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Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents

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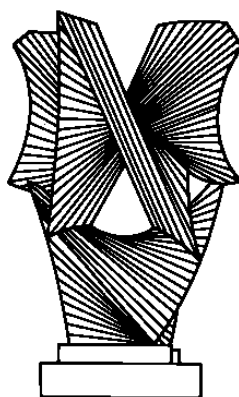
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Richard A. Epstein and A. Scott Kieff

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QUESTIONING THE FREQUENCY AND WISDOM OF
COMPULSORY LICENSING FOR PHARMACEUTICAL PATENTS

Richard A. Epstein and F. Scott Kieff *

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Abstract

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 paper we take issue with that proposition on several grounds. 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 paper 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 U.S. practices. These are the compulsory copyright licenses for music; the award of damages instead of injunctions after *eBay v. MercExchange*, 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 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.

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I. 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 life. On the one hand, patents are praised as a spur to innovation, which is only made possible 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 costs. 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 trade-off between innovation and dissemination has led to extensive debates about whether and how the 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 multi-factored and ongoing; their full range is beyond the scope of this paper.² We simply mention here that compulsory licensing is a species of forced exchange that is generally analyzed in

¹ See THAI MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, 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 (Vichai Chokevivat ed., 2007), available at <http://www.moph.go.th/hot/White Paper CL-EN.pdf> [hereinafter *Thai White Paper I*] (discussing CL for drugs to treat AIDS and heart disease); see also THAI MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, THE 10 BURNING QUESTIONS REGARDING THE GOVERNMENT USE OF PATENTS ON THE FOUR ANTI-CANCER DRUGS IN THAILAND (2008), available at <http://www.moph.go.th/hot/White paper CL II FEB 08-ENG.pdf> [hereinafter *Thai White Paper II*]. Brazil has also adopted a CL approach. See Jon Cohen, *Brazil, Thailand Override Big Pharma Patents*, 316 SCI. 816 (2007).

² For a helpful review, see Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047 (2009).

connection with the question of takings.³ 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 or her property. At the very least, these exchanges raise the question of which patents should be subject to these licenses and how that compensation should be computed, which gives rise to immense tactical and public choice issues when several similar patents are all subject to such use.

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. The defenders of CL for pharmaceuticals do so not only at the level of generality, 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

Accordingly, Part II of this paper starts with a discussion of the distinctive position of patents in the pharmaceutical sector, relative to other areas of technology. It 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 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 to which the Thai advocates of CL turn in order to expose their marked difference from a CL regime. Part VI concludes.

II. THE DISTINCTIVE NICHE OF PHARMACEUTICAL PATENTS

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 makes it difficult for other entrepreneurs to know whether their activities infringe on someone else's patents or not. As Bessen and Meurer put it, third parties have become "innocent violators" of patents, by making investments they think are not infringing but "[t]hose investments were exposed to unnecessary risk because of unclear property boundaries."⁵ Second is the idea that acute fragmentation of property rights blocks any entrepreneur from assembling the needed technologies for advancing their own operations.⁶ According to Heller and Eisenberg: "Current examples in biomedical research demonstrate two mechanisms by which a government might inadvertently

³ For discussion, see RICHARD A. EPSTEIN, *OVERDOSE: HOW EXCESSIVE REGULATION STIFLES PHARMACEUTICAL INNOVATION*, 82-96 (2006).

⁴ See, e.g., THAI MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, *Thai White Paper I*, *supra* note 1, at 4 and accompanying documents 14, 15 & 26.

⁵ JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK 2* (2008). For more detailed discussion of the topic, see *id.* at 46-72.

⁶ See, e.g., MICHAEL HELLER, *THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES* (2008).

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.”⁷

We recognize that these objections could prove weighty in many areas of technology.⁸ Computer hardware and software patents, for example, are often said to have little value because they are too small in scope, too evanescent in utility, and too numerous in practice.⁹ One way to eliminate 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.

Pharmaceutical patents, however, are not subject to these twin objections because they cover a single chemical entity, or a group of well-defined compounds in composition. The distinct nature of these products, and their precise chemical formulation, 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. Just this concern motivated the international trade agreement known as TRIPS to allow for the use of CL in times of national emergency.¹⁰ The Thai CL does not, however, meet the customary definition of an emergency because it is directed exclusively toward chronic and long-term conditions. In many cases, moreover, licenses can be negotiated while patents are pending, insulating most pharmaceutical products from this criticism.

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 exceed one billion dollars.¹¹ That large sum is needed to meet the extensive technical, regulatory, and dissemination barriers that drugs must overcome before reaching market—barriers that are wholly absent, for example, for patents on computer products. All pharmaceuticals,

⁷ Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCI.* 698, 699 (1998).

⁸ 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, e.g., Richard A. Epstein & Bruce N. Kuhlik, *Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch-Waxman 4* (Univ. of Chi. Law Sch. John M. Olin Program in Law & Econ. Working Paper No. 209 (2d ser.), 2004), available at <http://ssrn.com/abstract=536322> (exploring some reasons why the problems are likely to be less prevalent than feared); 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 & Troy A. Paredes, *Engineering a Deal: Toward a Private Ordering Solution to the Anticommons Problem*, 48 *B.C. L. REV.* 111 (2007) (offering a private ordering solution for cases where the problems persist).

⁹ See, e.g., Ian Ayres, *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 1 *INNOVATION POLICY AND THE ECONOMY* 119 (Adam B. Jaffe et al. eds., 2001), available at <http://faculty.haas.berkeley.edu/shapiro/thicket.pdf> (providing the same observation).

¹⁰ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 *I.L.M.* 1125 (1994).

¹¹ See Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 232 *J. HEALTH ECON.* 151 (2003) (estimating \$800 million); for a higher estimate, see Jim Gilbert, Preston Henske & Ashish Singh, *Rebuilding Big Pharma's Business Model*, 21 *IN VIVO: BUS. MED. REP.* 73 (2003) (estimating \$1.7 billion).

whether patented or generic, face the ever-longer clinical trials mandated by the Food and Drug Administration (“FDA”). These trials both impose high direct out-of-pocket costs; they reduce the number of years that a new drug can be sold on the market with patent protection; and they postpone the date when the new drug first generates any revenues. The Hatch-Waxman Act,¹² which extends the patent period up to five years to offset these FDA delays, only makes a dent in the problem. Ordinary products have close to a 17-year useful life, a period that reflects the three years that patent examination reduces from the 20-year statutory term. In contrast, the typical effective patent life for pharmaceuticals in the United States today is under 12 years for drugs with over \$100 million in annual sales, which, not surprisingly, comprised 90% of sales in the brand market in the United States in 2005. That effective period is even lower for some segments.¹³ 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 only payable to a few actors at most. Prizes, similar to draft picks in 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 the efforts by the multiple actors needed to convert medical knowledge into useful therapeutic products. The want of exclusive rights creates a giant barrier to commercialization.¹⁴

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. 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. Yet, ironically, 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. However, 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.¹⁵ 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

¹² Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301-397 (2006)).

¹³ See Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *MANAGERIAL AND DECISION ECON.* 491-502 (2007).

¹⁴ 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 *PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH* 34-40 (Toshiko Takenaka ed., 2009).

¹⁵ Michael E. Levine, *Price Discrimination without Market Power*, 19 *YALE J. REG.* 1 (2002).

invention, with deleterious effects on innovation.¹⁶ Nothing in theory or practice shakes the initial presumption against CL for pharmaceutical patents.

III. RISKS OF COMPULSORY LICENSING

The dangers of CL are more apparent when one sees how governments implement them in practice. A central risk of CL is that it gives the national government untrammelled 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 it faces no credible competition from alternative sources. These sources include non-infringing drugs that are already on the market or which will come on thereafter. However, 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 operation. 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.¹⁷ In some cases, the loss of revenues 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. For other long-term investments, recovery for 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.¹⁸

B. Coerced and Concealed Wealth Transfer

Implementing CL system in country A necessarily forces individuals in other nations to bear all those fixed costs. This back-door subsidy has serious negative consequences for consumers outside of the CL country. Those covert methods of wealth transfer avoid open deliberation, frustrate normal democratic discipline, deprive the donors of recognition for their beneficence, encourage wasted 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 cover chronic

¹⁶ See John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. CHI. L. REV. 37 (2004). On the importance of price discrimination in the context of antitrust litigation, see *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781 (7th Cir. 1999).

¹⁷ For costs, see *supra* note 11.

¹⁸ See *Duquesne Light Co. v. Barasch*, 488 U.S. 299 (1989) (detailing alternative methods of compensation).

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 a 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 these 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 grass roots 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 distributional 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. 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 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. 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 only deals 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 balky European distribution systems often increase the price of generic drugs. Those same risks, vastly amplified, exist in third world countries.

Driving out western 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 intellectual property protection may scare away foreign investors who might otherwise direct research to treat local subpopulations in need of novel but 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.¹⁹ 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 over their own national regulators, who are often reluctant to clamp down on domestic commercial firms.

IV. GOVERNMENT PURCHASE AS COMPULSORY LICENSING ALTERNATIVE

Most undeveloped countries think that access to needed drugs is an essential portion of a system that provides minimum health security to all its citizens. 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. However, 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, which 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.²⁰ 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.

If local governments want to drive prices even further, 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 is always an aid to democratic deliberation. CL is not the only system that produces these distortions; another example is the system of rent control used in some U.S. 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

¹⁹ Gardiner Harris, *U.S. Identifies Tainted Heparin in 11 Countries*, N.Y. TIMES, Apr. 22, 2008, available at <http://www.nytimes.com/2008/04/22/health/policy/22fda.html>.

²⁰ See Patricia M. Danzon, *Neglected Diseases: At what price?*, 449 NATURE 176 (2007); Patricia M. Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, HEALTH AFFAIRS - WEB EXCLUSIVE 521, 534 (2003), <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.pdf> (“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.”); Patricia M. Danzon & Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals in 2005*, 27 HEALTH AFF. 22 (2008).

tenant, and endless political maneuvering to either preserve or eliminate the subsidy.²¹ 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.²² 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 costs—often for humanitarian reasons—subject to conditions that are aimed to prevent their resale into third countries. 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.²³ These forms of CL use fall into the following categories: broadcast licenses, 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 in 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 from the CL used in Thailand for pharmaceutical products in key respects.

A. Broadcast licensing

The U.S. regime of compulsory licensing of copyrighted songs (which have their own problems) is worlds apart from pharmaceutical CL. It is important to note, as well, 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

²¹ For a discussion on the topic, see Richard A. Epstein, *Rent Control and the Theory of Efficient Regulation*, 54 BROOK. L. REV. 741 (1988). For the latest political distortion under rent stabilization in New York, see *Roberts v. Tishman Speyer Props.*, 918 N.E.2d 900 (N.Y. 2009).

²² See *Pennell v. City of San Jose*, 485 U.S. 1, 22-23 (1988).

²³ See, e.g., *Thai White Paper I*, *supra* note 1, at 1 and accompanying documents 14, 15, & 26.

that many parties use in the ordinary course of their 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 are subject to elaborate industry-wide negotiation systems that are intended, in part, to secure a fair return for the holder of the IP.²⁴ CHECK Expropriation and 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 their resources for sale. At this point, antitrust issues can emerge,²⁵ but these can be partly obviated by allowing all parties in the pools to license outside the pools—an option, of course, that is never available in CL systems. Indeed, 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.²⁶ Pharmaceutical products simply do not present the high volume and low value settings where CL licenses make their appearance.

B. 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*.²⁷ This case displaced the traditional rule for patent disputes, under which “courts will issue permanent injunctions against patent infringement absent exceptional circumstances.”²⁸ 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.²⁹

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 that reason.³⁰ We urged that the clear boundary lines secured by relief facilitated the voluntary transactions needed to commercialize patented technologies. Only such strong protection prevents potential customers

²⁴ *Twentieth Century Music Corp. v. Aiken*, 422 U.S. 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.”).

²⁵ See, e.g., *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1 (1979) (applying rule of reason to blanket broadcast licenses).

²⁶ See F. Scott Kieff, *Coordination, Property & Intellectual Property: An Unconventional Approach to Anticompetitive Effects & Downstream Access*, 56 EMORY L.J. 327, 379 (2006).

²⁷ *eBay, Inc. v. MercExchange LLC*, 547 U.S. 388 (2006).

²⁸ *MercExchange LLC v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005).

²⁹ *eBay*, 547 U.S. at 391. For more on the way these factors have long been applied by courts in equity, see F. SCOTT KIEFF & HENRY E. SMITH, *How Not to Invent a Patent Crisis, in* REACTING TO THE SPENDING SPREE: POLICY CHANGES WE CAN AFFORD 50, 68-69 (Terry L. Anderson & Richard Sousa eds., 2009).

³⁰ See Brief for Richard A. Epstein, F. Scott Kieff & R. Polk Wagner as Amici Curiae Supporting Respondent, *eBay, Inc. v. MercExchange LLC*, 547 U.S. 388 (2006) (David Teece is an additional co-author of the document but is not listed as counsel on it because he is not a lawyer). For an academic version of the defense, see Richard A. Epstein, *The Property Rights Movement and Intellectual Property*, 30 REG. 4, at 62 (2008).

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 any 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.³¹

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 device. It does not extend to an entire area of human endeavor. The telegraph was patented, but not total control over the electro-magnetic spectrum.³² A particular COX-2 inhibitor could be patented, but the patent on the general method of COX-2 inhibition required more disclosure than was presented to the court in that case.³³ 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 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.”³⁴ Even that formulation excludes from the class of “trolls” any persons who are actively engaged in licensing

³¹ See, e.g., *TruePosition, Inc. v. Andrew Corp.*, 568 F. Supp. 2d 500 (D. Del. 2008) (involving an injunction against a direct competitor); *TiVo, Inc. v. Echostar Commc'ns Corp.*, 446 F. Supp. 2d 664 (E.D. Tex. 2006) (same).

³² *O'Reilly v. Morse*, 56 U.S. 62, 112-13 (1854).

³³ *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

³⁴ See Bessen & Meurer, *supra* note 5, at 17. 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,” a definition that has no conceivable relevance to pharmaceutical patent disputes.

negotiations even if its 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 intermediaries, their product in the host country. The sole source of dispute in CL cases is over price.³⁵ 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. We know of no case that supports the use of CL. For example, in *z4 Technologies, Inc. v. Microsoft Corp.*,³⁶ z4 was denied an injunction against the use by Microsoft of z4's patent activation technology. 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 interest 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. Third, Microsoft had to pay \$115 million in damages for its past infringement, calculated as a reasonable royalty,³⁷ which rightly includes some allowance for front-end fixed costs. So understood, this award far exceeds the amounts transferred under any CL license.³⁸ 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 by 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. DirecTV Group, Inc.*,³⁹ decided shortly after *eBay*, the court denied the injunction because the patentee had never taken any steps to either use or license the patented technology. Yet, it also granted a lump-

³⁵ *Thai White Paper I*, *supra* note 1, at 6. 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.

³⁶ *z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437 (E.D. Tex. 2006).

³⁷ *See* Patent Act, 35 U.S.C. § 284 (2006).

³⁸ The operative statutory language is: "adequate to compensate for the infringement, but in no event less than a reasonable royalty." *See id.*

³⁹ *Finisar Corp. v. The DirecTV Group, Inc.*, No. 1:05-CV-264, 2006 U.S. Dist. LEXIS 76380, at *4 (E.D. Tex. July 7, 2006).

sum award of \$79 million for the breach, which was far in excess of any standard government imposed CL. Similarly, in *Paice LLC v. Toyota Motor Corp.*,⁴⁰ the court denied injunctive relief on two grounds that have no relevance to CL cases. First, the plaintiff, Paice, did not offer to license the patents until the termination of the trial. Second, the plaintiff's business misrepresentations drove away potential licensees.

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, Inc. v. Lending Tree LLC*,⁴¹ 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.⁴² Yet, even then, the court granted enhanced damages, 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 *eBay* rule.

C. Government Immunity and Takings

Under the Takings Clause no private patentee can resist the government demand for a compulsory license. However, the just compensation requirement covers both fixed and marginal costs, which the Thai CL does not.⁴³ 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 low 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.⁴⁴

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*,⁴⁵ or a lateral easement, as in *Nollan v. California Coastal Council*.⁴⁶ 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 their owners are thus clearer for patents than for physical property. Nor can anyone identify any market failure that justifies a government decree that allows

⁴⁰ *Paice LLC v. Toyota Motor Corp.*, No. 2:04-CV-211, 2006 U.S. Dist. LEXIS 61600 (E.D. Tex. Aug. 16, 2006).

⁴¹ *IMX, Inc. v. Lendingtree, LLC*, 469 F. Supp. 2d 203 (D. Del. 2007).

⁴² *Id.* at 224-25.

⁴³ The governments in the United States (state and federal) have either 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 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, 515-22 (2010). For a review of the technicalities of sovereign immunity and intellectual property in the United States, see Eugene Volokh, *Sovereign Immunity and Intellectual Property*, 73 S. CAL. L. REV. 1161 (2000).

⁴⁴ Richard A. Epstein, *The Constitutional Protection of Trade Secrets under the Takings Clause*, 71 U. CHI. L. REV. 57 (2004).

⁴⁵ 444 U.S. 164 (1979).

⁴⁶ 483 U.S. 825 (1987).

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.

D. Antitrust Proceedings

Finally, proponents of CL in Thailand also point to U.S. antitrust enforcement proceedings as examples of CL in the United States. To be sure, antitrust remedies often include specific compulsory licenses.⁴⁷ 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 abuse its significant market power.⁴⁸ As the U.S. Supreme Court has recently re-affirmed, the possession of a patent monopoly does not even count as evidence of market power in the presence of competitive patents.⁴⁹ The approach to CL that was adopted by Thailand in no way purports to depend on proof of market abuse, but may be imposed at the whim of the host country.

VI. 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 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 U.S. practices for copyrighted songs, injunctive relief, and antitrust policy, 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 pharmaceuticals. 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, CL is intended to drive price 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.

⁴⁷ See Michael A. Carrier, *Unraveling The Patent-Antitrust Paradox*, 150 U. PA. L.REV. 761, 848, n.366 (2002) (“Compulsory 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.”) (collecting sources).

⁴⁸ For a recent review of issues arising in cases involving antitrust and intellectual property, see F. Scott Kieff et al., *Comment on Intellectual Property, Concentration and the Limits of Antitrust in the Biotech Seed Industry* (Lewis & Clark Law Sch. Legal Studies Research Paper No. 2010-9, George Mason Law & Econ. Research Paper No. 10-24, 2009).

⁴⁹ *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).

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