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COMMENT

SAVING TOMORROW FROM TODAY: PRESERVING INNOVATION IN THE FACE OF COMPULSORY LICENSING

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ABSTRACT

This Comment describes a compensation method for use with pharmaceutical compulsory licenses. Specifically, it proposes a method for determining "adequate remuneration" under the TRIPS agreement in a way that balances intellectual property rights with government obligations to promote the public health. Beginning with an introduction to U.S. patent law and its economic justifications, it describes the effects of U.S. policy choices on innovation within the U.S. pharmaceutical industry. Next, it describes the need for access to medicines in countries like South Africa and explains how patents block access in these countries—thereby necessitating compulsory licensing. Given the relationship between trade and intellectual property, this nexus is briefly described and followed by a short introduction to the TRIPS agreement and the subsequent Doha Declaration. With this background in mind, and confined by the TRIPS requirements, this Comment describes a method for determining "adequate remuneration" so that courts can balance the need for technological innovation with the need to access essential medicines, making both realities for the future.

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I. INTRODUCTION

There is an emerging trend in the world, and some paint it as a threat to our future welfare.[1] That trend is the growing use of compulsory licenses in order to provide domestic generic pharmaceuticals. These painters of a bleaker tomorrow complain not because compulsory licenses are forbidden, but because they are being used by the wrong parties and for the wrong reasons. Consequently, they warn, the widespread use of compulsory licenses could cost us our future pharmaceutical resources, leaving us defenseless against tomorrow's diseases.[2]

A compulsory license is not a popular solution to any problem, but it is one the international community has endorsed in limited circumstances. Recently, for example, the community has authorized its poorest countries to use compulsory licensing as a means for battling diseases like HIV/AIDS, but only after certain conditions are met.[3] As the critics point out though, some countries are exploiting this freedom. Rather than use compulsory licenses to promote the public health, some countries appear to be using them to lower the costs for their own domestic pharmaceutical industries. By doing so, these countries shift costs to others who have made substantial investments in research and, by denying them the opportunity to recoup those investments, are hindering ongoing efforts aimed at battling tomorrow's diseases.[4]

This shifting of costs was not the policy behind compulsory licenses for pharmaceuticals. Instead, the international community

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1. *See, e.g.*, *A Gathering Storm*, ECONOMIST, June 9, 2007, at 71.

2. *See id.* (quoting the chairman of Novartis as saying that " 'without intellectual property there is no innovation' ").

3. *See infra* Part III (discussing the current international compromise regarding compulsory licenses).

4. At the forefront of those bearing these costs are large pharmaceutical companies who, fearing they will lose their investment in research, warn that compulsory licenses deny them the resources necessary for continued innovation. Standing with them are countries like the United States who, having invested in intellectual property to drive technological innovation, lose their international trade advantages when their technology is seized by other countries despite these countries' capacity to pay. For a detailed discussion of the relations between compulsory licenses and their costs, see *infra* Part II.B.

adopted a policy that endorsed increased access to medicines for those who otherwise could not afford them by balancing access, which occurs through lower costs,[5] with innovation, which is driven by intellectual property (IP) protection.[6] In doing so, the international community empowered individual countries to make decisions regarding their own public welfare; but when some countries refuse to pay for their fair share of innovation, they upset the balance and put future medicines at risk. Moreover, because a compulsory license shifts costs, it distorts international trade and causes developed countries to implement trade barriers to protect their IP advantages. In the end, compulsory licenses are often blocked and their life-saving benefits denied to those who need them most.

Thus, there is a need to bring the international solution back into balance, and this Comment examines how to do so by interpreting the compensation standard at the consequential end of the compulsory license decision. Specifically, this Comment proposes a compensation standard that minimizes the cost-shifting aspects of a compulsory license so that research will not be hindered and trade will not be distorted. In doing so, it describes the essential conflicts in the international patent system, outlines the current international compromise, and concludes by proposing a method for compensation that will balance the interests at stake.

II. THE INTERNATIONAL PATENT SYSTEM: INNOVATION, ACCESS, AND TRADE

In the international arena, differing economic maturities spawn a very complex patent system. In a developed economy, patents vigorously protect technology because of policy choices sourced in the local interest, particularly that of the domestic innovator who relies on the patent to recoup investments in research and development.[7]

In a developing economy, however, there is less technology to protect, and the local interest resides not in protection of technology, but in access to technology so that it may be borrowed for the benefit of developing industry.[8] For this reason, patents are disfavored, but when patents protect medicines, their negative effects on the public health make them even less appealing. For example, in those developing countries that are helpless before diseases like

5. *See infra* Part III.

6. *See infra* Part II (outlining the role of patent protection in driving innovation and the role of compulsory licenses in improving access).

7. KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 102 (2000) (stating that inventors require stronger IP protection in a developed economy and drive demand for stronger IP rights).

8. *Id.* at 105 (explaining data that shows weak IP protection is correlated with developing economies).

HIV/AIDS,[9] patents raise the prices of essential medicines and put them out of reach for dying patients. This takes an unacceptable toll on the rights of individuals to life and health, and as more resources are directed to treating the disease, it cripples an already struggling economy.[10]

As a result, and as described below using the United States and South Africa as examples of countries from both ends of the economic spectrum, the conflicting local interests of the innovator and the struggling poor result in international pressures that materialize in international trade, eventually erupting into a conflagration.[11]

A. The U.S. Patent System and the Domestic Pharmaceutical Industry

The United States exemplifies a country with a well-developed economy and one that uses patents to protect its technology,[12] maximize its trade advantages,[13] and promote future innovation within its industries.[14] This latter goal underlies the application of its patent laws, and the resulting system, many argue, is essential to innovating tomorrow's medicines.[15]

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9. *See*, *e.g.*, JOINT U.N. PROGRAMME ON HIV/AIDS, 2006 REPORT ON THE GLOBAL AIDS EPIDEMIC 4 fig.1.1 (2006) [hereinafter 2006 JOINT U.N. PROGRAMME ON HIV/AIDS], *available at* http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2006 (displaying the growing number of orphaned children in sub-Saharan Africa as a result of HIV/AIDS on that continent).

10. *See generally* INTERNATIONAL TRADE AND HUMAN RIGHTS: FOUNDATIONS AND CONCEPTUAL ISSUES (Fredrick M. Abbott et al. eds., 2006) (containing articles that address the impact of patent protection on human rights). The social cost arises from the temporary grant of the monopoly to the innovator that accompanies the patent. By enabling the innovator to market his or her invention at a price higher than a directly competitive market would allow, the patent provides the innovator a certain degree of pricing power. Given this pricing power, there is the possibility that the innovator may price out a large segment of the population. When the patent is protecting medicines, this practice can harm the public health and, with it, economic productivity. *See infra* notes 85-90 and accompanying text.

11. *See infra* Part II.B.

12. *See* MASKUS, *supra* note 7, at 102.

13. *See* Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 369 (1993) ("Under the theory of comparative advantage, a nation competes by taking advantage of those production factors which they possess in abundance; thus nonprotection of intellectual property distorts trade, for it provides the pirate with an artificial competitive advantage.").

14. *See generally* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) (discussing the role of patents in spurring innovation in multiple industries, particularly in the pharmaceutical, biotechnology, computer hardware, and computer software industries).

15. *See infra* Part II.A.2.

1. The U.S. Patent System: Economic Justifications and Enforcement

Patents, as an exception to the monopoly prohibition,[16] are difficult to understand and enforce without also understanding the policy choices behind them. Existing at the intersection of the collective interest and the individual right,[17] they can be justified on several grounds.[18] Yet, while anyone analyzing their role within the overall economy may find it hard to endorse the creation of a patent system,[19] it survives because it provides an incentive for innovation that promotes the public good.[20] As the Court explained in *Mazer v. Stein*,[21] "[t]he economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance [the] public welfare through the talents of authors and inventors in 'Science and useful Arts.' "[22]

Accordingly, armed with this conviction[23] and constitutional empowerment,[24] Congress has enacted a statutory patent scheme[25] that strives to advance the public welfare through the disclosure of technical information[26] and provide incentives to invent[27] that harmonize

16. *See* 21 CONG. REC. 2457 (1890) (statement of Senator Sherman, sponsor of the Sherman Act) (describing the patent on the Senate Floor as "[a] limited monopoly secured by a patent right is an admitted exception, for this is the only way by which an inventor can be paid for his invention").

17. THE FEDERALIST NO. 43, at 238-39 (James Madison) (E.H. Scott ed., 1894) (describing the Constitution's patent and copyright clause as one sourced at the intersection of the individual right and the public good since "[t]he public good fully coincides in both cases, with the claims of individuals").

18. *See* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 2-20 (4th ed. 2006) (discussing multiple justifications, including those based on Natural Rights and Hegel's Property Theory, both of which are beyond the scope of this Comment).

19. *See* SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM, STUDY NO. 15 58-62 (Comm. Print 1958) (prepared by F. Machlup) [hereinafter ECONOMIC REVIEW].

20. *See* WENDY H. SCHACHT, CONG. RESEARCH SERV., PATENT REFORM: ISSUES IN THE BIOMEDICAL AND SOFTWARE INDUSTRIES 2 (2006) ("Patent ownership is perceived to be an incentive to innovation, the basis for the technological advancement that contributes to economic growth.").

21. 347 U.S. 201 (1954).

22. *Id.* at 219; *see also* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974) (describing the patent grant as an incentive for inventors to risk both time and effort in the development of new products and processes so that, as a result, the public will benefit through increased employment and better livelihood from their introduction into society).

23. *See supra* note 22 and accompanying text.

24. *See* U.S. CONST. art. I, § 8, cl. 8 (patent and copyright clause).

25. *See* 35 U.S.C. §§ 1-376 (2000).

26. *See* 35 U.S.C. § 112 (2000).

27. *See* SCHACHT, *supra* note 20, at 4 (describing the two policy goals of the patent system as encouraging inventors to disclose technical information while also providing them with an incentive to invent).

with its underlying philosophy.[28] Under this system, in exchange for the full disclosure[29] of a product or process[30] that is useful,[31] novel,[32] and nonobvious,[33] the inventor receives a patent whose accompanying bundle of rights is enforceable for twenty years after the patent's filing date.[34]

Amongst this bundle of rights, the most valuable is the right to exclude others from making or using the patented product or process.[35] This exclusionary right enables the patent holder to recoup the original investment in the patented invention by prohibiting others from practicing the invention and competing with the innovator

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28. According to the 1966 Report of the President's Commission on the Patent System, there are four major economic justifications underlying the patent system:

> First, a patent system provides an incentive to invent by offering the possibility of reward to the inventor and to those who support him. This prospect encourages the expenditure of time and private risk capital in research and development efforts.
> Second, and complementary to the first, a patent system stimulates the investment of additional capital needed for the further development and marketing of the invention. In return, the patent owner is given the right, for a limited period, to exclude others from making, using, or selling the invented product or process.
> Third, by affording protection, a patent system encourages early public disclosure of technological information, some of which might otherwise be kept secret. Early disclosure reduces the likelihood of duplication of effort by others and provides a basis for further advances in the technology involved.
> Fourth, a patent system promotes the beneficial exchange of products, services, and technological information across national boundaries by providing protection for industrial property of foreign nationals.

MERGES ET AL., *supra* note 18, at 17.

29. 35 U.S.C. § 112 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.").

30. 35 U.S.C. § 101 (2000) (defining the category of patentable subject matter very broadly as any "process, machine, manufacture, or composition of matter, or any . . . improvement thereof").

31. *Id.*; *see also* Brenner v. Manson, 383 U.S. 519, 528-29, 534 (1966) (stating that "one may patent only that which is 'useful' " and describing utility as a necessary quid pro quo for the monopoly granted through the patent because it is the utility that benefits the public).

32. *See* 35 U.S.C. § 101 (requiring novelty); 35 U.S.C. § 102 (2000) (defining novelty).

33. 35 U.S.C. § 103 (2000); *see also* MERGES ET AL., *supra* note 18, at 124, 225 (describing nonobviousness as the " 'ultimate condition of patentability' " and stating that it requires an " 'inventive leap' " over what has previously been done to justify the grant of strong rights that accompany a patent).

34. 35 U.S.C. § 154(a)(2) (2000).

35. *Id.* § 154(a)(1) (defining the exclusionary right as the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process").

on the market.[36] If such competition arises during the statutory patent term, then the patent holder can enforce this right with a private cause of action[37] and seek statutory remedies[38] in the forms of damages,[39] injunctions,[40] and sometimes attorneys' fees.[41]

It is the enforcement of this exclusionary right that, like the enforcement of most rights under the law, sheds the most light on the patent system's underlying policies and complexities.[42] And, when enforcing this right, courts tend to rely on injunctions rather than damages[43] partly because Congress has chosen patents as a vehicle to promote innovation[44] and partly because patented technology is difficult to valuate.[45] In taking this route, a court preserves the patent's right to exclude because doing so blocks ongoing infringement and gives a potentially infringing party reason to license the patent in order to continue practicing the patented technology.[46] Moreover, a court avoids the valuation problem because, when licensing the patent, the injunction places the patent holder in a superior bargaining

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36. *See* MERGES ET AL., *supra* note 18, at 1102.

37. 35 U.S.C. § 271 (2000). One noted exception is for doctors performing an infringing medical activity. 35 U.S.C. § 287(c)(1) (2000).

38. Believing a private transaction is preferable to a legal one, some argue that a full range of remedies, including the infringer's profits, should be available to the patent owner because it would make any contemplated infringement worthless and force a would-be infringer to negotiate with the patent holder rather than infringe and await the legal consequence. WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 7-8 (2003). The idea that an infringer's profits should be a damages measure has not been codified. However, damages can be enhanced up to three times the amount assessed. 35 U.S.C. § 284 (2000).

39. 35 U.S.C. § 284 sets the floor for damages at a reasonable royalty and allows for an increase in damages of up to three times the amount found.

40. 35 U.S.C. § 283 (2000).

41. 35 U.S.C. § 285 (2000).

42. A noted example of how policy choices can determine legal outcomes is found in *Pierson v. Post*, 3 Cai. 175 (N.Y. Sup. Ct. 1805), where the majority of the court, which favored certainty, and the dissenting Judge Livingston, who favored the eradication of such "noxious beasts," each came to separate and opposite legal conclusions.

43. MERGES ET AL., *supra* note 18, at 336. The Court has explicitly held, however, that the injunction is not the preferred remedy in an infringement action. *See* eBay, Inc. v. MercExchange, LLC, 547 U.S. 388, 392 (2006). Instead, underscoring the statutory language that injunctions "may" issue "in accordance with the principles of equity," 35 U.S.C. § 283, and that their issuance is subject to the trial court's discretion, *see eBay*, 547 U.S. at 394, the Court has emphasized the traditional four factor test that a plaintiff must meet prior to the issuance of an injunction. *See id.*

44. *See eBay*, 547 U.S. at 395 (Roberts, C.J., concurring) (noting "the difficulty of protecting a right to *exclude* through monetary remedies").

45. This difficulty is referred to as the valuation problem. *See generally* MERGES ET AL., *supra* note 18, at 336; ROGER M. MILGRIM, MILGRIM ON LICENSING § 2.79 (Matthew Bender 1990) (2008) (noting "that proof of damages is at best a difficult and elusive task").

46. For a general discussion of the economics behind injunctions and their costs and benefits when compared to damage remedies, see Walgreen Co. v. Sara Creek Prop. Co., 966 F.2d 273, 275-76 (7th Cir. 1992) (Posner, J.).

position[47] where he or she can set a value on the patent and the terms and conditions surrounding its use.[48]

The right to exclude, however, does not end there. As a corollary of its strength, courts have held that a patent holder has full prerogative and can refuse a license, should his or her terms be rejected, without fear of compulsion from the government.[49] In other words, in the United States, while the government is free to issue compulsory licenses, it is rare that it will.[50] In fact, the only times that courts will favor this route are when there is evidence of anticompetitive conduct[51] or when legislation is triggered that protects the public interest.[52] In the special case, the public interest prong of the four factor

47. Although its holding that the injunction was a preferred remedy in a patent infringement action was reversed, the Court of Appeals for the Federal Circuit described a natural consequence of the exclusionary right as the patent holder's increased leverage in bargaining. MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1339 (Fed. Cir. 2005), *rev'd*, 547 U.S. 388 (2006).

48. MERGES ET AL., *supra* note 18, at 336-37.

49. MILGRIM, *supra* note 45, § 8.55 ("In general, given the patentee's freedom to refuse to license his invention, compulsory licensing is not a remedy available to an aggrieved competitor. In the usual case, therefore, absent some injurious or illegal conduct beyond the mere unilateral refusal to license, compulsory licenses will not be ordered either in private suits or in government enforcement actions." (citations omitted)).

50. A compulsory license is a license issued by the government against the patent holder's will. Edmund J. Sease, *Common Sense, Nonsense and the Compulsory License*, 55 J. PAT. OFF. SOC'Y 233, 233 (1973); *see also* John M. Wechkin, *Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection*, 5 PAC. RIM. L. & POL'Y J. 237, 239 (1995) ("A compulsory license . . . is an involuntary contract between an unwilling patent holder and a willing licensee, imposed and enforced by the state.").

51. *See*, *e.g.*, United States v. U.S. Gypsum Co., 340 U.S. 76, 94 (1950) (granting compulsory licenses for violations of the Sherman Act); Hartford-Empire Co. v. United States, 323 U.S. 386, 419 (1945) (granting compulsory licenses to alleged infringers when patentee violated the Sherman Act). *See generally* MILGRIM, *supra* note 45, § 8.55 (stating that "the rule of general application remains fixed: absent other anticompetitive conduct or public policy considerations, a patentee is free to unilaterally refuse to license and compulsory licensing will not be ordered").

52. *See*, *e.g.*, Clean Air Act of 1970, 42 U.S.C. § 7608 (2000) (stating that when a patent is necessary for implementing a certain provision of the Clean Air Act, a court "may issue an order requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine"); Atomic Energy Act, 42 U.S.C. § 2183(b) (2000) (allowing for the licensing of patents relating to atomic energy and effected with the public interest); Plant Variety Protection Act, 7 U.S.C. § 2404 (2000) (allowing for the denial of injunctive relief when it is in the public interest to all others to grow the protected plant); Instances of Gov't Subsidy, 35 U.S.C. § 203 (2000) (giving the federal government "march-in rights" for patents that were developed as part of a federal funding agreement). See also 28 U.S.C. § 1498, which has traditionally not been viewed as a compulsory license, but instead as an exercise of eminent domain. Sease, *supra* note 50, at 239. When 28 U.S.C. § 1498 is invoked and a patented invention is used or manufactured by or for the United States without a license or other lawful right, the patent owner's sole remedy is the recovery of reasonable compensation.

test for injunctive relief[53] can also be triggered,[54] and when it is, a court may favor damages over an injunction.[55] When it does, a court, in effect, issues a compulsory license.[56]

Nevertheless, such outcomes are rare, and according to the Supreme Court, this evidences a legislative intent against compulsory licensing and favors the patent holder.[57] This means that in the United States, without a general duty to license the patent,[58] the patent holder rests securely in the exercise of his or her patent rights.[59] As a result, this security, which is sourced in the patent's right to exclude and Congress's choice to use IP to drive innovation, grants the patent holder a limited monopoly in the invention and, as described below, encourages inventors to invent so that society can benefit.[60]

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53. 35 U.S.C. § 283 does not require a court to issue an injunction, but instead allows the court to issue injunctive orders in accordance with the principles of equity and on terms that the court deems reasonable.

54. See Sease, *supra* note 50, for a general survey of compulsory licensing incidents and the rationale behind their issue. These instances include the following: (1) those where equity finds an injunction to be inappropriate, *see*, *e.g.*, Foster v. Am. Mach. & Foundry Co., 492 F.2d 1317, 1324 (2d Cir. 1974) (affirming the issuance of a compulsory license while describing the injunction as an inappropriate remedy when it would result in irreparable injury to the infringer without giving any resulting benefit to the patentee other than a "club" to be wielded in negotiation); (2) instances where nonuse by the patentee intrudes on the public interest, *see*, *e.g.*, Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 405, 430 (1908) (noting that the patentee's nonuse is not reason alone to deny injunctive relief, but when a public interest is at stake because of the nonuse, injunctive relief may be denied); (3) instances where an infringement order would result in waste and denial of a public benefit, *see*, *e.g.*, McCreery Eng'g Co. v. Mass. Fan Co., 180 F. 115 (D. Mass. 1910) (denying injunctive relief when it would result in the loss of ventilation to county courthouse); and (4) instances where an injunction would place the public health, welfare, and safety at risk, *see*, *e.g.*, City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577 (7th Cir. 1934) (denying injunction when it would result in the shutdown of a city sewage plant and the dumping of raw sewage into Lake Michigan).

55. In all such instances, upon the finding of infringement, the patent holder is entitled to "damages adequate to compensate for the infringement but in no event less than a reasonable royalty." 35 U.S.C. § 284 (2000).

56. MILGRIM, *supra* note 45, § 8.55 (stating that the "refusal to enjoin future infringement in such a case is tantamount to a mandatory license").

57. *Cont'l Paper Bag Co.*, 210 U.S. at 429-30 (interpreting the lack of legislative activity in the area of compulsory licensing as reflecting Congress's intent not to have general compulsory licensing).

58. Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (noting that "[c]ompulsory licensing is a rarity in our patent system, and we decline to manufacture such a requirement"); *see also id.* at 215 n.21 ("Compulsory licensing of patents often has been proposed, but it has never been enacted on a broad scale.").

59. Adi Gillat, *Compulsory Licensing to Regulated Licensing: Effects of the Conflict Between Innovation and Access in the Pharmaceutical Industry*, 58 FOOD & DRUG L.J. 711, 714 (2003) (stating that patent holders have "full prerogative . . . in exercising their patent rights").

60. *See* SCHACHT, *supra* note 20, at 2.

2. The Pharmaceutical Industry: Linking Patents with Innovation

Patents benefit society in a number of ways, and although their specific role in each industry is unique, they are generally recognized for their ability to spur innovation.[61] In the pharmaceutical industry, for example, patents are essential to motivating and directing future innovation,[62] which generates new and better medicines for all.[63]

The incentive to innovate and invent is a function of four interrelated variables: (1) the costs of innovation and invention, (2) the risks, (3) the rewards for success, and (4) the rate at which competitive imitation occurs.[64] In the pharmaceutical industry, the patent preserves this incentive because after developing a new drug, patenting it provides a substantial reward that offsets the high costs of success.

Developing a new drug is extraordinarily expensive and highly unlikely to succeed. At least one author has indicated that the costs of developing a new drug can approach half a billion dollars while requiring more than a decade to research, test, and obtain regulatory approval.[65] Similarly, another author has discovered that only one percent of compounds researched make it into human testing and that because only twenty-two percent of those obtain approval from the Federal Drug Administration (FDA),[66] the odds of a discovered compound becoming an approved drug can be as low as one out of four thousand.[67]

Therefore, to preserve the incentive to innovate, patents serve a reward function that offsets the high costs and extraordinary risks

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61. *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 180 (1986). *See generally* FED. TRADE COMM'N, *supra* note 14 (comparing the role of patents in promoting innovation across multiple industries).

62. *See* FED. TRADE COMM'N, *supra* note 14, ch. 3.

63. *See infra* notes 98-100 and accompanying text (discussing how patents generate social returns in excess of their costs).

64. *See* F.M. SCHERER, THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING 14 (1977).

65. Harvey E. Bale, Jr., *Patent Protection and Pharmaceutical Innovation*, 29 N.Y.U. J. INT'L L. & POL. 95, 95 (1996). Although the numbers cited by Bale are more than a decade old, time has not eroded their validity. In late 2006, the Congressional Budget Office reported that developing and bringing to market an innovative drug takes about 12 years and it takes an average of 11.8 years for a type of drug known as a new molecular entity. *See* CONG. BUDGET OFFICE, U.S. CONG., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 2, 20 (2006) [hereinafter RESEARCH IN THE PHARMACEUTICAL INDUSTRY], *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.

66. Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 851 (2002); *see also* RESEARCH IN THE PHARMACEUTICAL INDUSTRY, *supra* note 65, at 23 fig. 3-2 (reporting that about twenty percent of new molecular entities actually enter the phase for FDA approval).

67. Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 303 (1994).

involved with bringing a new drug to market. That reward is a limited monopoly grant that gives innovative companies the freedom to include both production costs and other expenses in the price of their drugs[68] and positions them to appropriate at least part of their drugs' social value.[69] According to pharmaceutical representatives[70] and bolstered by studies,[71] this freedom preserves continued innovation within the industry.

In addition to providing a reward for success, patents fill a gap in legal protection and stifle competitive imitators that could otherwise copy the drug at less cost and risk than the innovator.[72] Unlike the development of a new drug, which is a risky endeavor taking as long as fifteen years[73] to research and costing as much as half a billion dollars,[74] the development of a brand-name equivalent drug is a highly successful endeavor costing as little as $1 to $2 million and can take only a few years.[75] This places the imitator at a competitive advantage because, even though the imitator and innovator share the same marginal costs,[76] the imitator pays substantially less for research and can sell the brand-name equivalent drug at a discount.[77]

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68. *Id*. at 304. Although the patent rewards the inventor with a monopoly on the new drug, it does not confer a monopoly on the treatment of a disease. Drug companies are still forced to compete with other drugs in the same therapeutic class, which limits the monopoly effect granted by the patent. *See* FED. TRADE COMM'N, *supra* note 14, ch. 3, at 10.

69. *See* Grabowski, *supra* note 66, at 850 (indicating that pharmaceutical companies rely greatly on patents in order to appropriate the benefits from their invention).

70. *See* FED. TRADE COMM'N, *supra* note 14, ch. 3, at 1.

71. *See* Mansfield, *supra* note 61, at 174 (citing studies that found ninety percent of pharmaceutical innovations would not have been introduced without patents, and sixty percent of pharmaceutical research and development funding was dependent upon patent protection); *see also id.* at 177 tbl. 2 (indicating that pharmaceutical companies patented more than eighty percent of their inventions from 1981 to 1983, which indicates their reliance on patents); *id*. at 175 tbl.1 (noting that of those inventions patented between 1981 and 1983, sixty-five percent would not have been introduced if patent protection was not obtained, and sixty percent would not have been developed if patent protection was not available).

72. *See infra* notes 81-84 and accompanying text.

73. *See* FED. TRADE COMM'N, *supra* note 14, ch. 3, at 5.

74. Bale, *supra* note 65, at 95.

75. Grabowski, *supra* note 66, at 852.

76. *See* LANDES & POSNER, *supra* note 38, at 313 (noting that in the pharmaceutical industry, marginal costs are low both for the innovator and the imitator). Marginal costs are the costs incurred for producing additional units of a particular good. Costs for labor and material are examples of marginal costs. E. THOMAS SULLIVAN & HERBERT HOVENKAMP, ANTITRUST LAW, POLICY AND PROCEDURE: CASES, MATERIALS, PROBLEMS 48 (5th ed. 2003).

77. *See* Grabowski, *supra* note 66, at 851 (stating that "imitation costs . . . are extremely low relative to the innovator's costs for discovering and developing a new compound"); *see also* Bale, *supra* note 65, at 101, 106 tbl. 2 (showing how quickly imitators of the drug Tagamet (Cimetidine) took market share because their prices were so much lower).

This is known as "free-riding," and though it saves the consumer money,[78] it limits the innovator's ability to recover the original investment and attract additional resources for continued research.[79] To prevent this problem, patents step in where other forms of legal protection fail.[80] In particular, pharmaceuticals find little protection as a trade secret because they are easily imitated[81] and require extensive disclosure prior to regulatory approval.[82] They are also not subject to copyright,[83] and trademark law offers only a limited amount of protection after a significant period of time on the market.[84]

Therefore, without patent protection, innovative companies would have no means of preventing imitating companies from cheaply producing their drugs,[85] and imitating competitors could enter the market freely and quickly erode the innovator's early entry advantage.[86] The patent's exclusionary right stifles this competition by granting a limited monopoly in the invention and secures the innovator in the market.[87] As a result, in the absence of competition, the innovator can recover fixed costs,[88] regain previously invested re-

78. *See* Grabowski, *supra* note 66, at 851 (indicating that a generic drug does not have to recoup research and development costs like its brand-name equivalent and is cheaper as a result).

79. *See* SCHERER, *supra* note 64, at 20 (explaining that when imitation is swift and widespread, the imitators—and not the innovator—will reap most of the social gains as a result of the price competition); *see also infra* notes 87-90 and accompanying text (describing how patents are essential to funding research).

80. *See* ECONOMIC REVIEW, *supra* note 19, at 58-62 (describing the patent system as being designed to prevent free-riding).

81. *See* SCHACHT, *supra* note 20, at 5 (noting that it is relatively easy to chemically analyze and duplicate a pill, and for this reason, patents are especially important to pharmaceuticals); *see also* Wechkin, *supra* note 50, at 241 (noting that "[p]harmaceuticals . . . are particularly easy to copy because 'reverse engineering' methods can be used to determine the constituent components of the drug").

82. Gillat, *supra* note 59, at 723 (noting that the detailed disclosure requirements necessary for a drug's regulatory approval deny the drug protection through trade secrecy).

83. *See* 17 U.S.C. § 102 (2000).

84. *See* LANDES & POSNER, *supra* note 38, at 314 (describing how a drug's trademark, in conjunction with the patent, creates reluctance in the consumer to leave the brand-name drug for the cheaper generic drug when the patent expires).

85. This may be an overstatement since circumstances may provide alternative remedies under state law. The point is, however, that even in light of these remedies, none are as effective or as broad as those provided by a patent.

86. *See* SCHERER, *supra* note 64, at 23 (noting that an additional barrier to competition is the advantage that accrues to the pioneer who is first to place an innovative product on the market); Bale, *supra* note 65, at 101 (stating that when generic manufacturers enter the market, they quickly erode the innovator's market share); *see also*, *e.g.*, Theodore C. Bailey, *Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs*, 2001 J.L. TECH. & POL'Y 193, 204 (recalling that when the patent expired for the drug Librium, a precursor to Valium, its price dropped from $15 to $1); Bale, *supra* note 65, at 106 tbl.2 (reflecting that when Tagamet's patent expired, the patent holder's market share declined from 100% to 45% in eight weeks).

87. *See* ECONOMIC REVIEW, *supra* note 19, at 58-62.

88. FED. TRADE COMM'N, *supra* note 14, ch. 3, at 4.

search and development funds,[89] and attract additional resources for future research.[90]

Besides attracting resources, a pharmaceutical patent has other beneficial effects. That is, the disclosure required of a pharmaceutical patent can maximize innovation efforts in ways beyond those that are directly beneficial to the patent holder.[91] Using the information disclosed in the patent, competing companies can maximize innovative research by minimizing duplication and directing efforts into areas not previously claimed.[92] Similarly, after knowing what technology a patent protects, competing companies can "design around" the patent and develop noninfringing competition to the patented product.[93]

In the end, the fruits of these innovation efforts arrive to the market in the form of new drugs that benefit society.[94] As has been reported, from 1981 to 1990, the pharmaceutical industry introduced over ninety percent of new FDA approved drugs,[95] and when compared to companies in countries with only "intermediate" patent protection, U.S. companies outpaced them more than two to one.[96] Similarly, when looking at the effects of strong patent protection in other

89. *See id.*; *see also* LANDES & POSNER, *supra* note 38, at 313 (stating that thirty percent of the cost of a new drug is related to research and development). Despite the patent monopoly, industry representatives have testified that most drugs do not generate enough in profit to cover their average development costs. As a result, brand-name companies rely on a small number of " 'blockbuster' " drugs to recoup their innovation investments, including those made for failed products. *See* FED. TRADE COMM'N, *supra* note 14, ch. 3, at 5.

90. RESEARCH IN THE PHARMACEUTICAL INDUSTRY, *supra* note 65, at 9-10 (noting that sales revenue drives research and development and reporting in Fig. 2-2 how the pharmaceutical industry's level of investment compares to other industries); Bale, *supra* note 65, at 97-98 (indicating that the " 'research-based' " segment of the pharmaceutical industry depends upon patents and that even though patent protection results in a " 'monopoly' effect," this effect is necessary to fund the substantial investments in research and development that are required for new drug development); Fisch, *supra* note 67, at 302 n.49 (reporting that in 1994, spending for research and development was projected to be 18.8% of company sales in the pharmaceutical industry).

91. *See* 35 U.S.C. § 112 (2000) (requiring disclosure that would enable a person skilled in the art to make and use the invention); *see also* FED. TRADE COMM'N, *supra* note 14, ch. 3, at 9 (describing the disclosure requirement as a trade-off for obtaining the right to exclude others from making, using, offering for sale, or selling an invention). This disclosure requirement harmonizes with the patent system's underlying objectives. *See supra* note 28.

92. FED. TRADE COMM'N, *supra* note 14, ch. 3, at 1.

93. *Id.* at 1-2.

94. This argument depends upon an inventor being motivated by the prospect of commercial success. There are exceptions where this will not always prove true. For example, it has been suggested that partly because Alexander Fleming was not motivated by commercial success, it took an additional fifteen years to commercialize penicillin and to make it available for the market. *See* George E. Frost, *The Case Against Drug Patent Compulsory Licensing*, 7 PAT. TRADEMARK & COPYRIGHT J. RES. & EDUC. 84, 100 (1963).

95. Fisch, *supra* note 67, at 302 n.46.

96. *See* Frost, *supra* note 94, at 98 (summarizing that during one specified period, for every drug produced in Great Britain, France, Germany, Switzerland, and Italy combined, the United States was producing more than two).

countries, the conclusion is much the same—strong patents lead to more and better drugs.[97]

For society, this means that even though pharmaceutical patents impose social costs, society reaps the greater benefit because new and better drugs increase longevity, enhance the quality of life, and improve both labor force participation and productivity.[98] Thus, while the patent system allows the inventor to appropriate the social value of his or her invention in the form of a private return,[99] the reality is that the inventor's return falls short and society reaps the greater benefit.[100]

B. Patents in the Developing World: Access and the Compulsory License

While countries like the United States reap the benefits of better drugs and can afford to grant strong patent protection to their innovators, the reach of their patents and associated rights are limited.[101] This leaves an innovator seeking foreign patent protection at the mercy of individual patent systems.[102] Because patents are a reflection of policy, their associated rights can vary according to the choices of individual countries.[103] Thus, while the United States prefers strong patent rights to spur innovation,[104] developing countries find them unpalatable, particularly when dealing with medicines essential to the long-term survival of their people. As a result, they endorse choices that erode IP rights and entangle themselves in international disputes.

1. The Clash Between Innovation and Access

Unlike in the United States, in a developing economy, strong patent enforcement is not generally seen as a tool for promoting the public welfare. Instead, patents impede economic growth and impose

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97. Grabowski, *supra* note 66, at 853-54 (arguing that strong patent protection for drugs is essential to new product introductions and to the prosperity of the drug industry while also summarizing the effects of stronger patent protection on the drug industries in Canada and Japan).

98. *Id*. at 849-50.

99. *See* ECONOMIC REVIEW, *supra* note 19, at 58-62.

100. *See* Gillat, *supra* note 59, at 715 (citing studies that conclude that the typical innovator captures, at most, only forty-five percent of the social returns on his or her innovation).

101. Wechkin, *supra* note 50, at 239 (noting that patents are limited to the jurisdiction of the laws in the issuing country).

102. *See* MERGES ET AL., *supra* note 18, at 330 (stating that most businesses seeking international patent protection turn to the laws of individual countries in order to obtain that protection).

103. *Compare supra* notes 42-60 and accompanying text *with infra* notes 105-30 and accompanying text.

104. *See supra* Part II.A.

social costs in excess of any gains they could be expected to return.[105] To control these effects, a developing country must intervene through negotiation with the patent holder or intrusion on the patent, and more often than not, intrusion in the form of a compulsory license is likely the best course for pharmaceutical patents.[106]

When a developing country issues patents for foreign medicines, its already struggling economy finds itself shouldering another load. Specifically, granting a patent for a foreign product can cost an economy technological advantages that would otherwise promote its industry and benefit its citizens. In terms of industry, productivity is lost when patents prevent imitators from pirating the technology for local production,[107] and when local production is denied, there is no opportunity for technology transfer.[108] This leaves local consumers dependent on foreign goods without the benefit of local competition, and absent competition, consumers are forced to pay higher prices.[109] When these goods are medicines, these higher prices injure the public health because when drugs are not readily available, treating and diagnosing disease is more difficult.[110]

Consequently, a developing country facing a health crisis finds itself in a difficult position. To provide access to medicines that would combat the crisis, it can take a passive approach and rely on drug donations from charities and pharmaceutical companies.[111] Alterna-

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105. EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 226 (1951) (noting that granting patents on foreign imports results in social costs such as higher prices, royalty payments to foreign patent holders, and the lost ability to use new techniques that far exceed any benefit derived from granting the patent protection).

106. There are two methods of reducing social costs that result from granting patents on foreign inventions. *Id.* at 230. One is the ineffective compulsory working requirement. *Id.* The other is the more effective and flexible compulsory licensing requirement mentioned here. *Id.* at 231.

107. *See* Julian-Arnold, *supra* note 13, at 356 (citing sources and explaining the effects of piracy and counterfeiting on the economies in developing countries).

108. *See id.* at 357. As a result of this concern, developing countries have contracted directly with pharmaceutical companies to have them build domestic production facilities in order to achieve technology transfer as well as to spur the developing country's technical capacity. Thomas F. Mullin, *AIDS, Anthrax, and Compulsory Licensing: Has the United States Learned Anything? A Comment on Recent Decisions on the International Intellectual Property Rights of Pharmaceutical Patents*, 9 ILSA J. INT'L & COMP. L. 185, 192 (2002).

109. *See supra* notes 88-90 and accompanying text (describing how patents enable the patent holder to charge higher prices to recoup past expenses and to gather future funds for research and development).

110. *See* Thomas J. Bollyky, *Balancing Private Rights and Public Obligations: Constitutionally Mandated Compulsory Licensing of HIV/AIDS Related Treatments in South Africa*, 18 S. AFR. J. ON HUM. RTS. 530, 531 (2002).

111. *See*, *e.g.*, Jeanne Whalen, *Glaxo to Cut Prices in Poor Countries*, WALL ST. J., Feb. 14, 2009, at B5 ("GlaxoSmithKline PLC, the world's second-biggest drug maker by sales, plans to cut prices in the world's poorest countries and invest 20% of its profit from those markets into building health clinics and other infrastructure."); *see* Bollyky, *supra* note 110, at 537; Grabowski, *supra* note 66, at 857-58.

tively, it can be proactive and negotiate bilaterally, purchase in bulk, or issue compulsory licenses.[112]

Of these choices, the availability of limited funds for medical treatment often leaves compulsory licensing as the only choice for those countries wishing to be proactive. In Africa, for example, where HIV/AIDS is ravaging the population, its nations are limited to budgets of less than ten dollars per capita for medicines annually.[113] Meanwhile, the annual price of treatment for the disease can be as high as several thousand dollars a year.[114] This means that while bilateral negotiations[115] and bulk purchasing efforts[116] enable a country to achieve some price reductions, the savings they generate are often not enough to make it worthwhile.[117] A compulsory license, on the other hand, increases the government's bargaining power,[118] opens the door to more competition, and leads to significant price reductions.[119] For this reason, although compulsory licenses are rare,[120] the promise of immediate cost savings make them very appealing for

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112. *See* Bollyky, *supra* note 110, at 533, 537.

113. Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001, § 6 (Magazine), at 26.

114. Bailey, *supra* note 86, at 196 (describing that access to AIDS drugs is almost impossible in nations like South Africa where the annual per capita income is $6,000 and a year's supply of AIDS treatment can cost more than $750 a month and up to $12,000 a year).

115. *See*, *e.g.*, Mullin, *supra* note 108, at 200-02 (discussing how the United States and Canada negotiated with Bayer AG to lower the price of Cipro, the first FDA approved drug for treating Anthrax infections, after the Anthrax attacks in 2001).

116. *See*, *e.g.*, Wechkin, *supra* note 50, at 238 (discussing how New Zealand has placed increased reliance on price regulation as a means for controlling drug prices).

117. *See* Grabowski, *supra* note 66, at 856 (noting that low prices on drugs alone do not result in adequate utilization of those drugs because of the limited funds available for medicines).

118. *See, e.g.*, Ubirajara Regis Quintanilha Marques et al., *Brazil AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 FOOD & DRUG L.J. 471, 474 (2005) (indicating that the mere possibility of a compulsory license pressures global pharmaceutical companies to lower their prices); Mullin, *supra* note 108, at 192-94 (discussing the increased bargaining power that the South African government enjoyed after it contemplated the use of compulsory licensing and the significant savings that resulted because drug manufacturers were much more willing to lower their prices to avoid the license).

119. "The effect of a compulsory license is to force a patent holder to license the invention to others in return for a royalty set by the government." Wechkin, *supra* note 50, at 237. Through the issuance of the license, competition is stimulated and prices are lowered because of the availability of low-priced generics that are manufactured or imported by third party licensees. Bollyky, *supra* note 110, at 533.

120. Sease, *supra* note 50, at 236. The rare instances when compulsory licensing has been used include those "where a dependent patent is being blocked, where a patent is not being worked, or where an invention is related to food or medicine." Julian-Arnold, *supra* note 13, at 349-50 (summarizing compulsory licensing provisions in selected countries); *see also* ECONOMIC REVIEW, *supra* note 19, at 13 (stating that, in addition to using compulsory licenses as a penalty or remedy for abuse, some countries use them "to safeguard the public interest"); Sease, *supra* note 50, at 235 (describing compulsory licensing as being used in foreign countries as a sanction when there is insufficient use within the country to satisfy the demand).

governments needing to reduce the price of pharmaceuticals, despite their potential effects on future innovation.[121]

The best example of this has occurred in Brazil, which some have described as a "beacon among developing countries."[122] In Brazil, the government has achieved significant pharmaceutical price reductions by forcing pharmaceutical companies to manufacture their drugs locally and by threatening compulsory licenses.[123] As a result, Brazil has contained the spread of HIV/AIDS and stabilized the disease.[124] In the process, Brazil has saved over $422 million between 1997 and 1999 to offset the $444 million it spent on drugs in 2000.[125]

With such promising results, it is little wonder that countries like South Africa, which is battling one of the most severe HIV/AIDS epidemics in the world, have turned to compulsory licensing. According to 2006 UNAIDS estimates, by the end of 2005, 5.5 million people were living with HIV in South Africa and almost 1,000 people were dying from AIDS every day.[126] Based on 2002 data, the disease was predicted to shrink the South African GDP by 17% and reduce output by $22 billion in 2010.[127]

Faced with such staggering consequences of inaction on the one hand and a constitutional mandate to improve access to health care on the other,[128] South Africa became proactive. In 1997, it passed the Medicines and Related Substances Control Act, empowering the South African Minister of Health to issue compulsory licenses for HIV/AIDS drugs for domestic manufacture.[129] It was hoped that this would lower the costs of new antiretroviral drugs, allowing South Africa to capitalize on their effectiveness and contain the disease.[130] Instead, it ignited a firestorm.

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121. *See* Wechkin, *supra* note 50, at 240.

122. Marques et al., *supra* note 118, at 472.

123. In 2003, for example, the annual treatment cost for an AIDS patient in Brazil was $2,000, as compared to $15,000 in the United States. *Id.* at 472. Furthermore, Brazil has significantly reduced the production costs of other drugs, including 59% for Efavirenz, 65% for Nelfinavier, 64% for Nelfinavir, and 63% for Invirase® and Fortovase®. *Id.* at 474.

124. Rosenberg, *supra* note 113, at 26 (stating that Brazil has "cut the AIDS death rate nationally by about 50 percent" and that "each AIDS patient is only a quarter as likely to be hospitalized as before").

125. Mullin, *supra* note 108, at 195.

126. *See* 2006 JOINT U.N. PROGRAMME ON HIV/AIDS, *supra* note 9, annex 1, at 455 (estimating that between 270,000 and 380,000 people died in South Africa as a result of HIV/AIDS in 2005 and that between 4.9 million and 6.1 million people have the disease).

127. Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT'L L.J. 563 (2002). Fortunately, the tide is beginning to turn for reasons mentioned below, and 2010 does not look as bleak as it did before. *See infra* notes 144-47 and accompanying text.

128. *See* Bollyky, *supra* note 110, at 532.

129. Bailey, *supra* note 86, at 195.

130. *See* Bollyky, *supra* note 110, at 534 (stating that new antiretroviral drugs have slashed mortality rates by seventy percent when compared to previously available treatment).

2. Compulsory Licensing and the International Consequences

The promise of immediate and improved access to brand name HIV/AIDS drugs is definitely alluring, but issuing or threatening a compulsory license has consequences. Compulsory licenses not only reduce foreign investment, they also impose costs related to litigation, safety, and efficacy.[131] More importantly, a compulsory license can to lead to trade sanctions, especially from the United States, that halt the license altogether.

The impetus behind such sanctions is the view that when a nation issues a compulsory license, it reaps the benefits of a substantial research and development investment without contributing its fair share to the costs.[132] As one author has stated:

> Research in the area of pharmaceuticals is so expensive that any country attempting to take a free ride on such research through the use of compulsory licensing is certain to be a target of severe international criticism. While developing countries have a justifiably strong interest in insuring that foods and medicines are available to their citizens at a reasonable price, they also have a strong interest in providing the incentive to research those diseases particular to the developing nations.[133]

In addition, by taking the "free ride" on research with the compulsory license, a country reaps a competitive trade advantage because its manufacturers do not have the burden of the substantial research and development costs.[134] This distorts trade, denies innovators the opportunity to recoup their own investments, and prohibits a developed country from taking advantage of its IP on the international market.[135]

To avoid this, developed countries like the United States use trade sanctions and other forms of political pressure against those coun-

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131. *See id.* at 543-44; *see also* NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 316 (2d ed. 2005) (noting that compulsory licensing discourages the establishment of independent, research-based industries that would be valuable in serving the local market).

132. *See* Julian-Arnold, *supra* note 13, at 357-58.

133. *Id.* at 368.

134. The effect of not protecting intellectual property among nations is an outgrowth of the effects within industry. For example, in the context of pharmaceuticals, the ability of a generic manufacturer to "free-ride" on the research and development of the innovator places the generic at a significant market advantage because, without having to recoup the same investment costs, it can place an equivalent product on the market for much less. When this generic manufacturer places its product in channels of international trade, these effects are magnified and the competitive advantage turns into a trade advantage. *See* DE CARVALHO, *supra* note 131, at 35-36.

135. *See* Julian-Arnold, *supra* note 13, at 369 (discussing the theory of comparative advantage in international trade and how the nonprotection of intellectual property puts a pirating country at an advantage).

tries whose IP protection is not similar in strength to their own.[136] In the United States, the "Special 301" provisions of the Trade Act of 1974, as amended, empower the U.S. Trade Representative to identify, categorize,[137] and investigate foreign countries with inadequate IP protection for possible future action.[138] If a country's IP protection falls below the expected threshold, then it is placed on either the Priority Watch List—where it is subject to further monitoring and possible subsequent action—or the Watch List—where it is recommended for subsequent action.[139] Oftentimes, such action is in the form of highly persuasive trade sanctions that are meant to encourage a Priority Watch List country to update its IP policies,[140] and often these sanctions succeed.[141]

This was the firestorm that engulfed South Africa. After that country passed the Medicines and Related Substances Control Act, the United States placed it on the Watch List, and although no trade sanctions followed, the mere fear that they would led South Africa to delay implementing its law.[142] Despite this delay, in response to the Act and as a testament to the effectiveness of compulsory licensing, drug manufacturers significantly lowered their prices and no doubt increased access to essential medicines for South Africa and its citizenry.[143]

The rest of the world has also responded. In 2003, the United States began providing direct relief to HIV/AIDS patients via the President's Emergency Plan for AIDS Relief.[144] Under this plan, the United States has provided over $15 billion and will provide $39 bil-

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136. Mullin, *supra* note 108, at 198.

137. Countries are categorized accordingly in the following groups: (1) Priority Foreign Country; (2) Section 306 Monitoring; (3) Priority Watch List; and (4) Watch List. *See* U.S. TRADE REP., 2005 SPECIAL 301 REPORT 1 (2005) [hereinafter SPECIAL 301 REPORT].

138. *See* 19 U.S.C. § 2242(g) (2000) (requiring an annual report to Congress from the U.S. Trade Representative identifying foreign countries that do not provide adequate intellectual property protection as well as actions taken against them during the preceding twelve months). *See generally* SPECIAL 301 REPORT, *supra* note 137, at 14 (providing an overview of the statutory reporting process).

139. SPECIAL 301 REPORT, *supra* note 137, at 14. Subsequent action is authorized by statute. 19 U.S.C. § 2411 (2000) (authorizing unilateral action against foreign nations that pursue discriminatory trade practices, including those nations that do not provide adequate intellectual property protection).

140. Rosenberg, *supra* note 113, at 26 (noting that a country's inclusion on the Special 301 Watch List is a precursor to trade sanctions).

141. *See* Wechkin, *supra* note 50, at 243-45 (describing how New Zealand's policies, which were related to compulsory licensing and pharmaceuticals, were repealed after the United States took the described actions).

142. *See* Kathy Chenault et al., *Will the AIDS Plague Change U.S. Trade Policy?*, BUS. WK., Sept. 13, 1999, at 58; *see also* Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. SCH. J. INT'L & COMP. L. 109, 110 (2001).

143. *See* Mullin, *supra* note 108, at 193.

144. About PEPFAR, http://www.pepfar.gov/about/index.htm (last visited Apr. 11, 2009).

lion more to combat the spread of AIDS worldwide.[145] Other countries and international actors have likewise weighed in to combat the spread of the disease.[146] As a result of their efforts, more than two million African patients have access to HIV/AIDS drugs that did not before.[147] This increase in access to medicine has lowered the death rate and controlled the spread of the disease,[148] but because the efforts are charitable, this leaves countries like South Africa reliant on others' goodwill to battle their health epidemics. Consequently, there is still a need for a comprehensive, international solution that empowers them to be proactive without fear of international retribution. As time goes on, this need continues to grow.

III. TRIPS, DOHA, AND THE CURRENT COMPROMISE

Trade disputes like the one above in South Africa did not go unnoticed. While they played out on the world stage, countries recognized that there was a nexus between trade and IP, and as IP became increasingly important to the developed world,[149] these countries saw that trade could be used as a vehicle for international IP harmoniza-

145. *See Win Some, Lose Some: The XVIIth International Aids Conference*, ECONOMIST, Aug. 9, 2008, at 75 (stating that the President's Emergency Plan for AIDS Relief "provides for $39 billion to be spent on AIDS over the next five years, up from $15 billion for the past five").

146. *See*, *e.g.*, Whalen, *supra* note 111 (reporting that GlaxoSmithKline PLC "already sells its HIV drugs in these [poor] countries at not-for-profit prices, and if those prices aren't already lower than 25% of the developed-world price, they will be reduced"); *see* JOINT U.N. PROGRAMME ON HIV/AIDS, 2008 REPORT ON THE GLOBAL AIDS EPIDEMIC 136-38 (2008) [hereinafter 2008 JOINT U.N. PROGRAMME ON HIV/AIDS], *available at* http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp (describing various ongoing efforts around the globe aiming to combat the spread of HIV/AIDS).

147. *See* U.S. President's Plan for Aids Relief, World AIDS Day 2008: Celebrate Life!, http://www.pepfar.gov (last visited Apr. 11, 2009) ("When President George W. Bush announced PEPFAR in 2003, it was estimated that only 50,000 people were receiving treatment for HIV/AIDS in sub-Saharan Africa. Today, PEPFAR supports treatment for more than 2 million people in sub-Saharan Africa—forty times the number receiving treatment only five years ago."); *see also Getting the Message*, ECONOMIST, June 7, 2008, at 91, *available at* http://www.economist.com/science/displaystory.cfm?story_id=11487365 (showing that according to the World Health Organization, over 2 million people are receiving anti-AIDS drugs in sub-Saharan Africa); Kimberley A. Strassel, Editorial, *The Weekend Interview: Bush on His Record*, WALL ST. J., Dec. 20, 2008, at A13 (noting that PEPFAR has "provided antiretroviral drugs to 2.2 million African HIV-AIDS victims").

148. *See* 2008 JOINT U.N. PROGRAMME ON HIV/AIDS, *supra* note 146, at 134 ("After decades of increasing mortality, the annual number of AIDS deaths globally has declined in the past two years, in part as a result of the substantial increase in HIV treatment access in recent years.").

149. As Professor Maskus has shown, strong intellectual property protection is a by-product of a growing and sophisticated economy. *See* MASKUS, *supra* note 7, at 102.

tion.[150] Consequently, they adopted new international trade agreements aimed at standardizing substantive IP protections.

Leading the way were the United States and Europe with a push to revise the General Agreement on Tariffs and Trade (GATT) at the Uruguay Round. As part of the Marrakesh Agreement, they pushed for the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) annex and succeeded in doing so.[151] This was a revolutionary international development. With the adoption of TRIPS, there was an international power shift from the World Intellectual Property Organization (WIPO)—a body acting under the United Nations that had routinely failed to obtain substantive harmonization[152]—to the WTO, which was a successor to the GATT. More importantly, the agreement's broad scope encompassed areas that previous agreements covered separately[153] and, for the first time, included provisions for the enforcement of IP rights.[154] Consequently, TRIPS has been described as the most "comprehensive international agreement on intellectual property protection ever established."[155]

The main objective of TRIPS is to promote free trade.[156] With a mandate "to reduce the distortions and impediments to international trade, taking into consideration the need to promote effective and adequate protection for intellectual property rights,"[157] it aims to remedy differences in IP protection[158] and to protect private property rights from arbitrary government acts.[159]

The compulsory licensing of pharmaceutical patents could arguably be categorized as an arbitrary government act, but this is not necessarily the case under TRIPS. While an arbitrary compulsory license, which seizes an IP right,[160] would be contrary to the mandate

150. Prior international agreements, like the Paris Convention of 1883 and the Patent Cooperation Treaty, were focused primarily on streamlining international procedures and had few substantive aspects. *See* MERGES ET AL., *supra* note 18, at 331-33.

151. *See* Mullin, *supra* note 108, at 187.

152. *See* Susan Vastano Vaughan, *Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation?*, 25 HASTINGS INT'L & COMP. L. REV. 87, 93 (2001) (stating that "WIPO negotiations, whether viewed as favorable to developing or developed countries, were routinely stymied").

153. *See* MERGES ET AL., *supra* note 18, at 330-33 (describing how the Paris Convention and the Patent Cooperation Treaty focused primarily on procedure and stating that individual treaties were used to provide substantive protection).

154. DE CARVALHO, *supra* note 131, at 28-29.

155. *Id.* at 28.

156. *Id.* at 35.

157. *See* Julian-Arnold, *supra* note 13, at 370 (citing the Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations—Statement by the Chairman, 25 I.L.M. 1623 (1986)).

158. DE CARVALHO, *supra* note 131, at 30.

159. *Id.* at 35.

160. IP rights are considered private property rights under TRIPS and are therefore protected from arbitrary government acts. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World

above, one that serves a public purpose[161] and is justified on social and collective interests[162] is categorically not. Under TRIPS, promotion of the public health is socially and collectively justifiable, and it allows its members to adopt any means necessary to serve this end as long as they are consistent with the remainder of the agreement.[163] This includes using compulsory licenses for pharmaceuticals.[164]

After its passing, though, members continually wrestled with interpreting the agreement and with defining the appropriate bases for issuing a compulsory license. According to Article 31(b), a compulsory license may issue only once "efforts to obtain authorization from the right holder on reasonable commercial terms and conditions" have failed after a reasonable period of time.[165] This negotiation requirement is dispensed with in cases of "national emergency or other circumstances of extreme urgency,"[166] but TRIPS does not define what these are, and when interpreting this language, countries adopted

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Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS]. The preambulatory language of the TRIPS agreement specifically "[r]ecogniz[es] that intellectual property rights are private rights." TRIPS, *supra*, pmbl., para. 4.

161. In U.S. law, a taking of private property for a public purpose is authorized under the Fifth Amendment and carries with it the requirement of just compensation. *See* U.S. CONST. amend. V. Partially because of this similarity, this Comment will later use U.S. law to analyze the TRIPS compensation requirement.

162. DE CARVALHO, *supra* note 131, at 317.

163. The relevant provision provides that "[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." TRIPS, *supra* note 160, art. 8.

164. The term "compulsory licensing" is not used in the TRIPS agreement, but instead it is framed as "use of the subject matter of a patent without the authorization of the right holder." *Id.* art. 31. When this provision is read in conjunction with Article 2:1, which incorporates Article 5.A.2 of the Paris Convention, it is understood to mean that WTO members may grant compulsory licenses. *See* Frederick M. Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71, 74 (2001).

165. The reasonableness of the negotiations time period is a function of national law and practice. *See* DE CARVALHO, *supra* note 131, at 319.

166. Article 31(b) specifically provides that

> such use may only be permitted if, prior to such use, 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. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

TRIPS, *supra* note 160, art. 31.

different meanings.[167] This led to subsequent international disputes, the most notable being the one between the United States and South Africa. Countries like the United States, for example, believed and interpreted TRIPS to bar the use of compulsory licenses to treat HIV/AIDS. Countries like South Africa, on the other hand, interpreted the agreement differently and saw compulsory licenses for the treatment of HIV/AIDS as fully justified within the agreement.[168]

Given these conflicting interpretations, on November 14, 2001, members released the Doha Declaration and clarified the TRIPS position.[169] Regarding the availability of compulsory licenses under the agreement, members declared that not only did each member have the right to grant compulsory licenses, but that each member also had the freedom to determine the grounds upon which they are granted.[170] Similarly, regarding the vague "national emergency" or "other extreme urgency" language that dispensed with the negotiation provisions in Article 31, each member was granted the right to

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167. *See* Vishal Gupta, *A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement*, 13 CARDOZO J. INT'L & COMP. L. 631, 633 (2005) ("As a result of ambiguity in the provisions, developing nations sought to relax the scope of intellectual property protection required under TRIPS while developed nations sought to choose a direction to enforce patent rights strongly."). The historical background leading up the Ministerial Declaration on the TRIPS Agreement and Public Health in Doha on November 14, 2001 and the international disputes over the scope of TRIPS further illustrate this point. *See*, *e.g.*, Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L ECON. L. 469, 470-72 (2002) (describing multiple international conflicts resulting from differing interpretations of the TRIPS provisions, specifically regarding what these provisions would allow and under what circumstances). These disputes were sourced in the different interpretations that members of the international community applied to the TRIPS provisions. *See id.* at 480-83 (describing the various positions segments of the international community took when interpreting TRIPS and the problems these interpretations caused); *see also id.* at 493-94 (stating that misperceptions existed among the press and it was likely to influence how governments would respond).

168. By being a signatory to the TRIPS agreement and by passing its law allowing for compulsory licenses, South Africa's actions testified to its belief that compulsory licenses were allowed. *See supra* notes 126-30 and accompanying text (discussing South Africa's new law allowing for the use of compulsory licenses); *see also* Abbott, *supra* note 167, at 471 (describing South Africa as a country that wanted to use TRIPS for health reform). When South Africa did delay implementing its law, it did so not because it believed TRIPS prohibited it, but because of fear that trade sanctions might follow. *See* Marc, *supra* note 142, at 110 ("South Africa has halted implementation of the Medicine Act for fear of trade sanctions."); *see also* Steven Lee Myers, *South Africa and U.S. End Dispute over Drugs*, N.Y. TIMES, Sept. 18, 1999, at A8 (summarizing that the United States felt the law was too broad under then-existing trade laws but that it would halt trade sanctions in exchange for South Africa's agreement to adopt stricter standards).

169. The Doha Declaration has been declared a victory for both health activists and the pharmaceutical industry. *See* Kevin Gopal, *New Accord*, PHARMACEUTICAL EXECUTIVE, Jan. 2002, at 28.

170. Paragraph 5(b) of the Declaration specifically provides that "[e]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration on Public Health].

determine what constitutes such an emergency and it was recognized that epidemics such as HIV/AIDS can represent one.[171] In doing so, it was laid to rest whether or not TRIPS would allow compulsory licenses to treat diseases like HIV/AIDS. But, one issue still remains. If TRIPS is "to reduce the distortions and impediments to international trade," and if compulsory licenses are a source of such distortions, then how should TRIPS step in when a compulsory license is issued?

IV. BALANCING TRADE AND PRESERVING INNOVATION: DETERMINING "ADEQUATE REMUNERATION"

After Doha, it was clear that a TRIPS member could battle HIV/AIDS and similar health epidemics with compulsory licenses, but it was not clear what obligations would follow from that decision. In the agreement's general terms, these obligations are two-fold. First, each member, bound by the purpose of the agreement, has the obligation "to reduce distortions and impediments to international trade."[172] Second, each member has the obligation to promote technological innovation or at least not to hinder it.[173] When a member issues a compulsory license, these general obligations are met in the one entitlement that the patent holder retains—that of due compensation[174] or, as TRIPS provides, "adequate remuneration."[175]

But "adequate remuneration" is a vague term open to multiple interpretations, and the uncertainty surrounding it has led some countries to issue or threaten to issue compulsory licenses to bolster domestic industry rather than domestic health,[176] a practice that distorts trade, shifts costs, and shackles ongoing innovation efforts.[177] In response, developed countries, fearing that inadequate compensation will result from the licensing decision, have no incentive to allow the license to issue and have every incentive to erect trade barriers that preserve their IP advantages and protect their domestic innovators. Using such barriers can block compulsory licenses in those countries

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171. Paragraph 5(c) of the Declaration provides that "[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency." *Id.* para. 5(c).

172. TRIPS, *supra* note 160, annex 1C, pmbl., para. 1.

173. *Id.* art. 7 (providing that "[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation").

174. *See* DE CARVALHO, *supra* note 131, at 37-39.

175. *See* TRIPS, *supra* note 160, art. 31(h) (providing that "the right holder shall be paid *adequate remuneration* in the circumstances of each case, taking into account the *economic value* of the authorization" (emphasis added)).

176. *See A Gathering Storm*, *supra* note 1.

177. *See supra* Part II.A.2. (discussing how pharmaceutical innovation efforts are funded with current revenue); Part II.B.2. (discussing how compulsory licenses distort trade).

that need them most, and this practice threatens to make Doha meaningless. In addition, without assurances of adequate compensation, the pharmaceutical industry could likely turn away from researching drugs essential to the developing world, making a dire situation worse.[178]

Therefore, to preserve the original purposes of TRIPS and Doha, a member's obligation to pay "adequate remuneration" must be clarified, and the remainder of this Comment will do just that. Specifically, to avoid the unnecessary consequences above, it will interpret "adequate remuneration" in a way that discourages countries from using compulsory licenses to gain an international advantage while ensuring others that the resulting compensation will be fair. In doing so, it will outline principles for TRIPS compliance, eliminate noncompliant alternatives, and establish a framework of trade-offs and considerations that a court or other government body can use when calculating "adequate remuneration" so that innovation will be preserved, trade balanced, and access enabled.

A. TRIPS Compliance Principles

To ensure that any resulting interpretation of "adequate remuneration" is consistent with TRIPS, it is necessary to establish some baseline principles to guide the analysis. Such principles must flow from the document itself and from the agreements of its signatories.[179] Therefore, when interpreting "adequate remuneration," the analysis begins with the Ministerial Conference's subsequent declarations and continues with analyzing them in light of individual TRIPS requirements. This is because "adequate remuneration," like the "national emergency" language, is an example of a TRIPS provision left deliberately vague on account of the differing interests and positions at stake amongst the parties to the agreement. These vague provisions were included as a compromise, and their meanings are found in future clarification from decisions of the Dispute Settlement Body or from subsequent negotiations and agreements of the Ministerial Conference.[180] Accordingly, after looking at the Ministerial Declaration on the TRIPS Agreement and Public Health from November 14, 2001,[181] two principles are discernable.

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178. *See A Gathering Storm*, *supra* note 1 (summarizing a pharmaceutical chief's view that compulsory licensing could deter the drug industry from researching diseases found in the impoverished areas of the world). *But see* Whalen, *supra* note 111 (reporting that GlaxoSmithKline PLC is increasing its efforts to combat disease in poor countries by reducing prices and focusing research in neglected areas).

179. *See* DE CARVALHO, *supra* note 131, at 31.

180. *See id.*

181. *See* Doha Declaration on Public Health, *supra* note 170.

The first principle is that compulsory licenses should not be seen as a "silver bullet" to the world's health crises, but should instead be part of a larger and more comprehensive international solution.[182] To preserve this principle, "adequate remuneration" must encompass some limitation that would prevent the broad use of compulsory licenses. In other words, "adequate remuneration" cannot be interpreted as a bright-line rule or compensation scheme because if it was, then it would undermine this end. It also would not comply with Article 31(b)'s preference for negotiation with the patent holder because the certainty of a bright-line rule could encourage broad declarations of "national emergenc[ies] or other circumstances of extreme urgency" that would dispense with this requirement.[183]

This is because the certainty afforded by a bright-line rule enables parties to calculate their legal liabilities a priori, and when a party believes a future legal remedy will be more beneficial than what can otherwise be negotiated in a private transaction, that party is likely to forego the private transaction in favor of the legal remedy.[184] In the context of TRIPS, this means that if a member estimates its "adequate remuneration" liability and finds it to be more favorable than what could be negotiated, then that member has an incentive to exploit the freedom that Doha recognizes[185] and declare a circumstance of extreme urgency rather than negotiate with the patent holder.[186] Similarly, when the patent holder feels favored by the legal remedy, there is the same incentive to refuse commercially reasonable terms.[187] In both instances, Article 31(b)'s preference for negotia-

182. *Id.* para. 2 (providing that TRIPS can only "be part of the wider national and international action to address these [public health] problems").

183. TRIPS, *supra* note 160, at 31.

184. This is the reverse proposition of economic theory's efficient breach of contract. Under that theory, the bright-line rule of expectation damages allows parties to calculate, with reasonable certainty, their liabilities for breach of contract prior to breach. When a breach of contract is efficient (that is when the legal remedy for breach is more favorable than the costs associated with completing the contract), a party will forego the private, contractual obligation in favor of the legal remedy. *See*, *e.g.*, Lake River Corp. v. Carborundum Co., 769 F.2d 1284, 1289 (7th Cir. 1985) (discussing the economic theory of efficient breach in the context of penalty clauses). Here, it is necessary to avoid the bright-line rule in order to avoid incentives to disregard preferences for negotiation and private transactions in favor of more beneficial legal remedies.

185. *See supra* notes 170-71 and accompanying text.

186. This is disfavored because of the preference for larger international cooperation with regard to battling public health crises rather than relying on compulsory licenses to be a "silver bullet." *See supra* note 182 and accompanying text.

187. Encouraging patentees to avoid negotiations would undermine the real value of the compulsory license, which is the inducement of the patentee to agree to reasonable terms. *See* Julian-Arnold, *supra* note 13, at 364 (suggesting that the reason few compulsory licenses are issued is because of their dormant power to urge successful negotiations); *see also* STEPHEN P. LADAS, PATENTS, TRADEMARKS AND RELATED RIGHTS—NATIONAL AND INTERNATIONAL PROTECTION 427, § 248 (1975) (stating that "[t]he practical value . . . of compulsory license provisions . . . [is that they] usually induce[] the grant of contractual licenses on reasonable terms").

tion is undermined, but when the member dispenses with negotiation, the broad use of compulsory licenses is encouraged. Therefore, a bright-line rule would be contrary to the Declaration[188] and inconsistent with the TRIPS mandate[189] because it would encourage parties to ignore procedural requirements in favor of expedience or other tangible benefit.

The second principle is that "adequate remuneration" cannot defeat the object and purpose of the agreement[190] by undermining technological innovation or by harming the public welfare.[191] This means that "adequate remuneration" must account for balancing access to essential medicines with the incentives to innovate them for tomorrow.[192] Consequently, any calculation that does not consider both perspectives will be inadequate.

B. What Is Not "Adequate Remuneration"

Applying these guiding principles in light of the TRIPS obligations eliminates two interpretations of "adequate remuneration" and establishes a promising compensation approach.

The first interpretation bases "adequate remuneration" on a lost profits standard as determined by full market value. This interpretation is inadequate because it defeats the very purpose of the compulsory license within the TRIPS regime. Given that a compulsory license should promote the public health through lower medicine costs,[193] when royalties are based upon lost profits, no subsequent

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188. *See supra* note 182 and accompanying text.

189. *See* TRIPS, *supra* note 160, pmbl., para. 1 (stating that a desire of the members was "to reduce distortions and impediments to international trade"); *see also supra* notes 134-35 and accompanying text (discussing how compulsory licenses introduce international trade distortions).

190. Doha Declaration on Public Health, *supra* note 170, para. 5(a) (providing that "[i]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.").

191. Article 7 contains the objectives of TRIPS and reads as follows:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

See TRIPS, *supra* note 160, art. 7.

192. This follows from the requirement that IP rights be enforced "to promote technological innovation . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations." *Id.* Defining "adequate remuneration" in any other way that does not reflect the interests of both sides would essentially be the same as ignoring them and would thereby defeat the objective of the agreement as defined in Article 7.

193. *See supra* notes 160-64 and accompanying text.

price reduction follows.[194] This means that access to essential medicines does not increase, and when the "adequate remuneration" calculation does not account for access, it is inconsistent with the second principle above.[195] Therefore, interpreting "adequate remuneration" as lost profits is inappropriate.

The second interpretation defines "adequate remuneration" as "no compensation." Like lost profits, "no compensation" is contrary to the second principle above because, although such a substantial decrease in costs increases access, it does not do so "to the *mutual advantage* of producers and users of technological knowledge" and is not "in a manner conducive . . . to a *balance* of rights and obligations."[196] This is because "no compensation" means no reimbursement for the necessary investment expended in developing the technology, which does not advantage the innovator. It also is not conducive to balancing rights and obligations because it does not account for the IP right, which, as a recognized private property right,[197] requires compensation.[198] Moreover, a "no compensation" scheme ignores the "silver bullet" principle because rather than deter the broad use of compulsory licenses, it encourages it,[199] which as previously described, distorts international trade.[200]

Instead, to be consistent with both the guiding principles and the TRIPS obligations, a proper approach calculates "adequate remuneration" in a way that reflects both perspectives of the compulsory licensing dilemma[201] and balances them through individual tradeoffs.[202] Such a calculation, though complex, preserves the preference

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194. *See* F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT'L ECON. L. 913, 921 (2002); *see also* SCHERER, *supra* note 64, at 35 (describing that the financial effect of setting royalties at full market value is the same as exclusive exploitation of the patent by the patentee).

195. TRIPS requires that "adequate remuneration" account for balancing access to essential medicines with the incentives to innovate them for tomorrow. Therefore, both must be reflected in the calculation. *See supra* note 192 and accompanying text.

196. TRIPS, *supra* note 160, art. 7. *But see* Vaughan, *supra* note 152, at 108 (concluding that based on U.S. precedent and on the inability of developing countries to pay monopoly prices for pharmaceuticals, patent holders for pharmaceuticals in developing nations are not entitled to any compensation when that country issues a compulsory license).

197. *See* TRIPS, *supra* note 160.

198. *See* DE CARVALHO, *supra* note 131, at 37-39 (arguing that IP, like private property, requires due compensation when confiscated by the government).

199. Since the first guiding principle disfavors certainty in a priori liability calculations, "no compensation," which means there is no liability, will certainly undermine this principle.

200. If inadequate compensation is likely to lead to distortions in international trade, then "no compensation" will only exacerbate those distortions and be contrary to the very mandate of TRIPS. *See supra* notes 134-35 and accompanying text.

201. This would make it compliant with the second guiding principle. *See supra* note 192 and accompanying text.

202. *But see* JAMES LOVE, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 6-7, WHO/TCM/2005.1 (2005), *available at* http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf (ad-

for negotiation by undermining the certainty of a priori calculations[203] and, in addition to balancing the interests of both sides, can account for other TRIPS requirements.

One such requirement is the requirement that "adequate remuneration" account for the economic value of the authorization,[204] particularly in a way that balances incentives for innovation with access to medicines.[205] The complexity of this requirement dictates that neither a single compensation standard nor a bright-line rule will be sufficient, but that multiple considerations should be made. Similarly, TRIPS requires that the basis for a compulsory license be its individual merits.[206] By considering both sides and selecting options that balance their interests, a court can tailor a license's compensation to the most relevant facts and thereby base it on its individual merits.

C. Calculating "Adequate Remuneration"

Based on the above, if a court is to calculate "adequate remuneration" as a balance of perspectives and as a tailored selection of multiple options, then it must know the parts of "adequate remuneration," what the options are, and how to consider them within the proper framework so that a balance can be struck. The analysis below presents these criteria after filtering them from the precedents of developed countries, and it uses these precedents on the basis of two theories. One is the theory that compensation schemes in these countries are best at calculating payments so that innovation is not stifled.[207] Another is the theory that a country will be less likely to respond to a compulsory license with trade sanctions when its own

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vocating a simple system to ensure ease of administration, transparency, and predictability for governments with limited capacity to administer a complex, multifactored approach, but advocating a complex, multifactored approach for countries with the resources necessary to make such administrative determinations); Mark C. Lang, *What a Long, Strange "TRIPS" It's Been: Compulsory Licensing from the Adoption of TRIPS to the Agreement on Implementation of the DOHA Declaration*, 3 J. MARSHALL REV. INTELL. PROP. 331, 352 (2004) (advocating a bright-line, minimal royalty rate justified on the certainty principle).

203. The complexity of the calculation undermines the certainty here, and it would make it compliant with the first guiding principle—the "silver bullet" principle. *See supra* note 182 and accompanying text.

204. *See* TRIPS, *supra* note 160, art. 31(h) ("[T]he right holder shall be paid *adequate remuneration* in the circumstances of each case, taking into account the *economic value* of the authorization." (emphasis added)).

205. *See supra* notes 190-92 and accompanying text.

206. *See* TRIPS, *supra* note 160, art. 31(a) (requiring that "authorization of such use shall be considered on its individual merits").

207. Some may say this assertion is dubious at best because developed countries could very well be best at preserving innovation because of their reluctance to issue compulsory licenses and not because their compensation schemes are better than those elsewhere in the world. *See supra* Part II.A.1 (discussing the rarity of compulsory licenses in the United States). Even if this is the case, one should recognize that this is only a starting point and not the end of the analysis.

precedents are used to compensate the patent holder,[208] thus avoiding an impediment to trade.[209]

Relying on these two theories, eminent domain law from the United States has been chosen as the foundation of this analysis. Specifically, this analysis relies on 28 U.S.C. § 1498,[210] because like an exercise of eminent domain, a compulsory license must serve a public purpose and must duly compensate the patentee.[211] Informing the analysis are practices from the United Kingdom and Canada, where experiences with pharmaceuticals and compulsory licenses have been the most thorough.[212]

Excluded from the analysis, though, are compensation schemes that serve as antitrust remedies because these schemes aim to correct anticompetitive practice, not preserve innovation.[213] Moreover, antitrust remedies fall outside the "adequate remuneration" requirement of TRIPS and therefore remain a separate consideration.[214]

1. "Adequate Remuneration" Framework

Before presenting various options for determining "adequate remuneration" and outlining a method for making individual tradeoffs, a framework must be established so these options can be placed

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208. For example, if the United States is likely to impose trade sanctions when a compulsory license is used, it may be less likely to do so if the patentee receives compensation in accordance with U.S. law because then the issuing country's IP protection would more closely match that of the United States. *See supra* notes 136-42 and accompanying text (discussing how the United States imposes trade sanctions against those countries whose IP protection is weaker than is expected).

209. Any compensation method that claims to be TRIPS-compliant must avoid impediments to trade. *See* TRIPS, *supra* note 160, pmbl., para. 1.

210. 28 U.S.C. § 1498(a) provides that

> [w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

28 U.S.C. § 1498(a) (2000); *see also* Leesona Corp. v. United States, 599 F.2d 958, 964 (Ct. Cl. 1979) ("When the government has infringed, it is deemed to have 'taken' the patent license under an eminent domain theory, and compensation is the just compensation required by the fifth amendment.").

211. *See supra* notes 162, 198 and accompanying text.

212. *See generally* David J. Henry, *Multi-National Practice in Determining Provisions in Compulsory Patent Licenses*, 11 J. INT'L L. & ECON. 325 (1977) (comparing multinational practices in compulsory licensing and focusing specifically on practices from Canada and the United Kingdom because of their multiple decisions in the area and their focus on the terms of individual licenses).

213. *See supra* notes 190-92 and accompanying text (discussing how innovation is essential to the calculation).

214. *See* TRIPS, *supra* note 160, art. 31(k) (providing that "[m]embers are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive").

in the proper context. This framework includes defining the component parts of "adequate remuneration" and identifying the steps necessary for determining "adequate remuneration" so that it will be TRIPS compliant.

Because U.S. eminent domain law is the foundation of this analysis, "adequate remuneration" is defined as a two-part royalty—one part a compensation base and the other part a royalty rate that applies to that base.[215] Fortunately, this coincides well with British and Canadian practices, which similarly define royalties.[216]

To ensure TRIPS compliance, a series of steps are needed so that a court can methodically make its calculation in accordance with the agreement. To meet this end, it is necessary to recall that TRIPS requires any royalty given in exchange for a compulsory license be based upon its "economic value"[217] as calculated from a perspective that balances assurances of future technological innovation with the right to access essential medicines.[218] This requires a court to analyze "economic value" from the perspective of both the patent holder and the issuing government, with an eye toward balancing an incentive to innovate for the former and a desire to access for the latter.[219]

This is a complex arrangement, but various options for both the compensation base and the royalty rate are available and presented below to meet this end. Therefore, to make sure that the royalty preserves innovation, the first step in the calculation requires a court to calculate the royalty in a way that ensures innovation does not suffer. The second step in the calculation requires a court to choose individual options that will decrease the royalty's total value in light of the issuing country's capacity to pay. By doing so, a court ensures that access is maintained and that the purpose of the compulsory license is not defeated. Although this may result in a royalty that is

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215. *See* ITT Corp. v. United States, 17 Cl. Ct. 199, 202 (1989) ("One approach . . . [is] to determine an applicable compensation base and to apply a reasonable royalty rate to this figure.").

216. In the United States, there is also an additional compensation element of "delay compensation" that is meant "to accomplish complete justice as between the plaintiff and the United States." Waite v. United States, 282 U.S. 508, 509 (1931). This element is not found in the compensation schemes of the United Kingdom and Canada when applied to pharmaceuticals, no doubt because these countries did not seize the technology but only dictated the terms for its license. This points out a resulting discontinuity of starting with 28 U.S.C. § 1498, and to avoid it, this Comment does not discuss or include it. It seems reasonable, however, that if an issuing country includes "delay compensation" in its eminent domain compensation calculation or seizes the pharmaceutical for state distribution, then this component can be included as well.

217. *See* TRIPS, *supra* note 160, art. 31(h) ("[T]he right holder shall be paid *adequate remuneration* in the circumstances of each case, taking into account the *economic value* of the authorization." (emphasis added)).

218. This is merely a restatement of the second principle described earlier. *See supra* notes 190-92 and accompanying text.

219. *See supra* note 192 and accompanying text.

not ideal from an innovation perspective, it is necessary to account for both perspectives.[220]

Therefore, "adequate remuneration" consists of two parts—a compensation base and a royalty rate that applies to that base. For both parts, various options exist for a court to consider, and a court should begin by determining a compensation base and royalty rate that is innovation-centric. Next, in light of the country's capacity to pay, it should consider other options for the royalty's parts and make individual trade-offs that afford access.

Finally, to ensure TRIPS compliance, a validation step is necessary to judge the royalty's reasonableness in light of the innovation and access restraints.[221] Only by validating the royalty with some objective measure can a court ensure the proper balance has been struck. For this reason, the final step in the calculation is a validation step that requires a court to evaluate the reasonableness of its "adequate remuneration" determination.

2. Determining a Royalty Rate

If the basis for a compulsory license is its individual merits,[222] then when considering the proper royalty rate, a court must first consider the surrounding facts. In doing so, the court can initially determine whether or not defining "adequate remuneration" according to the scheme proposed above is overly complex. That is, in some situations, the facts may dictate that an easier method for compensating the patent holder is available. And when available, a court can embrace it, conserving precious judicial resources in the process. Should the court decide otherwise, then as the first step in determin-

220. Note that innovation is not a function of one country's royalty but is a function of the compensation system's ability to control costs. Here, the proposed framework attempts to calculate an "ideal" royalty that reflects the cost of innovation and then brings it into harmony with an individual country's access abilities to make it "fair." Therefore, consumers benefit from lower costs and any resulting harms to innovation are contained. *See* John H. Barton, *The Economics of TRIPS: International Trade in Information-Intensive Products*, 33 GEO. WASH. INT'L L. REV. 473, 489-90 (2001) (discussing that under TRIPS, forms of international IP protection must provide long-term benefits to innovation that outweigh the costs to the world's consumers and that the global allocation of innovation costs should be fair).

221. This practice also is derived from U.S. law. *See* Leesona Corp. v. United States, 599 F.2d 958, 973 (Ct. Cl. 1979) (stating that "one way to monitor the reasonableness of our determination of just compensation is to compute the award by estimating a reasonable royalty on a proper compensation base, and then test this award by an examination of other available measures").

222. *See supra* note 206 and accompanying text (discussing the "individual merits" requirement).

ing the proper compensation base and royalty rate, the court can calculate the "economic value" of the license.[223]

Under U.S. law, when valuating a compulsory license, a court looks to the surrounding facts, particularly the terms of the license such as its scope and duration.[224] Since TRIPS requires that "the scope and duration of . . . [the license] be limited to the purpose for which it was authorized," then depending on the purpose, some licenses may be very short.[225] In these instances, rather than establish a two-part royalty, a court may simply lengthen the patent term, similar to what is done in the United States under the Hatch-Waxman Act.[226] Passed in response to previous legislation allowing generic manufacturers to intrude upon patents for the sake of regulatory approval,[227] this Act seeks to remedy the harm to the patent holder that results from a temporary intrusion by preserving the effective life of the patent.[228]

This approach could very well be the best for a court because it partially avoids the valuation problem, but unfortunately, it will likely be inappropriate for most pharmaceutical cases.[229] When dealing with health crises like HIV/AIDS that require long-term treatment or when a short-term intrusion on the patent will result in a much lower probability that the innovator will recover the associated costs

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223. As will be shown, both sides must be accounted for because it is the only way that a license can balance incentives for innovation with the need to access essential medicines. *See supra* note 192 and accompanying text.

224. *See* Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). Although royalty determinations often cite *Georgia-Pacific*, a court should distinguish it because it was decided under 35 U.S.C. § 284. Although there are a number of overlapping factors when calculating compensation rates based on 28 U.S.C. § 1498 and 35 U.S.C. § 284, infringements under the former are thought of as an " 'eminent domain taking of a patent license,' " not a tort claim like infringements under the latter. *See* ITT Corp. v. United States, 17 Cl. Ct. 199, 202 (1989).

225. *See* TRIPS, *supra* note 160, art. 31(c) (providing that "the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive").

226. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

227. 35 U.S.C. § 271(e)(1) provides that

> [i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1) (2000).

228. *See* 35 U.S.C. § 156(c) (2000) (allowing for an extension of patents that are subject to regulatory review for a period that is no greater than the period required to obtain approval).

229. *See supra* note 45 and accompanying text (discussing how the valuation problem leads courts to issue injunctions as remedies).

over time,[230] simply lengthening the patent term will be ineffective because, in both cases, the patent holder's opportunity to recover costs and reinvest them for development is lost.[231]

If this is the case, then a court should opt for the royalty-based compensation scheme and begin its analysis by determining the "economic value" of the license to the patent holder.[232] This can be done in two ways under U.S. law. One way uses the comparative royalty technique, and the other compensates the patent holder by valuating what was lost.

Under the comparative royalty technique, a court analyzes the remainder of the license's terms and compares them with similar licenses.[233] If similar licenses are found and indicate an already established royalty, then the court adopts that royalty.[234] If no similar licenses and established royalties are found, then the other option under U.S. law is to valuate what the patent holder has lost.[235] In this respect, since the "economic value" determination must preserve the incentive to innovate,[236] a suitable royalty rate should account for innovation and its attendant innovation variables—the costs of innovation and invention, the risks, the potential payoffs that accompany success, and the rate of competitive imitation.[237]

Hence, when defining a royalty in terms of what the innovator has lost, the first variable—the cost of innovation and invention—is simply an accounting for the costs to develop the drug as well as to

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230. No specific examples are apparent to the author at this time, but one can imagine the case of a specialty drug specifically engineered to combat a sudden pandemic. If the probability of this pandemic is relatively low, so that it can only be expected to occur once during the patent's term, then an intrusion on the patent without sufficient compensation during this period would have a harmful effect since for the remainder of the patent term, the demand will be significantly lower. As a result, if denied compensation when demand is highest, the likelihood of recovering the development costs will be much lower.

231. *See supra* note 90 and accompanying text (discussing how innovation in the pharmaceutical industry sprouts from a company's ability to recover costs through sales of patented products).

232. *See supra* notes 217-19 and accompanying text (discussing why "economic value" must be determined from both the patent holder's and issuing country's perspectives).

233 *See* Leesona Corp. v. United States, 599 F.2d 958, 973 (Ct. Cl. 1979) (discussing the comparative royalty technique for defining royalties and stating that "[t]he comparative royalty technique is the preferred method of determining just compensation").

234. Tektronix, Inc. v. United States, 552 F.2d 343, 347 (Ct. Cl. 1977) (stating that when "an established royalty rate for the patented inventions is shown to exist, that rate will usually be adopted as the best measure of reasonable and entire compensation"); *see, e.g.*, ITT Corp. v. United States, 17 Cl. Ct. 199, 223-40 (1989) (using a comparison of similar licenses to provide a basis for determining just compensation).

235. *See Leesona*, 599 F.2d at 969, 972, 977 (describing the value to the patentee as a basis for compensation, stating that "[t]he proper measure in eminent domain is what the owner has lost" and stating further that "[t]he just compensation to which an owner is entitled when his property is taken by eminent domain is regarded . . . from the point of view of the owner of the right and not from that of the taker").

236. *See supra* notes 217-19 and accompanying text.

237. *See supra* Part II.A.2.

bring it to market.[238] These costs are particularly relevant because they are the costs that any potential licensee will be "free-riding" upon,[239] and precedent for reimbursing them is found in the United Kingdom under Section 41 of its Patents Act of 1949. Under this Act, courts aimed to provide a "reasonable advantage" to the patent holder while also finding the lowest possible prices for drugs.[240] This "reasonable advantage" came in the form of a multielement royalty rate with one element accounting for the drug's research and marketing costs.[241]

Beginning with research costs, the British courts gave compensation according to the industrial practice for funding research.[242] Consequently, since the pharmaceutical industry funds current research out of current sales,[243] the first royalty percentage element should be a percentage defined as the ratio of total research expenses to world sales, as defined by the patent holder's balance sheet.[244] The basis for this ratio can either be the world sales of all products, which is more favorable to an issuing country, or the world sales of all research-developed products, which is friendlier to the patent holder.[245] In either case, this royalty element is both simple to calculate and administer in comparison to a more exacting alternative that would determine how much a particular drug's profits fund total research efforts.[246]

The next cost category is marketing costs, or promotion costs, and once again, British practice provides a model. Justified on the theory that promotion costs are part of the benefit that a licensee receives from the promotion of the drug by the patent holder,[247] the British

238. One could also argue that a royalty should include attorneys' fees as well since these are costs employed in obtaining an "adequate remuneration" that preserves innovation incentives. Attorneys' fees, however, are specifically excluded in U.S. law and thus this Comment does not include them. Traditionally, under 28 U.S.C. § 1498, attorneys' fees have not been awarded except in a limited number of statutory exceptions contained therein. Since the traditional view is that attorneys' fees are a punitive award, U.S. courts have declined to include them when determining just compensation after the government takes a patent. *See Leesona*, 599 F.2d at 970; *see also* Dohaney v. Rogers, 281 U.S. 362, 368 (1930) (holding that the just compensation award that follows an eminent domain taking does not include attorneys' fees).

239. *See supra* notes 72-80 and accompanying text.

240. "In settling the terms of licenses under the section the Comptroller shall endeavour to secure that food, medicines, and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights." J.R. Geigy S.A.'s Patent, [1964] R.P.C. 391, 398 (U.K.) (citing section 41(2) of the Patents Act of 1949); *see also* Henry, *supra* note 212, at 329.

241. *See J.R. Geigy*, [1964] R.P.C. at 398.

242. *See* Henry, *supra* note 212, at 331 (noting that British courts adopted this industrial practice when determining the research element of a royalty).

243. *See supra* note 90 and accompanying text.

244. *See* F. Hoffman-La Roche & Co. A.G.'s Patent, [1973] R.P.C. 601, 606 (U.K.).

245. Friendliness to either party is a function of the divisor in the ratio. A constant dividend divided by a larger divisor results in a smaller percentage and thus favors the issuing country. A smaller divisor would likewise favor the patent holder.

246. *See F. Hoffman-La Roche*, [1973] R.P.C. at 607.

247. J.R. Geigy S.A.'s Patent, [1964] R.P.C. 391, 400 (U.K.).

courts apportioned the patent holder's marketing expenditures across a number of categories—such as clinical trials, advertising expenses, marketing activity, and administrative costs—and included them as elements within the royalty rate.[248] Such a scheme in the international context would necessarily be case-specific and would require a court to make individualized findings. These findings would reflect the promotion funds expended and expected to be lost as a result of the license, and a court reimbursing costs based on these findings should use British practices as a guide.[249]

When compensating for risk, the second innovation variable, there are two approaches. The first compensates directly for risk by accounting for failures and successes. The second compensates through an arbitrary profit element added to the royalty rate. The British courts used both.

For example, when calculating the research element of the royalty percentage, British courts accounted for all funded research activity. Believing this to be "the only realistic method of recovering research costs,"[250] the courts determined a royalty rate that compensated for both successes and failures that occur in the research process and thereby accounted for risk.[251]

A court wishing to account for risk in the royalty rate could easily adopt this model, but should it fall short, the court could continue to follow the British model and add an arbitrary profit element to the royalty rate.[252] Based on prior practices, this profit element sometimes reached as high as 22.5% of those costs incurred for research and promotion.[253]

At first glance, such a high profit element may be difficult to justify solely as a matter of risk. But risk is only part of the innovation picture. When the detrimental effects that a compulsory license has on innovation are also considered, such a high profit element is easier to accept. In other words, using such a high profit element may only be justifiable after remembering that the compulsory license nullifies two of the four innovation variables. Specifically, when the license is issued, there is no longer any barrier to competitive imitation,[254] and as that competition enters the market, the patent's poten-

248. Henry, *supra* note 212, at 332.

249. *See, e.g.*, *F. Hoffman-La Roche*, [1973] R.P.C. at 612 (summarizing how promotion costs were apportioned).

250. *J.R. Geigy*, [1964] R.P.C. at 400.

251. *See* Henry, *supra* note 212, at 341.

252. *See, e.g.*, *F. Hoffman-La Roche*, [1973] R.P.C. at 617.

253. *See* Henry, *supra* note 212, at 330 n.17.

254. *See supra* notes 72-87 and accompanying text (discussing why, in the pharmaceutical context, patents are the most effective barrier to competitive imitation).

tial reward is diminished.[255] Therefore, this additional profit element in the royalty rate is justified not only because of risk, but also because of the entry of competition and the erosion in expected profits for the patent holder.[256]

Furthermore, because the loss of expected profits is relevant to the profit element, a court should also consider the particular characteristics of the licensed drug.[257] That is, a court should assess whether the drug can be described as a "blockbuster" drug because "blockbuster" drugs fund the majority of research and development activities.[258] If the drug is a "blockbuster," then it weighs in favor of a higher profit element.

In sum, to compensate for innovation when no comparable royalty exists and when lengthening the patent term is insufficient, a court should rely on a royalty rate that consists of the sum of three elements—a research element consisting of a ratio of research and development costs to sales, a promotions costs element defined according to an individual apportionment of expenses, and a profit element.

This is not the end of the calculation, however, because as previously described, "adequate remuneration" must account for access, and the final compensation must reflect this.[259] Therefore, if the royalty rate does not afford access, a court must decrease it until it reaches a balance between access and innovation. In the context of the above analysis, some of the options presented would lessen the total royalty, but assuming this is not enough, other options are available.

These options exist under Section 41 of the Canadian Patent Act of 1969 where compensation was primarily a function of "the value of the use . . . to the licensee,"[260] but because they do not fold well into the previously described innovation variables, they should not be re-

255. *See supra* notes 88-89 and accompanying text (discussing the patent's effect on recovering costs).

256. *See*, *e.g.*, *F. Hoffman-La Roche*, [1973] R.P.C. at 608 (noting that the profit element reflects the monopoly situation the patent provided prior to the license). This is not the end of the inquiry when considering expected profits. *See infra* Part IV.C.4 (describing how expected profits should be used to validate the royalty).

257. *See*, *e.g.*, Charles Pfizer & Co. v. Novopharm Ltd., [1970] 65 C.P.R. 132, 142-43 (Can.) (considering the importance of the drug Terramycin when evaluating the appropriateness of the royalty).

258. *See* FED. TRADE COMM'N, *supra* note 14, ch. 3, at 5 (noting that brand-name companies heavily rely on a small number of " 'blockbuster' " drugs to recoup their innovation investments, including those made for failed products).

259. *See supra* notes 217-19 and accompanying text.

260. Henry, *supra* note 212, at 340. While the Canadian practice addresses value to the "licensee," this Comment places the issuing government in this role since both are primarily interested in minimizing acquisition costs. The only difference is that the licensee wishes to maximize profits while the issuing government wishes to maximize access. In both, the means are the same because lower total acquisition costs act as an enabler to achieve the desired end.

lied on in absence of other considerations. To do so would not serve innovation well,[261] but they are options that Canada has employed to improve access to drugs in the past.

For example, when compensating the patent holder for the research and promotion costs of a particular drug, Canadian courts limited research costs to those leading to the invention and did not include any compensation for failures.[262] Furthermore, the courts did not compensate for promotion costs, and they specifically excluded postinvention expenses.[263]

Instead, Canadian practice surveyed the market landscape, taking account of the prior art, commercial surveys, and other market conditions,[264] and it focused on the total sum of the potential royalties over the life of the license.[265] In the end, most compulsory licenses resulted in an arbitrarily assessed rate of four percent[266] or fifteen percent,[267] depending upon the royalty's compensation base.[268]

Using these practices as a guide, a court desiring to lower a potential royalty to increase access can easily do so, but it should not rely on these practices in isolation. Instead, a court should only rely on the Canadian model in conjunction with the British model. In this way, a court can temper what some economists have described as the Canadian courts' tendency to undercompensate the patent holder and to harm innovation.[269] For this reason, while Canadian practices cannot provide a complete solution to the compensation equation, they do provide courts a balancing tool. That is, when balancing the need for access in developing countries with innovation incentives, a court can look to Canadian practices to reduce the overall royalty and, in doing so, can ensure that the capacity to pay does not remain a barrier to medicinal access.

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261. *See* Grabowski, *supra* note 66, at 855 (noting that the historical Canadian approach "strongly discouraged investment in . . . domestic industry").

262. *See* Henry, *supra* note 212, at 340 (noting that this research component could be nonexistent in the final royalty calculation).

263. *Id.* at 340-41.

264. *Id.* at 341.

265. *See, e.g.*, Hoffman-La Roche Ltd. v. Frank W. Horner Ltd., [1970] 65 C.P.R. 93, 112 (Can.).

266. Henry, *supra* note 212, at 341. This figure is also very similar to at least one proposal for "adequate remuneration" that suggests rates between three percent and five percent based on international comparisons and proposals from pharmaceutical representatives. *See* Lang, *supra* note 202, at 353.

267. Henry, *supra* note 212, at 341 n.63.

268. Royalty-based options are discussed *infra* Part IV.C.3. Under the Canadian model, a four percent royalty is applied to the net selling price, and a fifteen percent royalty is applied to the bulk sale price. *See* Henry, *supra* note 212, at 341.

269. *See, e.g.*, J.R. Geigy S.A.'s Patent, [1964] R.P.C. 391, 406 (U.K.) (calculating the royalty to be sixteen percent of the drug's selling price in the U.K., which would exceed the four percent rate applied to the selling price of the drug in Canada); *see* Grabowski, *supra* note 66, at 855 (noting that the historical Canadian approach "strongly discouraged investment in . . . domestic industry").

3. Determining a Compensation Base

Two options exist for the compensation base, and because both have their own implications, both should be considered in light of the royalty rate when balancing access rights with innovation incentives.

One option for the compensation base is the selling price of the drug as defined on an annual treatment or per dosage basis.[270] Using this option for a royalty base ties the royalty to the current market price and favors access rights because the royalty will decrease as the license's effect permeates throughout the local market. In other words, after a court issues the compulsory license, generics will quickly enter the market and cause a drop in the market price.[271] Over time, prices will continue to drop as supply increases to satisfy demand, and this will increase access, but it will also decrease the patent holder's royalty.[272] To repair this effect, some courts in the United Kingdom relied upon future projections to calculate an "uplift" percentage that would offset the corresponding reductions and align the total royalty with its intended value.[273] Courts concerned with innovation effects and attempting to balance rights under TRIPS can easily do the same.

In the alternative, a second and innovation-friendlier option uses the price-per-kilogram, or bulk sale price, of the active, manufactured substance as the compensation base. This alternative insulates the patent holder from market price reductions and ensures some stability because the bulk sale price is relatively stable in comparison to the dosage price.[274] On the other hand, it may have a harmful side effect and keep prices artificially high,[275] and in light of this, a court may wish to adjust the compensation base or royalty rate accordingly.

4. Validating the Whole: Ensuring that Remuneration Is "Adequate"

Finally, a court striving to weigh these factors in an effort to balance innovation and access requires some form of validation to judge the reasonableness of the final assessment. Under U.S. law, royalties are validated by comparing the royalty to what has been

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270. *See* Henry, *supra* note 212, at 335-36.

271. *See, e.g.*, Marques et al., *supra* note 118, at 474 (reflecting the market price reductions that follow compulsory license awards).

272. *See* F. Hoffman-La Roche & Co. A.G.'s Patent, [1973] R.P.C. 601, 608-09 (U.K.).

273. Henry, *supra* note 212, at 336.

274. *See id.* (describing the effect of this alternative as ensuring the patentee receives full and adequate recovery for the associated costs in developing and marketing the drug, which otherwise could be defeated by the decreasing royalty amounts that result from decreasing prices in a competitive market).

275. *See* J.R. Geigy S.A.'s Patent, [1964] R.P.C. 391, 402 (U.K.) (discussing how this alternative might keep prices higher despite the compulsory license).

gained and lost from each side.[276] Therefore, since U.S. law provides the baseline for this analysis, assessments of the license's "economic value" from the perspectives of the issuing government and the patent holder are necessary.

Beginning with the issuing government, a court analyzing the reasonableness of its economic value determinations should assess the savings to the government and its needy consumers. While such savings are not awardable to the patent holder, they are an acceptable measure of the royalty's reasonableness and should give an indication of its effect on public access.[277] This then should be compared to the license's economic value to the patent holder. In this regard, when evaluating the patent holder's economic value, a court should assess the profits that have been lost by comparing expected profits if the license had not been issued to the expected profits that will result from the license.[278] In this way, a court can evaluate the profit differential and rudimentarily forecast the potential effects on innovation since profits fund current research.

Consideration of this last factor, lost expected profits, has an added benefit. It encourages Ramsey pricing—a practice that is preferred because it tends to set price points in a way that maximizes access to essential drugs.[279] A patent holder who sells a patented drug in a country at a price that substantially limits access will lose less profit when a court issues a compulsory license, and if there is little profit expectation from a particular market, then it is not likely to fund future research. This means that the loss of that market should not hinder innovation. If Ramsey pricing is used, then a patent holder aims to maximize profits within a particular market by setting a lower price,[280] making it more likely that the market will fund future innovation efforts. Therefore, when lost expected profits

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276. Leesona Corp. v. United States, 599 F.2d 958, 973 (Ct. Cl. 1979) ("[O]ne way to monitor the reasonableness and fairness of our determination of just compensation is to compute the award by estimating a reasonable royalty on a proper compensation base, and then test this award by an examination of other available measures—savings to the government, lost profits, etc.").

277. *See id.* at 971 (discussing the role of savings to the government within the assessment of royalties under 28 U.S.C. § 1498).

278. The profits discussed here, however, are distinguishable from the "full market value" measure of lost profits discussed previously. *See supra* notes 193-95 and accompanying text. Here, the lost profits discussed refer to the profit the patent holder expected from the lost market, not the actual lost profit per dose, and are a function of access within the affected market. Furthermore, under U.S. law, which supplies the foundation for this analysis, actual lost profits are not available as a remedy under an eminent domain taking. Instead, they are only available as a remedy under a tort theory of damages. *See*, *e.g.*, Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978) (discussing how lost profits are obtained in a private infringement action under 35 U.S.C. § 284).

279. *See generally* Scherer & Watal, *supra* note 194, at 925-28 (discussing Ramsey pricing and the benefits it provides in providing access to medicines in the developing world).

280. *Id.* at 927.

are high, a higher royalty is warranted, but when they are low, the opposite is true.

V. CONCLUSION

Admittedly, the above interpretation of "adequate remuneration" is a complex determination. For this reason, some may critique it as impractical and disfavored in light of simpler, more straightforward solutions.[281] For those who do, it is worthwhile to note that the standard above is not complex without reason.

One reason for such complexity lies in the difficulty of accurately valuating patented technology. As this Comment previously described, in some circumstances courts can avoid this difficulty by issuing injunctions and by relying on parties to negotiate the valuation issue outside of court, but in the TRIPS context, this alternative is unavailable. Instead, when an issuing government compels licensing of a patent through a compulsory license, negotiation opportunities are lost, and only the compensation decision remains.

Another reason for the complexity resides in the nature of TRIPS. By requiring that each license reflect its "individual merits" and its "economic value," TRIPS makes bright-line standards unpalatable and necessitates a factual, case-by-case analysis. This becomes even more necessary when recognizing that "adequate remuneration" must balance the interests of innovation and access. The divergence of these two interests leaves a court bridging a gap that may at first appear insurmountable, but by making individual trade-offs in light of the circumstances of each individual case, a court can build a bridge that may not be perfect, but can work.

Finally, "adequate remuneration" is complex because it ensures that compulsory licenses are available, but not abused. When compensation for patented technology is minimal, it encourages countries to take the expedient route, avoiding negotiation with the patent holder and shifting costs in the process. This, in turn, can result in trade sanctions or other forms of international retaliation from those countries that have the most to lose in terms of trade. In the end, the license is halted despite the issuing country's capacity to pay, and without the license, drugs remain out of reach, suffering continues, and the international solution to issues of public health becomes meaningless.

When compensation is "adequate," as based on a number of factors derived from the source agreement, however, costs may still be shifted, but they are also minimized. Consequently, the likelihood

281. *See*, *e.g.*, *supra* note 202 (listing alternative compensation schemes based on principles of administration capacity and certainty).

that the license will impact ongoing research is greatly diminished, as is the incentive for protectionist behavior in the international arena. Developed countries, for example, that would otherwise block a compulsory license to preserve their trade advantages have less incentive to do so when their innovators are fairly compensated. Similarly, countries with the capacity to pay for pharmaceutical technology have no incentive to issue a compulsory license to bolster their domestic pharmaceutical industries when the attendant compensation fairly denies them the advantage they seek. This not only preserves the international solution, but it also preserves compulsory licenses as a viable alternative for those countries that need them most.

The method that this Comment presents is complex for all of these reasons, but especially because it strives to satisfy today's short-term needs without sacrificing those of tomorrow. Because access and innovation are intertwined, the necessity of a sufficient royalty is paramount to seeing that the former does not sacrifice the latter and vice versa. In other words, the compensation scheme described here, by providing a path for meeting our present needs without risking the future's, saves tomorrow from today.