2011

Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents

F. Scott Kieff
George Washington University Law School, skieff@law.gwu.edu

Richard A. Epstein

Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents

Richard A. Epstein† *& F. Scott Kieff*††

Many advocates for using compulsory licensing (CL) for pharmaceutical patents in developing countries like Thailand rest their case in part on the purported use of CL in the United States. In this Article we take issue with that proposition on several grounds. As a textual matter, the "commercially reasonable terms" language in Article 31 of TRIPS, even when qualified by the Doha declaration, prevents any host nation from using whatever royalties it wants in its CL arrangements, especially those that are below marginal cost. As a theoretical matter, we argue that the basic presumption in favor of voluntary licenses for IP should apply in the international arena, in addition to the domestic one. In the international context, voluntary licenses are of special importance because they strengthen the supply chain for distributing pharmaceuticals and ease the government enforcement of safety standards. Next, this Article analyzes several of the key illustrations of purported CL for drug patents in the United States and shows that the use of CL elsewhere deviates in material ways from the standard US practices. These are the compulsory copyright licenses for music, the limited statutory exemptions for pharmaceuticals and medical procedures, the award of damages instead of injunctions after eBay Inc v MercExchange, LLC*, government takings, and the use of compulsory licenses in antitrust settlements. Whatever the ultimate desirability of these American doctrines, none of them seeks to reduce the payment on licenses to the marginal cost of the licensed goods. Any need to help poor people gain access to vital drugs should not rely on CL, but instead should rely on tools precisely aimed at that purpose, including direct government purchases of patented drugs from their manufacturers at negotiated prices.*

INTRODUCTION

Patented pharmaceuticals play a key role in addressing a wide range of public health problems in both the developed and undeveloped world. As is commonly understood, all patents lead a two-sided

† Laurence A. Tisch Professor of Law, New York University Law School; Peter and Kirstin Bedford Senior Fellow, The Hoover Institution; Senior Lecturer, The University of Chicago Law School.

†† Professor of Law, The George Washington University Law School; Ray & Louise Knowles Senior Fellow, The Hoover Institution.

A draft version of this paper was presented at The Licensing of Intellectual Property symposium held at The University of Chicago Law School on June 18 and 19, 2010. This work is part of the ongoing Hoover Institution Project on Commercializing Innovation, which studies the law, economics, and politics of innovation and which is available online at http://www.innovation.hoover.org. We thank Kevin Outterson, Associate Professor at Boston University School of Law, for pointing out our errors in reading the emergency conditions in TRIPS Article 31 in an earlier version of this paper and Brett Davenport, New York University Law School, Class of 2012 for his prompt and expert research assistance.

life. On the one hand, patents are praised as a spur to innovation, which is made possible only with the predictable enforcement of rights of exclusion for the patented technology. These patents are typically strong for pharmaceuticals because they are often well-defined, single chemical entities that have no perfect substitute. That distinctive feature often leads to prices that exceed marginal cost. This price gap can, consequently, easily result in excluding drug use by individuals with limited financial means, especially those in undeveloped or developing nations. The hard tradeoff between innovation and dissemination has led to extensive debates about whether and how pharmaceutical patents are helping or hurting overall social welfare, especially in poorer countries. Worried that a patentee's right to exclude will unduly limit treatment of illnesses such as AIDS, heart disease, and cancer within its borders, Thailand has recently taken the bold move of ordering several major drug companies to engage in compulsory licensing (CL).[1] Debates about the wisdom of CL are multifactored and ongoing; their full range is beyond the scope of this Article.[2]

We think, therefore, that a presumption against CL follows from the more general presumption against forced exchanges found in a wide range of divergent legal settings.[3] The defenders of CL for pharmaceuticals do so not only on general normative grounds, but also on the narrower claim that CL must be an acceptable practice because it is a common norm in the United States, which has strong free market tendencies. As the government of Thailand put it: "Thailand is not the first country to apply compulsory licensing or the Government Use of patent, developed countries including the USA, European countries, and other developing countries have previously attempted and implemented compulsory licensing and Government Use of Patents."[4]

---

1 See Ministry of Public Health and National Health Security Office, Thailand, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand: Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent *3 (Feb 2007), online at http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf (visited Oct 15, 2010) ("Thai White Paper I") (discussing CL for drugs to treat AIDS and heart disease). See also Ministry of Public Health and National Health Security Office, Thailand, The 10 Burning Questions Regarding the Government Use of Patents on the Four Anti-cancer Drugs in Thailand *4–5 (Feb 2008), online at http://www.moph.go.th/hot/White%20paper%20CL%20II%20FEB%2008-ENG.pdf (visited Oct 15, 2010) ("Thai White Paper II") (discussing CL for cancer drugs). Brazil has also adopted a CL approach. See Jon Cohen, *AIDS Drugs: Brazil, Thailand Override Big Pharma Patents*, 316 Sci 816, 816 (2007) (discussing Brazil's decision to follow Thailand by using CL for an anti-HIV drug considered unnecessarily expensive).

2 For a helpful review, see Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 Houston L Rev 1047, 1049–51 (2009).

3 See generally Richard A. Epstein, *A Clear View of the Cathedral: The Dominance of Property Rules*, 106 Yale L J 2091 (1997).

4 *Thai White Paper I* at *12 (cited in note 1). See also id at *67–76, 97–102.

In order to examine the claims of the Thai government, we proceed as follows. Part I of this Article starts with a discussion of the status of compulsory licenses under the TRIPS[5] agreement as modified by the Doha Declaration of 2001. We point out that even in the case of admitted national emergencies, the agreement does not exempt member nations from the requirement that its licenses be issued on commercially reasonable terms and conditions. Thereafter in Part II, we show the distinctive position of patents in the pharmaceutical sector relative to other areas of technology. This Part shows that many of the current criticisms about patents are particularly weak for patents in the pharmaceutical field, while the case for enforcement of patents in pharmaceuticals is particularly strong. Part III then focuses on the risks of CL. Part IV explores alternatives to CL that more directly address the persistent problems of poverty that seem to drive the insistent demands for CL. Part V explores the central examples of purported CL in the United States on which the Thai advocates of CL have relied in order to expose their marked difference from a CL regime.

I. THE STATUS OF COMPULSORY LICENSES

The initial inquiry is whether the TRIPS Agreement in Article 31 provides a generalized authorization for CL, not only in the poorest countries, but also in places like Thailand, which is generally classified as a middle-income country. The key provision for CL has two parts, which together read as follows:

> [S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.[6]

The common argument that this section allows broad discretion for CL rests upon the interconnection of the two sentences. Thus, Kevin Outterson writes that the substantive provisions are contained in the first clause, which allows for the use of CL when the host nation fails to negotiate an agreement on reasonable terms.[7] That provision

---

5 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 33 ILM 1197 (1994).

6 TRIPS Art 31(b), 33 ILM at 1209.

7 See Kevin Outterson, *Disease-Based Limitations on Compulsory Licenses under Articles 31 and 31BIS* *3 (Boston University School of Law Working Paper No 09-26, May 2009), online at http://ssrn.com/abstract=1407522 (visited Oct 15, 2010).

contains no limitation on the types of products that are subject to CL. Nor does it contain any reference to emergency conditions, which do not expand the scope of the CL privilege, but serve only to waive the precondition that the host nation seek to make out some negotiated agreement. He then notes as follows: "In any event, Thailand does not rely on the waiver, since it also claims to have negotiated for two years in an attempt to reach an agreement with the patent holder."[8] He then conducts an exhaustive analysis of the negotiating history of TRIPS, establishing what is evident from the text: Article 31 is not limited to HIV/AIDS, tuberculosis, and malaria.[9]

Unfortunately, at no point in his lengthy critique does he so much as mention, let alone discuss, the key words "reasonable commercial terms and conditions." The critical inclusion of these words, which are applicable to all CLs, negates the argument that the sole test of whether the CL may be issued is whether the host nation attempts in good faith to negotiate some reasonable settlement with the patent holder. The treaty's "on reasonable commercial terms and conditions" language sets an objective standard that is not satisfied just because the host nation goes through the motions of negotiations. The exact content of the phrase is hard to define, but it points to at least two types of relevant inquiries. The first is that no host country offer should be regarded as reasonable if it does not cover at least the marginal cost of production and distribution of the drug within the host country—a most minimal condition. The second is that terms should not be regarded as commercially reasonable if they provide the host country with a deal that is unambiguously more favorable to itself than those that have been negotiated in voluntary markets by other countries within the same economic class as the host country.

The legal position under the TRIPS agreement is complicated by the Declaration on the TRIPS Agreement and Public Health, adopted in Doha in November 2001.[10] Its title suggests that the provision should be limited solely to those patents that deal with "the gravity of the public health problems afflicting many developing and least-developed countries, especially those problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."[11] At this point, the Doha Declaration is clearly torn between the need to create new incentives on the one hand and promote the immediate dissemination

8 Id.

9 See id at *1–5.

10 See WTO, Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/Min(01)/DEC/2 (2001) ("Doha Declaration"), online at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (visited Oct 15, 2010).

11 Id at ¶ 1.

of needed medicines on the other. Yet its resolution of that question in paragraph 5 does not undo the basic commercial limitations on CL contained in Article 31 of TRIPS:

> 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
>
> a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
>
> b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[12]

In our view, the chief effect of these critical provisions of the Doha agreement is to reaffirm that the member nation has complete discretion in choosing the *grounds* on which these licenses are granted. But the point is often missed that this term does not contradict or supersede the explicit textual command of TRIPS Article 31, which still requires these licenses to be issued on commercially reasonable terms and conditions.[13] These provisions cannot be ignored because, as drafted, they parallel those that analyze rate regulation under various types of arrangement where, without ambiguity, the requirement of reasonable commercial terms is introduced to provide protection against confiscation.[14] Put otherwise, CL is a species of forced exchange that is generally analyzed in connection with the question of takings.[15] The government taking of the license is, in theory at least, supposed to provide just compensation to the person who has been deprived of his property. At the very least, these exchanges raise the question of which

---

12 Id at ¶ 5.

13 For the conflation of "grounds" with "commercially reasonable terms and conditions," see Amy Kapczynski, et al, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 Berkeley Tech L J 1031, 1059 nn 122–23 (2005) (quoting the text of paragraph 4(b) but failing to mention the commercially reasonable terms and conditions language in Article 31 of TRIPS).

14 For the connection in American law, see *Federal Power Commission v Hope Natural Gas Co*, 320 US 591, 602–06 (1944) (dealing with just and reasonable rates); *Duquesne Light Co v Barasch*, 488 US 299, 310 (1989) (same). The precise context of these cases differs from the TRIPS agreement because the rate regulation effort there is focused on the overall return to the utility, not the contribution from the particular host company. But under TRIPS reasonableness must be determined relative to the situation between the two parties, for which the two tests stated in the text give the far better response.

15 For a discussion, see Richard A. Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation* 91–96 (Yale 2006).

patents should be subject to these licenses and how just compensation should be computed, which gives rise to immense tactical and public choice issues when several similar patents are all subject to such use. As shown in detail later, these conditions are not satisfied.

II. THE DISTINCTIVE NICHE OF PHARMACEUTICAL PATENTS

Turning away from TRIPS to normative issues, many critics of today's patent system insist that its system of exclusive rights frustrates the very forms of technological innovation that patents are supposed to advance. The heart of these arguments boils down to two key purported defects within the basic patent system that are said to compromise its effectiveness. First is the claim that the obscure boundary lines for individual patents make it difficult for other entrepreneurs to know whether their activities infringe on someone else's patents. As James Bessen and Michael Meurer put it, third parties have become "innocent violators" of patents, by making investments that they think are not infringing but are in fact "exposed to unnecessary risk because of unclear property boundaries."[16] Second is the idea that acute fragmentation of property rights blocks any entrepreneur from assembling the needed technologies for advancing his own operations.[17] According to Michael Heller and Rebecca Eisenberg:

> Current examples in biomedical research demonstrate two mechanisms by which a government might inadvertently create an anticommons: either by creating too many concurrent fragments of intellectual property rights in potential future products or by permitting too many upstream patent owners to stack licenses on top of the future discoveries of downstream users.[18]

We recognize that these objections could prove weighty in many areas of technology.[19] Computer hardware and software patents, for

---

16 James Bessen and Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovation at Risk* 2 (Princeton 2008). For a more detailed discussion of the topic, see id at 46–72.

17 See, for example, Michael Heller, *The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives* 49–78 (Basic Books 2008) (arguing that "[d]rugs that should exist are not being created" because licensing negotiations are plagued by insuperable holdout problems, thus retarding innovation and replacing it with litigation).

18 Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci 698, 699 (1998).

19 We also have previously offered a range of reasons why such concerns are often overblown or better addressed through private ordering than through legal reform. See, for example, F. Scott Kieff, *On Coordinating Transactions in Intellectual Property: A Response to Smith's Delineating Entitlements in Information*, 117 Yale L J Pocket Part 101, 106–09 (2007) (exploring additional reasons); F. Scott Kieff and Troy A. Paredes, *Engineering a Deal: Toward a Private Ordering Solution to the Anticommons Problem*, 48 BC L Rev 111, 114–16 (2007) (offering a

example, are often said to have little value because they are too small in scope, too evanescent in utility, and too numerous in practice.[20] One way to respond to these endless borderline disputes is to revert to a public domain system in which trade secrets become the only (if limited) form of intellectual property (IP) protection. But trade secrets are difficult both to protect and to define, given the rapid flow of information across firms as workers change jobs and communicate with others through publications, meetings, and social networks. Where the public domain begins and regimes of private property end are thus matters that no system of IP can evade.

Pharmaceutical patents, however, are not subject to these twin objections, because they cover single chemical entities or groups of well-defined compounds in composition. The distinct nature of these products, and their precise chemical formulations, significantly mitigates concerns about boundary disputes. In addition, these compounds typically have direct value to end users in treating particular patients, either alone or in conjunction with one or two other compounds. That direct link between patent and consumer product significantly mitigates concerns about fragmentation.

A third objection to general patent enforcement is that it requires product licensing, which can pose unwanted delays when the patented technology is most needed. Precisely this concern motivated the provisions in TRIPS that allow the host nation to use CL without negotiation in times of national emergency.[21] But when long-term stable conditions are involved, the procedural shortcuts look inappropriate and, as noted earlier, do not allow the host nation to issue a CL without offering commercially reasonable terms, which the Thai CLs do not appear to satisfy. Nonetheless, TRIPS does require the host nation to provide that, "[i]n situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable."[22] This notification allows the patent holder also to insist that this license be exercised on commercially reasonable terms and conditions. The rapid process thus operates similar

private ordering solution for cases in which the problems persist); Richard A. Epstein and Bruce N. Kuhlik, *Is There a Biomedical Anticommons?*, 27 Reg 54, 55 (Summer 2004) (exploring some reasons why the problems are likely to be less prevalent than feared).

20 See, for example, Ian Ayres and Gideon Parchomovsky, *Tradable Patent Rights*, 60 Stan L Rev 863, 864 (2007) ("Patent thickets can be found in several key industries, such as semiconductors, biotechnology, computer software, and the Internet."); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in Adam B. Jaffe, John Lerner, and Scott Stern, eds, 1 *Innovation Policy and the Economy* 119, 120–22 (MIT 2001) (providing the same observation).

21 See TRIPS Art 31(b), 33 ILM at 1209.

22 Id.

to a "quick take" statute in the eminent domain law.[23] Importantly, even such quick-take approaches operate only as procedural tools to address the temporal pinch of a logjam. At no time do they operate to eviscerate the substantive remedy afforded to the condemnee, which is still governed by the benchmark of takings law (discussed in more detail below).

Moreover, the positive case for patents is particularly strong for pharmaceuticals. The huge, lengthy, and risky investments that are needed to bring a typical new molecular entity to market today can exceed $1 billion.[24] That large sum is needed to meet the extensive technical, regulatory, and dissemination barriers that drugs must overcome before reaching actual patients in the market—barriers that are largely absent, for example, for patents on computer products. All pharmaceuticals, whether patented or generic, face the ever-longer clinical trials mandated by the Food and Drug Administration (FDA). These trials (1) impose high direct out-of-pocket costs, (2) reduce the number of years that a new drug can be sold on the market with patent protection, and (3) postpone the date when the new drug first generates any revenues. The Hatch-Waxman Act,[25] which extends the patent period up to five years to offset these FDA delays, makes only a dent in the problem. Ordinary products have close to a seventeen-year useful life, a period that reflects the three years that patent examination reduces from the twenty-year statutory term. In contrast, the typical effective patent life for pharmaceuticals in the United States today is under twelve years for drugs with more than $100 million in annual sales, which, not surprisingly, constituted 90 percent of the unit sales in the brand market in the United States during the period from 1995 to 2005. That effective period is even lower for some segments.[26] The revenues that major patents generate can be billions of dollars per year.

There is, moreover, no effective substitute for patents. Any government prizes and inducements are puny in comparison, and are payable only to a few actors at most. Prizes, similar to draft picks in

---

23 Quick-take condemnations involve "[t]he immediate taking of possession of private property for public use, whereby the estimated compensation is deposited in court or paid to the condemnee until the actual amount of compensation can be established." *Black's Law Dictionary* 310 (West 8th ed 2004).

24 See Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J Health Econ 151, 180 (2003) (estimating $802 million). For a higher estimate, see Jim Gilbert, Preston Henske, and Ashish Singh, *Rebuilding Big Pharma's Business Model*, 21 In Vivo: Bus & Med Rep 73, 74 (2003) (estimating $1.7 billion).

25 Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub L No 98-417, 98 Stat 1585, codified in various sections of Titles 15, 21, 35, and 42.

26 See Henry G. Grabowski and Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 Managerial & Decision Econ 491, 493, 496 (2007).

competitive sports, often rank products in the wrong order by commercial value. Like other forms of industrial policy, government agents or philanthropists are not good at picking winners. We recognize that patent protection should not be available in the production of ideas, but no Nobel Prize for patent development can hope to supply the broad-reaching and powerful incentives of patents or allow for the coordination of efforts by multiple actors needed to convert medical knowledge into useful therapeutic products. The want of exclusive rights creates a giant barrier to commercialization.[27]

To top it all off, the value of a pharmaceutical patent is further compromised by the proliferation of government programs—such as those administered under Medicare and Medicaid—that fix the sale of drugs at prices below market levels.[28] The government insists that reduced payments are needed to offset the government subsidy to individuals who would never be able to purchase these products on their own in the first place. These government-imposed systems of price discrimination can remove excessive profits on inframarginal sales. Yet these mandate programs will misfire if the government sets prices below the marginal cost of selling these additional units, which forces firms to lose money on these added transactions. It is, therefore, ironic that the very people who insist on Medicare and Medicaid discounts also criticize the common practice of price discrimination for patented drugs in voluntary markets on the ground that only equal prices can meet a norm of fundamental fairness to all potential takers. But voluntary markets exhibit no such norm. Constantly revised prices are commonplace in leasing, hotel, and airline markets, where they allow firms to efficiently spread their joint fixed costs over inelastic portions of their customer base.[29] These niceties often elude the critics, whose efforts to eliminate price discrimination could prevent the patentee from recovering the fixed costs of the original patented invention, with deleterious effects on innovation.[30] Nothing in theory or practice shakes the initial presumption against CL for pharmaceutical patents.

---

27 For more on the limitations of prizes, tax credits, and other rewards as substitutes for patents, see F. Scott Kieff, *On the Economics of Patent Law and Policy*, in Toshiko Takenaka, ed, *Patent Law and Theory: A Handbook of Contemporary Research* 3, 34–40 (Edward Elgar 2008).

28 For a description of the program and a rejection of constitutional challenges to it, see *Pharmaceutical Research & Manufacturers of America v Walsh*, 538 US 644, 650–55, 668, 670 (2003).

29 See Michael E. Levine, *Price Discrimination without Market Power*, 19 Yale J Reg 1, 2–3 (2002).

30 See John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U Chi L Rev 37, 40–41 (2004). On the importance of price discrimination in the context of antitrust litigation, see *In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F3d 781, 784–85 (7th Cir 1999).

III. RISKS OF COMPULSORY LICENSING

The dangers of CL are more apparent when one sees how governments implement such licenses in practice. A central risk of CL is that it gives the national government untrammeled discretion to select those firms that may sell the patented drug in the local country free of the patent. Thereafter, either the firm or the government, or both, set all prices for all units sold, which need not reflect any share of the high fixed costs of drug development, or even the licensor's full cost of drug distribution, which could easily exceed its manufacturing costs.

One standard justification offered for CL is that it removes the monopoly element of pricing for patented drugs when the drugs face no credible competition from alternative sources.[31] These sources include noninfringing drugs that are already on the market or that will come to market thereafter. But this vision of CL cannot be applied universally, because marginal-cost pricing makes it impossible for firms and their investors to recover their fixed costs of generating and running their operations. The long-term consequences are not acceptable.

A. Impaired Incentives to Develop New Drugs

CL at marginal cost will reduce the ability to tap key revenue streams needed to offset those fixed costs of development.[32] In some cases, the loss of revenue will result in a delay of new drugs. In other cases, it will result in the abandonment of newly unprofitable projects. These losses will be felt not only in the country that imposes CL, but everywhere else as well. The impact will be especially large for those drugs targeting so-called "orphan diseases" most prevalent in those countries that champion CL.[33] For other long-term investments, recovery of these fixed costs must be allowed to prevent confiscation when, for example, a public utility makes a large front-end investment that regulation prevents it from recovering over the life of its new facility.[34]

---

31 See, for example, *Thai White Paper II* at *39 (cited in note 1).

32 For costs, see note 24 and accompanying text.

33 Orphan drugs are those designed to treat rare conditions. In both the United States and Europe, special procedures are developed to reduce the cost of their approval. For the American response, see FDA, *Developing Products for Rare Diseases and Conditions*, online at http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm (visited Oct 15, 2010).

34 See *Duquesne Light Co v Barasch*, 488 US 299, 308–12 (1989) (detailing alternative methods of compensation).

B. Coerced and Concealed Wealth Transfer

Implementing a CL system in one country necessarily forces individuals in other nations to bear all of those fixed costs. This backdoor subsidy has serious negative consequences for consumers outside of the CL country. These covert methods of wealth transfer avoid open deliberation, frustrate normal democratic discipline, deprive the donors of recognition for their beneficence, encourage wasteful arbitrage transactions across national borders, and invite never-ending rounds of tit-for-tat trade wars.

The risks could easily multiply. First, a call for CL based on some alleged need can be applied to almost any area of technology. Second, the recent uses of CL are not addressed to any transitory crisis in a particular country—think plague—that requires instantaneous response, but instead cover chronic medical conditions like AIDS, heart disease, and cancer, for which it is possible to plan in advance. Within a competitive context, no litmus test helps decide which drugs within a particular class should be subject to CL and which should not. The selective use of CL reduces the rate of return for licensed drugs, which in turn subsidizes the competitor that escapes CL treatment. In the end, the rates of return are negatively impacted for both. Selective CL might also trigger fresh restrictions on the use of rival or complementary products, which negatively impacts the overall market.

C. Impaired Commercialization and Distribution of Drugs

CL also may have negative implications for the commercialization and distribution of drugs. The self-conscious deviation from standard property and contract rights undermines incentives for private actors to invest or conduct business in areas where property rights are not secure. The ironic effect is that weak property rights in drugs will create large gaps in drug coverage that the proponents of CL hope to close, usually by transfers to sympathetic groups such as the poor at below-market rates. Big businesses may not like CL, but they can fend for themselves by investing elsewhere. That mitigation strategy has both private and social costs, but the private costs will likely be small given the mobility of capital for the creation of information goods. Regrettably, the poor people in these underdeveloped regions are not so mobile, so they pay dearly when denied the benefit of grassroots distribution systems for food and medicines. The point may seem paradoxical, because drugs under CL should be cheaper as a first approximation than those that are not.

It is, of course, one thing to impose CL, but it is quite another to develop a reliable distribution system that gets the right drugs to the right places in the right conditions. This issue of distribution is no

small matter. Gaps in the supply chain can lead to theft and the substitution of counterfeit drugs for the real ones, which are in turn diverted to the black market.[35] In addition, the lack of commercial distribution channels could lead to a failure to maintain sensitive pharmaceutical compounds in proper condition, exposing users to manufacturing or transportation-induced defects that may not easily be detected by inspection prior to use, and for which there will be no effective legal remedy after the fact, because the absence of profitable commercial providers suggests that potential legal actions will either fail to find defendants or will find those who are judgment proof. Excluding private drug producers from the market thus places local citizens at the mercy of an inferior local distribution system. Additionally, that compromised system is not matched with cost savings. CL deals only with wholesale prices. Yet, to consumers, what matters is the price at retail, which could easily go up even as the wholesale price goes down. We know that the bulky European distribution systems often increase the price of generic drugs.[36] Those same risks, vastly amplified, exist in developing countries.

Driving out commercial distribution systems from local economies could also have serious collateral consequences. Reducing IP opportunities could help induce a mini–brain drain, as local engineers and entrepreneurs leave either the sector or the country in search of better opportunities elsewhere. In addition, weak IP protection may scare away foreign investors who might otherwise direct research to treat local subpopulations in need of novel and targeted therapies. Moreover, the reduction in overall commercial traffic could slow down the formation of the technical and political infrastructure needed to support a mature system of drug manufacturing and distribution.

The problems with weak distribution systems are already serious. In countries like China, distribution costs constitute an enormous portion of a drug's cost, which private distributors could reduce. At the same time, gaps in safety regulations have spawned public health crises both in China and in other countries that import Chinese-made drugs, including the United States.[37] Profitable private distribution problems are easier targets for state regulation, which can rely on brand-name loyalty to keep suppliers in line. Local distribution companies with weak brands are far more likely to exercise corrupt influence

35 See Bryan A. Liang, *A Dose of Reality: Promoting Access to Pharmaceuticals*, 8 Wake Forest Intel Prop L J 301, 324–26 (2008).

36 See Patricia M. Danzon and Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals in 2005*, 27 Health Aff 221, 228 (2008).

37 See Gardiner Harris, *F.D.A. Identifies Tainted Heparin in 11 Countries*, NY Times A1 (Apr 22, 2008).

over their own national regulators, who are often reluctant to clamp down on domestic commercial firms.[38]

IV. GOVERNMENT PURCHASE AS COMPULSORY LICENSING ALTERNATIVE

Most undeveloped countries think that access to needed drugs is an essential element of a system that provides minimum health security to all its citizens.[39] We forego any discussion here of how this program might be implemented, given that each nation should design whatever system of positive rights it regards as appropriate for its own citizens. But it hardly follows that each state thereby has some strong entitlement to fund these subsidies from the foreign pharmaceutical manufacturers or from their customers in other countries. Internal revenues should be the source of government-mandated domestic subsidies.

Poorer countries, moreover, can get attractive deals even without demanding any express or implicit subsidy. Price discrimination is a common feature in pharmaceutical markets that functions as a response to selling products with high initial and low marginal costs of production. Given the limitations on local wealth, price discrimination should let less developed countries buy goods at far lower prices than they sell for, say, in the United States.[40] So long as the local prices exceed the marginal costs of sale, everyone wins. To be sure, prices in developed countries are not likely to fall by having poorer countries pick up part of the slack. Pharmaceutical manufacturers are likely to sell at the previous profit-maximizing level even after making the new sales. Rather, the increase in the total return should, in the long run, increase new investment in drugs, which in turn will put price pressure on established products. In other cases, larger research budgets will open up possibilities to treat otherwise untreatable conditions. Either way, a robust global market with price discrimination should increase the sum of consumer and producer surplus, which is the correct social measure of welfare.

---

38 Consider, for example, Jay Hoenig, *Managing Business Risks: Wise Companies Prepare for—and Minimize Their Exposure to—Risks When Investing in China*, China Bus Rev 16, 17–18 (Nov–Dec 2006).

39 See, for example, *Thai White Paper II* at *6–7 (cited in note 1).

40 See Danzon and Furukawa, 27 Health Aff at 232–33 (cited in note 36); Patricia M. Danzon, *Neglected Diseases: At What Price?*, 449 Nature 176, 178–79 (2007); Patricia M. Danzon and Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, Health Aff Web Exclusive W3-521, W3-534 (2003), online at http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.pdf (visited Oct 15, 2010) ("Our finding that drug price differentials between countries roughly reflect income differences (except for Chile and Mexico) plausibly reflects the interaction of drug manufacturers' pricing strategies, using income as a rough proxy for demand elasticities, and regulation.").

If a local government wants to drive prices even lower, it should use its own resources by buying medicines (often in bulk) at one price and thereafter distributing them to its own citizens at lower prices, or indeed for free. Putting the subsidy on the public books increases transparency, which should aid democratic deliberation. CL is not the only system that produces these distortions; another example is the system of rent control used in some US cities. Rent control allows governments to force local landlords to rent property to tenants at below-market prices. The larger the subsidy, the greater the economic distortion in the form of reduced services to tenants, slower tenant turnover, heightened administrative costs, constant squabbles between landlord and tenant, and endless political maneuvering to either preserve or eliminate the subsidy.[41] Yet, once again, these problems are largely solved by having the government, after open political deliberation, rent units at market value, which it can then sublet at a reduced price or for free. The government thus retains the complete power to determine the size of the subsidy without forcing the individual landlords to bear the brunt of a program introduced for the benefit of the community at large.[42] This misguided technique thus can produce large social losses for any good. Any insistence that drugs are "special" is the sure road to policy mistakes.

Even if, moreover, domestic sources are insufficient to meet the challenge, it hardly follows that local governments should be free to use CL to expropriate protected patents. Foreign aid and international credit are often, but not universally, available. Programs of this sort make an attractive aim for foreign aid programs, but not necessarily ones of the highest priority; water purification and malaria control could easily rank higher in many places. But whatever the rankings, we see no reason why the access to foreign drug companies is a way to boost the priority of transfers for these purposes over those for others. The proper targets for foreign aid should depend in part on the prices that drug companies charge for their products. On this score, both volume discounts and price discrimination remain available as tools to keep prices down. Of course, in some instances, the drug companies themselves might (and indeed often do) offer these drugs at below cost[43]—often for humanitarian reasons—subject to conditions that are

41 For a discussion on the topic, see generally Richard A. Epstein, *Rent Control and the Theory of Efficient Regulation*, 54 Brooklyn L Rev 741 (1988). For the latest political distortion under rent stabilization in New York, see *Roberts v Tishman Speyer Properties*, 918 NE2d 900, 902 (NY 2009).

42 See *Pennell v City of San Jose*, 485 US 1, 22–23 (1988).

43 See, for example, Michael Waldholz and Rachel Zimmerman, *Bristol-Myers Offers to Sell Two AIDS Drugs in Africa at Below Cost*, Wall St J B1 (Mar 15, 2001).

aimed at preventing resale into a third country. These conditions are always to the benefit of the local poor, for without them the profits from resale to third countries only redound for the benefit of local oligarchs. In short, CL is not necessary to produce any of the legitimate local objectives of government.

V. INACCURATE CLAIMS OF COMPULSORY LICENSING IN THE UNITED STATES

The defenders of CL in Thailand point to the frequency of purported CL now in use in the United States.[44] These forms of CL use fall into the following categories: broadcast licenses, limited statutory exemptions for pharmaceuticals and medical procedures, federal court cases that deny injunctive relief, federal or state sovereign immunity and associated takings, and antitrust enforcement proceedings. We recognize that it is easy to lump all of these together as approaches that avoid full enforcement of a property right. Our purpose here is not to defend these decisions, which we have often opposed. We only wish to show that, however unwise on their own terms, these practices should not be viewed as instances of CL. The purported CL now being conducted in the United States is distinguishable in key respects from the CL used in Thailand for pharmaceutical products.

A. Broadcast Licensing

The US regime of compulsory licensing of copyrighted songs (which has its own problems) is worlds apart from pharmaceutical CL. It is also important to note that this system is not intended to displace a successful system of voluntary licenses because of unhappiness with the prices charged. Rather, this use of CL is a response to the need to compensate holders of songs that many parties use in the ordinary course of business. Each infringement is small, but the sum of all infringements is large. CL thus functions as a transaction cost–saving device that permits the rapid dissemination of copyrighted material. The prices of these licenses are, moreover, not determined by the fiat of an interested government party, but rather are subject to elaborate industry-wide negotiation systems that are intended, in part, to secure a fair return for the holder of the IP.[45] Expropriation and governmentally coerced wealth transfer are not part of this system. With that said, a CL framework may not be efficient so long as copyright holders can pool

---

44 See, for example, *Thai White Paper I* at *12, 67–76, 97–102 (cited in note 1).

45 See *Twentieth Century Music Corp v Aiken*, 422 US 151, 156 (1975) ("The immediate effect of our copyright law is to secure a fair return for an 'author's' creative labor . . . for the general public good.").

their resources for sale. At that point, antitrust issues can emerge,[46] but these can be partly obviated by allowing all parties in the pools to license outside of the pools—an option, of course, that is never available in CL systems.

B. Limited Statutory Exemptions for Pharmaceuticals and Medical Procedures

The application of CL in the context of pharmaceuticals and medical devices also needs some attention. On the negative side, CL systems often *block* the creation of efficient modes of voluntary sale, such as the reagent freezer programs that private firms have long used to supply patented biological reagents to basic research scientists. This approach has resulted in transaction costs for the scientists that are lower than those of purchasing a can of soda from a vending machine.[47] Pharmaceutical products simply do not present the high-volume and low-value settings where US copyright CLs make their appearance.

On the positive side, CL supplements market efficiency when, to use Joseph Sax's useful distinction, the government acts as an arbitrator of private disputes and not an entrepreneur acting for its own benefit, in which case its motives should be treated as more suspect.[48] For example, the Hatch-Waxman Act excludes from liability the use of medical devices reasonably related to obtaining FDA approval.[49] The Hatch-Waxman Act also implements a carefully wrought quid pro quo whereby generic pharmaceutical manufacturers receive the benefit of a limited experimental-use exception to ordinary patent liability in exchange for which the original patentee, usually a branded pharmaceutical manufacturer, gains an extension of up to five years in patent life to offset the time that the patented pharmaceutical is subject to regulatory review before the FDA.[50] This tradeoff ushered in huge new investments in pharmaceuticals, by both major companies and new boutique firms. In contrast, the Thai CL approach offers no benefit at all to those who invested in commercializing the patented drugs.

The Medical Procedures Act of 1996[51] (MPA) is similarly distinguishable from the Thai CL approach. The MPA removed all remedies

---

46 See, for example, *Broadcast Music, Inc v Columbia Broadcasting System*, 441 US 1, 7–8 (1979) (applying the rule of reason to blanket broadcast licenses).

47 See F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 Emory L J 327, 379 (2006).

48 Joseph L. Sax, *Takings and the Police Power*, 74 Yale L J 36, 62–63 (1964) (using this line to distinguish between a noncompensable exercise of "police power" and a compensable "taking").

49 35 USC § 271(e)(1).

50 See 35 USC § 156(c), (g).

51 35 USC § 287(c).

by way of damages, injunctions, and attorneys' fees "with respect to a medical practitioner's performance of a medical activity" against both the medical practitioner and any related health care entity.[52] The MPA is both general and prospective. It does not apply to a single patent whose validity had already been judicially upheld. Nor does it bar all remedies against all possible defendants. Instead, the MPA explicitly reserves ordinary damages actions against the various firms (who are not health provider–related entities) that actively promote these remedies for use by surgeons, in order to secure substantial profits for themselves. Thus, the MPA rests on an efficiency justification not available to the Thai CL, concentrating litigation against those few institutional promoters who consciously violate the patents while knocking out infringement actions against isolated physicians who might not even know that any patented procedure was involved at all. The Thai CL approach lacks this saving grace, as it eliminates all remedies against all defendants.

C. Denial of Injunctive Relief

The next purported example of CL in the United States relates to the 2006 Supreme Court decision in *eBay Inc v MercExchange, LLC*.[53] This case displaced the traditional rule for patent disputes, under which "courts will issue permanent injunctions against patent infringement absent exceptional circumstances."[54] In its place, the Supreme Court substituted a four-factor test to decide between damages and injunctive relief:

> A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[55]

In practice, this new test is both more complex and less protective of property than the earlier rule. Indeed, we jointly argued against its adoption for just those reasons.[56] We urged that the clear boundary

---

52 35 USC § 287(c)(1).

53 547 US 388 (2006).

54 *MercExchange, LLC v eBay Inc*, 401 F3d 1323, 1339 (Fed Cir 2005).

55 *eBay*, 547 US at 391. For more on the way these factors have long been applied by courts in equity, see F. Scott Kieff and Henry E. Smith, *How* Not *to Invent a Patent Crisis*, in Terry L. Anderson and Richard Sousa, eds, *Reacting to the Spending Spree: Policy Changes We Can Afford* 55, 68–69 (Hoover 2009).

56 See Brief of Various Law and Economics Professors as Amici Curiae in Support of Respondent, *eBay Inc v MercExchange, LLC*, No 05-130, *23–24 (US filed Mar 10, 2006) (available

lines secured by relief facilitated the voluntary transactions needed to commercialize patented technologies. Only such strong protection prevents potential customers from taking an end run around the contract system by first violating a patent and then daring the IP holder to initiate a costly action to recoup damages, which are always difficult to value. We also noted that any systematic decline of injunctions would make it difficult for IP holders to enter into exclusive contracts with preferred trading partners. Recent lower court cases have partly cut back on *eBay* in response to these concerns, typically by awarding injunctions to parties that practice or license their IP technologies.[57]

To be sure, injunctive relief always poses the risk that a single patent holder can dominate an entire technology. But the denial of injunctive relief poses far greater risks. Patents are always issued for limited times. Their subject matter is properly confined to a particular product or process. It does not extend to an entire area of human endeavor. The telegraph was patented, but not total control over the electromagnetic spectrum.[58] In addition, the Hatch-Waxman Act creates a narrowly crafted privilege for experimental use.

For all its weaknesses, however, the *eBay* rule bears no resemblance to the Thai CL regime, which depends solely on government discretion. Here are the key differences.

First, nothing in the *eBay* synthesis requires national governments that use CL to rely solely on the four *eBay* factors, or indeed even take them into account. For example, these governments need not abandon CL upon a showing that awarding only monetary damages will cause a patentee irreparable injury. Nor must such a government consider the relative hardship facing the patentee. Nor need the government show how the CL advances the public interest—that is, the concerns of outsiders to the immediate dispute. In particular, CL may be imposed on a patent holder who is willing to commercialize the patented technology, either directly or through intermediates in the local economy or government.

The relative hardship factor also points against injunctive relief for several reasons. National governments have powerful alternatives if CL is denied, while foreign corporations have no choice but to capitulate. Even withdrawing from a country does not preclude the local use of CL. And exercising that withdrawal option could require a patentee to

on Westlaw at 2006 WL 639164). For an academic version of the defense, see Richard A. Epstein, *The Property Rights Movement and Intellectual Property*, 30 Reg 58, 62–63 (Winter 2008).

57 See, for example, *TruePosition v Andrew Corp*, 568 F Supp 2d 500, 529, 530–34 (D Del 2008) (involving an injunction against a direct competitor); *TiVo v Echostar Communications Corp*, 446 F Supp 2d 664, 666–67 (ED Tex 2006) (same).

58 See *O'Reilly v Morse*, 56 US (15 How) 62, 112–13 (1854).

forego lucrative sales of products not subject to CL. In contrast, the option of state purchase at bulk discounts, followed by resale at below-market costs to citizens in need, is always available. As a result, the four-part *eBay* test offers no justification for CL.

In addition, CL has nothing to do with the specter of patent trolls that influenced the *eBay* decision (even though it was not presented on the facts of the case). Patent "trolls" are defined "as individual inventors who do not commercialize or manufacture their inventions."[59] Even that formulation excludes from the class of "trolls" any parties who are actively engaged in licensing negotiations, even if their first voluntary license has not been completed at the time of the defendant's patent infringement. Every patent is a wasting asset, so few patent holders prefer to lurk around the weeds waiting to pounce on infringers when they could license their products today for a fee. It is foolhardy to require a patentee to rush into an unwise agreement solely to preserve its right of injunctive relief against third parties. What is more, in the high-profile cases of CL for pharmaceutical patents, the patentees are never nonpracticing "trolls." Instead, they are large companies producing and selling large quantities of the patented drugs. Since all new entrants need to receive state licenses to market their goods, the class of inadvertent infringers is likely to be empty. The distinctive features of strong pharmaceutical patents drive the risk of "trolls" in this area to zero and strengthen the case for injunctive relief. We know of no instances in which nations have used CL because foreign pharmaceutical companies refused to license, directly or through intermediates, their products in the host country. The sole source of dispute in CL cases is price.[60] Ironically, any buying nation with monopolistic buying power undermines all conceivable claims of hardship that exist on the *eBay* scales. *eBay* brings the entire CL movement to a crashing halt.

The accuracy of this judgment is confirmed by the extensive case literature in the United States in the post-*eBay* period. First, we know

---

[59] See Bessen and Meurer, *Patent Failure* at 17 (cited in note 16). Note that in addition to this narrow definition, the authors offer a broader definition that covers "all sorts of patentees who opportunistically take advantage of poor patent notice to assert patents against unsuspecting firms," id, a definition that has no conceivable relevance to pharmaceutical patent disputes.

[60] See, for example, *Thai White Paper I* at *14 (cited in note 1) (pointing to previous failed attempts to negotiate lower drug prices as the reason for using CL). In the case of Thailand, the government argued:

> Prior negotiation with the patent holders is not an effective measure and only delays the improvement of access to essential medicines. It is only after the threat or the decision to use and implement Compulsory Licensing or Government Use of Patent that the negotiation will be more successful and effective.

Id.

of no case that supports the use of CL. For example, in *z4 Technologies v Microsoft Corp*,[61] z4 was denied an injunction against the use by Microsoft of z4's patented activation technology.[62] Yet the z4 patent was a tiny part of a larger mosaic in Microsoft Windows and Office products. Issuing an injunction could have required a full recall of the composite product. In ordinary land use cases, equitable relief is often denied where it prejudices the interests of third parties. We believe that the same result would have held under pre-*eBay* law as well. Second, Microsoft worked to eliminate any use of the offending technology, which was tantamount to granting z4 injunctive relief at some future date.[63] Third, Microsoft had to pay $115 million in damages for its past infringement, calculated as a reasonable royalty, which rightly included some allowance for front-end fixed costs.[64] So understood, this award far exceeds the amounts transferred under any CL.[65] This rigid standard of damages, which far exceeds the amount that is typically awarded under CL, offers a much stronger incentive for parties to play by the particular rules up front, including by designing around or negotiating for a license. Such reasonable royalty awards are the polar opposite of CL, which has as its goal to set the CL fee as close to marginal cost as possible, if not below.

Other cases also illustrate the difference between CL and *eBay*. In *Finisar Corp v The DirecTV Group*,[66] decided shortly after *eBay*, the court declined to grant an injunction because the patentee had never taken any steps to either use or license the patented technology. Yet, it also granted a lump sum award of $79 million for the breach, which was far in excess of any standard government-imposed CL.[67] Similarly, in *Paice LLC v Toyota Motor Corp*,[68] the court denied injunctive relief on two grounds that have no relevance to CL cases. First, the plaintiff, Paice, offered to license its patented products through post-trial options, which the court read as an implicit concession that damages were a sufficient remedy. Second, the plaintiff's business misrepresentations drove away potential licensees.[69]

---

61 434 F Supp 2d 437 (ED Tex 2006).

62 Id at 441–44 (holding that damages for future infringement were an adequate remedy and that the balance of hardships heavily favored Microsoft).

63 See id at 442.

64 See id at 438–41.

65 The operative statutory language is: "adequate to compensate for the infringement, but in no event less than a reasonable royalty." 35 USC § 284.

66 2006 WL 2037617 (ED Tex), affd in part, revd in part, and remd, 523 F3d 1323 (Fed Cir 2008).

67 *Finisar Corp v The DirecTV Group*, 2006 WL 2709206, *1 (ED Tex).

68 2006 WL 2385139 (ED Tex), affd in part, vacd in part, and remd, 504 F3d 1293 (Fed Cir 2007).

69 Id at *4–6.

In dealing with the current law, we continue to think that the *eBay* standard does not always lead to sound results. For example, in *IMX v LendingTree*,[70] the court misstepped in denying a licensor the right to invoke the interests of its exclusive licensee to obtain injunctive relief against the licensee's competitor. The plaintiff did not help its own cause by failing to file additional papers containing the "market or financial data" needed to support its claim.[71] Yet, even then, the court granted enhanced damages,[72] which are never impounded in CL. We view this case as a transitional development. Savvy plaintiffs now know that they can no longer rely on the older presumption of injunctive relief, so they will beef up their pleadings and proof. Over time, we think that the post-*eBay* equilibrium will shift back in favor of the older and simpler pre-*eBay* rule.

D. Government Immunity and Takings

Under the Takings Clause, no private patentee can resist a government demand for a CL. The just compensation requirement, however, covers both fixed and marginal costs, which the Thai CL does not.[73] The currently accepted takings analysis, moreover, easily carries over to intellectual property. To be sure, legal restrictions that the state imposes on patent uses by the patentee are governed by a lenient rational basis standard. But that rule should not apply when state intervention takes the form of using the patent itself or authorizing its use by private parties.[74]

Although some might suggest that patents are ill suited for takings analysis, the government's decision to allow a particular market actor to use the patents of another, which is the impact of the Thai CL approach, would be no different from the government's decision to allow the public to use a private marina, as in *Kaiser Aetna v United States*,[75] or a lateral easement, as in *Nollan v California Coastal Commission*.[76]

---

70 469 F Supp 2d 203 (D Del 2007).

71 Id at 224–25.

72 Id at 223.

73 Either governments in the United States (state and federal) have waived their sovereign immunity, making themselves available in various courts for payment of a reasonable royalty, or such suits are available to seek just compensation for government takings. For the connection between intellectual property and takings law, see Richard A. Epstein, *The Disintegration of Intellectual Property? A Classical Liberal Response to a Premature Obituary*, 62 Stan L Rev 455, 513–21 (2010). For a review of the technicalities of sovereign immunity and intellectual property in the United States, see generally Eugene Volokh, *Sovereign Immunity and Intellectual Property*, 73 S Cal L Rev 1161 (2000).

74 See Richard A. Epstein, *The Constitutional Protection of Trade Secrets under the Takings Clause*, 71 U Chi L Rev 57, 61–64 (2004).

75 444 US 164, 179–80 (1979).

76 483 US 825, 841–42 (1987).

Indeed, the case for constitutional protection of patents is in many ways stronger than it is for real property. First, people invest in patentable inventions solely for the purpose of reaping an economic return. Unlike land, patents have finite lives, so no patentee postpones the use of a patented technology today solely to make better use of it tomorrow. The revenues lost today can never be recouped. Patents have, moreover, no personal or aesthetic uses. Accordingly, the investment-backed expectations that drive owners are clearer for patents than for physical property. Nor can anyone identify any market failure that justifies a government decree that allows its preferred clientele to use the patented technology for free. Useful patents do not pollute the air or water, nor do they create any public or private nuisances that could justify state limitations on their use. And nothing is more common than patent licensing.

E. Antitrust Proceedings

Finally, proponents of CL in Thailand also point to US antitrust enforcement proceedings as examples of CL in the United States. To be sure, antitrust remedies often include specific compulsory licenses.[77] But this argument puts the cart before the horse. Antitrust enforcement is a drawn-out process that kicks in only after a defendant has been shown to have abused its significant market power.[78] As the Supreme Court has recently reaffirmed, the possession of a patent monopoly does not even count as evidence of market power in the presence of competitive patents.[79] The approach to CL that was adopted by Thailand in no way purports to depend on proof of market abuse, but instead may be imposed at the whim of the host country.

CONCLUSION

The efforts to justify CL for pharmaceutical patents are simply not tenable. The defenders of CL fail, first, to understand the power of the background presumption against CL. They then compound

---

77 See Michael A. Carrier, *Unraveling the Patent–Antitrust Paradox*, 150 U Pa L Rev 761, 848 n 366 (2002) (collecting sources and concluding that "[c]ompulsory licensing was a frequently applied remedy in the 1940s and 1950s, with 107 antitrust settlements between 1941 and 1959 calling for such licensing or dedication of between 40,000 and 50,000 patents").

78 For a recent review of issues arising in cases involving antitrust and intellectual property, see Geoffrey A. Manne, et al, *Comment on Intellectual Property, Concentration and the Limits of Antitrust in the Biotech Seed Industry* *8–18 (Lewis & Clark Law School Legal Research Paper No 2010-9, Dec 2009), online at http://ssrn.com/abstract=1553064 (visited Oct 16, 2010) (cautioning that there are high error costs associated with courts making mistaken judgments about the anticompetitive effects of IP in new contexts).

79 See *Illinois Tool Works v Independent Ink*, 547 US 28, 44–45 (2006).

their initial mistake by ignoring the adverse effects that CL has even in the countries in which it is used. Last, they wrongly seek to bolster their tenuous case by appealing to established US practices for copyrighted songs, limited exemptions for pharmaceuticals and medical procedures, injunctive relief, government immunity and takings, and antitrust, all of which are driven by profoundly different concerns. CL for songs is an effort to make markets work in high-transaction settings that are nowhere to be found in pharmaceutics. Similarly, CL through the limited statutory exemptions for pharmaceuticals and medical procedures brings improvements to the set of market actors—patentees and users alike. Both the denial of injunctive relief for patents and the use of government takings are far from universal, and are backstopped everywhere by extensive damages that allow the patentee to recover some portion of its fixed costs. In contrast, the Thai CL is intended to drive prices as close to marginal cost as possible, if not lower. Finally, antitrust remedies presuppose an abuse of a dominant market position that the mere possession of a patent establishes.

It is possible to have serious reservations about some aspects of the American legal synthesis and to still recognize that its breaches in the property wall pose none of the dangers associated with the use of CL in developing countries. The Thai CL was a matter of political fiat, unrestrained by law. It sets a dangerous precedent that other nations should avoid, given that they have other sensible methods, in the form of direct and bulk purchases, to help their own vulnerable populations. Perhaps these reasons are now persuasive even to the Thai government, which has not extended its dubious CL approach beyond a few patents.