develop new drugs if compulsory licensing continues. Empirical data is equivocal on whether compulsory licensing dampens innovation. Few studies address the issue, and in the ones that do, innovation is not shown to be

80. *See id.* at 415-16.

81. *U.S. Chides Thailand for Overriding Drug Patents*, REUTERS (Apr. 30, 2007, 5:37 PM), <http://uk.reuters.com/article/2007/04/30/health-usa-thailand-trade-patents-dc-idUKN3041525120070430>.

82. *See Ho, supra* note 11, at 419-24.

83. *See id.* at 438.

84. *See id.* at 457-58. Middle-income status may be a misnomer—in these countries there is often a wide disparity of income, such that only a very small population would be able to afford premium drug costs.

85. *See id.* at 378.

86. *See id.* at 448.

87. *See id.* at 444.

88. *See Ho, supra* note 9, at 1065.

89. *See Ho, supra* note 11, at 453.

90. *See id.*

negatively impacted.⁹¹ Even less is known about the effect of compulsory licensing in one country on innovation generally.

Second, both patent holders and human rights activists need to realize the breadth of technologies that could fall within compulsory licenses and realize that the compromise that led to compulsory licenses was not targeted particularly at the pharmaceutical industry. Medicines may instantly come to mind, but the list is not so limited. The right to food may be enhanced by new biotechnology inventions or irrigation systems; the right to shelter may benefit from new sewage treatment facilities. These are just a few of the many patented technologies that may have an impact on access and human rights. Compulsory licensing could cover these technologies too.

Third, both sides need to realize that there are a number of other issues that should be capturing their attention—areas where they should be allies. In the medical arena, particularly where there are differentiated pricing structures and compulsory licensing, grey market goods should be the real issue. Other medical concerns include the development of orphan drugs. And both the patent holder and the human rights activist could actively work together to improve distribution issues that will thwart any benefit of invoking a compulsory license. Outside the medical arena, there are areas such as biotechnology and improved food production, changes to agricultural habits, and genetically modified seeds.

By working together, rather than buying wholeheartedly into the traditional story, patent holders and human rights activists could work together to be responsible and help the helpless, while still protecting their own interests . . . in which case, they may finally get the balance right.

*Be responsible, respectable,
Stable but gullible
Concerned and caring, help the helpless
But always remain ultimately selfish
Get the balance right, get the balance right⁹²*

91. See, e.g., Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 288-89 (2008); Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853 *passim* (2003); F.M. SCHERER, *THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING* 84-88 (1977).

92. DEPECHE MODE, *supra* note 1.

