CONFRONTING MYTHS AND MYOPIA
ON THE ROAD FROM DOHA

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Forthcoming, 42 GEORGIA LAW REVIEW (2007-08)

ABSTRACT
Recent patent compulsory licenses issued by Thailand have focused attention on this property rights safety valve as a means for balancing access and innovation in essential medicines. While derided in some quarters, many view these measures as a legitimate exercise of the flexibilities that exist in international intellectual property agreements, recently enhanced as a result of the WTO’s Doha round of trade negotiations. But the increasing willingness to utilize patent compulsory licenses faces a troubled future: the international framework is dangerously ambiguous and significantly misaligned. Chief among the concerns is the level of compensation owed to a patent owner for the loss of exclusivity. There is an utter lack of standards in international law, and countries generally resort to compensation conventions that are beset by myths regarding the available options, and shortsightedness as to the future impact. Largely ignored in the literature, this lack of a clear floor or ceiling to compulsory license compensation can make patent property rights less predictable, encourage gamesmanship by developing or developed countries wishing to cut expenditures and, most perversely, even stifle access. This article attempts to clarify the issue by focusing on the economic basis of compulsory licenses and identifying the underlying principles in existing compensation models. It suggests an innovative licensing framework that separates countries into three economic development tiers with different royalty mechanisms. Such a nuanced system, the article argues, will lead to more predictability and effective institutional mechanisms, ensuring continued innovation and greater access to essential medicines.

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Introduction..................................................................................................................3
I. The Primacy of Remuneration in Compulsory License Economics ...............6
   A. Innovation Incentives and Safety Valves.........................................................8
   B. Remuneration Equals Impact........................................................................13
   C. International Rules Amplify Public Health Remuneration
      Consequences ..................................................................................................17
II. Three Myths that Have Obscured Workable Remuneration Rules .............20
   A. Myth One: Equitable Compulsory Licenses Must Offer a Savings
      from the Market ..............................................................................................22
   B. Myth Two: Pharmaceutical Companies should be Indifferent to
      Compulsory Licensing so Long as “Reasonable” Remuneration is
      Available ..........................................................................................................29
   C. Myth Three: Antitrust Compulsory Licenses Provide a Reliable
      Royalty Benchmark .........................................................................................35
III. Toward a Just and Sustainable Practice of Compulsory Licensing
     Compensation ....................................................................................................38
   A. Abandoning the Unitary System ....................................................................39
   B. Establishing a Predictable Three-Tiered Model of Compensation .............42
      1. Full Compensation as a Default, Regardless of Economic
         Status .............................................................................................................43
      2. Ensuring Access in Public Health Emergencies .....................................46
         a). Industrialized Nations Will Bear the Compensation
            Burden ........................................................................................................47
         b). In Health Care Emergencies, Developing
            Nations Can Be Permitted Some Amount of Free Riding .........49
         c). In Emergencies, Least Developed Nations Can Argue for
            a Royalty-Free License .............................................................................51
   C. Instituting a National Exhaustion Rule ............................................................52
Conclusion..................................................................................................................56
INTRODUCTION

At the end of 2006, the government of Thailand announced that it intended to issue several “compulsory licenses” for patents related to AIDS and heart medications. The move was directed specifically to reducing the price of branded drugs; the licenses set compensation to patent owners at a mere 0.5% royalty on generic sales. Adding fuel to the fire, Thailand’s government subsequently indicated that it would issue several more licenses on additional pharmaceuticals in the near future. Predictably, an outcry ensued regarding the ex post appropriation of established property rights by a middle-income country, countered immediately by demands for placing the needs of the infirm over corporate profits. But Thailand’s actions raise another, more important issue that has received little attention: the international legal regime supporting access to medicines appears to be dangerously ambiguous and disastrously misaligned. As exposed by this case, it has few limitations on which countries can “break” patents simply to control costs, what circumstances create a necessary condition, or even what level of remuneration is required. Myopic strategies by middle and high-income countries are becoming ever more apparent. Conversely, the rules that do exist create bureaucratic barriers that prevent less sophisticated governments from even participating. This lack of a floor or ceiling defines a system that is configured poorly for all concerned, and has apparently avoided a crisis.

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2 Thail. Efavirenz CL, supra note 1.
5 See, e.g., Marwaan Macan-Markar, WHO Chief’s Stand on Generic Drugs Slammed, GLOBAL INFO. NETWORK, Feb. 5, 2007, at 1 (recounting the anger of several NGOs toward Margaret Chan’s comments against Thailand’s compulsory license announcement).
through historic luck.  

The problem is rooted in the unitary nature of international intellectual property law. Treaties like the Trade-Related Aspects of Intellectual Property (“TRIPS”) agreement create only baseline requirements for all members, and important limitations like compulsory licenses are available equally. That flexibility has some benefits in permitting countries to adapt intellectual property law to the local political environment. However, it is particularly inadequate in addressing the needs and obligations of different actors under emergent conditions.

Consider the contrast between two significant global health crises. AIDS, which has had an undeniably devastating impact on the world, is also a relatively slow moving disease, as pandemics go. This has given developed countries the time to incorporate AIDS treatment and education into their health care budgets. The impoverished nations of the world have much less ability, and they suffer disproportionately. It presents the classic case for the simple and efficient relaxation of Western property rights in favor of medical access. On the other hand, recent fear of an
explosion of human-to-human transmission of the deadly H5N1 virus, also known as bird flu or avian influenza, presents a very different kind of concern. Such a pandemic could impact both the developed and developing world equally harshly, and at the same time, making the need for effective medicines urgent. Should property rights be relaxed in this case as well? And if so, should all nations — rich and poor — be able to benefit from lower costs as a result, perhaps to the detriment of innovation incentives? The current rules leave open this very possibility.

Attenuating access and obligation is no easy task, to be sure. World Trade Organization members at the recent round of negotiations in Doha, Qatar indicated strong support for increasing access to medicines, but struggled openly to reach consensus on the exact terms, settling on a relatively narrow and complex revision. A number of academic works have also addressed the structure of patent compulsory licenses, and there is no shortage of suggestions for a better international system. But there

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12 See Donald G. McNeil, Human-to-Human Infection by Bird Flu Virus is Confirmed, N.Y. TIMES, Jun. 25, 2006, at A.8 (stating that scientists have long feared that the H5N1 virus, which has killed millions of birds, could mutate and acquire the ability to spread among humans “setting off a devastating pandemic.”).

13 WHO, Ten Things You Need to Know about Pandemic Influenza (Oct. 14, 2005), http://www.who.int/csr/disease/influenza/pandemic10things/en/index.html (an especially frightening warning about the consequences of influenza pandemics, noting that up to 7.4 million deaths may occur and that every country must be prepared). Recent studies suggest the virus may not be so dangerous, but it still presents an interesting academic question. See Betsy McKay, Bird Flu’s Pandemic Capability May Not Be as Strong as Feared, WALL ST. J., Aug. 1, 2006, at A.2.

14 See Declaration on the TRIPS Agreement and Public Health, ¶¶ 4, 6 (Nov. 14, 2001), Doc. WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration] (“[W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”).

15 Paragraph 6 Decision, supra note 7, at ¶ 1(b) n.3.

16 Some of the most recent include Sherman & Oakley, supra note 11, at (398-99) (suggesting that the AIDS pandemic requires a holistic approach that incorporates
is an unshakable feeling that any major revision of the current regime that retains its flexibility will be dangerously unpredictable, unworkably complex, and/or overly broad with regard to the impact on property rights. It seems an intractable problem.

This article suggests that the barrier to consensus may be largely one of perspective. Specifically, the emphasis on triggering mechanisms rather than the more important issue of remuneration has confused the debate. Moreover, the existence of multiple myths and misconceptions about what a compulsory license is, and what it can be, has led to overly narrow conceptions of potential solutions. This article attempts to remedy the misunderstandings and proposes a strikingly different, but ultimately more workable, resolution to the problem. Part I begins with a discussion of the economics of compulsory licenses and how a remuneration-based approach provides a better understanding of their true impact. Part II discusses multiple remuneration myths that have led many to overlook the potential of such an approach. Finally, in Part III, the article proposes a unique solution for bridging the obligation/access chasm based on separating countries into three distinct economic tiers. Different remuneration rules apply to each tier, which should have the effect of increasing access in the most impoverished nations while preserving innovation by retaining profits in developed countries. Such bold revisions will not be easy or necessarily popular, the article concludes, but the need for a well-constructed road from Doha’s principled departure point requires the consideration of dramatic measures.

I. The Primacy of Remuneration in Compulsory License Economics

The majority of global health care funding is now derived from private sources. This means that we are dependent on the existence of intellectual property concessions with such things as delivery optimization and addressing basic poverty); David W. Opderbeck, Patents, Essential Medicines, and the Innovation Game, 58 Vand. L. Rev. 501, 548-53 (2005) (proposing a method of improving access and maintaining innovation by relaxing IP rights and requiring southern markets to fund part of the research burden through remuneration); Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. Int’l L. 317, 354-57 (2005) (recommending a return to a multilateral approach to counter the industrialized nations – particularly the United States’ – attempt to circumvent TRIPS flexibility with free trade agreements).

17 It is estimated that global medical research and development funding was over
sufficient incentives to compel private entities to invest in medicine. The most important incentive is, of course, the potential to profit from products and services resulting from the initial investment.\textsuperscript{18} The non-excludable nature of information, however, might limit the investment companies would be willing to make if not for the existence of a legal mechanism to reduce competition.\textsuperscript{19} Patent rights are intended to restore the excludability that provides the incentive to invest.\textsuperscript{20}

However, when it comes to public health, strong property rights require limitation. Compulsory licenses are one mechanism touted as

\textsuperscript{18} See Patrice Trouiller, et al., Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure, 359 \textsc{Lancet} 2188, 2191 (2002) (articulating the argument that research and development in pharmaceuticals requires sufficient market incentives in the form of “individual purchasing power” and “government-run health insurance programs. Underdevelopment of products and services may result when insufficient market forces exist. \textit{Id}.


\textsuperscript{20} \textit{Id}. at 9 (describing intellectual property rights as a “second-best solution” to the problem of non-excludability of information goods). Increasing the incentive to invest in innovation is the most commonly stated rationale for the existence of a patent system. \textsc{See}, \textit{e.g.}, \textsc{Nat’l Research Council of the Nat’l Acads., A Patent System for the 21st Century} 35 (Stephen A. Merril et al. eds., 2004) [hereinafter NAS Report] (reviewing the literature assessing a patent’s ability to act as an innovation incentive or barrier). They are considered an essential part of the system by industry. \textsc{See}, \textit{e.g Fed. Trade Comm’n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy}, ch. 3, at 4-14 (2003) [hereinafter \textsc{FTC Report}] (“Representatives from the pharmaceutical industry stated that patent protection is indispensable in promoting pharmaceutical innovation for drug products containing new chemical entities.”); Edwin Mansfield, \textit{Patents and Innovation: An Empirical Study}, 32 \textsc{Mgmt. Sci.} 173, 174–75 (1986) (describing the importance of patents for the pharmaceutical and chemical industries).
providing some measure of relief. Given the economic basis of patents, there is great concern about the impact of such licenses on innovation. Unfortunately, the understanding of how innovation effects occur or what licensing rules best address them is tenuous at best. By considering the problem from the perspective of compensation or remuneration, one can better appreciate the balance required to ensure that the access benefits exceed the innovation impacts. Moreover, recent revisions to international intellectual property agreements are even more likely to make compulsory license remuneration the critical factor in the future.

A. Innovation Incentives and Safety Valves

Patents accomplish an innovation incentive goal by providing their owners with a protected market for the invention for a specific period of time.\(^{21}\) While a patent owner may still face competition from close, non-infringing substitutes of the invention,\(^{22}\) at least the prospect of outright copying or inadvertent duplication is eliminated.\(^{23}\) The rewards from successful investment are reaped by charging the highest price the market will bear.\(^{24}\) Depending on the circumstances, such pricing could follow a monopoly model in a market in which the patented product stands alone, or take on a more competitive model when there are close substitutes unaffected by the patent owner’s rights.\(^{25}\) Critical to obtaining the greatest

\(^{21}\)William D. Nordhaus, Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change 70 (1969) (patents create incentives by conferring monopoly power for a limited period of time).


\(^{23}\)Patents give their owners rights over the invention described in the claims. 35 U.S.C. § 112 (2000). Technically, the protection extends beyond wrote duplication to so-called “equivalents” of the invention. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002) (reaffirming doctrine in U.S. law, stating, “The language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty.”);

\(^{24}\)F.M. Scherer, The Pharmaceutical Industry – Prices and Progress, 351 N.E.J. MED. 927 (2004) (explaining that pricing according to R&D costs is a fallacy and that for rational profit maximizes, “the position of the demand curve . . . and the variable costs of production and distribution” matter most); Ernst R. Berndt, Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price, 16 J. ECON. PERSPECTIVES 45, 58 (2002) (“Price reflects marginal value, not marginal production cost.”)

return on innovation investment is the patent owner’s control over the invention; by limiting supply through enforceable property rights, a legal scarcity is created in otherwise non-excludable information.26 Conversely, any incursion on a patent owner’s right to exclude use of the invention has the potential to cut into this return.

Of course, patents themselves come at a significant societal cost.27 The locking down of information that can be essential in improving the public health is troublesome.28 Due to the lack of availability or high cost, treatments may effectively be unavailable.29 Therefore, a means of different components of a semiconductor chip. So patent owners in the pharmaceutical industries don’t have to worry about an endless stream of patent owners asserting rights in their drugs.”).

26 See Edmund Kitch, The Nature and Function of the Patent System, 20 J.L. & ECON. 265, 275-80 (1977) (“[T]he property rights literature has viewed the central problem as one of scarcity, while information has appeared to be an example of something that can be used without limit. There is, however, a scarcity of resources that may be employed to use information, and it is that scarcity which generates the need for a system of property rights in information.”); Kenneth W. Dam, The Economic Underpinnings of Patent Law, 23 J. LEGAL STUD. 247, 250–51 (1994) (describing the concept of economic rents and how the contributions of patent-induced R&D can justify them).

27 ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 15 (2d ed. 2000) (“[I]ntellectual property laws can be justified by the public goods argument only to the extent that they do on balance encourage enough creation and dissemination of new works to offset [the social] costs.”).

28 Some would argue that access to medicines is a basic human right. In fact, such access may be enforceable through legal channels using a country’s guarantee of a right to health. See Hans V. Hogerzeil, et al., Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable Through the Courts?, 368 LANCET, 305, 308 (2006) (discussing a study of 73 cases from low income countries, primarily in central America, in which plaintiffs sued their respective governments for access to essential medicines).

29 Even when patent holders make their inventions available through products and services, the right to exclude others may permit a patentee to engage in monopoly pricing. ROBERT COOTER & THOMAS ULEN, LAW & ECONOMICS 122–23 (4th ed. 2004) (“[A] patent enables the inventor of something valuable to earn profits that exceed the ordinary rate of return on investment.”). Whether a patent owner actually has monopoly power depends on the market. See Edmund W. Kitch, Elementary and Persistent Errors in the Economic Analysis of Intellectual Property Law, 53 VAND. L. REV. 1727, 1730 (2000). When there are effective substitutes for the patented good, the patent owner’s ability to increase prices or reduce supply are limited. The newest, most groundbreaking treatments are often accompanied by a significant cost premium. See Joseph A. DiMasi, Price Trends for Prescription Pharmaceuticals: 1995–1999, at http://aspe.hhs.gov/health/reports/Drug-papers/dimassi/dimasi-final.htm (last updated Oct. 11, 2000) In industrialized nations, this may merely prompt a reallocation of financial resources, but in developing countries, the impact can be much more severe.
relaxing the restrictions of patent property rights without severely damaging the incentive mechanism that provides the essential medicines in the first place is a top priority.

Patent compulsory licenses are just such relief mechanisms. They are focused squarely at the sine qua non of property, the right to exclude others. They are literally a government’s right to practice an invention covered by a patent, or authorize another party to do so, without the authority of the patent holder. Essentially, the patent holder loses a bit of her property right to benefit the public. As a general matter, the patent holder retains the right to exclude others not licensed by the government, and to compete against the licensee. Additionally, the loss is usually restricted in time or by the continued occurrence of a triggering event. For these reasons, the compulsory license could be viewed as only a minor impingement of a patent owner’s property rights.

The primary impact of a compulsory license is to provide for a wider use of the invention than the patent owner would presumably allow. The binds of private ownership are released. Importantly, the act of compulsory licensing is usually retrospective in nature. Such measures


The U.S. Patent Act gives patent owners the right to exclude others from making, using, selling, offering to sell the invention in this country, or importing it from another without the authority of the patent owner. 35 U.S.C. § 271(a), 271(e)(4)(B) (2000). It is a fundamental aspect of property. See Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979) (“In this case, we hold that the ‘right to exclude,’ so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation.”).


The benefit to the public can be direct, as in the case of a license in the public interest, or indirect, as in the case of a license to increase competition in the marketplace. See Carlos M. Correa, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries, South Centre, at Part IV (1999), http://www.southcentre.org/publications/compllicence/toc.htm

Reichman & Hasenzahl, supra note 31, at 23 (“[T]he issuance of a non-voluntary license cannot normally impede a patent holder from entering the market in competition with the licensee.”). The most powerful general international intellectual property treaty, the Trade-Related Intellectual Property Agreement ("TRIPS"), actually requires that compulsory licenses be non-exclusive. TRIPS, supra note 6, at Art. 31(d).

The event limitation is also an explicit part of the TRIPS agreement. TRIPS, supra note 6, at Art. 31(g) (requiring that a compulsory license be “terminated if and when the circumstances which led to it cease to exist and unlikely to recur.”).
are generally imposed only after considering property that already exists,\(^\text{35}\) and then reallocating ownership rights by nationalizing them. Although the incentive to invent with respect to the licensed invention cannot be changed (since invention has already taken place), innovation policy advocates argue that the incentive to create future inventions is decidedly reduced.\(^\text{36}\)

Increased access through compulsory licensing is often considered in instances when a patent owner simply refuses to practice an invention, depriving one or more countries of the technology.\(^\text{37}\) Good business judgment suggests that this is an unusual occurrence because it would be economically irrational to withhold a product that could produce some profit over marginal costs. However, in the context of pharmaceuticals it is possible to imagine some scenarios in which that would occur. For example, a company may wish to maintain tight control over distribution and pricing of its patented good across several markets.\(^\text{38}\) One market’s refusal to limit redistribution into other markets may confound this scheme, compelling a company to simply reduce or eliminate sales in the offending country.\(^\text{39}\) Additionally, a company may wish to favor one product technology over another by simply precluding the sale of the

\(^{35}\) However, this \textit{ex post} approach is not a requirement. In other intellectual property contexts, there are compulsory licenses that apply to all property rights of a certain type, without regard to individual value or the predilections of the owner. \textit{See} 17 U.S.C. § 115 (2000) (compulsory license for making and distributing copyrighted phonorecords); Robert P. Merges, \textit{Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations}, 84 CAL. L. REV. 1293, 1295 (1996).

\(^{36}\) For an overview of this position, \textit{see} Colleen Chien, \textit{Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?}, 18 Berkeley Tech. L.J. 853, 856 (2003) (stating that there is a perception that compulsory licenses harm the incentive for innovation and quoting an executive from the pharmaceutical industry). \textit{But see} Kevin Outterson, \textit{Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets}, 5 YALE J. HEALTH POL’Y, L & ETHICS 193, 230 (2005) (arguing that if patent rents are “supra optimal,” compulsory licensing at marginal costs will not reduce innovation).


unwanted technology through patent rights. In either case, if the technology in question relates to an essential medicine, the result of an otherwise neutral, rational business decision could be very negative.

In addition to access, one may seek to employ compulsory licensing to redefine a patent owner’s market influence. Most important in this regard from a public policy perspective is modifying the patent right’s effect on price. Theoretically, if the patented good or service has no close substitute, the monopolist can control supply and/or price. In the context of intellectual property rights, relaxing the right to exclude has the effect of erasing part of this monopoly, allowing competitors to enter the market. If their marginal costs are lower than the monopolist’s prices, the price could be expected to come down (absent any payment back to the monopolist).

Pharmaceuticals may be quite sensitive to this kind of manipulation, as high prices are generally believed to be the result of monopoly rent seeking on the part of patent owning companies. True monopoly pricing by pharmaceutical companies is probably not common, given the fact that few medical treatments are so unique and essential that they literally provide the power to arbitrarily reduce supply or raise prices. However, when new classes of pharmaceutical compounds are introduced, several companies may engage in oligopropolistic behavior to maintain branded prices for such compounds while under patent. Circumventing the exclusive rights may be the only effective measure for relief.

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42 Id. at 56 (describing developing country use of compulsory licenses to lower prices by with royalties near zero).
43 Cahoy, supra note 39, at 630.
44 F.M. Scherer, supra note 24, at ___ (“Few drugs lack any substitutes at all. What matters most is that the drugs are differentiated substantially from their substitutes . . . .”).
45 For example, there are several members of the class of cholesterol drugs known as “statins.” Created by different companies, they have historically maintained high prices because each had patent protection. When one member of the class, Merck’s Zocor, lost its protection, its price was expected to drop. See Alex Berenson, Merck Loses Protection for Patent on Zocor, N.Y. TIMES, Jun. 23, 2006, at C.1. Similarly, the prices of the other statins, like Pfizer’s Lipitor, were also immediately expected to drop, despite the fact they still held patent protection. Id.
B. Remuneration Equals Impact

To date, much of the debate surrounding compulsory licenses has focused on the conditions a country may use for imposing a license. On the property rights side, concern that licenses may be too easily invoked absent the threat of an emergent health crisis or that they may be available to countries that do not need them has led to fear that the profit needed to fund innovation will be eroded. On the access side, concern that unwieldy and unrealistic rules could lead to underutilization of an important public health tool has channeled efforts toward an easily implemented system that would be widely available at each government’s discretion.

However, an appreciation of the circumstances under which compulsory licenses may be issued provides only partial insight into the impact on patent holders. The subsequent effect — what happens as a result of the hammer falling — is in many ways far more important. In fact, in the context of a right of primarily economic significance such as a patent, the impact on the property owner’s wealth is more central to the question of innovation effects.

In understanding impact, it is important to keep in mind that,

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46 Sherman & Oakley, supra note 11, at 369-72 (providing an overview of the major controversies in compulsory licensing under TRIPS). The TRIPS and paragraph 6 implementation negotiations primarily concerned the context under which the license could be imposed. See infra notes 64-71 and accompanying text.


49 See supra note 26, and accompanying text.

50 See, e.g., Opderbeck, supra note 16, at 548-53 (proposing a solution to the access/innovation conflict with a unique interpretation of TRIPS’ remuneration provision); Cahoy, supra note 39, at 683-84 (describing the significance of compensation in the context of patent takings).
unlike tangible property rights such as real estate that carry along with them the concept of a basic “dignity” of ownership,\footnote{The common law generally protected a man’s house as “his castle of defense and asylum.” 3 \textsc{W. Blackstone}, Commentaries 288 (1765).} patents provide their owners with a tool for creating wealth only.\footnote{See, e.g., Mark A. Lemley, \textit{Property, Intellectual Property, and Free Riding}, 83 Tex. L. Rev. 1031 (2005) (arguing that, although intellectual property is generally treated as equivalent to tangible property, fundamental differences in the nature of intellectual property suggest that it should not receive such treatment).} It is not abstract ownership of the right that is important in this relationship, but rather what that right can do for its owner. The possibility of monopoly rents induces invention that otherwise might not exist.\footnote{FTC \textit{Report}, supra note 20, ch. 1, at 9–12 (“[O]ne could ask whether the claimed invention would have emerged in roughly the same time frame ‘but for’ the prospect of a patent.”). Roberts v. Sears, Roebuck & Co., 723 F.2d 1324, 1346 (7th Cir. 1983) (Posner, J., dissenting) (“[I]f a court thinks an invention for which a patent is being sought would have been made as soon or almost as soon as it was made even if there were no patent laws, then it must pronounce the invention obvious and the patent invalid.”). Disclosure rules ensure that the rest of the world will have access to such newly created technologies that can further spur development. FTC \textit{Report}, supra note 20, ch. 2, at 6–7; Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) (“In consideration of its disclosure and the consequent benefit to the community, the patent is granted.”).} The economic foundation of patents means that an incursion on the right can be measured in terms of monetary loss. Even the right to exclude through injunctive relief, commonly considered a species quite different from monetary compensation,\footnote{See \textit{H.H. Robertson Co. v. United Steel Deck, Inc.}, 820 F.2d 384, 390 (Fed. Cir. 1987) (“The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the patentee whole, for the principal value of a patent is its statutory right to exclude.”), \textit{abrogated on other grounds}, Markman v. Westview Instruments, Inc., 52 F.3d 967, 977 (Fed. Cir. 1995) (en banc).} could be viewed as a merely a means to extract additional profits by controlling access to the invention.\footnote{Scholars have noted that injunctive relief in the context of patent litigations is often used as a means to extract a higher settlement rather than preventing a competitor to enter the market. \textit{See}, e.g., Patent Law Reform: Injunctions and Damages: \textit{Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary}, 109th Cong. (2005) (comments of Mark A. Lemley) (noting how injunctive relief can be used to “settle for an amount of money that significantly exceeds what the plaintiff could have made in damages and ongoing royalties had they won”). Almost every injunction likely has a negotiable price.} In practice, it has an economic value. Therefore, the impact of any elimination or redefinition of patent rights can be quantified, and more importantly, \textit{any} loss of patent property rights can theoretically be
remedied with compensation. In other words, it should always be possible to compensate a patent owner to indifference for any reduction of her rights.

The critical role of economic returns effectively frames the debate on compulsory licensing. The core question is not under what circumstances they will be imposed, but rather what the economic consequences of any imposition will be. Whether the license adequately accounts for economic losses suffered by the patent owner says everything significant about the impact of the license. An example involving a pharmaceutical product is illustrative. Imagine a drug that has a certain dollar value of sales across the African continent based on a particular level of demand. A standard cost curve for a monopoly market depicts the profit maximizing price and output for the drug’s manufacturer (see Figure 1).\textsuperscript{56}

\textsuperscript{56} Judge Posner provides a detailed explanation of the dynamics underling the relationship between price and quantity under monopoly conditions. \textit{RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW} 295-308 (5th ed. 1998). Additionally, Professor Fisher explores this relationship in the context of patent compulsory licenses. William W. Fisher, \textit{Intellectual Property and Innovation: Theoretical, Empirical, and Historical Perspectives}, Prog. Seminar on IP and Innovation and the Knowledge-Based Economy 12-13 (May 2, 2001), \textit{available at} cyber.law.harvard.edu/people/tfisher/Innovation.pdf. Figures 1, 2 and 3 are extensions of these basic concepts. \textit{See also COOTER & ULEN, supra} note 29, at 35-36. The impact of licensing in demand elasticity has been similarly described in the context of parallel importation. \textit{See F.M. Scherer & Jayashree Watal, Post-TRIPS Options for Access to Patented Medicines in Developing Countries, 5 J. INT’L ECON. L.} 913, 925 (2002).
Compulsory licensing reduces the income a patentee receives by reducing the profit above marginal costs from $P$ to the royalty $(R)$ received from a compulsory licensed product sold by a third party at $P_{CL}$ with higher marginal costs $MC_{CL}$. The lower price increases the quantity utilized from optimal monopoly levels $Q$ to $Q_{CL}$. The revenue lost from the price reduction $(DR)$ will be partially, but not completely, offset by revenue from increased royalty revenue $(IR)$, resulting in a net profit loss. However, if the patent owner is compensated for the difference in profit $(DR - IR)$, he or she should be indifferent as to the loss of control.

If the imposition of a compulsory license means that the sales of the patentee’s drug will made by another, profits will be eliminated. The extent to which those profits are replaced by a remuneration mechanism dictates the impact on the patent owner. If the entire amount lost is replaced, a rational pharmaceutical company should be indifferent, no matter how often or how long such a license is imposed. However, if the remuneration offered is a small fraction of the lost profits the company will suffer, every imposition hurts. At some point, a company’s loses

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57 This assumes that the patentee prices optimally with respect to marginal revenue and costs.

58 Of course, there is some value in the control of one’s property, per se, and the loss of that control could theoretically be quantified. However, an attempt to do so objectively by looking at hold-up values from the side of the licensee or licensor is likely to be wildly inaccurate. See Wendy J. Gordon, Toward a Jurisprudence of Benefits: The Norms of Copyright and Problem of Private Censorship, 57 U. CHI. L. REV. 1009, 1042-43 (1990) (explaining, in the context of copyright injunctive power, that the price a property right owner and a user declare are not necessarily related to the true value of the right). Such control may even have an impact of overall efficiency in the allocation of societal resources. See Posner, supra note 56, at 36-39 (“The creation of individual (as distinct from collective) ownership rights is a necessary rather than a sufficient condition for the efficient use of resources.”). But this is cognitively beyond the scope of a particular patent owner.
could reduce revenue below that projected as necessary to optimally fund research and development, and changes in behavior with respect to future investment may ensue.\textsuperscript{59}

Given the remuneration question, the public policy debate boils down to a relatively straightforward issue: how much of the burden of providing for developing nations should be shouldered by private companies? Is it appropriate to place any obligation on pharmaceutical companies to bridge public health gaps that governments will not, or should governments be required to step in? International intellectual property law attempts to answer these difficult questions, but the results are decidedly incomplete.

\begin{altenumerate}
\item \textbf{International Rules Amplify Public Health Remuneration Consequences}

Compulsory licensing has a long history in the legal systems of many countries\textsuperscript{60} and international law through the Paris Convention for the Protection of Industrial Property.\textsuperscript{61} Perhaps the greatest major international milestone for substantive compulsory licensing rules is the TRIPS agreement,\textsuperscript{62} which came into effect in 1995 as part of the Uruguay Round of trade discussions.\textsuperscript{63} Referring to “use without the authorization

\textsuperscript{59} A 1973 study by Taylor and Silberston purported to quantify this effect through the use of surveys. See F.M. Scherer, \textit{The Economic Effects of Compulsory Patent Licenses} 59-62 (1977). Dramatically, it found that 64% of R&D in the pharmaceutical field would be displaced if patents were replaced with automatic reasonably royalty mechanisms, as opposed to a weighted average of 8% in all industries. \textit{Id.} at 60.

\textsuperscript{60} See Correa, \textit{supra} note 32, at Part II (stating that compulsory licensing exist in various forms in the patent laws of approximately one hundred countries and dates back to the English Statue of Monopolies in 1623); Reichman & Hasenzahl, \textit{supra} note 31, at 10-11 (noting that compulsory licensing was originally an alternative to forfeiture for violating numerous restrictions in early patent law). See also \textit{Jay Dratler, Jr., Licensing of Intellectual Property} § 3.03 (2001) (“Many foreign countries have provisions for compulsory licensing in their patent and copyright laws, which are designed to insure that innovation is not neglected or suppressed by private forces within or without their borders.”).


\textsuperscript{62} TRIPS, \textit{supra} note 6. The TRIPS compulsory license provision was the result of a push for specific international standard that began in the late 1970s. See \textit{United Nations Conference on Trade and Development (“UNCTAD”) & International Centre for Trade and Sustainable Development (“ICTSD”), Resource Book on TRIPS and Development} 462-63 (2005) [hereinafter UNCTAD-ICTSD Resource Book].

\textsuperscript{63} \textit{Christopher May & Susan K. Sell, Intellectual Property Rights: A Critical History} 161-62 (2006). The Uruguay Round was also significant for creating the World Trade Organization (“WTO”), which as the co-overseer of TRIPS with the World Intellectual Property Organization (“WIPO”), provided significant enforcement
of the right holder,” TRIPS article 31 explicitly permits member states to issue licenses under three circumstances: (1) after efforts to obtain a license from the patent holder on “reasonable commercial terms and conditions” have failed, (2) in the case of national emergency or other circumstances of extreme urgency or (3) for public non-commercial use. The latter two circumstances are significant in that they do not require prior negotiation with the patent holder (which should theoretically make a compulsory license easier to obtain). A list of requirements for a valid compulsory license is listed in article 31, including the payment of compensation:

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization...

Neither “adequate remuneration” nor “economic value” is defined in the agreement. Although TRIPS was created as a treaty of general application, the compulsory license exception was, in part, implicitly directed toward certain technology areas. It was understood that a primary purpose of the exception was to increase access to essential goods such as food and pharmaceuticals.

Not long after TRIPS went into effect, developing countries argued that its provisions were still too strict to permit the optimal impact on health care. Specifically, the provision requiring supply of the domestic market was viewed as restricting article 31 use to those countries with the powers. Id. 64 See TRIPS, supra note 6, at art. 31. Additionally, Article 30 allows members to create exceptions to patent rights if such exceptions do not “unreasonably conflict with a normal exploitation of the patent” or “unreasonably prejudice the legitimate interests of the patent owner.” Id. The latter provision may appear to create a wide opening for unfettered compulsory licensing, but it has been generally been viewed as relatively narrow in application and limited to circumstances like experimental use. See UNCTAD-ICTSD RESOURCE BOOK, supra note 62, at 432-39.

65 TRIPS, supra note 6, at art. 31 (“[The negotiation] requirement may be waived by a member if the case of a national emergency or other circumstance of extreme emergency or in cases of public non-commercial use”).

66 Id. at art. 31(h). Other requirements include non-exclusive government use and authorization to supply the home market. Id. at art. 31(d) & (f).

67 Id. at 480-81 (describing a WTO dispute settlement panel interpretation of TRIPS art. 30 that found “non-discrimination” was not the same as “non-differentiation,” and that countries could reasonably treat technology areas differently for a bona fide purpose).
ability to manufacture an article covered by a license.\footnote{See Frederick M. Abbott & Rudolf V. Van Puymbroeck, Compulsory Licensing For Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision, World Bank Working Paper No. 61, at pp. 8-9 (2005).} To remedy this provision’s unintended effects on the most impoverished of developing nations, proposals were made at the 2001 round of trade talks in Doha, Qatar to amend TRIPS to permit importation of licensed goods from another country.\footnote{Abbott, supra note 16, at 326.} The resulting Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") supported the notion that TRIPS should be interpreted in a manner supportive of the right to protect public health.\footnote{Doha Declaration, supra note 14, at ¶4.} Ultimately, the declaration was implemented in 2003 after assurances were secured that industrialized nations would not take advantage of the revised rule\footnote{Paragraph 6 Decision, supra note 7, at ¶ 1(b) n.3 (noting that the following countries agree not to use the Paragraph 6 provisions as importing members: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America); Abbott, supra note 16, at 336. Since they joined the European Union, the list now includes ten more: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia. WTO, Compulsory Licensing of Pharmaceuticals and TRIPS (Oct. 2005), available at http://www.wto.org/English/tratop_e/trips_e/public_health_faq_e.htm. Eleven other members announced voluntarily that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates. Id.} In response to the change, several governments amended or proposed to amend their patent laws to permit the manufacture and sale of pharmaceuticals to countries that had imposed a compulsory license.\footnote{WTO General Council, Amendment of the TRIPS Agreement, Doc. WT/L/641 (Dec. 6, 2005), available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. To date, less than 4% of the required 66% WTO membership has accepted the amendment. Countries Accepting Amendment of the TRIPS Agreement (Updated Jan. 25, 2007), http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.} Since the publication of the Doha Declaration, the
broader use of compulsory licenses has received wide international support.74

One would presume that the international community would simply move forward to establish clear and rational compensation parameters. However, the rhetoric of the current compulsory license debate has permitted the process to devolve into an undirected, metaphysical search for objective measures of fairness under the notion that compulsory licensing can be an “everybody wins” proposition. Various licensing regimes and divergent notions of fair pricing and reasonable returns on R&D spending have been thrown into the mix to argue for a variety of discounted remuneration models that supposedly treat everyone equitably. A closer inspection of the evidence underlying such arguments reveals that there is a great deal of misunderstanding.

II. THREE MYTHS THAT HAVE OBSCURED WORKABLE REMUNERATION RULES


74 Most prominently, the World Health Organization’s (“WHO”) Commission on Intellectual Property Rights, Innovation and Public Health (“CIPIH”) issued a comprehensive report on the optimal relationship between patent protection and access to essential medicines. CIPIH REPORT, supra note 11, at 58. The report explicitly advocated the use of compulsory licenses as a means to increase drug discovery and delivery in developing countries:

Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production.


75 TRIPS, supra note 6, at art. 31(h). This includes the authority to review any country’s determination as to whether remuneration is adequate. Id. at art. 31(j) (“any
ascribing value to compulsory licenses. However, the subject of remuneration rules has received relatively little attention. If addressed at all, it is generally a small component — seemingly an afterthought — in broader compulsory license discussions. For the most part, the relevant research evinces a common notion that appropriate remuneration levels can be derived from historical averages and individual country experiences. It is suggested that analysis of such information yields a very narrow range of reasonable compensation parameters, and the adoption of a policy within these parameters is by definition equitable due

 decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member”).


For example, Opderbeck acknowledges that the level of compensation for use of a patented invention is related to innovation impact. Opderbeck, supra note 16, at 548. Scherer & Watal review the theory and practice of compulsory license compensation as part of an overall analysis of access to medicines through TRIPS. Scherer & Watal, supra note 56, at 920-24. Sykes notes that the tendency of a country to license at a low royalty rate undermines TRIPS’ intellectual property enhancing goals. Sykes, supra note 41, at 66.

See, e.g., Love, supra note 76, at 81-82 (discussing appropriate remuneration under the WTO, noting variation of government-set IP royalties from 0.5% to 5% , and stating “[t]he average rate of royalties in the United States pharmaceutical industry, including royalties for multiple patents, trademarks and know-how, is approximately 4 to 5% of sales.”); Scherer & Watal, supra note 56, at 24-28 (describing royalty rates ranging up to 15% in a variety of context in the U.S. and the U.K.); Peter K. Kolker, TRIPS Agreement: Patent Protection 30 (2000) (prepared for the European Commission, Directorate-General for Trade) (describing approved compulsory license royalty rates as high as 45%); Carlos Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries 108-09 (South Centre 2000), http://www.southcentre.org/publications/publichealth/publichealth.pdf (stating that commercial pharmaceutical royalty rates usually range “from 0.5% to 10% of the (net) sale of the licensed product . . .”)
to its proximity to the mean. Unfortunately, such notions are subject to misunderstandings regarding the derivation of compensation rates, and tend to treat radically different compulsory license remuneration mechanisms as philosophical equivalents. In the end, the research ends up painting a historical picture of seemingly random royalty rates that converge on purportedly acceptable averages. This only confounds the search for solutions to the remuneration problem.

In most if not all cases, there are actually overarching principles that guide the selection of a particular royalty rate. Not all of these principles are applicable to the typical public health-oriented compulsory license. Royalty rates under such regimes should therefore not be considered when ascertaining an average compulsory license rate or modeling a rate determination system. It is useful to confront the myths and misconceptions so that a true picture of compulsory licensing options and their likely impacts can be obtained.

A. Myth One: Equitable Compulsory Licenses Must Offer a Savings from the Market

Although compulsory licenses have been imposed to achieve many different ends over the years, recent attention has focused on this tool almost exclusively as a cost-saving measure. The idea is that such licenses “break” the patent owner’s power to impose monopoly pricing for

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79 See, e.g., Scherer & Watal, supra note 56, at 24 (“The choices made in industrialized nations provide ample precedent for royalty setting on the modest side of the range of possibilities.”); Kolker, supra note 78, at 30 (“There is much case-law now on royalty rates for compulsory licenses and these should be a precedent for future situations.”).

80 For example, both Correa and Scherer & Watal suggest that the range of acceptable royalties for TRIPS compulsory licenses extends to the entire range of practices, including antitrust penalties. Correa, supra note 78, at 108-09; Scherer & Watal, supra note 56, at 292-24. In a very comprehensive overview, James Love acknowledges that the many approaches “[reflect] a particular set of policy objectives.” Love, supra note 76, at 30. Nonetheless, he does not assess which of the variety of licensing schemes is most analogous to public health licensing under TRIPS, and thus tends to suggest that they are equally important.

81 See Correa, supra note 78, at 94 (noting the WHO’s and UNAID’s position in favor of compulsory licensing to lower the cost of drug prices). Most pointedly, the Doha Declaration is quite clear in promoting the use of compulsory licenses to increase access to medicines by relaxing patent obligations. Doha Declaration, supra note 14, at ¶¶ 4 & 5(b). Interestingly, compulsory licensing to promote access to public health probably does not represent the majority of actual occurrences. See Reichman & Hasenzahl, supra note 31, at 19-20 (describing historical and not infrequent use of compulsory licensing under TRIPS in the U.S.).
a greater good.\textsuperscript{82} A predicate understanding in such policy is that fair remuneration or compensation is inevitably restricted to a small royalty figure.\textsuperscript{83} If this were not the case, the compulsory license would otherwise have no public purpose, it is argued.\textsuperscript{84} But is this necessarily true? In fact, there is a very rational argument for requiring market compensation for compulsory licenses that does not completely undermine their use. Significantly, there is a well-developed historical model in support. Market compensation is a reality that should at least be integrated into the debate.

From theoretical perspective, a market compensation regime has a property rights focus. As noted above, the financial impact of reducing the right to exclude is an unanticipated burden imposed on the patent owner; the expected income that provided the investment incentive is retroactively reduced, and future investment may be viewed as a greater risk.\textsuperscript{85} Under this theory, while powerless to enjoin the government’s act, the patent owner has a right to be insulated from the government’s decision to increase public access to the invention.\textsuperscript{86}

To determine the appropriate remedy, one must assess what the patent owner has lost as a result of the compulsory license.\textsuperscript{87}

\begin{itemize}
  \item \textsuperscript{82} 
  \textit{Stephen P. Ladas, Patents, Trademarks and Related Rights: National and International Protection} 427 (1975) (“The practical value of the existence of compulsory license provisions in the Patent Law is that the threat of it usually induces the grant of contractual licenses on reasonable terms, and thus the objective of actually working the invention is accomplished.”).
  \item \textsuperscript{83} 
  \textit{See, e.g.,} Love, supra note 76, at 51 (“An overriding consideration at all times should be that royalty obligation should not undermine access – the key goal sought from the exercise of compulsory licensing of pharmaceuticals.”).
  \item \textsuperscript{84} 
  \textit{See, e.g.,} id (“Some of these alternatives – such as ensuring no lost profits to the patent holder – ensure that remuneration rates will be high, thus undermining compulsory licensing’s promise of lower prices and expanded access.”); Scherer & Watal, supra note 56, at 921-22 (“Since the purpose of virtually all known compulsory license schemes is to increase competitive supply and reduce process, the ‘profits lost’ [sic] test cannot logically be the standard to be met in determining compensation for compulsory licensing.”).
  \item \textsuperscript{85} 
  \textit{See supra} notes 41-42, and accompanying text.
  \item \textsuperscript{86} 
  This is essentially the theory behind the U.S. concept of eminent domain. \textit{See} William Michael Treanor, \textit{The Origins and Original Significance of the Just Compensation Clause of the Fifth Amendment}, 94 \textit{Yale L.J.} 694, 711-12 (1985); Thomas J. Miceli, \textit{Economics of the Law} 138 (1997) (Reviewing several theories regarding the rationale for eminent domain power and concluding “The justification for eminent domain, then, is the need to prevent hold-outs, which is a form of transaction costs.”).
  \item \textsuperscript{87} 
\end{itemize}
extent this involves a demonstrable loss of sales, the compensation could reasonably constitute the profits that were lost as a result. Alternatively, if only a licensing opportunity was eliminated, the royalties that would have flowed from such an arrangement could provide the measure of remuneration. This model of compensation is quite well described in the context of private patent litigation, wherein the infringer is compelled to pay damages sufficient to place the patent owner in the financial position he or she would have occupied had the infringement not occurred. It also has grounding in the American jurisprudence of eminent domain, which compels the government to provide “just compensation” for takings of private property. In the latter context, just compensation has been clearly identified as the market value of the taken property right.

88 Analogizing to a patent infringement context, this could be termed the “but for” world, as it is an assessment of the profits a patentee would have made but for the incursion. State Indus. v Mor-Flo Indus., 883 F.2d 1573, 1577 (Fed. Cir. 1989) (“To get lost profits as actual damages, the patent owner must demonstrate that there was a reasonable probability that, but for the infringement, it would have made the infringer’s sales.”).

89 See Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) (noting that the patent damages statute allows for the recovery of actual damages while providing for a reasonable royalty as an alternative, lower limit). This is known as the “but for” world.

90 U.S. CONST. amend. V.

91 The U.S. Supreme Court has held that “just compensation means the full monetary equivalent of the property taken. Almota Farmers Elevator & Warehouse Co. v. United States, 409 U.S. 470, 473 (1973) (emphasis added). Moreover, The owner is to be put in the same position monetarily as he would have occupied if his property had not been taken.” United States v. Reynolds, 397 U.S. 14, 16 (1970); see also RICHARD A. EPSTEIN, Takings: Private Property and the Power of Eminent Domain 182 (1985) (“In principle the ideal solution is to leave the individual owner in a position of indifference between the taking by the government and retention of the property.”). In cases addressing takings of real property, which is generally qualified by its “market value,” the owner is entitled to the fair market value of his property at the time of the taking. City of New York v. Sage, 239 U.S. 57, 61 (1915) (“But what the owner is entitled to is the value of the property taken, and that means what it fairly may be
While such severe remuneration obligations may suggest that this theory has no place in compulsory licensing, there is an important historical example. The market compensation theory is essentially the one followed by the United States in determining the accountability of the federal government for unauthorized use of a patent invention. By virtue of 28 U.S.C. § 1498, a jurisdictional statute that waives sovereign immunity and permits patent owners to sue the government in the Court of Federal Claims, compensation may be obtained. Although there is some disagreement among courts and academics as to whether the compensation authorized by this statute is based on the Constitutional protections of the Fifth Amendment, recent appellate decisions have declared that full, infringement-like compensation may be appropriate in many instances. Specifically, it should permit lost profits compensation in some cases:

Since both section 284 and section 1498 speak of “compensation,” albeit “adequate” compensation in the former and “reasonable and entire” in the
latter, lost profits should be recoverable in at least some infringement actions against the government, even though the Fifth Amendment is implicated.96

A reasonable royalty can be obtained in cases wherein the plaintiff cannot meet the lost profits criteria.97

The main benefit of the market compensation theory is that it preserves almost all of the reasons for having a property system for innovation in the first place.98 A patent owner has the ability to exploit and profit from the invention to the fullest, and reap the rewards of providing the world with an important piece of biomedical information.99

The licensing country, on the other hand, must bear the full costs of obtaining the drug. By imposing the market cost as a compensation measure, countries will only license when negotiation fails or the desired quantities cannot be produced by the patent owner.100 It has been argued that this creates exactly the right kind of incentives.101 Instead of transposing the costs of a medical crisis on the drug manufacturer, society will bear them, preserving the initial investment incentive. However, price gouging or supra-monopoly rents through holdout behavior will not be possible due to the elimination of injunctive relief as an option.102

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96 Id.
97 Id. at 1580; Dow Chemical Co. v. U.S., 226 F.3d 1334, 1347-48 (Fed. Cir. 2000) (discussing the use of a royalty for government use of a patent on controlling subsidence of land overlying depleted mines).
99 See supra note 26, and accompanying text.
100 Adelman, supra note 87, at 3 (“Under such conditions compulsory licensing is only useful when the patent owner is unwilling or unable to provide a sufficient supply of a needed patented drug.”) Again, there are analogies to American eminent domain law. One of the justification for a just compensation rule is that the government would otherwise be inclined to take property. Frank I. Michelman, Property, Utility, and Fairness: Comments on the Ethical Foundations of “Just Compensation” Law, 80 HARV. L. REV. 1165, 1214-18 (1967).
101 Adelman, supra note 87, at 4 (“if the patent owner is willing and able to supply the needed drug, there is no economic advantage to purchasing it elsewhere using the mechanism of a compulsory license or using the power of eminent domain possessed by governments.”).
102 For example, injunctions are clearly not allowed in the context of § 1498. See Motorola, Inc. v. United States, 729 F.2d 765, 768 n.3 (Fed. Cir. 1984) (“injunctive relief under 35 U.S.C. § 283 is not available to a patent owner in a § 1498 action.”). Note that one can question whether injunctive relief actual leads to supra-optimal rents or gouging. It could be argued that the efficiency of property rules (as opposed to liability) lead to more correct determinations of property value. See Roger D. Blair & Thomas F.
Opponents of the market compensation theory have noted that it has the potential to eviscerate important beneficial effects of a compulsory licensing program.103 If a licensing government is compelled to pay lost profits to a patent owner and costs to a third-party manufacturer (which are likely to be higher than the patent owner’s marginal costs), the price of compulsory licensing could actually be higher than market price.104 It would eliminate any cost advantage to compulsory licensing, and limit the utility to prevention of unreasonable hold-ups.105 If applied universally, market compensation would probably act as an effective barrier to substantially increased access to medicines through compulsory licensing.106

There is also the question of which market one should consider in setting the price for compensation. Certainly, if the pharmaceutical product is sold in the licensing country, that price could provide an accurate measure.107 However, in many countries, new drugs are not always widely available in any forum resembling a free market.108 Markets that are skewed by radically different income levels or government single-payer systems may be of little assistance. In such a case, the determination of a market price could become a substantially arbitrary process. A likely solution would be to require the patent owner to justify any market losses. For example, if profits would be lost as a result of the compulsory license, one must prove it, otherwise one would

\begin{footnotesize}
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\item[	extsuperscript{104}] Love, \textit{supra} note 76, at 51; Scherer & Watal, \textit{supra} note 56, at 921-22. An interesting context was provided by the U.S. government’s recent experience with anthrax and the antibiotic ciprofloxacin. The market compensation theory would make the government’s “overriding” of Bayer’s patent an extremely expensive prospect; in essence, it would require a double payment for each ciprofloxacin tablet - one payment to Bayer and one to the generic pharmaceutical manufacturer that actually made the drug.
\item[	extsuperscript{105}] Adelman, \textit{supra} note 87, at 4; Scherer & Watal, \textit{supra} note 56, at 921-22. Love, \textit{supra} note 76, at 51-52 (“the outcome . . . is inconsistent with the Doha Declaration mandate to promote ‘access to medicines for all.’”).
\item[	extsuperscript{106}] The fact the pharmaceuticals are sold for different prices among various countries precludes the use of a single market price to define “lost profits.” Danzon & Furukawa, \textit{supra} note 38, at exhs. 4 & 7. See Cahoy, \textit{supra} note 39, at 637-39 (describing the effect of government-controlled nationalized health care systems of pharmaceutical availability and price); Love, \textit{supra} note 76, at 52 (“unequal income distributions globally and also within countries will provide economic incentives to priced goods for elites . . .”).
\end{enumerate}
\end{footnotesize}
be left with some token compensation like a reasonable royalty. This has been very effective in the context of private litigation.109

Apart from the practical problems with market compensation, there are principle-based issues as well. Compensating a patent owner for all losses could suggest that wrongful, or at least unanticipated, behavior has occurred. A government is in essence making reparations for the loss of exclusivity. Compulsory license proponents might argue that such a power is properly viewed as an exception to the grant of intellectual property — a power possessed by the government from the outset of the grant which may or may not be exercised. If this view is followed, the patent owner is not actually harmed by the imposition of a license, but merely faces the consequences of a societal bargain to which he or she was complicit.110 In countries with a compulsory license statute111 (unlike the United States),112 the nature of a statutorily defined exception to patent property rights may not coalesce with a damages model of compensation.113 However, this concern is likely overstated, as market compensation is not constrained to a tort framework. This is reflected by the fact that such measures have been adopted in the context of § 1498 actions, which are explicitly not based on compensation for a tortious

109 In the United States, a plaintiff must show a “reasonable probability” that the plaintiff would have made the lost sales and corresponding lost profits claimed but for the defendant’s infringing acts. Grain Processing Corp. v. Am. Maize-Prod. Co., 185 F.3d 1341, 1349 (Fed. Cir. 1999).

110 See Cahoy, supra note 92, at 146-151 (describing the phenomenon as “the established statutory theory” of government patent use); De Graffenried v. U.S., 29 Fed. Cl. 384, 387-88 (Fed. Cl. 1993).

111 It appears that most countries that employ compulsory licensing do so by exercising a power granted by statute. See Correa, supra note 32, at Part II; Scherer & Watal, supra note 56, at 915.

112 To be fair, the U.S. has no general compulsory license statute for patents, but it does have several statutes covering particular technology areas, usually relating to government funding or relevant for national security. rights. See 35 U.S.C. §§ 200–11 (2000) (Bayh-Dole Act provisions that give private parties the right to own patents in federally-funded inventions, but reserves in the federal government a nonexclusive, nontransferable, irrevocable, paid-up license for the invention to practice it or have it practiced for or on the government’s behalf throughout the world); 42 U.S.C. § 2183 (2000) (providing for compulsory licensing of patents having “primary importance in the production or utilization of special nuclear material or atomic energy”); 42 U.S.C. § 7608 (2000) (providing for compulsory licensing of patents necessary to enable any person to comply with the implementation of Clean Air Act requirements).

113 This issue could be ultimately overridden by amending TRIPS, which would provide a base-line rule on compensation.
wrong.\cite{114}

In the end, the desire to preserve innovation incentives in a given context must be balanced against the shortcomings of market-based incentive systems. But as a general matter, this approach presents an important remuneration alternative that should not be discounted out of hand. Its serious consideration adds an important dimension to the remuneration debate.

\section*{B. Myth Two: Pharmaceutical Companies should be Indifferent to Compulsory Licensing so Long as “Reasonable” Remuneration is Available}

Regardless of whether there are justifications for the market compensation model of remuneration, many compulsory licensing advocates would argue that this high level of payment is simply not necessary.\cite{115} So long as a pharmaceutical company can make back its costs, it will break even and not face a disincentive to future investment.\cite{116} Alternatively, one could argue that, even if investment costs are not recouped, so long as the true “value” of the drug to its user is accounted for, justice is accomplished.\cite{117} Market price may significantly exceed either valuation.\cite{118} This is particularly so if it is presumed that a patent

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  \item \cite{114} The absence of tort-like remedies such as injunctions and treble damages are the distinguishing point in this regard. See Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 672, 648 n.11 (1999).
  \item \cite{115} In a survey of the literature on global pharmaceutical pricing, Professor Kevin Outterson cites several sources that argue market compensation can be “supra-optimal” when patent rents are used to fund marketing or R&D directed to lifestyle medicines. Outterson, \textit{supra} note 36, at 220-222. But see Edwin Mansfield, et al., \textit{Social and Private Rates of Return From Industrial Innovation}, Q.J. OF ECON. 221 (May 1977) (noting that in general, social returns on invested capital are greater than private returns).
  \item \cite{116} See, \textit{e.g.}, Bradley Condon & Tapen Sinha, \textit{Global Diseases, Global Patents and Differential Treatment in WTO Law: Crirical for Suspending Patent Obligation in Developing Countries}, 26 NW. J. INT’L. L. & BUS. 1, 27-29 (2005) (arguing that “global patents” are not necessary for innovation given the income produced by developed countries). Given that innovation costs are the primary industry argument against compulsory licensing, this appears logical.
  \item \cite{117} This notion is actually reflected in the text of the TRIPS agreement. TRIPS, \textit{supra} note 6, at art. 31(h).
  \item \cite{118} Members of the pharmaceutical industry have acknowledged in recent years that even development costs are not necessarily related to market prices. See, \textit{e.g.}, HANK MCKINNELL, A CALL TO ACTION 46 (2005) (former chairman and CEO of Pfizer stating
owner often seeks and obtains an unreasonably high, windfall price for patented goods.\textsuperscript{119} In such a case, the substitution of a hypothetical arm’s length business transaction with public interest considerations is required to remedy an otherwise unequal bargaining relationship. The resulting discounted, but “adequate” royalty payment\textsuperscript{120} is more than sufficient for compulsory license remuneration, so the argument goes.

Additionally, if the target market is one not currently exploited by the patent owner — often the case in developing nations — the use of a sub-market royalty system seems even more appropriate. Any license that results in a royalty that exceeds the profits from current sales in the

that it is a fallacy that pharmaceutical pricing is related to R&D costs because “those are sunk costs.”); MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 50-51 (2000) (quoting Merck’s Gilmartin: “The price of medicines isn’t determined by their research costs.”). A few years ago, the estimate of average R&D costs developed by DiMasi, et al. was touted as a primary justification for the high cost of drugs. Joseph DiMasi et al., The Price of Innovation: New Estimates of Drug Development Costs, 22 J. HEALTH ECON. 151, 166–68, 180 (2003). As with other goods, the market price reflects the value consumers (or governments) place on the item, not its scientific value or its “book costs.” See GORDON V. SMITH & RUSSELL L. PARR, VALUATION OF INTELLECTUAL PROPERTY & INTANGIBLE ASSETS 170-72 (3d ed. 2000) (discussing the market method of valuation). For a truly ground breaking and unique medicine, the price should be significantly higher than a “me too” variant. Unfortunately for the drug industry, that argument cuts both ways, as it suggests that medicines experiencing easier development paths — particularly those developed with public funding — should be much less expensive.

\textsuperscript{119} See Nevin M. Gewertz & Rivka Amado, Intellectual Property and the Pharmaceutical Industry: A Moral Crossroads Between Health and Property, 55 J. BUS. ETHICS 295, 298 (2004) (discussing the moral and ethical issues involved in a patent right’s ability to provide a “windfall” to its owner).

\textsuperscript{120} Reasonableness valuations are almost always expressed in terms of a royalty that is a percentage of sales or profits. Love, supra note 76, at 19-43 (reviewing several examples of “reasonable or adequate remuneration,” almost all of which are base on a royalty on sales). Some have suggested that historical average license rates provide the best evidence that a general royalty rate as discussed above is properly set around five percent. See supra notes 78-79, and accompanying text. When evidence of actual licenses related to the patent is slim, a possible proxy can be found in “rule of thumb” licensing rates. Love, supra note 76, at 48 (noting that “pharma & bio” have a rule of thumb rate of 5.1%). These rates are purportedly industry norms for particular technology areas, perhaps even for specific classes of drugs. Id. The use of a rule of thumb rate attempts to ensure that historically acceptable terms serve as a baseline for the mandatory license. Of course, as with the above calculations, the assumptions that enter into the analysis are extremely important, and subject to bias. Additionally, generalizations cannot acknowledge a company’s truly unique research and development efforts. Therefore, rule of thumb rates are likely to squeeze the extremes of creation and development incentives.
market should satisfy a pharmaceutical company. If use of the invention actually increases, a company might even be better off (see Figure 2).

![Diagram of Overall Impact of a Compulsory License in an Untapped Market](image)

If a compulsory license increases the quantity delivered by adding a segregated market \(Q_{\text{CL}}\) with price \(P_{\text{CL}}\) and royalty \(R\) without affecting the patent owners price maximizing behavior and monopoly profits in other markets, it results in an overall increased revenue as indicated by the sum of the shaded boxes.

There is an attractive logic to this reasoning, particularly when paired with the lives that lower-cost drugs could save. But is it truly (and objectively) fair to all parties, and is innovation likely to be preserved in its wake? Upon further examination, it is not at all clear that such a mythical equitable payment scheme exists or that pharmaceutical companies are likely to be satisfied with the result.

First and foremost, the determination of adequacy or

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121 One could characterize such royalties to be necessary for complete Ramsey pricing, and therefore not supplemental or additional. Patricia M. Danzon & Adrian Towse, Theory and Implementation of Differential Pricing for Pharmaceuticals, in KEITH E. MASKUS & JEROME H. REICHMAN, INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY 434-35 (2005). However, if no additional costs are incurred, higher prices in developed countries will not be required to offset. And, assuming such royalties are assessed ex post to a company’s R&D planning, it would seem to make little difference in innovation investment.

reasonableness is inevitably a loaded analysis; the reasonableness of any payment depends on one’s perspective. At least two views exist, and they are in most respects diametrically opposed. Under a patent owner-based analysis, the main concern is recouping investment in research and development of the pharmaceutical. An unusually expensive R&D program would be compensated more than one that benefited from lucky circumstance, even if the outcome of the later is more effective. As a variant of the book form of valuation, it may lead to unsatisfactory outcomes from a policy perspective by rewarding inefficiency in research. Additionally, given the global nature of the market for a particular pharmaceutical, any attempt to value the impact of a single license on a drug’s investment return could be largely speculative and somewhat arbitrary.

In truth, the patent owner-based analysis misses an important point about drug discovery: research and development spending and returns are not completely segregated by drug. A company’s overall R&D efforts may represent a give and take between several drugs, and tracing the costs of a single molecular entity may not be easy. For example, there are many failures for every successful blockbuster drug, and the funds sunk in producing the failures might not be entirely reflected in a successful drug’s direct R&D costs. Additionally, so-called “excess profits” can be used to fund less valuable but important drug development programs. A company may plan to sell one drug at or below cost using the support of another high priced medicine. Thus, the fairness of a given drug’s price

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124 Love, supra note 76, at 60-61 (“[A] cost-based system can lead to irrational results, particularly as applied to products that have far different manufacturing costs, but similar therapeutic value.”).

125 See SMITH & PARR, supra note 118, at 209 (describing the book or cost approach and declaring “cost does not equal value.”).


127 See Sherman & Oakley, supra note 11, at 406 (“Only three of ten approved drugs, on average, recoup their research and development costs . . .”).

128 One of the most poignant examples of pharmaceutical philanthropy involves Merck. The company donates a drug it developed for another purpose, Mectizan, to impoverished nations as one of the most effective cures for “river blindness.” Stephanie A. Barbosa, Note, Implementation of the Doha Declaration: Its Impact on American Pharmaceuticals, 36 RUTGERS L.J. 205, 246-48 (2004) (describing Mectizan and several other examples of pharmaceutical company “philanthropy”).
must be considered in light of a company’s overall product portfolio. However, this rather complex marketing case is difficult to make in the context of compulsory licensing, and few politically responsive compensation schemes are likely to acknowledge it.

The converse approach, the user’s perspective, attempts to analyze the value of the patented product itself. Questions such as the effectiveness of the treatment and the degree of advancement over existing alternatives form the basis of the analysis.129 Whereas the market may place a considerable premium on a protected medicine that has only slight physiological benefits over unprotected alternatives, a user-based valuation may close the gap by reducing exaggerations of the property right.130 In addition, social and financial characteristics of the licensing country may be taken into account in a kind of demand elasticity analysis.131 Quixotically, a country with widespread health problems and few resources might find less “value” in a drug than a wealthier, healthier neighbor. In general, the user perspective should create a greater reward for significant advancement, reinforcing at least part of remuneration’s connection to the patent’s investment incentive.132 Even so, it is likely to be quite arbitrary given the inherent difficulty in objectively valuing a

129 The concept of pharmaceutical price and value is reflected in the pharmacoeconomic systems practiced in some countries. See AUSTL’N PRODUCTIVITY COMM’N, INTERNATIONAL PHARMACEUTICAL PRICE DIFFERENCES 25-26 (July 2001) (“Under a reference pricing system, reimbursement prices are commonly set for a group or cluster of similar or identical pharmaceuticals. . . . If the reference price is set at the level of the lowest-priced item in the group, manufacturers of the higher priced items may be required to lower their price to the benchmark.”)


131 A convenient, though imperfect, measure of a country’s social and financial health is the UNDP Human Development Index, which ranks countries based on qualities such as life expectancy, GDP and education. UNDP HUMAN DEVELOPMENT REPORT 2005, supra note 9, at 219-22.

132 Cf. MICHAEL DICKSON, ET AL., SURVEY OF PHARMACOECONOMIC ASSESSMENT ACTIVITY IN ELEVEN COUNTRIES 22-23 (Organization for Economic Cooperation and Development 2003) (describing various pharmacoeconomic evaluation systems and noting that drugs that offer a significant improvement over other drugs in a treatment class may receive an increased price, based on a cost-benefits assessment). Arguably, this perspective is more in line with the patent system’s rewards, as invention is rewarded as opposed to expenditure.
particular pharmaceutical’s contribution.

There are several examples of reasonableness systems across the world. In practice, they often use a combination of the above two perspectives, further obscuring any connection to a logical remuneration rationale. Some compensation mechanisms use several explicit patent-owner and user-based factors that are added to arrive at a final rate. Others implicitly incorporate one or both perspectives in the form of general remuneration principles. While such systems are ideally drug-specific, countries may choose an accounting measure that attempts to generalize for the entire pharmaceutical industry. In this case, the patent-owner and user-based factors may be used as multipliers to make the compensation measure more representative of the actual economics involved. The resulting rates are therefore quite diverse. If any

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133 James Love provides a nice capsule overview of a number of compulsory license remuneration methods, only some of which are cited below. Love, supra note 76, at 67-76.

134 For example, the UNDP advocated the increased use of compulsory licenses for public health purposes and suggested that a base royalty rate be set at 4%, adjustable upward by up to 2% “for products of particular therapeutic value” or downward by up to 2% “when research and development had been partially covered with public funds.” UNDP, HUMAN DEVELOPMENT REPORT 2001, at p.108 (2001), http://hdr.undp.org/reports/global/2001/en/pdf/completenew.pdf. On the other hand, the Japanese Patent Office uses royalty guidelines for licensing government patents that range from 0% to 6% that can be increased by, inter alia, taking into account “the degree to which the invention benefited from publicly available research” and “evidence of particularly high therapeutic value.” Love, supra note 76, at 68-70.

135 See Love, supra note 76, at 37-41 (describing examples of royalty setting from the Philippines, Malaysia and Singapore that make somewhat vague assertions to protecting R&D investment or promoting public health). From the perspective of compensation magnitude, the experience of the UK stands in stark contrast, with royalty rates for “licenses of right” ranging from about 23% to 31%, with most of the published rates at 25%. David Cohen, Applications for Licenses of Right in the United Kingdom, PATENT WORLD, Feb. 1990, at 28. But in similar fashion, the criteria for royalty amounts were ad hoc determinations (id.) that likely incorporated value and R&D compensation.

136 Canada’s former compulsory license system, which was abandoned in 1987 (Reichman & Hasenzahl, supra note 31, at 20), applied a 4% royalty almost uniformly following an Exchequer Court decision involving Hoffman LaRoche’s Valium. S Scherer & Watal, supra note 56, at 924. That decision suggested that royalties on licensed sales “should reimburse a pro-rated share of the patent holder’s research and development program outlays,” and this rationale was apparently incorporated into future applications of the same rate in the context of pharmaceuticals. Id.

137 For example, under Canada’s new Access to Medicines Regime, enforced under the Jean Chretien Pledge to Africa Act, House of Commons, 3d Sess., 37th Parliament, 52-53 Eliz. II, 2004 (Bill C-9) (received Royal Assent on 14 May 2004), a royalty rate is
commonality can be discerned from systems that portend to employ an objectively reasonable measure, it is that the amount often has little relation to market value, and is likely significantly less.

An obvious advantage to a reasonableness valuation, whatever form it may take, is that the established discounts provide a clear means of increasing access to medicines on a price basis. But that also qualifies as the most significant detraction. A reasonableness valuation may create the incentive to license rather than negotiate in good faith with the patent owner. If the set royalty rate is far below the market price, a country has no incentive to ever offer anything more. This is a basic conundrum of compulsory licensing as it is currently envisioned in international law. Additional predictability may blunt some of the negative effects, but it will not completely resolve the conflict.

In general, the arbitrary nature of a reasonableness approach makes it best positioned to serve as a negotiating tool rather than a means to fairly address the concerns of all stakeholders. Given the possibility for such measures to undercut the prices in the high profit, developed world, either directly or through price leakage, it is understandable that pharmaceutical companies would be opposed. However, if properly controlled, reasonableness valuations may serve as a method of spreading some controlled amount of the health care burden to private pharmaceutical companies.

C. Myth Three: Antitrust Compulsory Licenses Provide a Reliable Royalty Benchmark

In considering evidence of historical royalty rates, a well-cited data set are the royalties resulting from compulsory licenses used to remedy a patent holder’s wrongful acts. As a general matter, simply enforcing the exclusivity of one’s intellectual property right is not considered illegal. Carlos M. Correa, Internationalization of the Patent System and New Technologies, 20 Wis. Int’l L.J. 523, 543 (2002). However, additional acts can create a situation in which a “refusal to deal” with competitors is

determined by taking a base rate of 0.04 and multiplying it by the importing country’s position on the UNDP’s Human Development Index. Canada’s Access to Medicine Regime, Royalty Payment, http://camr-rcam.hc-sc.gc.ca/compan-entrepris/applic-demande/royal_pay-vers_redev_e.html (last updated Jul. 28, 2006) [hereinafter Canada Royalty Guidelines].

138 Love, supra note 76, at 42 (presenting a summary table of royalty rate examples from a variety of technologies ranging from 45% to 0.02%).

139 As a general matter, simply enforcing the exclusivity of one’s intellectual property right is not considered illegal. Carlos M. Correa, Internationalization of the Patent System and New Technologies, 20 Wis. Int’l L.J. 523, 543 (2002). However, additional acts can create a situation in which a “refusal to deal” with competitors is
association with antitrust law, a common forum for the use of the remedial action license is a lawsuit based on restraint of trade or monopolization.\textsuperscript{140} Often as a consequence of monopolistic acquisition or licensing behavior, a patentee will be compelled to offer access to the patented invention to competitors on favorable licensing terms.\textsuperscript{141} Such terms could be based on a relatively small royalty, or even royalty free depending on the severity of the triggering offense.\textsuperscript{142} For proponents of greater use of low-cost licenses, remedial rates look attractively low.\textsuperscript{143} Additionally, information is relatively easy to access, as it often accompanies published legal cases.\textsuperscript{144} However, that the distinct nature of this remedial form of licensing casts doubt on whether such rates contribute much to the debate.

problematic under competition laws. See generally Melanie J. Reichenberger, The Role of Compulsory Licensing in Unilateral Refusals to Deal: Have the United States and European Approaches Grown Further Apart after IMS?, 31 J. CORP. L. 549 (2006) (reviewing several E.U. and U.S. cases involving refusals to license intellectual property and the arguing that the E.U. is much more likely to impose compulsory licensees as a remedy).

\textsuperscript{140} Scherer & Watal, supra note 56, at 916 (“The United States has led the world in issuing compulsory licenses to restore competition when violations of the antitrust laws have been found . . . .”). See also United States v. Besser Mfg. Co., 343 U.S. 444, 447 (1952) (compulsory licensing is “a well-recognized remedy where patent abuses are proved in antitrust actions and it is required for effective relief.”). But see Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004) (“No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise. The problem should be deemed irremedia[ble] by antitrust law when compulsory access requires the court to assume the day-to-day controls characteristic of a regulatory agency.”)(quoting Phillip Areeda, Essential Facilities: An Epithet in Need of Limiting Principles, 58 ANTITRUST L.J. 841, 853 (1989)).

\textsuperscript{141} See Lawrence Schlam, Compulsory Royalty-Free licensing as an Antitrust Remedy of Patent Fraud: Law, Policy and the Patent-Antitrust Interface Revisited, 7 CORNELL J.L. & PUB. POL’Y 467, 500-507 (1998) (reviewing the use of compulsory licenses of patents as remedies for antitrust violations and noting that they have been deemed necessary when a patentee has created an illegal monopoly).

\textsuperscript{142} Id.; Makan Delrahim, Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property Rights and Antitrust (May 10, 2004), http://www.usdoj.gov/atr/public/speeches/203627.htm (noting that compulsory licenses can be issued without royalties attached).

\textsuperscript{143} Scherer & Watal, supra note 56, at 923 (noting that royalty rates in reported cases range from 0.2% to 3%); Love, supra note 76, at 30 (noting the royalty rate paid to Microsoft as a result of its antitrust-based compulsory licensing of certain protocols was on the order of 0.05% per protocol).

\textsuperscript{144} Some other types of compulsory licenses may be confidential. For example, Cohen reported great difficulty in attempting to learn the conditions of compulsory licenses issued under the U.K. regime due to confidentiality restrictions. Cohen, supra note 135, at 28.
Essential in understanding remedial licensing is that the rates act as part of a corrective measure for bad behavior on the part of a patentee, with a veneer (if not explicit declaration) of punishment.145 The fair representation of the patent owner is not necessarily a consideration. On the other hand, a government appropriation of patent rights in the absence of anticompetitive behavior is a very different scenario. 146 In that case, the patent owner had done nothing more than happen to own a patent on a valuable invention. It is by definition a different animal.

Another reason that remedial license rates can confuse the debate is that they may not affect innovation incentives in the same way as no-fault compensation mechanisms. A non-remedial compulsory license impacts innovation because a patentee may conclude that certain research endeavors will be less profitable due to the likelihood that monopoly pricing will be eliminated \textit{ex post}; a research investment is too great a risk.147 On the other hand, when the compulsory license is a penalty for illegal behavior, a company recognizes that it is the behavior that created the risk, not the investment, and it will likely modify the former in the future. For example, a patent-owning company compelled to license a pharmaceutical at a very low or non-existent rate as a consequence of monopolization or restraint of trade should not conclude that the field of research is not sufficiently profitable. Rather, it should conclude that anticompetitive behavior is not profitable. The company should continue to make research investments as before. Therefore, attempting to assess the impact of compulsory licenses using remedial rates can be very misleading.148

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145 See Schlam, supra note 141, at 500-507.
147 See supra notes 56-58, and accompanying text.
148 Perhaps the most prominent of such assessments is a recent paper by Chien. Colleen Chien, Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation, 18 BERKELEY TECH. L.J. 853 (2003). She considered innovation impact of six compulsory license required by the FTC as an alternative to divestiture, primarily in the context of mergers and acquisitions. Id. at 880. Chien found no drop in R&D investment following the licenses. Id. at 891-92. This study may be less than transferable because, while the FTC actions in the cases surveyed by Chien were not prompted by illegal behavior per se, the point remains that no involved company could logically conclude that their particular research endeavors are a problem as compared to their interest in becoming a bigger player in the market. In addition to Chien’s work, Scherer produced a study of the R&D impact of remedial
As a rule, remedial license rates should be excluded from the remuneration debate. The contamination of historical averages and the ambiguous impact on innovation impact merely confuses the issue. And suggestion that they evidence a willingness on the part of industrialized nations to take advantage of low-cost licensing when it serves them is inaccurate at best. A remuneration scheme premised on the market-based and reasonableness approaches described above provides a better foundation.

III. TOWARD A JUST AND SUSTAINABLE PRACTICE OF COMPULSORY LICENSING COMPENSATION

If one thing is clear in the complexities of compulsory license systems, it is that there are many possible perspectives and no single practice is optimal in all circumstances; every method carries with it some ambiguity in its overall impact. It seems obvious that any workable system will require significant compromise. In fact, this has been the mindset of international compulsory licensing negotiations to date. To be fair, considerable progress has been made in attempting to eliminate inefficiencies and promote access when feasible. Yet, there is still great dissatisfaction with the current system and a lingering impression that it will ultimately be unable to produce satisfactory results on public health.

Using a remuneration-oriented approach, some distinct and intriguing, albeit difficult, solutions begin to emerge. In particular, after dispelling the myths and misconceptions underlying current attempts at cohesion, it is possible to conceive a more equitable and ultimately compulsory licenses that is problematic for the same reasons. SCHERER, supra note 59, at 67-68, 74.

149 See UNCTAD-ICTSD RESOURCE BOOK, supra note 62, at 463-67 (detailing the negotiating history of article 31, including several drafts with very different provisions, both pro and anti-property rights); Reichman & Hasenzahl, supra note 31, at 13-14 (describing the occasionally contentious negotiations surrounding the Paragraph 6 Declaration).

150 See, e.g., Yu, supra note 48, at 36 (noting several criticisms of the initial Decision on modifying TRIPS to promote public health, including the lack of technology transfer; Frederick M. Abbott, Toward a new Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism, 8 J. INT’L ECON. L. 77, 87-88 (2005) (discussing pharmaceutical company dissatisfaction with the revisions to TRIPS and the push to through the U.S. government to get around it with free trade agreements). See also Peter Yu, TRIPS and Its Discontents, 10 MARQ. INTELL. PROP. L. REV. 369, 379-386 (2006) (describing general dissatisfaction with the TRIPS agreement in the developing world).
sustainable system by focusing on the diversity of available remuneration methods. Because no individual method is universally superior, such a system necessarily involves a hybrid of various compensation models. To achieve predictability, such a hybrid model must be more than a suggestion to the international community, but rather locked into a revised TRIPS agreement. The resulting price discrimination framework allocates the public health burden with greater equity and certainty. Coupled with additional dispute resolution and patent exhaustion tools, a more efficient and sustainable marriage between innovation and access can be achieved.

A. Abandoning the Unitary System

A remuneration system that preferentially treats least developed countries while maintaining property protections in the rest of the world seems fairly obvious. Measures providing compensation rules low enough to permit access to the most impoverished nations could effectively wipe out innovation investment incentives if they leak over to industrialized nations. On the other hand, a system with a uniformly high remuneration protocol could reduce access to essential medicines. For this reason, the TRIPS agreement preserves remuneration flexibility. However, this flexibility has a downside. Because the TRIPS provision on compulsory licensing does not distinguish between industrialized and developing nations, any member state may take advantage of its ambiguous remuneration rules. In other words, all nations are empowered to take advantage of the compulsory license power and set their own “adequate remuneration” standards, whether there is any economic need or not. The Doha Paragraph 6 implementation agreement contains a voluntary abstention by high-income nations, but it may not be binding. If an

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151 The ultimate in price discrimination is Ramsey pricing, which yields the highest possible social welfare subject to ensuring a target level of profit for the producer. See Danzon & Towe, supra note 121, at 431.

152 See UNCTAD-ICTSD RESOURCE BOOK, supra note 62, at 475-77 (noting that “The TRIPS agreement rules on compensation embody substantial flexibility . . .” and discussing a number of different situations and conditions that could produce different royalty calculations).

153 Article 31 explicitly permits patent use without authorization of the right holder (subject to the aforementioned conditions) “Where the law of a Member allows for [it].” TRIPS, supra note 6, at art. 31. In fact, it was understood during the negotiations that the United States took advantage of a kind of compulsory license through § 1498, and such use was expected to fit within article 31. UNCTAD-ICTSD RESOURCE BOOK, supra note 62, at 468.

154 See supra note 71, and accompanying text.
industrialized nation decides that the cost-savings of compulsory licensing are too great to ignore, it may succumb to such a “dysfunctional” access means. To put it another way, the current innovation environment essentially depends on the irrational behavior of representational governments, a daunting prospect to say the least.

The possibility that a wealthy nation would “break” a patent and engage in compulsory licensing purely for its own financial interests may seem remote. But, in fact, the world’s most economically secure nations have done so in the past. When the United States government was in need of a large quantity of a relatively common antibiotic following a 2001 anthrax attack, several legislators and highly-placed government officials threatened to use compulsory license powers as a means of negotiating a lower price. The reaction to the looming bird flu pandemic provoked similar threats. Moreover, bills were introduced in the 109th U.S. Congress to permit low-cost licensing that might not otherwise be supported by the restrictions of 28 U.S.C. § 1498, and they may reappear in the 110th.

Some global health care advocates actually suggest that industrialized nations like the United States should be able to take advantage of any TRIPS provisions that will permit low cost medicines during any future emergency. From an economic perspective,
industrialized-nation use of the compulsory license power is very rational outcome. A wealth-maximizing nation should consider the savings that would accompany low-cost licensing. From a moral perspective, one could argue that the saved funds could be put to other health care uses in furtherance of the public good. In fact, a representative government that did not make use of such power could be considered unresponsive to the needs of its people.

This powerful incentive to broaden the compulsory license threat beyond developing nations presents a persistent problem to funding health care innovation. Since the use of emergency compulsory licenses has been relatively limited to date, the impacts are hard to discern. But growth is reasonably expected. To avoid the problem, the only reasonable solution is to abandon the notion that all nations must treat intellectually property equally in this context. In the specific matter of public health, divergent treatment is better. Commentators have argued for years that the intellectual property system does not benefit all nations in the same way. And the acknowledgement of the need for greater protection in industrialized nations is an important corollary.

To be sure, the concept of a unitary system of intellectual property rights has become ingrained in the international community and it will not be easy to abandon. When TRIPS was negotiated, proponents strongly asserted that common intellectual property rights were one of the most important means for elevating the fortunes of impoverished nations. However, concessions have already been made in the field of pharmaceuticals. Countries defined as “developing countries” and middle of concern over an avian flu pandemic.”

See, e.g., MAY & SELL, supra note 63, at 170 (2006) ("Rather than facilitating the importation of new technologies for production (or service fulfillment), patents have historically been used to maintain import monopolies."); Yu, supra note 48, at Part IV.A. (arguing that “there is no denial that the TRIPS agreement is biased against developing countries”).

See Yu, supra note 150, at 375-76 (describing an “ignorance narrative,” in which developing countries were convinced to adopt TRIPS protections for intellectual property because of their inability to see the benefits of doing so unilaterally).

The term “developing countries” is self-defined under the WTO. See WTO, Who are the Developing Countries in the WTO?, http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm (last visited Aug. 6, 2006). Members indicating developing status include: Antigua and Barbuda, Argentina, Bahrain, Barbados, Belize, Bolivia, Botswana, Brazil, Brunei Darussalam, Cameroon, Chile, Colombia, Congo, Costa Rica, Côte d’Ivoire, Cuba, Cyprus, Dominica, Dominican Republic, Egypt, El Salvador, Estonia, Fiji, Gabon, Ghana, Grenada, Guatemala, Guyana, Honduras, Hong Kong, China, India, Indonesia, Israel, Jamaica, Kenya, Korea,
“least-developed countries” were given a transition period to enact pharmaceutical patent protection. The signing members intended those periods to be bounded; the developing-nations transition ended in January 2005 and the least-developed-nations transition will end in 2016. A permanent distinction between industrialized and developing countries was not planned.

In the end, breaking up the unitary system of intellectual property rights in this limited area provides important advantages that outweigh the negatives of disharmony. Most importantly, it ensures the maximum ability to profit from high-income countries while reducing economic barriers to access in developing nations. The argument that nations should be treated differently is an implicit acknowledgement of the significance of balancing innovation and access interests in world trade and health care.

B. Establishing a Predictable Three-Tiered Model of Compensation

To create the optimal conditions for an efficient multi-level compulsory licensing system, clear, delineating rules must be adopted. Rather than building off of the somewhat ad hoc nature of TRIPS article 31, a new version should be drafted that provides better guidelines for a workable system. The new rules should attempt to eliminate most of the complex and ambiguous conditional aspects of TRIPS, such as required negotiation with the patent holder. In their place would be a system that

Kuwait, Macau, Malaysia, Malta, Mauritius, Mexico, Morocco, Namibia, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Qatar, Saint Lucia, Singapore, Sri Lanka, St. Kitts and Nevis, St. Vincent and Grenadines, Suriname, Swaziland, Thailand, Trinidad and Tobago, Tunisia, Turkey, United Arab Emirates, Uruguay, Venezuela, Zimbabwe. See WTO, Frequently Asked Questions About TRIPS, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Aug. 6, 2006)

165 WTO, Least Developed Countries, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm. The countries falling under this definition are: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Congo, Democratic Republic of the, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, and Zambia. Id.

166 TRIPS, supra note 6, at art. 65 & 66.


168 UNCTAD-ICTSD RESOURCE BOOK, supra note 62, at 706.

169 TRIPS, supra note 6, at art. 31(b).
primarily focuses on how the patent holder will be compensated.

A preferred system distinguishes between a default condition of general intellectual property protection and an emergent condition that permits low cost licensing based on developmental status. While the lines separating different economies are not bright, some general factors can be articulated that provide a roadmap for future discussion and a more explicit plan.

1. Full Compensation as a Default, Regardless of Economic Status

Outside of the antitrust context, the clamor for compulsory licensing is clearly centered in the public health arena. When public health issues are not involved, however, there are fewer strong arguments in favor of licensing as an across the board cost-cutting measure. Even within health care, many routine conditions and treatments are such that private citizens and governments should incorporate them in a normal budget. The incentives for appropriate resource allocation are best achieved when the true cost of goods and services is maintained.

Therefore, as an overriding point to a remuneration-based system, patent compulsory licensing outside of public health emergencies should be generally treated as a means to prevent holdups. This is effectuated by employing a market compensation scheme as a default measure. When a patent owner is unwilling to provide the invention to the public market, or to the government on reasonable terms in a country where there is no effective public market, the patent owner would be provided with a compensatory royalty (i.e. one that attempts to mimic the percentage of sales a patentee would have received in an arms-length negotiation). Importantly, measures are best constrained to economic impacts. Consideration of additional access-promoting factors such as the UNDP Human Development Index would not be considered explicitly. Additionally, this market-based remuneration system should apply to all technologies without discrimination.

170 Remedial-based licenses should be unaffected by this system because such court-created punishments or market corrections fall outside the basic compulsory license scheme. See supra Part II.B.3.

171 UNDP HUMAN DEVELOPMENT REPORT 2005, supra note 9, at 219-22. In fact, access-promoting factors are implicitly considered by taking into account the country’s market. In other words, impoverished nations are likely to pay much less compensation than the industrialized world due to the market.

172 Possible exceptions could include the ones currently listed in TRIPS related to medical methods and higher order plant and animals. TRIPS, supra note 6, at art. 27, ¶ 3.
To ensure true market compensation (or as close as possible in the context of a license that takes place outside of a real market), TRIPS should be amended to provide for an infringement-like damages regime. Aside from the absence of injunctive relief, such schemes are based on fully compensating the property owner. Determining the market price will not always be a simple exercise. The structure of the U.S. system is a useful parallel. The burden of demonstrating any remuneration due as a consequence of the compulsory license would rest squarely on the patent owner.  

A manufacturer that actively markets its products in the licensing country and is able to meet the government’s demand should have a relatively easy time of establishing any profits lost. The U.S. Panduit case has long provided a model for assessing the hypothetical market for lost profits, and its criteria could be adopted under TRIPS. Conversely, if a product is not sold at the time of the license and immediate future plans to sell do not exist, the patent owner would be limited to a reasonable royalty. Factors such as those outlines in the U.S. Georgia Pacific case should be mandated (and modified as necessary). Evidence of other licenses would assist the patent owner in establishing a fair royalty rate. In the case of multiple patents on a single product, the remuneration per patent should be limited to its contribution to the patented invention.

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173 Gargoyles Inc. v. U.S., 113 F.3d 1572, 1576-77 (Fed. Cir. 1997) (assessing the patent owner’s proof that it was entitled to lost profits under § 1498). See also Micro Chemical, Inc. v. Lextron, Inc., 318 F.3d 1119, 1122 (Fed. Cir. 2003) (to recover lost profits, a patentee must show that “but for” infringement it reasonably would have made the additional profits enjoyed by the infringer) (citing King Instruments Corp. v. Perego, 65 F.3d 941, 952, 36 USPQ2d 1129, 1137 (Fed.Cir.1995)); Under Sea Indus., Inc. v. Dacor Corp., 833 F.2d 1551, 1557 (Fed. Cir. 1987) (the burden is always on the patentee to show infringement).

174 Gargoyles, 113 F.3d at 1577-78.

175 Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1545 (Fed. Cir.1995) (en banc). The factors are: 1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capacity to exploit the demand; and (4) the amount of profit it would have made.” Id. (citing Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir.1978)).

176 Gargoyles, 113 F.3d at 1580-81.

177 Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y.). There are fifteen different factors used to assess an appropriate reasonable royalty. Id.

178 This is incorporated in the Georgia Pacific analysis as factor 1, “The royalties received by the patentee for the licensing for the patent in suit, proving or tending to prove an established royalty.” Id.

179 It has been suggested that the 13th Georgia pacific factor, “The portion of the
As a means of reducing transaction costs, the requirement for negotiation before a compulsory license issues should be eliminated.\textsuperscript{180} Given the level of compensation, the patent owner should be indifferent as to whether or not a license occurs,\textsuperscript{181} so there is no reason to be deferential. That said, there are extreme advantages to negotiating with a patent holder under the market compensation model — namely, avoiding the payment of compensation to both a patent owner and a third-party manufacturer — and basic economics will certainly encourage such transactions.

There is increased social utility in encouraging a patent owner to voluntarily license at a price $P_{VL}$ equal to or even slightly above the royalty received under a market-based compulsory license plus marginal costs, because it eliminates quantity ($Q_{CL}$) and deadweight losses that would otherwise be associated with the additional profit a third-party licensee must make over its royalty payments and additional marginal costs ($M_{CL}$) from the sale of a compulsory licensed product ($P_{CL}$). The net consumer surplus is represented by the shaded area.

Under the above market-based remuneration system, the U.S. eminent domain model would become the dominant paradigm, with market compensation available and no possibility of an injunction.\textsuperscript{182}

realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer” (\textit{id.}), should be elevated to the most prominent status. \textit{See Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005), at § 6 (making factor 13 an explicit part of the patent code).}

\textsuperscript{180} TRIPS, \textit{supra} note 6, at art. 31(b).
\textsuperscript{181} \textit{See supra} notes 57-58, and accompanying text.
\textsuperscript{182} \textit{See, e.g.}, Motorola, Inc. v. United States, 729 F.2d 765, 768 n.3 (Fed. Cir.
Generally speaking, no cost savings would result from a license. Countries would continue to possess the right to compulsory license as they do now, but the benefits would be essentially limited to those circumstances in which the patent owner attempts to hold-up the market.\(^{183}\) Widespread compulsory licensing as a non-public health cost savings measure would be essentially eliminated. Conversely, companies would be freer to engage in discriminatory or Ramsey pricing\(^{184}\) without concern that compulsory licensing would disrupt profit predictions \textit{ex post}. In standard market circumstances, patent property is treated no differently than other property. This correctly sets the incentives against licensing and in favor of negotiated settlement, except in extraordinary circumstances. However, this system should be substantially altered when a public health emergency is declared. In that case, access to medicines becomes a primary concern.

2. Ensuring Access in Public Health Emergencies

The declaration of a public health emergency related to a particular disease in a certain country requires that access considerations come into effect. With respect to those nations that will have difficulty providing medicines in a crisis, some form of economic relief is justifiably offered by a TRIPS regime. However, all nations are not equal in their need for assistance. Thus, an optimal public health compulsory license regime explicitly takes into account the differing developmental states of member countries.

To permit the most equitable accounting of the burden of public health expenses while ensuring relative ease of administration, a three-level system could be adopted: (1) a high compensation state for industrialized nations, (2) a development-factored royalty state for developing countries ("DC"), and (3) a zero-royalty state for least developed countries ("LDC"). The strata might be initially defined by the WTO's grouping of nations,\(^{185}\) which would be subject to change as a

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\(^{183}\) In other words, through use of a compulsory license, a patent owner will not be able to obtain a premium price from the government by threatening to withhold the good altogether.

\(^{184}\) \textit{See supra} note 151.

\(^{185}\) \textit{See supra} notes 164-165, and accompanying text.
nation’s economic state either improves or declines. Although it would be preferable to make membership in each stratum a voluntary process, it is reasonable to assume that disputes could arise in some cases. Thus, WTO dispute resolution could be employed to ensure that nations are categorized properly.  

Importantly, the three-level system should be defined enough to be predictable. A rational pharmaceutical company should be able to generate a relatively foreseeable picture of the future market for a particular kind of health care treatment. This will be a significant advantage over the current state of TRIPS, which now permits the upset of the delicate access/innovation balance at any time.

a). Industrialized Nations Will Bear the Compensation Burden

The first, and most important, tenet of a workable public health emergency compulsory license structure is to establish a market-price baseline for industrialized nations. Compensation would be addressed in a manner equivalent to the default system described above: lost profits when a market presence exists, and a compensatory royalty in all other circumstances. Even in the case of a worldwide pandemic in which huge quantities of certain medicines are needed, industrialized nations would be on the hook for the full market consequences of their purchase decisions. The driving principle behind this rule is innovation incentives over short-term financial benefits. Locking in market-based industrialized nation compensation is the best way to ensure that innovation incentives are maintained to the greatest extent possible. Industrialized countries can reasonably afford to pay the bulk of pharmaceutical health care costs.  

Because the incentive to free ride is powerful, a method for

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187 Could a situation arise wherein an industrialized country is in great need of a treatment for a large number of citizens, but cannot afford market costs? In principle, this should not occur under the market compensation model. A standard calculation of lost profits takes into account only the sales a patentee would have made, and prices she would have charged, in the absence of the taking of the property right. See Micro
requiring equitable contribution from wealthy member states is essential. Given the huge percentage of pharmaceutical sales that are generated by North America, Europe and Japan, the world can ill-afford to lose this contribution to research and development. Conversely, by making sure this core source of funds is reasonably available for future innovations, the research burden is removed from developing and least developed countries (at least in the case of drugs with broad markets).

In this environment, would industrialized nations retain any ability to force prices downward? The answer is most certainly yes, by using the pricing mechanisms already in place such as reference pricing and single-payer negotiation. However, a country’s overuse of such tactics to force prices below reasonable market levels may cause pharmaceutical companies to abandon that market or greatly reduce sales. That, in turn, might lead to a compulsory license, which would be assessed at a market royalty rate. This may appear to provide an advantage over paying a market price as high as that in the United States. But with the additional transaction costs involved — issuing the license, ensuring a generic company is ready and willing to make the drug, paying both the generic

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189 See Opderbeck, supra note 16, at 536-42

190 See infra notes 212-215, and accompanying text.

191 Cahoy, supra note 39, at 636 (noting the great power that governments have in negotiating prices when the health care system is nationalized).

192 A market royalty rate would not necessarily offer a savings over a low reference price. In fact, it may offer a considerable increase in payment depending on how low the offered reference price is.

193 The United States is understood to have the highest prices among industrialized nations on branded drugs. Danzon & Furukawa, supra note 38, at exhs. 4 & 7. However, prices on over-the-counter and generic pharmaceuticals are often lower in the United States than most other countries (due to aggressive competition). Id.
and the branded pharmaceutical company for each sale, etc.—one would anticipate greater gains in simply negotiating with a pharmaceutical company to enter a market on its volition (see Figure 3). This, in many respects, is the most important strength of such a system: negotiation leading to more efficient resource allocation.

b). In Health Care Emergencies, Developing Nations Can Be Permitted Some Amount of Free Riding

A relatively broad, middle class of countries exists that can afford to pay for basic health care costs. However, due to the extent of a particular health care crisis and/or the existence of limits on resources, economic considerations will prevent access to essential patented medicines in some cases. Some relief from market rates is reasonable, but it must not erase the innovation completely from this market segment, which is not insignificant. To balance the limited ability to pay with the extreme need in emergent situations, a development-indexed royalty system should be employed. In essence, the developing nation takes on the role of a limited free rider in the three-tiered compulsory licensing regime. The contribution to overall profits is limited to something close to a compensation royalty that is discounted according to a country’s ability to pay.
There are many examples of discounted royalty systems in the literature, and some are already in effect. For example, Canada’s new royalty guidelines for exporting medicines requested under a Paragraph-6 compulsory license set an arbitrary royalty rate on sales of the generic copy that fluctuates on the basis of that country’s standing on the UNDP Human Development Index. The resulting royalty has a ceiling of 4%. Alternatively, a more accurate discounted royalty might be based on the market price of a drug, with appropriate human development factors figured in. The resulting rates will be a bit more wide-ranging, but they arguably better take into account the actual value of the medicine licensed.

Exactly how to define the set of developing countries is no small matter, as the potential savings for public health goods if one is so-designated could be enormous. Absent additional considerations, the incentive to become designated a DC is strong. Confusing matters a bit

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194 Love, supra note 76, at 67-76.
195 Canada Royalty Guidelines, supra note 137.
196 Id. According to the Guidelines, this ceiling “is consistent with the humanitarian and non-commercial considerations that are the foundation of the Regime.” Id.
197 Love, supra note 76, at 85.
198 Id.
more, the WTOs list of DCs is entirely voluntary and technically unofficial. Member countries are left to determine for themselves whether they are developing or developed, though the decision can be challenged. However, if incentives for accepting developed status are offered and apparent (e.g., provided through international organizations and two-party free trade agreements), a country may rationally and voluntarily give up DC status when it is not truly necessary.

c). In Emergencies, Least Developed Nations Can Argue for a Royalty-Free License

Perhaps the most controversial part of a three-layer remuneration scheme is the treatment of LDCs. Rather than attempting to enforce token royalties through an overly complex and burdensome process, LDCs should be excused entirely. This maximizes stated public health goals and focuses the effect where it is most likely to do the most good.

The administration for this provision should be as simple as possible. No notice requirements should be in place for LDC-produced treatments. For the more common case of treatments that must be produced by another country, the notice burden should rest with the producing country instead of both importing and exporting as currently required by the Paragraph 6 Decision. The royalty-free provisions should cover patent intellectual property rights only. If a nation desired additional know-how and trade secrets, it would be responsible for acquiring that on its own.

The most important detraction of a royalty-free scheme for LDCs

199 See supra note 164, and accompanying text.


201 When rules are unduly onerous and complex, some countries might just choose to ignore the process all together and attempt to keep it secret. See World Bank, Workshop 4&5: Compensation and Compulsory Licenses: Implementing the Doha Declaration and Advancing the Millennium Development Goals (2003), http://info.worldbank.org/etools/BSPAN/PresentationView.asp?PID=793&EID=402 (presentation of James Love) (indicating that officials of several developing or least developed nations had indicated to him that they were engaging in secret patent piracy rather than attempting to sort through the complex Paragraph 6 rules). This serves no useful purpose.

202 Paragraph 6 Decision, supra note 7, at ¶ 2(a) & (c). The most important reason for maintaining at least a nominal notice provision is to trigger the monitoring of parallel trade protections. See infra note 219, and accompanying text.
is that it may unduly harm the development of treatments for diseases that have little or no market in the industrialized world. It is true that pharmaceutical companies would have little economic incentive to expend large amounts of R&D funds on patented compounds and processes that could simply be appropriated by generic companies. The institution of royalty-free compulsory licenses only detracts from the limited research incentive that exists under the status quo. However, the benefits of the status quo and harm of licensing are, in the end, minimal figures. It is fair to say that R&D return from LDCs is so insignificant that research is not dramatically affected. Although maintaining patent incentives for LDC diseases appears on paper like a path to innovation, today many public health advocates acknowledge that supplemental funding sources are necessary. The loss of remuneration from LDCs is simply not enough to outweigh the benefits that could be achieved my maximizing access.

C. Instituting a National Exhaustion Rule

Even with a move toward protecting market prices in industrialized countries, one could still imagine concern on the part of the

204 Even when developing countries are included, the total revenue from pharmaceutical sales amounts to only about 10% of the world market. CIPIH REPORT, supra note 11, at 15 & tbl. 1.4.
206 An important limitation in the relaxation of intellectual property rules for developing nations is the possibility that pharmaceutical R&D will remain westernized. In other words, investment in research that is likely to primarily benefit developing nations will not be conducted due to the limitation on profit. This is a real problem, but it is mitigated somewhat by the fact that the lost income is not great to begin with. Regardless, a plan for supporting research into such “orphan” diseases should be supported. Various alternate incentive or patent prize systems have been proposed. See, e.g., Michael Kremer, Patent Buyouts: A Mechanism for Encouraging Innovation, 113 Q.J. ECON. 1137 (1998) (proposing a system wherein property rights for important innovations are purchased by the public and freely available for developmental research). But see Michael Abramowicz, Patent Prizes, 56 VAND. L. REV. 115, 170–71 (2003) (introducing a detailed discussion as to why such “patent prize” systems are inherently flawed).
One important reason is that pharmaceutical markets are not nearly as clearly segmented as geographical borders. The impact of prices of drugs supplied to one country can leak into the markets of other countries. If these impacts carry over to the industrialized nations that provide the bulk of the profits for a given pharmaceutical, the company has a very real and rational reason for protesting. The likelihood that industrialized markets will yield reduced profits as a consequence of compulsory license negotiations is non-trivial due to two related, price-limiting strategies: (1) parallel importation and (2) reference pricing.

Parallel importation occurs when an authorized version of a drug sold in a low-priced country is imported into a country where the drug demands a higher price. In general, the term applies to low-priced drugs produced and sold by the branded company, but it could also be applied to those produced under a compulsory license. Price discrimination becomes more difficult as the pharmaceutical manufacturer’s pricing scheme is driven toward the lowest cost country. While parallel importation is difficult enough to manage in the context of sales made under the authority of a pharmaceutical company, it becomes far more problematic if drugs produced for marginal costs plus a small royalty, such as those produced under a compulsory license, are in play. If quantities of the ultra low-priced drugs are also uncontrolled, the profit for a particular drug could be severely slashed. To partially address this


208 Cahoy, supra note 39, at 643 n.75 (describing parallel importation in the context of the United States).

209 See Opderbeck, supra note 16, at 531; Scherer & Watal, supra note 56, at 928.

210 Scherer & Watal, supra note 56, at 929-30.

211 Id. Outterson claims the negative effects of parallel pricing – he refers to it as pharmaceutical arbitrage – are greatly inflated. Outterson, supra note 36, at 231-32. However, he bases this assertion on his theory of supra-optimal pharmaceutical rents, which may not be realistic in consideration of the funding necessary for a company’s
issue, drugs produced under a Paragraph 6-compliant compulsory license must be altered to distinguish them from standard branded products.\textsuperscript{212} Additionally, the importing country is supposed to be limited to the amount of pharmaceutical products necessary to meet its needs, and take “reasonable measures” to prevent re-exportation and trade diversion.\textsuperscript{213} The persistence of counterfeit medicines — by one estimate accounting for ten percent of the world trade in medicines\textsuperscript{214} — suggests that such practices are in no way foolproof in preventing unauthorized pharmaceuticals from entering high-profit markets.

Reference pricing is the practice of indexing a country’s maximum pharmaceutical prices or reimbursement policy to the prices charged in another “reference” country (or the lowest price among several reference countries).\textsuperscript{215} The idea is to essentially erase the practice of price discrimination by imposing a “most favored nation” pricing policy by administrative law.\textsuperscript{216} While it is doubtful that any country’s referenced pricing system would be indexed to drugs produced under a compulsory license, it is certainly possible that a price agreed to under the threat of a compulsory license could be factored in.\textsuperscript{217} If compulsory licensing is not

\textsuperscript{212} Paragraph 6 Decision, supra note 7, at ¶ 2(b)(ii) (“products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking”). For example, the package labeling may be altered or the pill color or shape may be changed. \textit{Id.}

\textsuperscript{213} \textit{Id.} at ¶ 2(b)(i) & 4. Member states also promise to ensure the availability of effective legal means to prevent importation in their own countries without a license (i.e., even a country with an international patent exhaustion rule must prevent Paragraph 6 imports). \textit{Id.} at ¶ 5. Some countries have already taken such action. See Thomas F. Cotter, \textit{Market Fundamentalism and the TRIPS Agreement}, 22 CARDOZO ARTS & ENT. L.J. 307, 338 n.138 (2004) (describing a European Union regulation prohibiting the reimportation of certain types of drugs from developing countries).


\textsuperscript{215} This is more properly referred to as “external reference pricing.” See Austl’n Productivity Comm’n, supra note 46, at 29; Opderbeck, supra note 16, at 532.

\textsuperscript{216} Patricia Danzon & Adrian Towse, \textit{Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents}, 3 INT’L. J. HEALTH CARE FIN. & ECON. 183, 191 (2003) (“[E]xternal referencing is used formally by the Netherlands, Canada, Greece and Italy, among others, and used informally by many other countries. External referencing is equivalent to fully importing a foreign price.”).

\textsuperscript{217} See Cotter, supra note 213, at 338 n.138.
restricted to developing nations, reference-pricing policies could serve to amplify the impact of individual negotiations.\(^{218}\)

Therefore, for a three-tiered compensation system to succeed, it is absolutely critical that medical products produced under the DC or LDC regimes not be permitted to migrate into industrialized nations. The potential impact on innovation incentives in the absence of such control is obvious. An obligation similar to that described in the Paragraph 6 Implementation document be instituted for the new article 31 regime described above.\(^{219}\) Rules preventing export/import of emergency compulsory licensed drugs an additional control measure such as product distinctions should be adopted.

Although migration of patented products from nations paying market prices presents far fewer problems than drugs from emergency DC or LDC regimes, there are still concerns. Using intellectual property law to separate market segments can aid in a pharmaceutical company’s ability to engage in Ramsey or similar discriminatory pricing in non-emergency contexts.\(^{220}\) Such pricing structures tend to optimize pricing and profit, allowing companies to predictably address development costs. Parallel trade can undercut efforts to predictably obtain returns by maximizing profit throughout the world. Spreading the sales around may yield more equitable pricing to boot. Today, countries with closed pharmaceutical distribution networks — the U.S. in particular — bear the burden of such rules.\(^{221}\)

For this reason, it would be useful for nations to consider instituting general regional or national exhaustion rules rather than employing it on an international scale.\(^{222}\) Patent exhaustion is essentially the companion doctrine to “first sale” in copyright or trademark law.\(^{223}\)

\(^{218}\) Scherer & Watal, supra note 56, at 934.

\(^{219}\) See Paragraph 6 Decision, supra note 7, at ¶ 2(b).

\(^{220}\) Danzon & Towse, supra note 121, at 431; Scherer & Watal, supra note 56, at 928.


The idea is that a sale of a product covered by a patent that occurs under the authority of a patent owner exhausts that owner’s ability to control future sales. The exhaustion can be on a national or regional scale, meaning that such rights disappear only for a particular area, and a patent owner is free to use patent rights to stop sales of covered products into other areas. Alternatively, if exhaustion takes place on an international scale, the sale of a patented product anywhere eliminates a patent owner’s ability to control subsequent sales of that product in all countries.

There are two ways a country might adopt a national exhaustion rule. One is to make national-scope exhaustion an explicit part of a nation’s statutory or court-created patent law. Commentators have noted that this could be a very tough row to hoe, and may ultimately be somewhat unrealistic. On the other hand, the same result can be accomplished through private sales contracts that limit resale of patented items. Countries could implicitly support national exhaustion by ensuring such contracts remain legal under antitrust and unfair competition statutes. Through the wide-spread implementation of national exhaustion rules, the remuneration structure critical to efficient and fair access to medicines can be maintained.

CONCLUSION

The tension between patent property rights as innovation incentives and the needs of developing nations is never more dramatic than in the context of public health. To the extent that patent rights can be

over the importation of copyrighted goods is subject to the limitations in § 109(a)); Davidoff & CIE, S.A. v. PLD Int’l Corp., 263 F.3d 1297, 1301-02 (11th Cir. 2001); Iberia Foods Corp. v. Romeo, 150 F.3d 298, 303 n.4 (3d Cir. 1998); Enesco Corp. v. Price/Costco Inc., 146 F.3d 1083, 1085 (9th Cir. 1998).

See Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d 1368, 1376 (Fed. Cir. 2005) (articulating the doctrine in the context of an infringement case concerning disposable cameras).

Cahoy, supra note 39, at 657-660 (describing regional exhaustion rules such as that employed by the European Economic Area, or national exhaustion rules such as that employed by United States).

Id. at 660 (the U.S. and Canada employ common law exhaustion rules, whereas France and other civil law countries employ a statutory form).

Opperbeck, supra note 16, at 533.

See Daniel R. Cahoy, Oasis or Mirage: Efficient Breach as a Relief to the Burden of Patent and Copyright Limitations, 17 HARV. J.L. & TECH. 135, 155 (2003) (noting that, under U.S. law, even a label placed on an article may be sufficient to create a patent license) (citing Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 708-09 (Fed. Cir. 1992)).
meaningfully relaxed in times of crisis, such concessions seem not only reasonable, but eminently noble. However, nations with no economic need for intellectual property relief valves should not be empowered to hold the system in unpredictable limbo as we await the next pandemic. A revision of essential international law is required to both better enable access and shore up innovation incentives.

Considering the problem in terms of remuneration rather than the legal right to license, one can arrive at clearer, more equitable solutions. A great range of possibilities exists in terms of remuneration possibilities. Most importantly, the utility of market rates as a workable default should be considered and not discounted based on misconceptions of lack of connection to compulsory licensing. On the other hand, in cases of public health emergency, a more nuanced approach is called for. A system that follows the TRIPS/WTO model of separating least-developed countries and developing countries appears optimal. Developing countries should be prepared to compensate based on their relative development, and as they grow into developed nations, compensation should increase. Least-developed nations should also have this same chance to emerge from the financial burden of diseases, but they should receive additional assistance in the form a waiver of responsibility for patent property rights. Through a top-protected, base-accessible system, the burden on private actors is reduced while the most important public health challenges are addressed.