

ARTICLES

Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation

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INTRODUCTION	624
I. HIGH PHARMACEUTICAL PRICES AS A FUNCTION OF THE COMPLEX LEGAL, REGULATORY, AND ECONOMIC ENVIRONMENT	629
A. <i>The Interaction of Patents and Regulation</i>	630
B. <i>Differences in International Pharmaceutical Prices Ratchet Up the Pressure on American Consumers</i>	636
II. IMPORTATION INITIATIVES AS A POLITICALLY ACCEPTABLE FORM OF PRICE CONTROL	641
A. <i>Federal Regulatory Barriers Currently Prohibit Pharmaceutical Importation</i>	643
B. <i>Importation Proposals by Certain State or Local Governments Seek to Circumvent or Supplement Federal Legislative Action</i>	648
III. PROPERTY BARRIERS TO IMPORTING PHARMACEUTICALS WITHOUT AUTHORIZATION OF THE PATENT OWNER.....	654
A. <i>The United States' Refusal to Recognize an</i>	

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624	<i>FORDHAM INTELL. PROP. MEDIA & ENT. L.J.</i> [Vol. 15:623]	
	<i>International Exhaustion Rule</i>	657
B.	<i>A Patentee's Success Using the Traditional Infringement Litigation Depends on the Defendant</i>	664
C.	<i>The Constitution Provides an Additional Source of State and Municipal Liability for Intruding on Patent Rights</i>	672
	1. Access to State Courts to Obtain Relief	673
	2. Establishing a Compensable Taking	677
	3. "Just Compensation" for Patent Infringement.....	683
D.	<i>The Impact of the Constitution on Federal Liability is in Flux</i>	686
IV.	A CATCH-22: CONSTITUTIONAL ROADBLOCKS IN REVISING PATENT RIGHTS TO PERMIT IMPORTATION.....	696
A.	<i>Legislation that Negatively Impacts Established Property Rights</i>	696
	1. Constitutional Obstacles to Revising Property Rights.....	697
	2. Legislative Initiatives Will Not Pass Muster Unless Diluted to Ineffectiveness.....	700
B.	<i>Rewriting the Rules through the Courts: An Exception to Constitutional Protections</i>	703
	CONCLUSION.....	705

INTRODUCTION

As the cost of health care in the United States continues to rise, consumer advocates and politicians push for more extreme and creative measures to keep prices down. A significant factor in health care costs is the price of pharmaceuticals still under patent, so it is not surprising that this has become a particularly tempting target. It has been widely reported that U.S. consumers pay more (in some cases significantly more) for patented pharmaceuticals¹

¹ In the debate over drug prices, advocates for greater access to affordable drugs generally exclude pharmaceuticals no longer under patent and those that can be obtained without a prescription because they tend to be more competitively priced due to the existence of either generic equivalents or acceptable alternatives. In fact, it has been reported that U.S. generic and over-the-counter pharmaceutical prices are actually *lower* than most other industrialized countries. See Patricia Danzon & Michael Furukawa,

than consumers in other industrialized nations.² If consumers in the U.S. could import pharmaceuticals purchased at lower foreign prices, advocates argue, the price savings could be enormous.³ Representatives and supporters of the branded pharmaceutical companies counter that importation is merely a short-term solution that will harm medical innovation in the long run.⁴

To date, legal, regulatory, and safety issues have prevented large-scale importation. However, the groundswell of support for cheaper pharmaceuticals is slowly chipping away at the obstacles.

Prices and Availability of Pharmaceuticals: Evidence from Nine Countries, HEALTH AFFAIRS, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1?ck=nck> (Oct. 29, 2003).

² See, e.g., William Neikirk, *Stakes Rise in Drug Import Fight*, CHI. TRIB., Mar. 29, 2004, at 10 (“Because Canada has a nationwide health system with price controls, prescription drugs sold north of the border are 30 percent to 80 percent cheaper than in the U.S., depending on the drug.”); Editorial, *End Drug Import Hysteria*, L.A. TIMES, Apr. 27, 2004, at B12 (“It’s no accident that Americans still pay 38% more for similar prescription drugs than Canadians, 45% more than the French and 48% more than Italians.”).

³ See, e.g., *Examining the Implications of Drug Importation: Hearings Before the Senate Comm. on the Judiciary*, 108th Cong. (2004) (statement of Senator Charles Grassley) (“Legalizing the importation of prescription drugs through a highly regulated system overseen by FDA will stem the tide of unregulated pharmaceuticals coming into the U.S. and create a safe and effective system for obtaining low-cost prescription drugs.”).

⁴ See, e.g., Pharmaceutical Researchers and Manufacturers (“PhRMA”), *Imports Carry Risks* (Aug. 20, 2003) (“[F]oreign governments’ price controls . . . are drying up the discovery of new medicines in Europe. America now leads the world in discovering new medicines.”), <http://www.phrma.org/publications/publications/20.08.2003.832.cfm>; U.S. Senate Repub. Pol’y Comm., *Pharmaceutical Price Controls Abroad: An Unfair Trade Policy* 6–7 (Nov. 6, 2003) (“Importation of pharmaceuticals only treats the symptom, not the cause—it may reduce drug prices temporarily, but it can lead to two devastating scenarios: first, it would be difficult to impossible for the United States to assure the safety and efficacy of the imported drugs; and second, indirectly imposing pharmaceutical price controls in the United States eventually will lead to reduced spending on R&D and fewer new drugs coming into the market.”), available at http://tpc.senate.gov/_files/hc110603.pdf; John E. Calfee, *The High Price of Cheap Drugs*, WKLY. STANDARD, July 21, 2003, at 20 (“[P]rice controls would end up suppressing innovation here, just as they have done abroad. It is one thing for the Canadians and Europeans to free-ride on American R&D, but we can’t free-ride on ourselves.”). The base of public support for this position appears significantly smaller than that for the importation advocates. See, e.g., Christopher Rowland, *Thompson Shifts on Drug Imports*, BOSTON GLOBE, May 5, 2004, at C1 (noting that pressure from a number of groups appeared to be eroding the Bush administration’s firm stance against importation).

Ire over drug prices, in combination with the recent political environment, suggests that low-priced, imported drugs may become an option in the near future. Perhaps the most visible problem to be surmounted is the questionable safety of drugs purchased from foreign countries.⁵ Such problems are exacerbated when purchases are made by individual consumers, who, as a rule, have little ability to evaluate the quality of what they purchase. An alternate importation method that may address these concerns has recently surfaced in the form of bulk purchases by government entities. Several states and municipalities have requested approval from the U.S. Food and Drug Administration (“FDA”) to become, in essence, clearinghouses for local pharmaceutical sales.⁶ While this appears to largely solve the problem of unsafe drugs being imported into the U.S., and thus clears the way for mass importation, there remains another, more complex barrier: the threat of patent infringement lawsuits by branded pharmaceutical companies.

What is the risk of infringement litigation for importation? Interestingly, it depends on the nature of the importer. Some actors, like state governments, have limited immunity from such lawsuits, but utilizing alternative causes of action may circumvent this protection. If significant state liability exists, could the federal government step in as a risk-free importer? The rules are in flux, and the potential downsides are severe. In view of the ambiguity, perhaps a wholesale change in the law is necessary to eliminate

⁵ Safety concerns are the primary reason the U.S. Food & Drug Administration opposes pharmaceutical importation. See *Buyer Beware: The Danger of Purchasing Pharmaceuticals over the Internet: Hearings Before the Perm. Subcomm. on Investigations, Comm. on Gov't Affairs*, 108th Cong. (2004) (statement of Associate Commissioner for Regulatory Affairs, John M. Taylor III) (“FDA remains strongly concerned about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they are outside the legal structure and regulatory resources provided by Congress.”), available at http://hsgac.senate.gov/_files/072204-taylor2234.pdf (last visited Jan. 26, 2005).

⁶ See *id.* The State of Vermont has now sued the FDA to compel the agency to permit state importation. See *Complaint for Declaratory and Injunctive Relief* at 7–8, *State of Vermont v. Tommy G. Thompson* (Aug. 19, 2004), available at http://www.atg.state.vt.us/upload/1092941916_Complaint_For_Declaratory_And_Injunctive_Relief.pdf (last visited Jan. 26, 2005); Pam Belluck, *Vermont Will Sue U.S. for Right to Import Drugs*, N.Y. TIMES, Aug. 11, 2004, at A13.

any possibility of infringement liability. Unfortunately, the extent to which such a revision would be both legally and economically viable is also uncertain.

Why is there so much uncertainty regarding the treatment of such an established intellectual property right when the extensive jurisprudence surrounding tangible rights seems to produce much clearer results? The basis appears to be a lingering resistance—in both the public psyche and the law—to accord full property rights to intellectual property. While we support the recognition of property protections for intangibles on paper, at some level Americans are uncomfortable in granting intellectual property owners the complete range of powers given to tangible property owners, particularly in cases of social or political crisis.⁷ In other words, the fundamental respect for property over transitory legislative or judicial policy—full “proptertization”—is struggling to emerge.⁸ To gauge the progress of the intellectual property rights equalization, it can be useful to consider extreme contexts that bring the most difficult issues to the forefront; the drug importation controversy more than meets this criteria.

To date, there has been no comprehensive analysis of these relevant issues as they relate to pharmaceutical importation. Constitutional protections for intellectual property have been considered, but in broad brushes that do not address the issues

⁷ See, e.g., Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro®: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 125–28 (2002) (describing the extreme public reaction to the fact that a foreign pharmaceutical company held exclusive patent rights to a medicine that was essential for the effective treatment of anthrax infection).

⁸ As this Article explains in detail, according legal protection to intellectual property that is similar to tangible property rights has important consequences. But this is not an inevitable choice. It could be argued that intellectual property rights should have a lower, weaker status due to their intangible nature. See generally Mark A. Lemley, *Property, Intellectual Property and Free Riding*, Stan. L. & Econ. Working Paper No. 291 (Aug. 2004), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=582602 (last visited Apr. 8, 2005) (proposing that unauthorized use or “free riding” of intellectual property should be permitted in all but a few cases due to the irrationality of internalizing the associated positive externalities). Deciding how much protection society should give to intellectual property is a fundamental public policy issue that is outside the scope of this article. However, the analysis herein should help to contextualize the debate.

unique to this situation.⁹ Conversely, the specific context of importation and patents has been narrowly addressed, without the treatment of more expansive constitutional applications.¹⁰ In the meantime, state and municipal governments are beginning to implement importation proposals, while Congress has proposed several pieces of new legislation to facilitate imports.¹¹ Thus, pharmaceutical importation represents a critical juncture in the

⁹ See, e.g., Richard H. Seamon, *The Asymmetry of State Sovereign Immunity*, 76 WASH. L. REV. 1067, 1140–46 (2001) (discussing state sovereign immunity from takings claims in the context of patent cases); Daniel J. Meltzer, *Overcoming Immunity: The Case of Federal Regulation of Intellectual Property*, 53 STAN. L. REV. 1331, 1334–43 (2001) (assessing the remedies available for state infringement of intellectual property in view of Eleventh Amendment immunity); Mitchell N. Berman et al., *State Accountability for Violations of Intellectual Property Rights: How to “Fix” Florida Prepaid and How Not to*, 79 TEX. L. REV. 1037, 1088–1101 (2001) (reviewing state liability for intellectual property infringement based on Fourteenth Amendment actions); Eugene Volokh, Essay, *Sovereign Immunity and Intellectual Property*, 73 S. CAL. L. REV. 1161, 1167–69 (2000) (considering the effect of eminent domain actions for government infringements of intellectual property); Christina Bohannon & Thomas F. Cotter, *When States Steal Ideas: Is the Abrogation of State Sovereign Immunity from Federal Infringement Claims Constitutional in Light of Seminole Tribe?*, 67 FORDHAM L. REV. 1435, 1458–69 (1998) (arguing that Congress intended to preempt takings claims for intellectual property infringement); Thomas F. Cotter, *Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?*, 50 FLA. L. REV. 529, 558–65 (1998) (considering the extent to which federal intellectual property infringements are compensable as a general takings claim); Shubha Ghosh, *Reconciling Property Rights and States’ Rights in the Information Age: Federalism, the “Sovereign’s Prerogative” and Takings after College Savings*, 31 U. TOL. L. REV. 17, 33–36 (1999) (discussing a potential constitutional route for pursuing intellectual property infringement actions against state governments).

¹⁰ See, e.g., Rebecca Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 485–86 (2003) (considering importation in the context of the FDA’s role in the dissemination of biotechnology and pharmaceutical innovation); Daniel Erlikhman, *Jazz Photo and the Doctrine of Patent Exhaustion: Implications to TRIPs and International Harmonization of Patent Protection*, 25 HASTINGS COMM. & ENT. L.J. 307, 323–31 (2003) (reviewing the law of the U.S., E.U. and Japan with respect to patent exhaustion); Shubha Ghosh, *Pills, Patents & Power: State Creation of Gray Markets as a Limit on Patent Rights*, 53 FLA. L. REV. 789, 820–23 (2001) (discussing international patent exhaustion in the context of essential medicines); Bryan Baer, *Price Controls through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 113–20 (2001) (discussing United States patent exhaustion in the context of pharmaceuticals, but with an analysis of U.S. doctrine that predates the most significant case law). See generally Darren Donnelly, *Parallel Trade and International Harmonization of Rights Doctrine*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 445 (1997) (providing a useful outline of the exhaustion doctrines of Europe and Japan).

¹¹ See *infra* Parts III.B, V.A, respectively.

continued evolution of intellectual property rights, and this necessitates a thorough assessment of the issue.

This Article will consider the legal implications of pharmaceutical importation, focusing primarily on state and federal liability as a context for the reemergence of constitutional protections in intellectual property law. Part I discusses the social and political background for the conflict between patent property rights and essential medical care. Part II describes the social policy-based initiatives that would have a significant impact on established patent rights. Next, Part III investigates the avenues of recourse available for property owners, with a special focus on the power of novel approaches that are grounded in basic constitutional rights. The inability of the legislature to circumvent constitutional rights is described in Part IV, with a brief note on the special exception available to the courts. Finally, the Article provides conclusions regarding the likely impact of this dispute on the future of intellectual property protection.

I. HIGH PHARMACEUTICAL PRICES AS A FUNCTION OF THE COMPLEX LEGAL, REGULATORY, AND ECONOMIC ENVIRONMENT

The last thirty years of drug discovery have, without question, produced a multitude of important pharmaceutical treatments that have increased the quality of life for millions of people; indeed, many lives have literally been extended through innovative pharmacology.¹² Additionally, drug development has resulted in lifestyle improvements in areas fundamental to self image and worth.¹³ It can even be argued that drug discovery saves health care dollars as it may reduce the use of more expensive care

¹² The impressive record of the pharmaceutical industry is touted by PhRMA, its primary lobbying group. See generally PhRMA, *THE VALUE OF MEDICINES* (2001), available at <http://www.phrma.org/publications/publications/value2001/value2001.pdf>. Regardless of one's position on the economics and ethics of the industry, the benefits the world has received from drug discovery in the last twenty years are hard to discount.

¹³ See, e.g., Tim Atkinson, *Lifestyle Drug Market Booming*, 8 *NATURE MED.* 909, 909 (2002) (stating that the market for lifestyle drugs is projected to rise to \$29 billion by 2007).

options, such as hospital stays.¹⁴ These fruits come at the price of billions of dollars in research and development spending on the part of pharmaceutical and biotechnology companies, as well as the government.¹⁵ Such expenditures are made with the expectation that they can eventually be recouped. The primary mechanism by which the profits from those successful drugs can be maximized is access limitation through patent rights.¹⁶ Thus, patents and pharmaceutical prices are intimately intertwined, and it is hard to affect one without impacting the other.

A. *The Interaction of Patents and Regulation*

In the United States, all patents, including those covering pharmaceutical products, are recognized as personal property rights¹⁷ granted for inventions that meet three primary

¹⁴ See, e.g., Frank Lichtenberg, *Do (More and Better) Drugs Keep People out of Hospitals?*, 86 AM. ECON. REV. 384, 388 (1996) (concluding that an increase in 100 prescriptions is associated with 16.3 fewer hospital days, and a \$1 increase in pharmaceutical expenditure is associated with a \$3.65 reduction in hospital costs and a \$1.54 increase in ambulatory care).

¹⁵ See ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (“OECD”), RESEARCH AND DEVELOPMENT EXPENDITURE IN INDUSTRY: 1987–2001, 32–33 (2003) (noting that pharmaceutical companies in the United States spent almost \$13 billion on research and development in 2000).

¹⁶ See *id.* at 20 (“Patents play a critical role for both the level of R&D investment in pharmaceuticals and the timing of generic competition.”); U.S. DEPT. OF COMMERCE, INT’L TRADE ADMIN, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION xi (2004) [hereinafter ITA REPORT] (“In short, intellectual property protection is a necessary prerequisite to ensure that innovative companies can continue to develop new drugs, which will eventually be available on the generic market.”). Certainly there are other ways a pharmaceutical manufacturer can obtain a competitive advantage, such as manufacturing skill or the acquisition of initial market share, but patents are critical in the pharmaceutical industry. See FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, at 9–10 (2003) (“Participants in the Hearings overwhelmingly expressed the view that patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments in research and development of [new chemical entities.]”, available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>).

¹⁷ See 35 U.S.C. § 261 (2000) (“Subject to the provisions of this title, patents shall have the attributes of personal property.”).

requirements: novelty, nonobviousness, and utility.¹⁸ They issue only after an inventor has convinced the United States Patent & Trademark Office (“USPTO”) that these three requirements have been met.¹⁹ Subsequently, the issued patents are in force for a term that expires twenty years after the original filing date.²⁰ During that time period, the patent owner has the right to exclude all others from making, using, selling, offering to sell or importing the inventions into the United States.²¹

The right to exclude is particularly significant if it covers an invention that is in great demand, such as an important medical treatment. The patent owner can use the property right to create a legal scarcity²² and charge higher prices than one could normally

¹⁸ See 35 U.S.C. §§ 101–03 (2000). Actually, the utility requirement applies to only one type of patent, the aptly named “utility patent.” One can also obtain a plant patent, see 35 U.S.C. § 161 (2000), and design patents, see 35 U.S.C. § 171 (2000), but due to their respective limitations, they are not widely used in the pharmaceutical industry to protect innovation.

¹⁹ See 35 U.S.C. § 131 (2002).

²⁰ 35 U.S.C. § 154(a)(2) (2002). In 1995, the GATT amendments to the Patent Act changed the method of calculating patent term from seventeen years from issuance of the patent to twenty years from filing of the patent application. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546–47 (Fed. Cir. 1996). Owners who held patents still in force as of 1995 were given a choice of electing whichever calculation method would give the longest patent term. *Id.* at 1547 (citing 35 U.S.C. § 154(c)(1) (1994)).

²¹ 35 U.S.C. § 271 (2003); *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1578 (Fed. Cir. 1991) (“The act of invention itself vests an inventor with a common law or ‘natural’ right to make, use and sell his or her invention absent conflicting patent rights in others . . .”). A patent conveys the additional right to exclude others from making, using, selling or offering to sell the invention. *Id.* (citing *Six Wheel Corp. v. Sterling Motor Truck Co.*, 50 F.2d 568, 571 (9th Cir. 1931)).

²² Intellectual property is not actually scarce in an economic sense, but only in a legal sense, since it is inherently non-rivalrous—one’s use does not diminish the property available for another’s use. See ROBERT COOTER & THOMAS ULEN, *LAW & ECONOMICS* 120 (4th ed. 2004) (1988); RICHARD POSNER, *ECONOMIC ANALYSIS OF LAW* 43 (5th ed. 1998) (1973). However, resources associated with intellectual property may be scarce, benefiting from efficient allocation. See Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 275–80 (1977) (“[T]he property rights literature has viewed the central problem as one of scarcity, while information has appeared to be an example of something that can be used without limit. There is, however, a scarcity of resources that may be employed to use information, and it is that scarcity which generates the need for a system of property rights in information.”)

obtain in a perfectly competitive market.²³ Some refer to this as monopoly pricing,²⁴ but market dynamics rarely allow a patent owner to literally obtain monopoly control of a market.²⁵ Importantly, a patent may cover more than one aspect of a product. Pharmaceuticals, for example, may be covered by patents on the basic chemical compound, methods of making the compound, methods of formulating the compound for effective treatment, and methods of administering the compound in the treatment of a disease—in some cases all four aspects may be embodied by a single product.²⁶ Later-filed patents on ancillary aspects of a product may have the effect of nominally extending core patents, assuming they continue to prevent competitors from making the product.²⁷ Because all of the relevant patents will expire eventually, these protections give the patent owner a limited amount of time to recoup research and development expenditures.

The pharmaceutical regulatory regime in the United States adds a layer of complexity to the intellectual property scheme in an

²³ See COOTER & ULEN, *supra* note 22, at 122 (“[A] patent enables the inventor of something valuable to earn profits that exceed the ordinary rate of return on investment.”).

²⁴ See *id.*

²⁵ See Edmund Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 VAND. L. REV. 1727, 1729–38 (2000) (“Whether or not any patent or other intellectual property right confers an economic monopoly is an empirical question, but it seems likely that all trademarks, almost all copyrights, and most patents are not monopolies.”).

²⁶ For example, a search of the FDA’s on-line record of drug application approvals (the “electronic orange book”) for the anti-cholesterol drug Lipitor (application no. 020702) shows that it is covered by ten different patents. See FDA, *Electronic Orange Book*, at <http://www.fda.gov/cder/ob/default.htm> (last visited Jan. 26, 2005). But note, this is not the same as obtaining multiple patents on the same *invention*; rather the product encompasses multiple inventions. Technically, each patent claim is, under the law, a separate invention. See *Jones v. Hardy*, 727 F.2d 1524, 1528 (Fed. Cir. 1984). Interestingly, some widely-known drug treatments actually have patents only on the most effective method of using the compound, rather than the compound itself. See General Accounting Office, *NIH-Private Sector Partnership in the Development of Taxol*, GAO-03-829, 24 (June 2003) (noting that, although the active ingredient of the blockbuster anti-cancer drug, Taxol (paclitaxel), has not been patented, methods of administration of the drug have been patented), at <http://www.gao.gov/new.items/d03829.pdf>. The compound may be otherwise freely available.

²⁷ See Mark Lemley & Kimberly Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 81–83 (2004) (describing the process of obtaining multiple patents on the same pharmaceutical product as “evergreening”).

attempt to balance the interests of patent owners against the public's interest in obtaining generic versions of patented drugs as soon as possible.²⁸ This effectively results in additional pressure on branded pharmaceutical companies to quickly obtain maximum profits. The FDA, the primary regulatory agency that oversees pharmaceuticals, must approve all new drug applications ("NDAs") for marketing in the United States.²⁹ Such applications require the submission of, *inter alia*, clinical data sufficient to show that the drug is "safe and effective" for its intended use.³⁰ Prior to the 1980s, an innovator pharmaceutical company (i.e., the company that invents a new, often patentable, drug or treatment) could count on some delay in the filing of competitor (generic) NDAs following the expiration of the innovator's patent rights. This is because generating clinical data takes time,³¹ and the process could not be started until the expiration of the patent, as it would likely involve an infringing "use" of the patented drug or treatment.³² All of that changed with the passage of the Hatch-

²⁸ See Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 51 (2003). For an excellent overview of the background behind the enactment of the most important piece of legislation, see generally Gerald Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187 (1999).

²⁹ 21 U.S.C. § 355(a) (2003). Technically the requirement is for marketing in interstate commerce, but few if any drugs would fail to meet that threshold. See also DONALD BEERS, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS* § 1.01 (1999).

³⁰ 21 U.S.C. § 355(b)(1)(A) (2003).

³¹ See Soehnge, *supra* note 28, at 53–54; Mossinghoff, *supra* note 28, at 187. Although an "experimental use" exception does exist in patent law, it is very rarely applied. See, e.g., *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) ("This court has construed both the experimental use and *de minimis* exceptions very narrowly."). Moreover, the courts have determined conclusively that this common law-derived exception does not apply in the case of a competing pharmaceutical company preparing data for submission to the FDA. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984) (holding that use of patented ingredient to perform tests necessary for a competitor to obtain approval of the FDA was an infringement).

³² See *Roche*, 733 F.2d 858. Although an "experimental use" exception does exist in patent law, it is very rarely applied. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1361–62 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003). In particular, the courts have determined conclusively that this common law-derived exception does not apply in the

Waxman Act in 1984.³³ The new law created a statutory “experimental use” exception that permitted a generic competitor to use a patented drug or treatment for the creation of data for submission to a federal regulatory agency during the term of the patent, though marketing approval would still be delayed until the patent expired.³⁴ The Act also streamlined the application process for generic pharmaceutical applicants by allowing them to file an abbreviated new drug application (“ANDA”), which requires only that an applicant demonstrate the subject drug to be “bioequivalent” to an existing NDA, as opposed to the more stringent “safe and effective” standard.³⁵ Additionally, generic companies were given the ability to challenge all listed patents before marketing a product by virtue of the Act’s declaration that the submission of an ANDA constitutes a technical infringement, thus satisfying the “case and controversy” requirement of the U.S. courts.³⁶ Taken together, these measures ensure that patent rights for a valuable pharmaceutical will be strictly limited.³⁷

By possessing a patent’s exclusive rights, pharmaceutical companies have the ability to take full advantage of the value that the market places on the drug or treatment in question.³⁸ And when a broadly-applicable, lifesaving medication is under this

case of a competing pharmaceutical company preparing data for submission to the FDA. *See Roche*, 733 F.2d at 863.

³³ Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (2003)).

³⁴ 35 U.S.C. § 271(e) (2003).

³⁵ 21 U.S.C. §§ 355(b)(2–3), (c)(3), (j) (2003); BEERS, *supra* note 29, at § 3.03[A][4].

³⁶ 21 U.S.C. §§ 355(j)(2)(A)(vii) (2003); BEERS, *supra* note 29, at § 3.03[B][3]; Mossinghoff, *supra* note 28, at 190 (citing 35 U.S.C. § 271(e)(2)).

³⁷ Concerns that patent owners had discovered techniques to game the Hatch-Waxman provisions led to recent revisions in the law that close a number of loopholes. *See* Medicare Prescription Drug and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2448–53 (2003) [hereinafter “Medicare Act”] (restricting an NDA holder’s ability to prevent ANDA approval through strategic listing of multiple patents). Although these changes were vigorously challenged by the pharmaceutical industry, the effect is likely to be quite minor.

³⁸ Although new drugs covered by patents are not necessarily more expensive than existing treatments, launch prices do tend to be higher when new classes of compounds are introduced. *See* Joseph A. DiMasi, *Price Trends for Prescription Pharmaceuticals: 1995–1999*, at <http://aspe.hhs.gov/health/reports/Drug-papers/dimassi/dimasi-final.htm> (last updated Oct. 11, 2000).

control, consumers are willing to pay a high price.³⁹ While some may see it as gouging,⁴⁰ others accept that innovator pharmaceutical companies must fund risky research programs with the few commercial successes they achieve.⁴¹ A widely cited estimate from the Tufts Center for the Study of Drug Development suggests that each new pharmaceutical has over \$800 million in research and development failure costs to recoup before it is technically profitable.⁴² The ability to set the highest price the market will bear is an incentive that all research-based drug companies likely use to craft their drug discovery programs.

The price pressures in the U.S. that are created by endogenous forces would be significant enough, but the national pharmaceutical market does not exist in a vacuum. There is no doubt that the economics of the system are greatly exacerbated by the influence of foreign health care regimes. In fact, the global market has been a significant factor in pushing the cost of American health care to the crisis point.

³⁹ See John Carey & Amy Barrett, *Drug Prices: What's Fair?*, BUS. WK., Dec. 10, 2001, at 60 ("The nation's drug bill has been rising at 14% to 18% a year, and for 2001 it will be between \$160 billion and \$170 billion, according to private sector estimates.").

⁴⁰ See FAMILIES USA, OFF THE CHARTS: PAY, PROFITS AND SPENDING BY DRUG COMPANIES 10 (2001) ("[I]f meaningful steps are taken to ameliorate fast-growing drug prices and costs, it is corporate profits; expenditures on marketing, advertising, and administration; and executive compensation that are more likely to be affected, not R&D spending."), available at <http://www.familiesusa.org/site/DocServer/drugceos.pdf?docID=767> (last visited Jan. 12, 2005). This perception is especially common when the profits from the sale of the pharmaceutical significantly outstrip the cost of producing and marketing it.

⁴¹ See Henry Grabowski, *Politics, Policy and Availability: Patent and New Product Development in the Pharmaceutical and Biotechnology Industry*, 8 GEO. PUB. POL'Y REV. 7, 9 (2003) ("One of the reasons why R&D is so costly in pharmaceuticals is that most new drug candidates fail to reach the market."); PHRMA, *WHY DO PRESCRIPTION DRUGS COST SO MUCH . . . AND OTHER QUESTIONS ABOUT YOUR MEDICINE* 8–9 (2000), available at <http://www.phrma.org/publications/publications/brochure/questions/questions.pdf> (last visited Jan. 26, 2005).

⁴² See Joseph DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166–68, 180 (2003) (reporting that the research conducted under the Tufts Center for Drug Development found that research and development costs are \$802 million, and nearly \$900 million if post approval research and development is taken into account).

B. Differences in International Pharmaceutical Prices Ratchet Up the Pressure on American Consumers

The patent system's pressure to obtain monopoly profits for as long as possible is not unique to the United States; most nations have a strikingly similar property right incentive system by virtue of international agreements like the Paris Convention⁴³ and TRIPs.⁴⁴ If intellectual property protection was the only factor in the cost of drugs, prices might still be high in the U.S., but the burden would likely be spread out a bit more throughout the world and the veneer of inequity that currently sullies the industry might not exist.⁴⁵ However, studies have demonstrated that pharmaceutical prices in most other industrialized nations are often significantly less than in the United States, depending on the drug.⁴⁶ The reason for this price difference despite the similarity in

⁴³ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

⁴⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1994) [hereinafter TRIPs Agreement].

⁴⁵ A recent International Trade Administration study of international pharmaceutical price controls found that minor differences in intellectual property rights among the nations studied did not have a significant affect on pricing. See ITA REPORT, *supra* note 16, at ix.

⁴⁶ See AUSTL'N PRODUCTIVITY COMM'N, INTERNATIONAL PHARMACEUTICAL PRICE DIFFERENCES xxiii–xxvii (July 2001) (charts demonstrating that U.S. prices for all categories of pharmaceuticals—innovative, “me too” and generic—and innovative pharmaceuticals specifically, are significantly higher than in Canada, the UK, Sweden, France, Spain, Australia and New Zealand), available at <http://www.pc.gov.au/study-pbsprices/finalreport>; HOUSE MINORITY STAFF REPORT, COMM. ON GOV'T REFORM AND OVERSIGHT, PRESCRIPTION DRUG PRICING IN VERMONT: AN INTERNATIONAL PRICE COMPARISON (Nov. 1, 1998) (finding that the average prices that senior citizens in Vermont must pay for the ten brand name prescription drugs that have the highest dollar sales to the elderly in the United States are 81% higher than the average prices that Canadian consumers must pay and 112% higher than the average prices that Mexican consumers must pay), available at <http://bernie.house.gov/prescriptions/international.asp>; Danzon & Furukawa, *supra* note 1, ex. 4 (chart demonstrating that the pharmaceutical prices for on-patent brand name drugs in many other industrialized nations are significantly less than in the United States); ITA REPORT, *supra* note 16, at 11–15 (stating that prices for particular patented drugs in nine OECD countries were only 33–59% of the U.S. price, based on standard units).

intellectual property protections involves a rather complex set of factors.

First and foremost, the health care systems of most industrialized nations are quite different from the United States. In general, most countries have some sort of nationalized health care program.⁴⁷ These programs entail deep government intervention in all aspects of providing health care services, including staffing facilities, determining the available level of care, and purchasing medical supplies like pharmaceuticals.⁴⁸ This level of involvement makes government entities powerful negotiators, and in the case of drugs, has allowed them to set maximum prices.⁴⁹ Many countries do this through a system of reimbursement for patient purchases of drugs, in which a given amount is provided through a national insurance supplement.⁵⁰ Often, the reimbursement amount is linked to a class of drugs rather than each individual treatment, in a practice known as “reference pricing.”⁵¹ Patients are permitted to pay more, but there is obviously a strong disincentive to choose a drug that is priced above others in the class (and conversely, a

⁴⁷ See WORLD HEALTH ORGANIZATION (“WHO”), WORLD HEALTH REPORT 2000 95–96 (2000), at <http://www.who.int/whr2001/2001/archives/2000/en/contents.htm> (“Most high income countries rely heavily on either general taxation or mandated social health insurance contributions [to finance health care]”).

⁴⁸ See AUSTL’N PRODUCTIVITY COMM’N, *supra* note 46, at 17–21 (“Most developed countries are similar to Australia in that governments, for social welfare and equity reasons, subsidize the consumption of prescription pharmaceuticals that have been approved for marketing by regulatory authorities.”).

⁴⁹ See *id.* at 21–25; ITA REPORT, *supra* note 16, at 3 (“All OECD governments studied in this report rely on some form of price controls to manage spending on pharmaceuticals.”).

⁵⁰ See AUSTL’N PRODUCTIVITY COMM’N, *supra* note 46, at 22 (“[M]ost OECD countries have moved away from [direct price] controls in favor of reimbursement pricing systems. Under reimbursement pricing systems, public or private pharmaceutical insurers set price ceilings for subsidized items (where the list of subsidized items is commonly referred to as a formulary). Insurers agree to cover or reimburse the cost of listed pharmaceuticals up to the ceiling (reimbursement price). Manufacturers are free to price above the reimbursement price but the patient usually must pay the difference between the reimbursement price and the manufacturer’s price.”).

⁵¹ See *id.* at 25–26 (“Under a reference pricing system, reimbursement prices are commonly set for a group or cluster of similar or identical pharmaceuticals. . . . If the reference price is set at the level of the lowest-priced item in the group, manufacturers of the higher priced items may be required to lower their price to the benchmark.”); ITA REPORT, *supra* note 16, at 4 (describing the practice and noting that many countries consider it to be less restrictive than outright price controls).

strong incentive for pharmaceutical companies to price drugs at the level at which they will be reimbursed).⁵² Drug classification and reimbursement may be determined, in part, by an economic analysis of the treatment regimen that links the appropriate drug cost to its benefits in view of existing treatments.⁵³ While this pricing method could be termed an indirect form of price control, some governments go further and actually set by law the maximum price for which a drug or class of drugs may be sold.⁵⁴ Whether pricing is set by direct control or reimbursement, a great number of countries add another powerful factor that elevates this process to an international level. Instead of setting controls or negotiating in an isolated context, they use international benchmarking (or “external reference pricing”), which looks to the prices in certain countries as an objective measure of reasonableness.⁵⁵ Often, the reference formula states that a pharmaceutical’s price must match the lowest price among several reference nations.⁵⁶ Taken together, these techniques along with a few other sporadically used controls on pricing⁵⁷ provide a powerful force to keep prices down, and by all estimates they have been quite effective.⁵⁸

⁵² See AUSTL’N PRODUCTIVITY COMM’N, *supra* note 46, at 26.

⁵³ See *id.* at 22–24. In contrast, doctors in the United States are generally permitted to prescribe drugs “off label” if they believe effective treatment will be provided. See James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 76 (1998) (“[P]hysicians may use legally marketed drugs or devices in any way that they believe, in their professional judgment, will best serve their patients.”). Insurance coverage is often still available. See *id.* at 76–77.

⁵⁴ See AUSTL’N PRODUCTIVITY COMM’N, *supra* note 46, at 29. Perhaps the most relevant example of a direct price control system is Canada’s. The Canadian government, through the Patented Medicine Prices Review Board (“PMPRB”), sets the maximum price at which patented medicines may be sold to ensure that they are “not excessive.” See PMPRB, COMPENDIUM OF GUIDELINE, POLICIES AND PROCEDURES 4–6 (Oct. 2003), at <http://www.pmprb-cepmb.gc.ca/CMFiles/2004compendium-e21LTW-152004-1350.pdf>.

⁵⁵ See AUSTL’N PRODUCTIVITY COMM’N, *supra* note 46, at 29; Patricia Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT’L J. HEALTH CARE FIN. & ECON. 183, 191 (2003) (“[E]xternal referencing is used formally by the Netherlands, Canada, Greece and Italy, among others, and used informally by many other countries. External referencing is equivalent to fully importing a foreign price.”).

⁵⁶ See AUSTL’N PRODUCTIVITY COMM’N, *supra* note 46, at 29.

⁵⁷ Other methods of influencing drug prices include setting a volume limit on a particular price (following which the price must be reduced) and limitations on the

An additional factor in pricing is the variation within the market for pharmaceuticals in different countries. Some drugs that are in high demand in the United States may not be the preferred form of treatment in other countries due to physician preferences or differences in marketing practices.⁵⁹ As a consequence of simple supply/demand microeconomics, prices for a specific drug could be lower in countries with less demand.

Finally, there is the simple difference in the ability of health care systems and individual patients in various countries to pay for high-priced drugs. Pharmaceutical companies may take into account the fact that a certain country—for example, an African state—has a great need for a drug, but insufficient economic health to support either government or private purchase in substantial quantities.⁶⁰ In such cases, the company may dispense the drug for little or no profit above cost. Income-related incentives to reduce prices are likely present in many countries, but the influence of other factors means that drug prices do not always correlate perfectly with a nation's per capita income level.⁶¹

The aforementioned pressures on drug prices lead to essentially two options for research-intensive pharmaceutical companies: (1) accept lower profits overall or (2) attempt to make up the difference in a market that does not have the above constraints. The latter choice seems obvious given the basic industry model.

amount of profit a company may make on sales to a country's health service per product or during a particular time period. See ITA REPORT, *supra* note 16, at 5–6.

⁵⁸ AUSTL'N PRODUCTIVITY COMM'N, *supra* note 46, at 77–78 (concluding that cost containment mechanisms are an important factor in international price differences, but that it is difficult to correlate the particular mechanism to the amount of cost containment).

⁵⁹ See Danzon & Furukawa, *supra* note 1, ex. 7. A very important difference is the prohibition on “direct-to-consumer” advertising in many countries. See Geoff Dyer, *Europe Seeks to Calm Nerves over US-Style Drug Advertising*, FIN. TIMES, Oct. 23, 2002, at 20 (“Ironically, while Europe is moving towards restricting information from companies, the FDA is considering further relaxation after a number of recent cases found it was violating freedom of speech.”).

⁶⁰ See Gautam Naik, *Glaxo to Cut Price of AIDS Drug Used in Africa*, WALL ST. J., Apr. 28, 2003, at B3.

⁶¹ See Danzon & Towse, *supra* note 55, at 191–92 (stating that factors such as a country's negotiating power may preclude a perfect correlation between per capita income level and pharmaceutical pricing, because higher prices are often found in poorer countries).

The continued vitality of a pharmaceutical company is intimately tied to its investment in future pharmaceutical innovations because health care products can face a potentially more truncated lifespan than other products. In fact, pharmaceutical companies are often measured as much by their “pipeline” of future drugs as their current portfolio.⁶² The lifespan of a drug product is dictated by the practice of modern medicine, which generally attempts to incorporate the newest, most effective (and almost always patented) treatments. Existing treatment regimens will experience a loss in market share and may even disappear when objectively better treatments become available.⁶³ Being forced to use a product that is “second best” on the market is, to some degree, immoral, so products do not usually remain available on the basis of a price break from the premium product.⁶⁴ The pharmaceutical industry responds to this pressure with aggressive, expensive research to find the next blockbuster treatment.⁶⁵ Thus, pharmaceutical companies have generally undertaken a policy of maximizing profits in the last free-market health care realm: the United States.⁶⁶

⁶² See, e.g., John Simons, *Lilly Goes off Prozac*, FORTUNE, Jun. 28, 2004, at 179 (“Lilly is a bright spot in Big Pharma, widely acknowledged to have the industry’s most bountiful pipeline of new products.”).

⁶³ An excellent example is provided by the market for gastrointestinal medications (e.g., heartburn and acid reflux drugs). From the 1970s to the 1990s, acid suppression medications (H₂ receptor antagonists) such as Zantac and Tagamet dominated the market, but sales were dramatically driven down when more effective proton pump inhibitor drugs like Prilosec were approved. See Cindy Parks Thomas & Grant Ritter, *Drug Utilization Trends by Therapeutic Class* (Aug. 31, 2000), available at <http://aspe.hhs.gov/health/reports/Drug-papers/index.htm>.

⁶⁴ Note that we have a belief in American society that denial of treatment based on lack funds is immoral. Unlike most countries that long ago accepted monetary limitations on their health care systems, the U.S. continues to try to make everything available to everyone. Perhaps this is inherently unsustainable. It is, however, a topic for a different paper.

⁶⁵ See Robert Franco, *Beyond the Blockbuster*, PHARMACEUTICAL EXECUTIVE, Nov. 2002, at 74 (noting the blockbuster model tends to dictate the strategy of Big Pharma, but suggesting that a more moderate approach that aims toward slightly less successful drugs could be more profitable across the board), available at <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=36729&&pageID=2>.

⁶⁶ One could argue that prices in the United States actually reflect the free market price rather than an attempt to obtain high profits to offset lower profits in other countries. See ITA REPORT, *supra* note 16, at 10 (“U.S. prices are undeniably more market-oriented and suffer from less direct government intervention than is true among its trading

As a result of the forces acting on drug prices, the chasm between U.S. prices and those in foreign industrialized nations is likely to increase each year, particularly in the case of essential medicines. Prices for these select drugs seem to continuously spiral upward with no sign of abatement. It has become abundantly clear that American consumers are no longer content to bear the majority of financing for pharmaceutical research that benefits the entire international community. Assuming that the United States would have little success in convincing other countries to change their systems in order to pay for a greater share of the research burden, the only option is to try to control prices in this country. There are a number of possible avenues for achieving this goal, but for various reasons, none have been successful in lowering prices for most Americans.

II. IMPORTATION INITIATIVES AS A POLITICALLY ACCEPTABLE FORM OF PRICE CONTROL

The most direct way of controlling drug costs in the United States is for the federal government to create and enforce a national schedule of maximum prices. Legally mandated price caps already occur to a limited extent with drugs purchased by federal programs like Medicaid and the Veteran's Administration.⁶⁷ However, as a general matter, a national price control initiative that would affect private transactions is a rare

partners. . . . U.S. prices [offer] the closest approximation of deregulated prices . . ."). This notion requires one to accept that pharmaceutical companies will always price to maximize profits when possible. However, because non-price factors such as political concerns and public relations are undoubtedly figured in, companies do retain some flexibility in determining the sales price. Thus, it is not unreasonable to presume that pharmaceutical manufacturers have raised prices above that which they would normally charge in reaction to the pressures from countries with price controls.

⁶⁷ See Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (1990). The law requires drug manufacturers to provide a rebate based on the average manufacturer price. See Ctrs. for Medicare & Medicaid Servs., *Medicaid Drug Rebate Program*, at <http://www.cms.hhs.gov/medicaid/drugs-drughmpg.asp>? (last modified Sep. 16, 2004). The rebate equals the difference between the drug manufacturer's average wholesale price and the best price it offers to other buyers (other than the federal government), or at least 15.1%. *Id.*

event in recent U.S. history,⁶⁸ one that is politically dangerous to undertake as it represents the antithesis of a free market,⁶⁹ and difficult for a centralized government to set and apply effectively.⁷⁰ Another price containment method would be to use the purchasing power of the federal government's Medicare program (which has a greater impact than the Medicaid program)⁷¹ as a negotiating sword. This was actually proposed during the last round of Medicare reforms, but it was ultimately rejected (with specific language in the Public Law actually *prohibiting* the federal government from taking such actions⁷²).⁷³ Private insurance companies may also have some ability to negotiate pharmaceutical prices to reduce consumer costs; however, most have chosen

⁶⁸ See Hugh Rockoff, *Price Controls*, in THE CONCISE ENCYCLOPEDIA OF ECONOMICS, Library of Economics and Liberty, available at <http://www.econlib.org/library/Enc/PriceControls.html> (last visited Jan. 29, 2005). The exception has been in times of war. *Id.*

⁶⁹ *Id.*

⁷⁰ See W. David Slawson, *Price Controls for a Peacetime Economy*, 84 HARV. L. REV. 1090, 1092 (1971):

An efficient price-control system would reduce inflation but would not: (1) require a very large bureaucracy, (2) impose heavy compliance costs upon industry, (3) set prices which would misallocate [sic] resources more than would the economy in its absence, or (4) set prices so low as materially to reduce incentives for hard work, innovation, or investment. These are the characteristic evils of price controls. Price control systems in the past have exhibited each of these shortcomings, and critics have claimed that they are inescapable byproducts of any comprehensive scheme of price regulation.

⁷¹ The Medicare and Medicaid programs have similar numbers of people enrolled—each about 40 million. See CTRS. FOR MEDICARE & MEDICAID SERVS., 2004 CMS STATISTICS 3 (2004), available at <http://www.cms.hhs.gov/researchers/pubs/CMS-statistics/2004CMSstat.pdf>. However, many of Medicaid's recipients are children and young adults, who consume only a small percentage of the nation's prescription drugs. See HEALTH CARE FIN. ADMIN., A PROFILE OF MEDICAID: CHARTBOOK 2000 12 (2000), at <http://www.cms.hhs.gov/charts/medicaid/2Tchartbk.pdf>.

⁷² See Medicare Prescription Drug and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 1860D-11(i), 117 Stat. 2066, 2098 (2003):

Noninterference.—In order to promote competition under this part and in carrying out this part, the Secretary—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

(2) may not require a particular formulary or institute a price structure [line up]for the reimbursement of covered part D drugs.

⁷³ See Medicare Prescription Drug Price Negotiation Act, H.R. 3299, 108th Cong. (Oct. 2003).

instead to decrease the percentage of prescription drug prices that are covered for their policy holders (or eliminate prescription plans altogether).⁷⁴

The current lack of success in controlling the prices offered in this country has naturally led to the popular consideration of directly tapping into discounted foreign prices. While this solution would, on its face, seem to be as simple as purchasing drugs abroad and importing⁷⁵ them into the United States, it has quickly become apparent that many barriers exist.⁷⁶

*A. Federal Regulatory Barriers Currently Prohibit
Pharmaceutical Importation*

The federal agency charged with ensuring the safety of the nation's drug supply, the Department of Health and Human Service ("HHS"), which oversees the FDA, has a considerable interest in the drug import debate. Understandably, there is concern when a stream of foreign pharmaceuticals enters into the United States with less FDA scrutiny than drugs intentionally produced for the domestic market. Here, HHS' mandate regarding safe and effective treatments is applied to both foreign-made or

⁷⁴ See Vanessa Fuhrmans, *Higher Co-Pays May Take Toll on Health*, WALL ST. J., May 19, 2004, at D1.

⁷⁵ When pharmaceuticals are exported from the United States for sale overseas and then imported back, the practice is technically referred to as "reimportation." If done without the permission of the authorized U.S. dealer, the practice is referred to as "parallel importation." This Article will not distinguish between these terms, and will use "importation" as a general term for all three varieties.

⁷⁶ Importation works only as long as there are drugs to import. It has been noted, for example, that if drug imports were immediately permitted across the board, the international market could supply no more than 10–15% of the U.S. drug market. See CONG. BUDGET OFFICE, *WOULD PRESCRIPTION DRUG IMPORTATION REDUCE U.S. DRUG SPENDING?* 4 (2004) ("Potential savings in the United States would depend on import volume, which reflects the size of the total drug market in source countries. CBO estimates that the volume of world supply outside the United States is about twice the size of the U.S. market. Assuming that volume slippage from outside the United States would resemble that from source countries within Europe, CBO estimates that the import volume would be in the range of about 10 percent to 15 percent of the U.S. market."). Additionally, pharmaceutical companies have the ability to cut foreign exports of certain drugs to ensure that countries have no more drugs than necessary to satisfy their own markets (i.e., not enough to export).

purchased drugs as well as those produced domestically.⁷⁷ Also, no matter what HHS rules specifically address importing drugs, the FDA still has the power to regulate any marketing activity for drugs in the U.S.⁷⁸

Interestingly, the specific question of importing drugs—though it has garnered the reputation as a recent political issue—has been debated for some time and addressed to varying degrees in several legislative undertakings. For example, the safety of imported pharmaceuticals was a cause for concern as early as the 19th century, when public pressure regarding impure or adulterated medicines compelled Congress to pass the Import Drug Act of 1848.⁷⁹ This law created a system at important U.S. ports for inspecting medicines for “quality, purity, and fitness for medical purposes,” as well as to “their value and corresponding identity called for on the invoice.”⁸⁰ Although initially under the jurisdiction of U.S. Customs, the responsibility for scrutinizing imports eventually was allocated to the FDA where it resides today.⁸¹

More recently, a resurgence of safety concerns in the 1980s resulted in the passage of the Prescription Drug Marketing Act of 1987 (“PDMA”).⁸² The PDMA is directed to several aspects of prescription pharmaceutical safety and was a response to widespread fear over counterfeit or adulterated pharmaceuticals appearing on the market from foreign countries.⁸³ The most

⁷⁷ See 21 U.S.C. § 355(a) (2003).

⁷⁸ See BEERS, *supra* note 29, § 1.01 (noting that the FDA must approve the marketing of any “new drug” in interstate commerce); Div. of Imp. Operations & Policy, Food & Drug Admin., *Information on Importation of Drugs*, at <http://www.fda.gov/ora/import-pipinfo.htm> (Apr. 3, 1998).

⁷⁹ Ch. 70, 9 Stat. 237 (1848) (repealed 1953); see also Wesley J. Heath, *America’s First Drug Regulation Regime: The Rise and Fall of the Import Drug Act of 1848*, 59 FOOD & DRUG L.J. 169, 175–77 (2004).

⁸⁰ Heath, *supra* note 79, at 179.

⁸¹ *Id.*

⁸² Pub. L. No. 100-293, 102 Stat. 95 (1988) (codified as amended at scattered sections of 21 U.S.C.).

⁸³ See Robert Angarola & Judith Beach, *The Prescription Drug Marketing Act: A Solution in Search of a Problem?*, 51 FOOD & DRUG L.J. 21, 21 (1996) (“Congress’ intent in passing this legislation was to avoid what it considered ‘an unacceptable risk that counterfeit, adulterated, misbranded, subpotent or expired drugs will be sold to American consumers.’”).

relevant provision prohibits anyone but the original manufacturer of a prescription drug from importing or “re-importing” it to the United States (unless it is required for emergency medical care).⁸⁴

In the 1990s, concern over pharmaceutical safety began to give way to public outrage over high prices. This resulted in the passage of the Medicine Equity and Drug Safety Act of 2000 (“MEDS”), which contains a specific Congressional resolution that “Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries.”⁸⁵ Though it is often lost in recent rhetoric, the four-year-old law actually creates a specific exception to the PDMA that would allow for the non-manufacturer importation of pharmaceuticals with appropriate FDA oversight.⁸⁶ It requires the HHS Secretary to “promulgate regulations permitting pharmacists and wholesalers to import into the United States [products covered by the Federal Food, Drug, and Cosmetic Act].”⁸⁷ However, the Act requires that safeguards be in place to ensure that imported drugs comply with the safety and effectiveness requirements of domestic drugs.⁸⁸ Unfortunately, it does not detail what would be sufficient to demonstrate a showing of safety and effectiveness short of satisfying all of the formal requirements of an NDA or an ANDA. More importantly, the Act has a major limitation on its implementation. It explicitly states:

This section shall become effective only if the Secretary demonstrates to the Congress that the implementation of this section will —

(1) pose no additional risk to the public’s health and safety;
and

⁸⁴ 21 U.S.C. § 381(d) (2003).

⁸⁵ Pub. L. No. 106-387, 114 Stat. 1549 (2000) (codified at 21 U.S.C. §§ 333, 384).

⁸⁶ 21 U.S.C. § 384(j) (2000) (abrogating the authority of the Secretary to regulate imports under 21 U.S.C. § 381(d)(1)); William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, 9 TUL. J. INT’L & COMP. L. 483, 487–88 (2001).

⁸⁷ 21 U.S.C. § 384(a) (2003).

⁸⁸ 21 U.S.C. § 384(b) (2003).

(2) result in a significant reduction in the cost of covered products to the American consumer.⁸⁹

In other words, the HHS Secretary must vouch for the safety and effectiveness of drugs imported through this procedure. Although this section of the law was revised in 2003, the certification provision was left intact.⁹⁰ To date, both HHS Secretaries who have held office after the enactment of MEDS have concluded that no such demonstration can be made.⁹¹ This has obviously frustrated the original proponents of the bill, as well as advocates of importation; recent legislative initiatives have attempted to modify this requirement.

Of course, safety concerns are not entirely spurious and care is required in revising relevant regulatory statutes. If the HHS Secretary's prerequisite obligation to investigate and certify safety is relaxed or eliminated, some other mechanism must be created to ensure safety, lest a lawless and uncontrollable trade in foreign drugs emerges. Even without formal HHS inspection of all imported drugs, the safety of the drugs could be addressed by a restructuring of the importation system or through the use of an alternate oversight agency.

The simplest solution is to allow only imports from countries with pharmaceutical regulatory systems similar to that in the United States.⁹² Canada, and the more advanced members of the

⁸⁹ 21 U.S.C. § 384(l) (2003).

⁹⁰ See MMA, Pub. L. No. 108-173, § 804, 117 Stat. 2066, 2464-65 (2003). Although the MMA revisions inserted an entirely new § 804, most of the language is identical to the prior section. It is not clear that all differences were intended to substantively change the law. For example, in the HHS Secretary's safety and efficacy voucher, the word "demonstrates" was changed to "certifies," but it does not appear to modify the essence of the requirement. See *infra* note 91 and accompanying text.

⁹¹ See Letter from HHS Secretary Tommy G. Thompson to Sen. James Jeffords (July 9, 2001), <http://www.fda.gov/oc/po/thompson/medsact.html> ("You and other Senators and Representatives asked that I reconsider former Secretary Shalala's decision and make the determination necessary to implement the MEDS Act. . . . After a thorough review of the law, FDA has concluded that it would be impossible to ensure that the MEDS Act would result in no loss of protection for the drugs supplied to the American people.").

⁹² See Robert Pinco, *Implications of FDA's Proposal to Include Foreign Marketing Experience in the Over-the-Counter Drug Review Process*, 53 FOOD & DRUG L.J. 105, 110-11 (1998) (stating that the countries in Western Europe have sophisticated drug

European Union⁹³ have a reputation of regulatory sophistication that should satisfy the safety and efficacy requirements of the United States. This argument is often presented as a counter to the pharmaceutical industry's position that imported drugs necessarily compromise safety.⁹⁴ Another solution, which could be used in combination with a controlled-country scheme, is to limit imports to large, commercial importers who can better guarantee the source of the drugs purchased overseas. Both of these ideas were addressed in a comprehensive review of the costs and benefits of drug importation recently completed by the HHS Task Force on Drug Importation.⁹⁵ The Task Force found that the safety advantages of limiting importation to certain countries with advanced regulatory systems may not be as promising as would appear, because those countries have no incentive to ensure the safety of exports.⁹⁶ This is particularly true for products that are merely "transshipped" through a foreign country, never threatening to impact the health and safety of that country's citizens.⁹⁷ On the other hand, the Task Force found that a safe commercial importation program is theoretically feasible, though it would require the commitment of significant additional resources and the revision of current statutory authority if the federal government

regulatory systems and reviewing the EU Directives that ensure regulatory continuity among member states).

⁹³ Importantly, although importation proponents often include "European Union" countries as equivalent in terms of regulatory sophistication, the recent addition of ten members to the Union has altered that landscape somewhat. See Richard Bernstein, *Change Coming Slowly for New Members of European Union*, CHI. TRIB., May 9, 2004, at 10. It may be prudent to consider the regulatory regimes of each member individually rather than for the Union as a whole.

⁹⁴ See, e.g., *Examining the Implications of Drug Importation, Hearings Before the Senate Comm. on the Judiciary*, 108th Cong. (2004) (statement of Senator Byron Dorgan) (describing importation provisions in Senate Bill S. 2328, and declaring "commercial importation by pharmacists and wholesalers could only occur from a limited number of countries—Canada, Europe, Japan, Australia, New Zealand, and Switzerland—that have drug regulatory systems comparable to our own.").

⁹⁵ DEPT. OF HEALTH AND HUMAN SERVICES, HHS TASK FORCE ON DRUG IMPORTATION, *REPORT ON PRESCRIPTION DRUG INFORMATION* (2004) [hereinafter HHS REPORT], available at <http://www.hhs.gov/importtaskforce/Report1220.pdf> (last visited Apr. 8, 2005).

⁹⁶ *Id.* at 60–61 ("[M]ost countries do not have the legal or regulatory tools available to guarantee the safety, quality, or efficacy of products exported to the U.S.").

⁹⁷ *Id.*

were to administer it effectively.⁹⁸ The Task Force determined that the economic benefits of drug importation could be quite small in comparison to these costs, potentially less than a percent of current spending.⁹⁹

In view of the Task Force's conclusions regarding the strain on current federal regulatory resources, perhaps the most provocative option involves the participation of state governments, which have the purchasing and police power of a state actor at their disposal. The entry of these players into the importation game may significantly modify the playing field. Moreover, the lack of Congressional action over recent months has spurred other governmental entities to become involved, and their proposed programs are not necessarily dependent on a change in the current federal statute.

B. Importation Proposals by Certain State or Local Governments Seek to Circumvent or Supplement Federal Legislative Action

Fighting for low priced pharmaceuticals has emerged as a popular position for both major political parties¹⁰⁰ and thus, a large number of officials at various governmental levels have offered an opinion. It is easy to argue that opening the borders to drug imports is a simple way of reducing costs without the political risk and administrative hassle of imposing U.S. price controls or some alternative new regulatory measure. In addition, it has the outward

⁹⁸ *Id.* at 41–44. The more controlled nature of a commercial importation program would allow the FDA to maintain a so-called “closed system” of drug distribution, which is essential for assuring safety. *Id.* at 41. Conversely, the Task Force concluded that permitting wide-scale personal importation was likely to lead to preclude the ability to maintain a safe drug supply. *Id.* at 44.

⁹⁹ According to the Task Force, three factors primarily reduce the likelihood of savings: (1) most of the savings is likely to be captured by commercial importers, (2) thirty percent of total drug spending is for drugs that cannot be imported, and (3) the supply of foreign drugs is limited. *Id.* at 67. Conversely, the Task Force determined that the negative impact on resources for innovation could be quite large. *Id.* at 82 (“Our analysis show that legalizing importation would adversely affect R&D of new drugs, causing future drug consumers to forego the health benefits associated with innovation.”).

¹⁰⁰ Both Republican and Democratic Senators and Representatives have expressed support for legislation to ease pharmaceutical import restrictions. *See, e.g.*, Pharmaceutical Market Access and Drug Safety Act of 2004, S. 2328, 108th Cong. (2004) (noting co-sponsors such as Trent Lott, John McCain and Edward Kennedy).

2005] *PROPERTY BARRIERS TO PHARMACEUTICAL IMPORTATION* 649

appearance of a free market solution to an unfair price discrimination scheme (though many would argue with that characterization).¹⁰¹ The state governments of Minnesota,¹⁰² Illinois,¹⁰³ Wisconsin,¹⁰⁴ Vermont,¹⁰⁵ New Hampshire,¹⁰⁶ and Iowa,¹⁰⁷ together with cities like Springfield¹⁰⁸ and Boston,

¹⁰¹ See, e.g., *Importation of Prescription Drugs, Hearings Before the Senate Comm. on Health, Education, Labor & Pensions*, 108th Cong. (2004) (statement of Prof. James Vernon):

[R]eimporting patented pharmaceuticals from outside the United States is not a free trade issue. This is a common misunderstanding. The rationale for free trade is based on the doctrine of comparative advantage: where countries specialize in the production of goods and services for which they are, comparatively speaking, low-cost producers, and then trade freely with other countries doing the same thing. . . . But pharmaceutical prices in Canada and elsewhere are lower because drug prices are regulated in those markets, and not because those countries have a comparative advantage in the production of pharmaceuticals. . . .

¹⁰² See Minn. Dep't of Human Servs., Fact Sheet, *Minnesota's Plan to Access Affordable Prescription Medicines* [hereinafter "*Minnesota Plan*"] ("In September 2003, Governor Pawlenty directed the Minnesota Department of Human Services (DHS) to review the feasibility of importing prescription medicine from Canada. Like Minnesota, Canadian provinces license and regulate pharmacies in their jurisdictions. As a result of that review, Minnesota is pursuing a three-phase approach that will allow Minnesotans to safely purchase low-cost brand name prescription medicine."), available at http://www.state.mn.us/mn/externalDocs/Rx/Rx_Fact_sheet_pdf_012804101245_Rxplanfactsheet061704.pdf (last modified June 17, 2004).

¹⁰³ See State of Ill., Fact Sheet, *The Fight for Affordable Prescription Drugs* [hereinafter "*Illinois Plan*"] ("Illinois is exploring ways to safely import less expensive Canadian drugs."), at <http://www.affordabledrugs.il.gov/factsheet.cfm> (last visited Jan. 29, 2005).

¹⁰⁴ See State of Wis., *Prescription Drug Resource Center* [hereinafter "*Wisconsin Plan*"] ("If the federal government isn't willing to take on the drug companies and fight for more affordable prices, states like Wisconsin will have to lead the way."), at <http://www.drugsavings.wi.gov> (last visited Jan. 29, 2005).

¹⁰⁵ See Vt. Dep't of Pers., *Tackling the Prescription Drug Crisis*, at <http://vermontpersonnel.org/htm/prescription.php> (last updated Sept. 3, 2004) [hereinafter "*Vermont Plan*"] ("[T]he State of Vermont petitioned the FDA to approve a pilot program of importation and State of Vermont officials continue to advocate for a change in the position taken by the federal government.").

¹⁰⁶ See Christopher Rowland, *N.H. to Obtain Drugs via Canada*, BOSTON GLOBE, Dec. 10, 2003, at A1 ("New Hampshire will set up a program to import prescription drugs from Canada . . . to reduce state prescription drug costs even if it means defying the Food and Drug Administration.").

¹⁰⁷ See Press Release, Office of the Governor, State of Iowa, *Vilsack Says Iowa Could Save Millions Purchasing Prescription Drugs from Canada* (Nov. 7, 2003), available at http://www.governor.state.ia.us/news/2003/november/november0703_1.html; Ceci

Massachusetts,¹⁰⁹ Montgomery, Alabama,¹¹⁰ and Los Angeles, California,¹¹¹ have proposed drug import plans.

In what is perhaps a reflection of the ambiguity regarding the legality of drug imports, several of these government entities have taken only the tentative step of establishing Internet “portals” to Canadian pharmacy websites.¹¹² These initiatives are promoted primarily as an information dissemination program, allowing consumers to make the ultimate choice in purchasing their drugs.¹¹³ Additionally, some states that have proposed much more

Connolly, *Iowa Plans to Procure Drugs from Canada; State Joins Growing Group Seeking Cheaper Medicines Outside U.S.*, WASH. POST., Sept. 24, 2003, at A2.

¹⁰⁸ See Ceci Connolly, *Drug Reimportation Plan Saves City \$2.5 Million; Apparent Success in Massachusetts Is Still a Fight in Washington*, WASH. POST., July 15, 2004, at A3 (“Thanks to the Landrys and 3,200 other city workers who have opted to order their prescription drugs from a licensed Canadian pharmacy, deficit-plagued Springfield has saved \$2.5 million in the year since it became the first city in the nation to sponsor such a program.”).

¹⁰⁹ See Christopher Rowland, *City Launches Program to Buy Imported Drugs*, BOSTON GLOBE, Jul. 22, 2004, at A1 (“While the program is open to 14,000 people, city officials expect only a small fraction to participate because the incentive is small. The city is waiving copayments for the Canadian option, but it is keeping copayments for domestic orders at a relatively low \$10. Savings for an individual would amount to just \$40 a year over a domestic drug received through the mail.”).

¹¹⁰ See Cameron W. Barr, *Montgomery Drug Plan Has Support Despite FDA*, WASH. POST., Jul. 28, 2004, at B1 (“A majority of the Montgomery County Council is on record supporting a program that would probably involve importing lower-cost prescription drugs from Canada for county employees and retirees.”).

¹¹¹ See Lisa Rapaport, *City Council Plan Would Buy Prescription Drugs for Los Angeles Residents*, KNIGHT RIDDER TRIB. BUS. NEWS, Mar. 19, 2004, at 1.

¹¹² See, e.g., State of New Hampshire, *New Hampshire's Medicine Cabinet* (discussing various options for obtaining cheaper drugs including importation from Canada, and containing a link to the Canadian Internet pharmacy, CanadaDrugs.com), available at <http://www.egov.nh.gov/medicine%2Dcabinet/default.asp> (last visited Apr. 8, 2005). It is worth noting that state drug importation websites often include disclaimers disclaiming liability “with respect to any product offered, or pharmaceutical care provided, by the pharmacies listed on this website.” See, e.g., State of Minn., *Minnesota RxConnect Online*, Legal Information, at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/content.do?programid=536902438&agency=Rx> (last visited Apr. 8, 2005).

¹¹³ See, e.g., *Wisconsin Plan*, *supra* note 95 (“The goal is to let consumers make an informed choice among all of the available options—including local pharmacies, lower price generics available domestically, and safe Canadian pharmacies.”).

involved import plans view the establishment of an Internet portal as a first stage.¹¹⁴

A somewhat more powerful category of initiatives includes those programs that would alter the current system for health care reimbursements to provide a preference for lower-priced, imported drugs.¹¹⁵ This is not unlike the cost-control design of many European health care systems.¹¹⁶ However, state reimbursement control is likely to have a limited impact due to the relatively small percentage of the population served by such programs.¹¹⁷

The most aggressive programs actually envision government importation of pharmaceuticals for their citizens.¹¹⁸ In essence, the government entity would act as a pharmaceutical wholesaler, directly selling drugs that are priced at, or only marginally above, the discounted foreign purchase prices. A primary advantage of this mechanism is the ability of a state government to utilize its own health inspection services, such as a state pharmacy board, to investigate not only the quality of the drugs being imported, but also the facilities in which they are manufactured and packaged.¹¹⁹

¹¹⁴ See, e.g., *Minnesota Plan*, *supra* note 93 (explaining Minnesota's three-phase importation plan beginning with a Web portal).

¹¹⁵ See, e.g., *City of Boston Meds By Mail*, at <http://www.cityofboston.gov/publichealth/medsbymail.asp> (last visited Feb. 9, 2005) ("People who use this program will pay no co-payment for the medicines from this service. Right now, the program is available only to employees and retirees enrolled in the Blue Cross Blue Shield health plans.").

¹¹⁶ See *supra* notes 50–53 and accompanying text.

¹¹⁷ See Rowland, *supra* note 109.

¹¹⁸ See *Minnesota Plan*, *supra* note 102 ("State officials are working with the Minnesota congressional delegation to acquire statutory authority to allow Minnesota to import medicine after establishing a reasonable system that provides for the safety of Minnesota citizens.").

¹¹⁹ *Id.* An example of the use of state resources in this fashion is the State of Minnesota's recent inspection of Canadian pharmaceutical facilities in support of that state's own importation initiatives. See *Prescription Drug Importation; Among Pharmacy Complaints in Minnesota, None Are About Canadian Imports*, *DRUG WK.*, Apr. 16, 2004, at 309 ("Among the problems, their report found that some Canadian pharmacies do not take complete patient medical histories, do not ask whether patients have had allergic drug reactions in the past, and do not use child-resistant safety caps on drug containers."); Letter from William Hubbard, Assoc. Comm'r of Pol'y and Plan., FDA, to Minn. Gov. Tim Pawlenty (May 24, 2004) ("While I understand that Minnesota sent inspectors on pre-announced visits to Canada to 'inspect' the Canadian pharmacies that would dispense these drugs, it has become apparent that your inspectors found numerous deficiencies in those pharmacies, refused to certify the vast majority, and had doubts even about the few

One of the most advanced initiatives to date is the I-SaveRx program developed by the State of Illinois.¹²⁰ The program permits residents of member states to obtain discount refills of more than one hundred different drugs imported from Canada, the United Kingdom, and Ireland.¹²¹ According to the program website, it “operates under a stringent system of quality controls,” uses pharmacies that “are inspected and approved by state regulatory agencies,” and assures its participants that “pharmacies [used by the program] in other countries follow the same standards and procedures used by Illinois pharmacies.”¹²² In addition to Illinois, the states of Wisconsin, Kansas, Missouri, and Vermont have agreed to the program.¹²³

Despite the advantages in terms of safety and impact, state involvement in pharmaceutical importation raises a broad range of problems—foremost is the risk that a state could face tort liability for the resale of dangerous or defective drugs.¹²⁴ Opponents of state importation programs argue that the costs from future litigation settlements and judgments will offset many gains in cost savings for state treasuries.¹²⁵ The likelihood of incurring liability

that you ultimately accepted for your Minnesota RxConnect program.”), at <http://www.fda.gov/importeddrugs/pawlenty0524.html>.

¹²⁰ See I-SaveRx, About I-SaveRx, at <http://www.i-saverx.net/> (last visited Apr. 8, 2005).

¹²¹ See I-SaveRx, Frequently Asked Questions: General Questions, at <http://www.i-saverx.net/general.htm> (last visited Apr. 8, 2005).

¹²² *Id.*

¹²³ See I-SaveRx, About I-SaveRx, at <http://www.i-saverx.net/> (last visited Apr. 8, 2005).

¹²⁴ See, e.g., HHS REPORT, *supra* note 95, at 107–08 (reviewing the potential for states and municipalities to face liability for drug importation, assuming the waiver of sovereign immunity for such suits); Gloria Gonzalez, *Governments’ Immunity to Drug Injury Lawsuits Questioned*, BUS. INS., Jun. 14, 2004, at 10.

¹²⁵ See Ctr. for Individual Freedom, *Importing Liability*, at http://www.cfif.org/htdocs/legislative_issues/state_issues/drug_importation.htm (Apr. 22, 2004) (“With the average American filling 10 prescriptions per year and the last U.S. Census counting Wisconsin’s population at more than 5 million, liability awards will swiftly wipe out any anticipated ‘savings,’ leaving taxpayers digging deep in their pockets to pay for more drug-induced claims.”).

may be enhanced because unauthorized pharmaceutical imports violate federal laws meant to ensure drug safety and efficacy.¹²⁶

Throughout this extensive drug import dialog, with respective camps debating issues like drug safety and accessibility, hardly a word has been uttered regarding the property rights of the companies producing the drugs.¹²⁷ Perhaps the lack of conversation is partly because the American public is unlikely to sympathize with the patent owner. However, even those who try to anticipate the pharmaceutical companies' efforts to thwart importation almost never mention patents.¹²⁸ It appears that the very idea that an intellectual property right could stand in the way of a health care crisis remedy is difficult to conceive.¹²⁹ That patents should be accorded the blockade powers of tangible property seems somehow novel.

In contrast, the relevant law indicates that the intellectual property rights at play in the import debate are quite powerful, as well as complex. This is especially true if the full property protections mandated by the U.S. Constitution are applied. An analysis of precisely what property rights exist and how they will affect the various parties who may be involved in drug imports is necessary as a predicate to predictions on the future of property recognition.

¹²⁶ See Gonzalez, *supra* note 124 (“Legal experts, though, say the liability protection the governments are counting on may not withstand legal challenges, because reimportation is illegal.”).

¹²⁷ *But see* HHS REPORT, *supra* note 95, at 92–95 (providing a broad overview of intellectual property obstacles to importation, though with little substantive analysis).

¹²⁸ For example, although pharmaceutical importation has been a legislative issue since at least the MEDS Act (*see supra* notes 85–89 and accompanying text), it was not until 2004 that a bill was introduced that addressed the patent issues involved in importation (*see infra* notes 378–81).

¹²⁹ See, e.g., Cahoy, *supra* note 7, at 125–28 (describing the public outrage upon finding that a patent right could indeed restrict access to a drug needed during a health care crisis).

III. PROPERTY BARRIERS TO IMPORTING PHARMACEUTICALS WITHOUT AUTHORIZATION OF THE PATENT OWNER

Each type of intellectual property has associated with it a slightly different set of exclusions; to know whether a property right's borders have been transgressed requires an appreciation of these specific characteristics.¹³⁰ In the case of U.S. patents, one who without authorization makes, uses, sells, offers to sell, or imports into this country the invention covered by the patent is deemed an infringer.¹³¹ This is quite far-reaching. If a pharmaceutical company owns a patent that covers the basic composition of a drug or its primary medical use, it may essentially prevent others from doing anything with the compound that would undercut the company's limited period of exclusivity.¹³² Because there is essentially no "fair use" defense in patent law, the right extends to activities that are seemingly not in direct conflict with the patent holder's pecuniary interests, such as academic research.¹³³ A so-called "research exemption" exists for those in

¹³⁰ This can be better understood if one imagines an object covered by patent, copyright, and trademark protection. One infringes the patent if, without authorization, one "uses" the invention embodied in the object (*see* 35 U.S.C. § 271(a) (2003)), but infringes the copyright only if the use constitutes a public performance or display (*see* 17 U.S.C. § 106 (2003)) of copyrighted expression, and infringes the trademark only if the use of a mark creates a likelihood of confusion or dilutes the owner's mark (*see* 15 U.S.C. §§ 1114, 1125 (2003)). One act may infringe all three, some, or none of the rights.

¹³¹ *See* 35 U.S.C. § 271(a) (2000).

¹³² *See, e.g.,* John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 449–53 (1997) (noting that broad patents are common in fields like biotechnology, but arguing that the "follow-on" innovator must be protected). It has been noted that there is an economic rationale for allowing a patentee to exclude a field of subsequent innovation with a strong initial patent right. *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 871 (1990) (describing Edmund Kitch's "prospect theory" of patent rights).

¹³³ In the context of patents, the closest equivalent to "fair use" is experimental use, which has been so narrowly construed as to be essentially hypothetical. *See* *Madey v. Duke Univ.*, 307 F.3d 1351, 1361–62 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003) (finding that Duke University's use of a patented laser for academic research did not qualify because "regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.").

the process of submitting applications to a U.S. regulatory agency (such as an ANDA),¹³⁴ but it is extremely narrow.

While this would seem to confer oppressively far-reaching power on those who own patents, there is an important limitation that curbs such control. After a patent owner has made an unconditioned sale¹³⁵ of an article covered by the patent right, the patentee's power over that article is deemed "exhausted."¹³⁶ In particular, the purchaser cannot be restrained in his or her use or disposal of that particular article (unless substantial reconstruction would have the effect of creating a new article).¹³⁷ The idea is that a patent owner has received compensation for the rights attached to the article as a consequence of the sale, and allowing the patentee to tax continued use would constitute double compensation.¹³⁸ Although a straightforward reading of the patent statute makes no reference to the exhaustion doctrine, it is well established in

¹³⁴ See 35 U.S.C. § 271(e)(1) (2003); *Apotex v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003) ("The Act permitted a company wishing to develop a generic version of an approved drug to manufacture and use the drug for development purposes without infringing any patent claiming the approved drug.").

¹³⁵ The sale of a patented article with certain conditions may transform the sale into a license, eliminating the application of the exhaustion doctrine. See Daniel R. Cahoy, *Oasis or Mirage: Efficient Breach as a Relief to the Burden of Patent and Copyright Limitations*, 17 HARV. J.L. & TECH. 135, 155 (2003) (noting that even a label placed on an article may be sufficient to create a patent license) (citing *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708–09 (Fed. Cir. 1992)).

¹³⁶ See, e.g., *United States v. Univis Lens Co.*, 316 U.S. 241, 250 (1942) ("[S]ale of [a patented article] exhausts the monopoly in that article and the patentee may not thereafter, by virtue of his patent, control the use or disposition of the article."); *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) ("The law is well settled that an authorized sale of a patented product places that product beyond the reach of the patent.").

¹³⁷ See *FMC Corp. v. Up-Right, Inc.*, 21 F.3d 1073, 1077 (Fed. Cir. 1994).

¹³⁸ See Margreth Barrett, *The United States' Doctrine of Exhaustion: Parallel Imports of Patented Goods*, 27 N. KY. L. REV. 911, 913–14 (2000). Subsequent sales are presumed to be outside of the inventor's view. *Id.* at 913.

common law patent jurisprudence¹³⁹ and is reflected in the law related to other intellectual property rights.¹⁴⁰

The application of the patent exhaustion principle in the world of pharmaceuticals is relatively clear: once a drug covered by one or more patents is sold, the pharmaceutical company has no power to limit further use or resale of that drug by the purchaser. The purchaser of a bottle of pills, for example, should be able to use or dispose of them without an accounting to the patent owner (so long as no other state or federal laws are violated). This would seem to resolve the conflict of patent rights and importation. Unfortunately, this description is incomplete. The concept of exhaustion depends upon an authorized sale under the patent owner's rights, and in the global context, it is difficult to determine the appropriate borders for that right. Surprisingly, the situation has not become much clearer in recent years. Indeed, the limitations of patent exhaustion are one of the most contentious issues for the international legal community to solve, due in no small part to the effect on the pharmaceutical market.

¹³⁹ *Bloomer v. Millinger*, 68 U.S. 340, 350 (1864) (“[W]hen a patentee has himself constructed the machine and sold it, or authorized another to construct and sell it, or to construct and use and operate it, and the consideration has been paid to him for the right, he has then to that extent parted with his monopoly, and ceased to have any interest whatever in the machine so sold or so authorized to be constructed and operated.”); *Bloomer v. McQuewan*, 55 U.S. 539 (1852); *Wilson v. Rousseau*, 45 U.S. 646 (1846).

¹⁴⁰ Specifically, the exhaustion doctrine also restrains the power of copyright and trademark owners. It is more commonly referred to as the “first sale doctrine” in those contexts, but its operation is essentially the same. The sale of an item containing copyrighted material conveys to the item's new owner the right to sell or destroy it, and a somewhat more limited right to use it. *See* 17 U.S.C. § 109(a) (2000); *Quality King Distribs., Inc. v. L'Anza*, 523 U.S. 135, 150–51 (1998) (finding that a provision giving copyright owners exclusive rights over the importation of copyrighted goods is subject to the limitations in § 109(a)). Similarly, the authorized sale of an item bearing the trademark of another prevents the trademark owner from restricting the subsequent use or sale of the item. *See, e.g., Davidoff & CIE, S.A. v. PLD Int'l Corp.*, 263 F.3d 1297, 1301–02 (11th Cir. 2001); *Iberia Foods Corp. v. Romeo*, 150 F.3d 298, 303 n.4 (3d Cir. 1998); *Enesco Corp. v. Price/Costco Inc.*, 146 F.3d 1083, 1085 (9th Cir. 1998). In the case of copyright law, the first sale doctrine is expressly written into the Copyright Act. 17 U.S.C. § 109(a) (2000).

A. *The United States' Refusal to Recognize an International Exhaustion Rule*

The issue of intellectual property exhaustion for sales *within* a sovereign nation is, for the most part, well settled; a rule similar to that in the United States is almost uniformly applied among the industrialized nations.¹⁴¹ However, there are differences with regard to the treatment of sales that take place outside of the country in question,¹⁴² particularly in the case of patent rights. While many countries apply a blanket exhaustion rule that encompasses all sales, regardless of the locale, the U.S. is far from alone in distinguishing between national and international exhaustion.¹⁴³ Some countries even apply a hybrid rule, which recognizes exhaustion for sales within a particular group of countries, but not internationally.¹⁴⁴ Interestingly, while

¹⁴¹ See, e.g., Erlikhman, *supra* note 10, at 323–31 (reviewing the patent exhaustion rules of the U.S., Japan, and the EU, and showing that all have at least a national or regional exhaustion policy).

¹⁴² Is there a difference if the first sale is made in the United States to an exporter for sale in another country? A distinction may exist if the exporter is bound by express contract to sell outside the United States. In that case, U.S. rights would not be exhausted by the sale. See, e.g., *Ariz. Cartridge Remanufactures Ass'n v. Lexmark Int'l Inc.*, 290 F. Supp. 2d 1034, 1043 (N.D. Cal. 2003) (“In the case of a conditional sale, the purchaser does not receive the same implied license that the purchaser in an unconditional sale receives. Thus, where the purchaser of an unconditional sale has every right to repair the device, the purchaser of a conditional sale does not.”); *Monsanto Co. v. Scruggs*, 249 F. Supp. 2d 746, 753 (N.D. Miss. 2001) (“The exhaustion doctrine only applies where the sale or license of the patented invention is an unconditional one.”).

¹⁴³ See Int'l Ass'n for the Prot. of Intell. Prop. (“AIPPI”), *International Exhaustion of Industrial Property Rights*, Summary Report, Question Q 156 (Mar. 23–30, 2001) [hereinafter “AIPPI Report”] (“The following states do not apply a rule of international exhaustion of patents: Australia, Belgium, Brazil, Bulgaria, Czech Republic, Denmark, Egypt, Finland, France, Germany, Hungary, Italy, Japan, Korea, Mexico, the Netherlands, Paraguay, Portugal, Republic of Korea, Romania, Spain, Sweden, the United Kingdom, United States and Yugoslavia. In contrast, Argentina, Canada, Singapore and Venezuela do apply a rule of international exhaustion to patents.”), available at <http://www.aippi.org/reports/q156/q156-Summary-e.htm>; see also Darren E. Donnelly, Comment, *Parallel Trade and International Harmonization of the Exhaustion of Rights Doctrine*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 445, 468–84 (1997).

¹⁴⁴ See AIPPI Report, *supra* note 143 (“Some groups [representing member states] described regional Exhaustion of Patents within the EEA, following the decisions of the ECJ in *Centrapharm v Sterling Drug* (C-15/74, 31 October 1974) and *Merck v Stephar* (C-187/80, 14 July 1981), as occurring when a product covered by a patent is marketed within the EEA by the patent owner or with consent.”).

harmonization of such disparate intellectual property rules has been a primary goal of several international treaties, intellectual property exhaustion has so far eluded consensus treatment. In fact, the relatively recent and comprehensive treaty known as Trade-Related aspects of Intellectual Property agreement (“TRIPS”) expressly states that it does *not* address intellectual property exhaustion, leaving the issue for individual countries to resolve.¹⁴⁵ Similarly, regional treaties, such as the North American Free Trade Agreement (“NAFTA”) also tend to skirt the issue,¹⁴⁶ even though one would think the opportunities for consensus are greater when only two or three parties are negotiating. One exception is the recent U.S.-Australia Free Trade Agreement (“UAFTA”) which contains an exhaustion provision, but it may be limited to contractual restrictions.¹⁴⁷ Today, there is no evidence that the international community is any closer to agreement on this issue. Thus, a patchwork of exhaustion rules exists across the globe.

The international exhaustion paradigm is typified by the Canadian scheme, which covers all intellectual property rights in that country.¹⁴⁸ Because Canada is a common law country, its exhaustion rule is based largely in the decisions of its courts, but the effect is the same as if enacted by statute.¹⁴⁹ If a product

¹⁴⁵ See TRIPS Agreement, *supra* note 44, art. 6 (“[N]othing in [TRIPS] shall be used to address the issue of the exhaustion of intellectual property rights.”).

¹⁴⁶ Lans Noah, *NAFTA’s Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293, 1303 (1997).

¹⁴⁷ See U.S.-Australian Free Trade Agreement, May 18, 2004, Art. 17.9, ¶ 4 (“[T]he exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.”), available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/asset_upload_file148_5168.pdf (last visited Apr. 8, 2005). The phrase “at least” may have been added to permit each country to adopt an international exhaustion rule that could be limited by contract. See *infra* note 149–151 and accompanying text.

¹⁴⁸ See *International Exhaustion of Industrial Property Rights*, Canadian Group Report, Report Q 156 [hereinafter *Canadian Report*], available at <http://www.aippi.org/reports/q156/gr-q156-Canada-e.htm> (last visited Feb. 10, 2005); Erlikhman, *supra* note 9, at 337–38.

¹⁴⁹ *Canadian Report*, *supra* note 148, at 48 (“The question of international exhaustion of I.P. Rights is, with the exception of an express provision in the Canadian *Copyright Act*, one which has not been addressed in any of the I.P. legislation in Canada to date and, accordingly, it has been left to the Canadian courts to seek to develop a body of law

covered by an intellectual property right, including a patent, is sold or produced in a foreign country under authorization of the intellectual property owner, the right to control the product by virtue of the property right disappears.¹⁵⁰ However, it may be possible for an intellectual property owner to retain some rights if the foreign sale is restricted by explicit contract (and the importer is aware of the contract).¹⁵¹ This rather liberal rule creates a presumption of exhaustion, and is the approach most favored by developing nations.¹⁵²

Members of the European Economic Area (“EEA”),¹⁵³ on the other hand, are obligated to apply a regional exhaustion rule that pertains to sales within the member states.¹⁵⁴ Countries that would otherwise have no international exhaustion rule will treat sales within the EEA as if they occurred within the member state, regardless of whether the intellectual property owner consented to EEA-wide marketing.¹⁵⁵ Interestingly, proposed European

based in part on the jurisprudence in other common law countries such as the United Kingdom.”).

¹⁵⁰ *Id.* at 49–50.

¹⁵¹ *Id.* at 51.

¹⁵² See Catalin Cosovanu, *Piracy, Price Discrimination, and Development: The Software Sector in Eastern Europe and Other Emerging Markets*, 31 *AIPLA Q. J.* 165, 197 n.104 (2003) (“Moreover, developing countries have generally favored international exhaustion, while developed countries have been mostly on the side of territorial (i.e., either national or regional, e.g., European Union wide) exhaustion.”).

¹⁵³ The EEA consists of members of the European Union plus other European nations that wish to have the economic benefits of EU membership without all of the responsibilities. See Agreement on the European Economic Area, May 2, 1992, 1994 O.J. (L 1) 3 [hereinafter EEA Agreement]; see also European Commission, *European Economic Area: Overview*, at http://europa.eu.int/comm/external_relations/eea (last updated Oct. 2004).

¹⁵⁴ See Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, COM(2003)839 final at 10 (“[T]he owner of an industrial and commercial property right protected by Member State legislation may not rely on that legislation to oppose the importation of a product which has been lawfully placed on the market in another Member State by, or with the consent of, the proprietor of that right. The right is considered to have been exhausted once the product has been put on the market somewhere in the Community.”), available at http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2003/com2003_08-39en01.pdf.

¹⁵⁵ See *International Exhaustion of Industrial Property Rights*, French Group Report, Report Q 156 [hereinafter *French Report*], available at <http://www.aippi.org/reports-q156/gr-q156-France-f.htm> (last visited Feb. 10, 2005) (noting that France has no

Community legislation actually appears to take a position against a broader international exhaustion rule.¹⁵⁶ The community exhaustion rule could be suspended by a licensee's breach of a restrictive personal contract (so long as the contract complies with applicable competition rules). However, absent a specific restriction, exhaustion within the EEA is presumed.

While the United States is in line with proponents of international exhaustion in its legal scheme for copyright and trademark rights, it is truly on the other end of the spectrum in its treatment of patent rights. As with Canada, U.S. patent rules are a consequence of a series of common law decisions rather than an explicit statutory structure. The leading case is actually the 1890 Supreme Court decision in *Boesch v. Graff*.¹⁵⁷ It concerned Boesch's alleged infringement of Graff's U.S. patent on an improved lamp burner by importing infringing burners from Germany.¹⁵⁸ Boesch was authorized to manufacture and sell the burners in Germany, but the U.S. patent owners (who were assignees of the party that originally owned both the U.S. and German rights) had not given Boesch permission to import the burners.¹⁵⁹ The Supreme Court determined that a sale authorized under foreign law had no bearing on the rights of a U.S. patent owner.¹⁶⁰ The importation was deemed infringing.¹⁶¹

While the *Boesch* decision may seem ancient in the context of modern intellectual property law, as well as arguably distinguishable from many of the scenarios likely to occur in pharmaceutical imports, no other Supreme Court case has touched so specifically on the exhaustion issue. A smattering of non-

international exhaustion rule, but does practice regional exhaustion as a member of the EEA).

¹⁵⁶ See, e.g., Commission on the European Communities, *Amended proposal for a European Parliament and Council Directive approximating the legal arrangements for the protection of inventions by utility model*, 2000 O.J. (C 248 E) 56, 66 ("The rights conferred by a utility model shall, however, extend to acts concerning a product covered by that utility model which are done after that product has been put on the market outside the Community by the right-holder or with his consent.").

¹⁵⁷ 133 U.S. 697 (1890).

¹⁵⁸ *Id.* at 701-02.

¹⁵⁹ *Id.* at 702.

¹⁶⁰ *Id.* at 702-03.

¹⁶¹ *Id.* at 709.

precedential¹⁶² lower court cases have addressed the issue, either in accord with *Boesch* or distinguishing it on technical grounds,¹⁶³ but those rulings were neither disputed nor affirmed at a national level.¹⁶⁴ However, in 2001, the U.S. Court of Appeals for the Federal Circuit, the court authorized to hear all patent appeals and responsible for articulating national patent rules, decided a case that brought the scope of patent exhaustion back into the spotlight.¹⁶⁵

In *Jazz Photo v. International Trade Commission*,¹⁶⁶ the Federal Circuit was primarily concerned with whether patents owned by Fuji Photo Film Co. covered the concept of single use cameras, and whether these patents were infringed by Jazz Photo's refurbishment and resale of legally purchased Fuji cameras.¹⁶⁷ Since most of the cameras had been purchased in the U.S., the patent rights were exhausted except to the extent that Jazz Photo's refurbishment constituted impermissible reconstruction of the

¹⁶² When the Federal Circuit became the sole circuit to which one can appeal cases arising under U.S. patent laws, it adopted as its precedent only the case law of the U.S. Court of Claims and the Court of Customs and Patent Appeals announced before September 30, 1982. *See* *South Corp. v. United States*, 690 F.2d 1368, 1370 & n.2 (Fed. Cir. 1982). Thus, the weight of existing patent decisions from all other circuit courts was instantly reduced to merely persuasive. *See generally id.* at 1371 (“[N]o body of law established by any other court [other than the predecessor courts] would appear a suitable candidate for adoption.”).

¹⁶³ *See, e.g.,* *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp.*, 266 F. 71, 79–80 (2d Cir. 1920) (finding that airplanes manufactured under patent license in Britain and imported into the United States did not infringe); *Griffin v. Keystone Mushroom Farm, Inc.*, 453 F. Supp. 1283, 1285–87 (E.D. Pa. 1978) (sale of patented composting machines in Italy did not exhaust the U.S. patent); *Sanofi, S.A. v. Med-Tech Veterinarian Prods., Inc.*, 565 F. Supp. 931, 940–41 (D.N.J. 1983) (finding that the foreign sale of chemical compounds by the patent owner did not exhaust the U.S. patent right where that right was the subject of an exclusive license to another).

¹⁶⁴ *See* 7 DONALD S. CHISUM, *PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT* § 16.03[2][a][iv] (2001) (noting that “In the United States, the issue has arisen often with regard to trademark and copyright but relatively rarely with regard to patents.”).

¹⁶⁵ The Federal Circuit is the only circuit court empowered to hear cases arising under U.S. patent laws. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982).

¹⁶⁶ 264 F.3d 1094 (Fed. Cir. 2001), *cert. denied*, 536 U.S. 950 (2002).

¹⁶⁷ *Id.* at 1098–99. The ITC is a named defendant because the case involved Fuji's request that the agency restrict importation of Jazz Photo's refurbished cameras under 19 U.S.C. § 1337 (2000).

patented device.¹⁶⁸ Making this assessment consumed most of the court's opinion. However, in a short but powerful passage, the court noted that Jazz Photo purchased some of the cameras at issue outside of the United States, and found that these would infringe regardless of whether reconstruction took place:

United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent. See *Boesch v. Graff*, 133 U.S. 697, 701-703 (1890) (a lawful foreign purchase does not obviate the need for license from the United States patentee before importation into and sale in the United States). Our decision applies only to LFFPs for which the United States patent right has been exhausted by first sale in the United States. Imported LFFPs of solely foreign provenance are not immunized from infringement of United States patents by the nature of their refurbishment.¹⁶⁹

By invoking such a broad articulation of the exhaustion rule, the court essentially foreclosed the argument that an overseas sale of a product under authority of the owner of U.S. patent rights could be re-imported without running afoul of the U.S. patent.¹⁷⁰

Some immediately proclaimed the decision in *Jazz Photo* to be an aberration and a fundamental misinterpretation of existing precedent.¹⁷¹ Others argued that the decision was contrary to the principle underlying the exhaustion rule and bad public policy as well, particularly in view of its negative effect on pharmaceutical importation.¹⁷² But there are also important economic and public

¹⁶⁸ *Id.* at 1105.

¹⁶⁹ *Id.* at 1105.

¹⁷⁰ *See id.*

¹⁷¹ *See* Erlichman, *supra* note 10, at 337.

¹⁷² *See* James Love & Sean Flynn, *Legal and Policy Issues Concerning Parallel Trade (aka Re-Importation) of Pharmaceutical Drugs in the United States* 1 (Mar. 31, 2004) (discussing the decision and stating "To authorize parallel importation of medicines, legislation should make it clear that U.S. patent rights are exhausted by the first sale of the patented product by the patent owner, or by a party who is authorized to use the patent. Specifically, it needs to be clear that the United States has elected the rule of

policy reasons in support of the decision. For example, it could be demonstrated that a national exhaustion rule would permit more efficient pharmaceutical pricing through international price discrimination.¹⁷³ Additionally, given that exhaustion is premised on the idea that a patent owner is due payment for the use of the right only once, the fact that the “right” may be different from country to country (or even non-existent in some cases)¹⁷⁴ is important.¹⁷⁵ It is illogical to eliminate a right in one country based on a payment for a qualitatively different right in another country, particularly in view of the fact that such rights must be individually secured from each sovereign nation.¹⁷⁶ Deciding whether *Jazz Photo* articulates the best rule clearly depends on one’s perspective.

An intriguing aspect of Judge Newman’s opinion in *Jazz Photo* is that she articulated the national exhaustion rule with such brevity. One could be forgiven for wondering if the powerful effect attributed to that one sentence in her opinion has been inflated or simply misinterpreted. Fortunately, the Federal Circuit took the opportunity to revisit the issue four years later in an appeal of a subsequent matter in the same case. In *Fuji Photo Film Co. v. Jazz Photo Corp.*,¹⁷⁷ the defendant specifically requested that the Federal Circuit consider whether the earlier opinion

international exhaustion of patent rights.”), at <http://www.cptech.org/ip/fsd/love03312004.pdf> (last visited Jan. 12, 2005); Erlichman, *supra* note 10, at 337.

¹⁷³ See Danzon & Towse, *supra* note 53, at 201–02 (concluding that price differentiation “would go a long way towards making drugs that are developed for high income countries available and affordable in [developing countries], while preserving incentives for R&D”).

¹⁷⁴ For example, the scope of business methods patentable in the United States is much greater than in countries of the European Union. See Keith Maskus & Eina Wong, *Searching for Economic Balance in Business Method Patents*, 8 WASH. U. J.L. & POL’Y 289, 302–303 (2002) (noting the difficulties in comparing the economic effects of business method patents across countries due to the differences in protection accorded).

¹⁷⁵ See John R. Thomas, *Patents and Drug Importation*, CONG. RES. SERV. REPT. RL32400 at 7–8 (May 2004). Although agreements like TRIPs set a baseline for patent rights, there is no “international patent,” and subtle differences exist between each country’s national patent laws.

¹⁷⁶ See MARTIN ADELMAN ET AL., *CASES AND MATERIALS ON PATENT LAW* 813 (1998).

¹⁷⁷ 394 F.3d 1368 (Fed. Cir. 2005).

limited exhaustion to unauthorized foreign sales.¹⁷⁸ The court determined that the rule was not so limited:

The patentee's authorization of an international first sale does not affect exhaustion of that patentee's rights in the United States. . . . Moreover, Fuji's foreign sales can never occur under a United States patent because the United States patent system does not provide for extraterritorial effect. . . . In *Jazz*, therefore, this court expressly limited first sales under the exhaustion doctrine to those occurring within the United States.¹⁷⁹

Given the fact that the 2001 *Jazz Photo* decision was denied certiorari,¹⁸⁰ it is not clear that the 2005 decision, which is at most a clarification of the earlier stated exhaustion principle, is subject to Supreme Court review or *en banc* reconsideration by the Federal Circuit.¹⁸¹ Unless another case arises that provides an opportunity to revisit the issue, it appears to be unambiguously the law in the United States that foreign sales will not exhaust U.S. patent rights. Therefore, unauthorized importation of goods covered by U.S. patents creates significant liability for all who participate.

B. A Patentee's Success Using the Traditional Infringement Litigation Depends on the Defendant

Pharmaceutical companies are experienced at pursuing alleged infringers in federal court.¹⁸² The civil patent infringement system has the benefit of being relatively established through abundant case law,¹⁸³ and predictable due to the existence of a single federal

¹⁷⁸ *Id.* at 1376.

¹⁷⁹ *Id.*

¹⁸⁰ *Jazz Photo Corp. v. Int'l Trade Comm'n*, 536 U.S. 950 (2002).

¹⁸¹ The author of the 2005 opinion, Judge Rader, noted his desire to have the original decision heard *en banc*. See *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094, 1094 n.* (Fed. Cir. 2001). Now that six judges of the twelve-judge Federal Circuit have joined in stating a national exhaustion rule, it is unlikely that an *en banc* review would change the decision in any case.

¹⁸² See Jean O. Lanjouw & Mark Schankerman, *Characteristics of Patent Litigation: A Window on Competition*, 32 RAND J. ECON. 129 (2001) (finding that "drug" patent owners are more likely to engage in litigation than owners of patents in other fields).

¹⁸³ See ADMIN. OFF. OF THE U.S. CTS., JUDICIAL FACTS AND FIGURES Tbl. 2.2 (Mar. 2003) (noting that there were 2814 patent cases filed in the U.S. district courts in 2003),

appeals court.¹⁸⁴ Many believe that patent owners have an unfair advantage in the current litigation climate,¹⁸⁵ but others have found that empirical evidence does not support that notion.¹⁸⁶ In any case, the complexity and expense of patent litigation alone can be enough to dissuade potential infringers.¹⁸⁷

Considering the current legal environment with regard to exhaustion, it is clear that individuals who import pharmaceuticals face patent infringement liability. One who imports a drug that was first sold overseas and is covered by composition and/or formulation patents would infringe both the patent owner's sale and import rights.¹⁸⁸ Additionally, if a drug is manufactured using a patented process, the importer is liable for infringement under a separate provision of the Patent Act, even if the resulting composition or formulation is not protected.¹⁸⁹ However, it is unlikely that pharmaceutical companies will undertake the political risk and financial burden of pursuing patent infringement lawsuits against individual importers. Large private businesses that engage in importation present a more tempting target, and could be pursued by private litigants much as the federal government pursues these companies for violating FDA regulations,¹⁹⁰ though it is unclear to what extent this brand of infringement is likely to

available at <http://www.uscourts.gov/judicialfactsfigures/table2.02.pdf> (last visited Jan. 12, 2005).

¹⁸⁴ See *supra* note 165.

¹⁸⁵ See Hon. Richard Lin, *The Future Role for the United States Court of Appeals for the Federal Circuit Now that it Has Turned 21*, 53 AM. U. L. REV. 731, 732 (2004) (noting the development of a general perception that the Federal Circuit was pro-patent).

¹⁸⁶ See Donald R. Dunner et al., *A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994*, 5 FED. CIR. B.J. 151, 152 (1995); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 187 (1998).

¹⁸⁷ Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1502 (2001) (stating that "the median cost of patent litigation to each side is \$799,000 through the end of discovery, and \$1,503,000 through trial and appeal").

¹⁸⁸ 35 U.S.C. § 271(a) (2000).

¹⁸⁹ *Id.* § 271(g) (2000).

¹⁹⁰ See Press Release, FDA, FDA Takes Action Against Companies That Are Importing Unapproved, Potentially Unsafe Drugs (Sept. 9, 2003) (describing an FDA request to the Justice Department to file a complaint against RX Depot for facilitating illegal shipments of prescription pharmaceuticals from foreign countries), available at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00939.html> (last visited Apr. 8, 2005).

occur. Moreover, enforcement of patent infringement judgments against foreign defendants can be difficult.¹⁹¹

Government pharmaceutical importation plans that envision direct involvement in bringing patented drugs across international borders create the greatest risk of litigation, partly because such importation initiatives are already in place,¹⁹² and also because of the deep pockets of these state actors. In general, a government entity that engages in importation would violate the same provisions of the Patent Act as a private infringer. And, even if a government's plans merely facilitate import by others, the government entity may still face infringement liability. Patents include the right to exclude the acts of parties that induce infringement.¹⁹³ All that is required to make such a claim is that a defendant acted knowingly to induce another and that infringement actually occurred as a result of that inducement.¹⁹⁴ To put it another way, the defendant must have the "specific intent" to encourage another's infringement.¹⁹⁵ One look at the state and municipal websites that direct consumers to Canadian pharmacies suggest that this would be a fairly easy argument to make in an infringement suit.¹⁹⁶ The rather dramatic result would be liability

¹⁹¹ Because patents are inherently territorial, the enforcement of U.S. judgments overseas is notoriously thorny. See John Gladstone Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Rights*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 83, 90–93 (2000) ("Enforcement of judgments can be an arduous process even within a single nation and the enforcement of a foreign patent judgment presents additional tests to ensure fairness and comity in view of the large amounts of investment at stake."). International treaties have been proposed to remedy the situation. See, e.g., Rochelle C. Dreyfuss & Jane C. Ginsburg, *Draft Convention on Jurisdiction and Recognition of Judgments in Intellectual Property Matters*, 77 CHI-KENT L. REV. 1065, 1065–66 (2002).

¹⁹² See *supra* notes 102–14, 118–20 and accompanying text.

¹⁹³ 35 U.S.C. § 271(b)–(c) (2004).

¹⁹⁴ See, e.g., *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004) ("Although not express in the statute, this section requires proof of intent to induce infringement.").

¹⁹⁵ See *id.*; *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990).

¹⁹⁶ See, e.g., *Minnesota RxConnect*, at <http://www.state.mn.us/cgi-bin/portal/mn/jsp/-home.do?agency=Rx> (last visited Feb. 10, 2005) (home page with button stating "Click here to order your prescription from Canada.").

for *all* damages resulting from the infringing acts, due to the joint and several nature of patent torts.¹⁹⁷

The liability for infringing a U.S. patent can be extreme, particularly when the infringement cuts into the profits of a so-called “blockbuster” drug.¹⁹⁸ Though patents lack the minimum statutory damages associated with copyrights,¹⁹⁹ they nonetheless strip an infringer of damages equal to all profits lost as a result of the infringement.²⁰⁰ In the case of a pharmaceutical with a high U.S. price, but low foreign price—the situation importation is intended to address—the measure of damages could simply be the difference in prices.²⁰¹ In other words, a government entity may end up paying for any savings in drug prices through an award in a patent infringement case. Indeed, if export middlemen take a cut of the savings as predicted,²⁰² a government entity could actually end up paying *more* for imported drugs. Even if a patent owner cannot establish a lost profits case, a “reasonable royalty” is the minimum with which an infringer can escape;²⁰³ thus, taxpayers would end up subsidizing the cost of drugs at some level. Additionally, if the infringement is found to be willful, damages may be increased up to three times at the discretion of the court.²⁰⁴

¹⁹⁷ See CHISUM, *supra* note 164, § 8:21.03[3][e] (“The owner may also have a remedy against persons who induce or contribute to infringement by another . . . However, because such infringers are by long tradition severally as well as jointly liable, they may be sued separately (that is, they are not necessary parties).”) (citations omitted).

¹⁹⁸ See Franco, *supra* note 65.

¹⁹⁹ See 17 U.S.C. § 504(c) (2000).

²⁰⁰ See *State Indus. v. Mor-Flo Indus.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989) (“To get lost profits as actual damages, the patent owner must demonstrate that there was a reasonable probability that, but for the infringement, it would have made the infringer’s sales.”).

²⁰¹ Note that this assumes that sales made at the low foreign price would still be made at the high U.S. price. For essential, maintenance drugs, this may be true, but for lifestyle drugs, one could argue that at least some percentage of the purchases would not have been made at the higher price. See *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999) (stating that lost profit damages must be proven only to a reasonable probability).

²⁰² See, e.g., HHS REPORT, *supra* note 95, at 67.

²⁰³ See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) (citing 35 U.S.C. § 284 (1988)) (noting that the patent damages statute allows for the recovery of actual damages while providing for a reasonable royalty as an alternative, lower limit).

²⁰⁴ See 35 U.S.C. § 284 (2000).

Injunctive relief is also a possibility,²⁰⁵ though overtly restricting access to drugs could be a politically dangerous measure for patent owners to undertake.

While the potential for crushing liability seems to bode ill for the future of government importation initiatives, there is an extremely important codicil that must be considered: state governments currently *cannot* be sued for patent infringement in federal court. The Constitution's Eleventh Amendment absolutely precludes such suits against states, a fact well established in patent jurisprudence.²⁰⁶ Congress has of course abrogated this broad constitutional immunity in other contexts,²⁰⁷ and the same could be done in the case of patents. Indeed, in the Patent and Plant Variety Protection Remedy Clarification Act,²⁰⁸ Congress provided federal jurisdiction for suits against state governments for both patent and trademark infringement.²⁰⁹ However, the Supreme Court in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*²¹⁰ struck down that legislation, finding that Congress had not properly supported abrogation in cases of intellectual property infringement by state governments.²¹¹

²⁰⁵ See 35 U.S.C. § 283 (2000).

²⁰⁶ See, e.g., *Chew v. State of California*, 893 F.2d 331 (Fed. Cir. 1990), *superseded by statute as stated in* *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931 (Fed. Cir. 1993); *Jacobs Wind Electric Co. v. Fla. Dep't of Transp.*, 919 F.2d 726, 728 (Fed. Cir. 1990), *superseded by statute as stated in* *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931 (Fed. Cir. 1993).

²⁰⁷ See, e.g., Lisa M. Durham, *Protection from Age Discrimination for State Employees: Abrogation of Eleventh Amendment Sovereign Immunity in the Age Discrimination in Employment Act*, 33 GA. L. REV. 541 (1999).

²⁰⁸ Pub. L. No. 102-560, 106 Stat. 4230 (1992) (codified at 35 U.S.C. §§ 271(h)–296 (2000)).

²⁰⁹ See 35 U.S.C. § 271(h) (2000).

²¹⁰ 527 U.S. 627 (1999).

²¹¹ *Id.* at 640–43 (1999) (“In enacting the Patent Remedy Act, however, Congress identified no pattern of patent infringement by the States, let alone a pattern of constitutional violations. Unlike the undisputed record of racial discrimination confronting Congress in the voting rights cases . . . Congress came up with little evidence of infringing conduct on the part of the States. . . . Congress, however, barely considered the availability of state remedies for patent infringement and hence whether the States’ conduct might have amounted to a constitutional violation under the Fourteenth Amendment.”).

Since the decision in *Florida Prepaid*, bills have been proposed to abrogate state immunity for intellectual property infringement.²¹² The proposed acts seek to squarely ground the abrogation in the lack of remedies available in state courts.²¹³ Surprisingly, no measure has yet passed, but most anticipate that this loophole will eventually be closed. The ever-increasing rate at which states take advantage of the federal patent system²¹⁴ may spur public sentiment against the contradiction of allowing them continued immunity from suit.²¹⁵ Significantly, for states interested in taking advantage of the immunity in the interim, if and when abrogation is reinstated, liability should be retroactive for all acts of infringement.²¹⁶

²¹² See, e.g., Intellectual Property Protection Restoration Act of 2002, S. 2031, 107th Cong.; Intellectual Property Protection Restoration Act of 2003, S. 1191, 108th Cong.

²¹³ See S. 1191, 108th Cong. § 2(1) (2003).

²¹⁴ See *U.S. Colleges and Universities—Utility Patent Grants, Calendar Years 1969–2000*, Tbl. 1.B., at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table_1.htm (last modified May 14, 2002) (showing that patents assigned to Universities have increased from 82,952 in 1987 to 157,495 in 2000).

²¹⁵ Theoretically, there may be another way to prevent state drug importation using federal patent laws that avoids the issue of Eleventh Amendment immunity. The U.S. Customs Service may seize imports to prevent unfair trade practices if ordered to do so by the U.S. International Trade Commission (“ITC”) in what is known as a “337 investigation.” See 19 U.S.C. § 1337(i) (2000) (implemented by 19 C.F.R. § 12.39 (2004)). One of the primary bases underlying an ITC determination of unfair trade practices is importation that would infringe a valid patent. See 19 U.S.C. § 1337(a)(1)(B) (2000). If a patent owner files a complaint with the ITC, it should be possible for the Commission to make such a determination without the participation of the alleged infringer, rendering immunity moot. This is because the alleged infringer is not technically sued; rather, the issue comes before the ITC through *in rem* jurisdiction over the imported articles. See *Enercon GmbH v. Int’l Trade Comm’n*, 151 F.3d 1376, 1380–83 (Fed. Cir. 1998); see also Kimberly Moore, *Xenophobia in American Courts*, 97 NW. U. L. REV. 1497, 1528–29 (2003) (noting the advantages of suing foreign entities in the ITC versus federal courts). Of course, this route suffers from the same political failing as an injunction in patent infringement litigation, namely, that access to essential medicines is prevented. Additionally, as a practical matter it could be difficult for the Customs Service to distinguish legal pharmaceutical imports (e.g., those not regulated by the FDA) from illegal ones.

²¹⁶ Eleventh Amendment immunity is a jurisdictional issue, rather than a substantive defense. See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 634 (1999). In other words, state governments that infringe violate federal patent law, but there is simply no federal forum available for the suit. One restraint on the liability of states is the limitation on damages to the six years preceding the suit. 35 U.S.C. § 286 (2000). If it takes longer than that to abrogate state immunity in this area, some acts of infringement may be untouchable.

Interestingly, state immunity does not completely moot the question of liability for government importation plans. A long-standing doctrine permits suit in federal court against individual state officers who violate federal law while acting in their official capacities, even when the Eleventh Amendment precludes calling the state itself into federal court. The genesis of this curious litigation route is *Ex parte Young*,²¹⁷ a 1908 Supreme Court case in which Young—the attorney general of Minnesota at the time—was sued to enjoin his enforcement of an unconstitutional state statute establishing railroad rates.²¹⁸ Despite the fact that the state was immune from suit, the court held that an officer enforcing an act in violation of federal law was open to suit as a mere individual committing an illegal act in the state's name.²¹⁹

The doctrine of *Ex parte Young* has been asserted in the context of patent infringement cases. One successful example is the 1972 case of *Hercules Inc. v. Minnesota State Highway Dept.*,²²⁰ in which a patent owner sued state highway officials for infringing patents on pesticide and weed control compounds. The court found that an injunction prohibiting future infringement fell squarely within the rationale of *Ex parte Young* by enjoining an individual illegal act rather than impacting state sovereign immunity.²²¹ Although the doctrine has received scant use in the thirty years following *Hercules*, its general continued viability has been affirmed in other contexts by very recent Supreme Court jurisprudence.²²² Additionally, one judge on the U.S. Court of Appeals for the Federal Circuit has at least suggested, if not

²¹⁷ 209 U.S. 123 (1908).

²¹⁸ *Id.*; see also Thomas, *supra* note 175, at 12.

²¹⁹ *Id.* at 159–60.

²²⁰ 337 F. Supp. 795 (D. Minn. 1972).

²²¹ *Id.* at 799.

²²² See, e.g., *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431 (2004); *Verizon Md., Inc. v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635 (2002); *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261 (1997). Note that, in *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 74–75 (1996), the Court limited the application of *Ex parte Young* when a lesser remedial scheme prescribed by statute would be enhanced or increased by standard federal injunctive remedies. That would not appear to be the case with regard to federal patent law, which provides for federal injunctive relief as a discretionary remedy. See 35 U.S.C. § 283 (2004).

endorsed, the use of the doctrine as a means of circumventing state immunity in patent cases.²²³

Importantly, the doctrine of *Ex parte Young* is somewhat circumscribed in that it permits only prospective declaratory or injunctive relief against the officer, rather than compensation for past harm such as damages.²²⁴ Thus, the threat of such an action would likely not dissuade state infringement to the same degree as a patent infringement suit.²²⁵ Also, it appears that only illegal acts directly committed by a state official may be enjoined,²²⁶ which arguably introduces the possibility that third-party acts like contributory infringement or inducing others to infringe would not be actionable. Although this would be a rather strained interpretation of “legality” under the Patent Act,²²⁷ such exclusion could render *Ex parte Young* useless in many cases.²²⁸

An additional consideration in assessing government liability is the nature of the entity. Several municipalities have expressed their intent to undertake their own initiatives.²²⁹ Government entities like cities and counties are technically subdivisions of the state, but act autonomously and raise their own funds through taxes. The Supreme Court has therefore determined that such local government entities are *not* an arm of the state for Eleventh

²²³ See *Xechem Int'l, Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 382 F.3d 1324, 1333–34 (Fed. Cir. 2004) (Newman, J., additional views).

²²⁴ See *Alden v. Maine*, 527 U.S. 706, 747 (1999).

²²⁵ Another limitation on *Ex parte Young* is that it may not enlarge the remedies normally available by statute. See *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 75–76 (1999) (“Nevertheless, the fact that Congress chose to impose upon the State a liability that is significantly more limited than would be the liability imposed upon the state officer under *Ex parte Young* strongly indicates that Congress had no wish to create the latter [in the list of remedies available though the statute]”). But since injunctive relief is available under the Patent Act, 35 U.S.C. § 283 (2000), this limitation should not work to preclude a patent infringement-related cause of action under the doctrine.

²²⁶ See *Ex parte Young*, 209 U.S. 123, 157 (1908) (noting the need for a connection between the state official and the state’s illegal act).

²²⁷ A better interpretation of the Patent Act suggests that, given their specific statutory treatment (35 U.S.C. §§ 271(b)–(c) (2000)), inducement and contributory infringement are illegal acts in and of themselves and should therefore fall under *Ex parte Young*. However, it appears that the doctrine has not actually been applied in this manner.

²²⁸ See *supra* notes 176–80 and accompanying text.

²²⁹ See *supra* notes 108–11 and accompanying text.

Amendment immunity purposes.²³⁰ In other words, while state governments can avoid patent infringement liability for the time being, any city within the state that imports or induces the import of patented pharmaceuticals from another country without the authorization of the patent owner will be liable for all attendant damages. This exposure could be sufficient to choke off local importation plans. However, state-level plans could still face an attack on another front.

C. The Constitution Provides an Additional Source of State and Municipal Liability for Intruding on Patent Rights

Even if infringement is committed by, or under, the authorization of a state government, immunity from liability is not certain simply because access to the federal courts is denied. There may be an additional route for obtaining relief based on the fact that patents are, at base, personal property,²³¹ a fact recognized under both state and federal law.²³²

From this point of view, patent infringement is basically a type of trespass to personal property.²³³ In tangible property contexts, when a trespass to personal or real property is undertaken by a government entity, the infringement on personal property rights is viewed as an exercise of the state's eminent domain power or "taking," in which case the aggrieved property owner is due constitutionally mandated "just compensation."²³⁴ The property owner may pursue such an action in the relevant state court.²³⁵

²³⁰ See *Mt. Healthy City School District Bd. of Educ. v. Doyle*, 429 U.S. 274, 280 (1977) ("The bar of the Eleventh Amendment to suit in federal courts extends to States and state officials in appropriate circumstances . . . but does not extend to counties and similar municipal corporations.").

²³¹ See 35 U.S.C. § 261 (2000).

²³² See CHISUM, *supra* note 164, § 8:21.02[1][c].

²³³ Note that a civil action against a private party for trespass to personal or real property is, like patent infringement, considered a tort. See, e.g., RESTATEMENT (SECOND) OF TORTS § 158 (1965) [hereinafter "RESTATEMENT"] (describing liability for intentional intrusions on land). This is obviously not a barrier to eminent domain actions.

²³⁴ See *Almota Farmers Elevator & Warehouse Co. v. United States*, 409 U.S. 470, 473 (1973) ("'[J]ust compensation' means the full monetary equivalent of the property taken.") (quoting *United States v. Reynolds*, 397 U.S. 14, 16 (1970)).

²³⁵ See, e.g., *Palazzolo v. Rhode Island*, 533 U.S. 606, 615–16 (2001) (detailing plaintiff's lawsuit in Rhode Island Superior Court for compensation based on an alleged

There is no reason that this basic protection of property rights should not extend to intangible property like patents when a trespass or infringement is proven. Although compensation for takings may not match all of the relief a patent owner may receive under the Patent Act,²³⁶ the liability could be significant enough to thwart the state importation schemes. Since pursuing an intellectual property infringement claim through this route is relatively novel, a number of hurdles must be overcome to establish the viability of such a suit.

1. Access to State Courts to Obtain Relief

The first issue a patent owner must negotiate in pursuing a patent infringement case on an eminent domain theory is access to the relevant state court. Federal jurisdictional statutes appear to give federal courts the exclusive right to hear civil actions “arising under any Act of Congress” in “patent, plant variety protection and copyright cases.”²³⁷ However, there is good reason to believe that this statute will not bar a state court from hearing a takings case.

An eminent domain (or inverse condemnation action) against a state is not based on an act of Congress, but rather is grounded in the Fourteenth Amendment to the U.S. Constitution.²³⁸ The

regulatory taking by the state). The recognition of this form of action has apparently been a gradual process for the states. *See Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1056–60 (1992) (Kennedy, J., concurring) (describing the historical evolution of eminent domain law in the states).

²³⁶ In the context of federal takings of private patent rights, the courts have restricted the available remedies to actual damages. *See, e.g., Motorola, Inc. v. United States*, 729 F.2d 765, 768 n.3 (Fed. Cir. 1984) (“[I]njunctive relief under 35 U.S.C. § 283 is not available to a patent owner in a § 1498 action.”) (citing *Leesona Corp. v. United States*, 599 F.2d 958, 968 (Ct. Cl. 1979) (en banc) (“The injunctive relief of 35 U.S.C. § 283 could not be awarded, of course, since this court lacks the power to grant such relief.”)). Yet another route besides suing the state in eminent domain would be to ask the relevant state legislature to pass a bill appropriating the compensation. *See Jacobs Wind Elec. Co., Inc. v. Fla. Dept. of Transp.*, 919 F.2d 726, 728 (Fed. Cir. 2004) (suggesting that plaintiff could have sought relief from patent infringement by state in form of legislative “claims bill.”). However, compensating pharmaceutical companies for the losses due to importation of lower priced drugs is unlikely to be popular enough to pass through the legislatures.

²³⁷ 28 U.S.C. § 1338 (2000).

²³⁸ *See Seamon, supra* note 9, at 1144 n.374 (“The claim would not be barred by the federal statute that gives federal district courts exclusive jurisdiction of cases ‘arising

Federal Circuit in *Jacobs Wind Electric Co. v. Florida Department of Transportation*²³⁹ recognized that distinction when it considered a federal court's jurisdiction over a patent owner's infringement suit against the State of Florida in view of the Eleventh Amendment.²⁴⁰ The court noted, in *dicta*, that the plaintiff had other litigation venues available such as "assert[ing] a 'takings' claim against the state under the Fifth and Fourteenth Amendments."²⁴¹ The Florida Supreme Court in the same litigation later confirmed that notion by holding that Florida courts indeed had jurisdiction over Jacobs' patent takings claim.²⁴² Interestingly, the Florida court's rationale was based on the determination that Congress could not have preempted actions that the federal courts had no jurisdiction to hear.²⁴³ Although a state's jurisdiction to hear an inverse condemnation case related to a patent may not necessarily depend on a lack of remedy at the federal level, that situation does exist today as a result of *Florida Prepaid* and the lack of any action by Congress to date.²⁴⁴

The corollary to the federal preemption issue is the fact that a state must also consent to be sued in its own courts. The fact that a party may have a legitimate cause of action against a government entity, but no procedure for pursuing it may seem odd, but the ability to determine the circumstance and forum under which a government may be sued is recognized under the doctrine of sovereign immunity.²⁴⁵ Moreover, the recent Supreme Court decision in *Alden v. Maine*²⁴⁶ held that Congress cannot compel a

under any Act of Congress relating to patents,' 28 U.S.C. §1338, because the case would arise under the Constitution, not under the patent laws.").

²³⁹ 919 F.2d 726, 728 (Fed. Cir. 1990), *superseded by statute as stated in* Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931 (Fed. Cir. 1993).

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² *Jacobs Wind Elec. Co. v. Fla. Dep't of Trans.*, 626 So. 2d 1333, 1336–37 (Fla. 1993).

²⁴³ *Id.*

²⁴⁴ See *supra* notes 206–11 and accompanying text.

²⁴⁵ See *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 54 (1996) ("[I]t is inherent in the nature of sovereignty not to be amenable to the suit of an individual without its consent . . .") (quoting *Hans v. Louisiana*, 134 U.S. 1, 13 (1890)); Seamon, *supra* note 9, at 1090–93.

²⁴⁶ 527 U.S. 706 (1999),

state to open itself to a lawsuit based on a statute grounded in an Article I power.²⁴⁷ This prompts the question: Can a state refuse to hear a case relating to inverse condemnation of a property right created by the Patent Act, derived from Congress's section eight enumerated powers?²⁴⁸

As a starting point, it is important to recognize that one can distinguish between the remedial scheme outlined in the federal Patent Act²⁴⁹ and the statute's independent creation of a property right.²⁵⁰ Although the former can be pursued only in the context of a specific type of litigation in federal court (i.e., an Article I-based case as described in *Alden*), the essential aspects of the property right can be transferred to another sovereign's property framework. In fact, the courts have firmly established that matters relating to the ownership of patent property, including transfer and licensing, are exclusively a matter of *state law* rather than federal.²⁵¹ If a state has a procedure for pursuing property takings cases through its own courts, it seems reasonable that patent property rights would be included.²⁵² In fact, this treatment of patent property has support in court decisions from a few states,²⁵³ though most have

²⁴⁷ *Id.* at 713 (“[T]he States’ immunity from suit is a fundamental aspect of the sovereignty which the States enjoyed before the ratification of the Constitution, and which they retain today (either literally or by virtue of their admission into the Union upon an equal footing with the other States) except as altered by the plan of the Convention or certain constitutional Amendments.”).

²⁴⁸ U.S. CONST., art. 1, § 8, cl. 8.

²⁴⁹ 35 U.S.C. §§ 283, 284 (2000).

²⁵⁰ 35 U.S.C. § 261 (2000).

²⁵¹ *See, e.g., Int’l Nutrition Co. v. Horphag Research Ltd.*, 257 F.3d 1324, 1329 (Fed. Cir. 2001) (“[T]he question of who owns patent rights, and on what terms, typically is a question exclusively for state courts and not one arising under United States patent laws. . . . A contractual agreement to apply French law as to ownership is just as valid as an agreement to apply the law of a particular state.”); *Studiengesellschaft Köhle, m.b.H. v. Hercules, Inc.*, 105 F.3d 629, 632 (Fed. Cir. 1997) (holding that proper construction of a patent license agreement “is a question of contract interpretation” under state law).

²⁵² *See* 1 JULIUS L. SACHMAN & PATRICK J. ROHAN, NICHOLS’ THE LAW OF EMINENT DOMAIN § 2.1[2] (3d ed. 1993) (“Intangible property, such as choses in action, patent rights, franchises, charters, or any other form of contract are within the scope of this sovereign authority as fully as land or other tangible property.”).

²⁵³ *See, e.g., Jacobs Wind Elec. Co. v. Fla. Dep’t of Transp.*, 626 So. 2d 1333, 1336–37 (Fla. 1993); *Wilcox Indus., Inc. v. State*, 607 N.E.2d 514 (Ohio Ct. App. 1992), *dismissed, jurisdictional mot. overruled by* 598 N.E.2d 1168 (Ohio 1992); *see also A.C. Aukerman Co. v. State*, 902 S.W.2d 576, 578 (Tex. Ct. App. 1995) (considering an

not addressed it. Support can also be found in state court decisions regarding other types of intellectual property.²⁵⁴

This still leaves open the question of whether a state can structure the jurisdiction of its courts to specifically refuse to hear an intellectual property inverse condemnation case. The failure of such a case due to a lack of jurisdiction is not unprecedented. The federal government was immune from suits to recover compensation for property takings until the passage of the Tucker Act in 1887²⁵⁵ (and from most torts until the passage of the Federal Tort Claims Act in 1946).²⁵⁶ In other intellectual property contexts, some state courts have been reluctant to find eminent domain jurisdiction.²⁵⁷ However, many commentators have argued

eminent domain action against the state based on patent infringement, but denying it only because the state was not shown to have been involved in the infringing activity); *Chew v. California*, 893 F.2d 331, 336 (Fed. Cir. 1990) (noting that Eleventh Amendment immunity precludes only one avenue of recourse against a state for patent infringement), *superseded by statute as stated in* *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931 (Fed. Cir. 1993); *Lemelson v. Ampex Corp.*, 372 F. Supp. 708, 710–13 (N.D. Ill. 1974) (stating that state's use of a patent constituted an eminent domain taking). There is also vague support in cases regarding other intellectual property types. *See, e.g., Smith v. Lutz*, 149 S.W.3d 752, 760–61 (Tex. App. 2004) (considering a plaintiff's allegation that the University of Texas engaged in a taking of copyrights and trade secrets, but ultimately dismissing the claim as inappropriate because it was based on a failed contractual relationship).

²⁵⁴ *See, e.g., State Dep't of Natural Res. v. Arctic Slope Reg'l Corp.*, 834 P.2d 134, 138 (Alaska 1991) ("The companies contend that their oil well data constitute trade secrets protected under both the Alaska and the United States Constitutions. We agree."); *N.J. State Chamber of Commerce v. Hughey*, 600 F. Supp. 606, 626 (D.N.J. 1985) ("Although no case has been brought to my attention determining whether an uncompensated taking of a trade secret would violate the State Constitution, I see no reason why the New Jersey Supreme Court would not take the same approach as the United States Supreme Court in this regard."), *aff'd in relevant part*, 774 F.2d 587, 598 (3d Cir. 1985).

²⁵⁵ Ch. 359, 24 Stat. 505 (1887) (current version at 28 U.S.C. §§ 1346, 1491 (2003)); *see, e.g., Schillinger v. United States*, 155 U.S. 163, 169 (1894) (holding that plaintiff could not bring an action against the U.S. under Tucker Act for infringing plaintiff's patented process); *see also* *Seamon*, *supra* note 9, at 1090–94.

²⁵⁶ *See* Hon. Leon R. Yankwich, *Problems Under the Federal Tort Claims Act*, 9 F.R.D. 143, 146–49 (1949) (discussing the background to the Federal Tort Claims Act soon after it was enacted, as well as other federal waivers of immunity, such as the Tucker Act and the predecessor to 28 U.S.C. § 1498).

²⁵⁷ *See, e.g., Gen. Tire, Inc. v. Kepple*, 917 S.W.2d 444, 454 (Tex. App. 1996) ("While Texas law treats trade secrets as property in some contexts, they have not been classified as property for the purposes of the taking clause."), *rev'd on other grounds*, 970 S.W.2d 520 (Tex. 1998).

that the U.S. Supreme Court in *First English Evangelical Lutheran Church of Glendale v Los Angeles County*²⁵⁸ strongly suggested that state sovereign immunity does not exist for takings cases because it is overridden by the just compensation requirement.²⁵⁹ Even if *First English* cannot be read so broadly, it has been argued that the most reasonable interpretation of the Due Process Clause indeed requires states to waive sovereign immunity for inverse condemnation cases, despite the fact that the obligation appears to be asymmetric with that of the federal government.²⁶⁰ This due process obligation in the context of patent property was recently articulated in “additional views” submitted by Judge Newman in *Xechem International v. University of Texas*.²⁶¹ Assuming the Supreme Court continues its recent support for enforcing due process obligations on the states,²⁶² it would appear that a state would face an uphill battle in attempting to remove jurisdiction for those seeking just compensation for takings under either federal or state constitutions.

2. Establishing a Compensable Taking

A second obstacle for patent owners may result from the somewhat ambiguous nature of an intellectual property taking. A

²⁵⁸ 482 U.S. 304, 314–16 (1987).

²⁵⁹ See, e.g., Paul J. Heald & Michael L. Wells, *Remedies for the Misappropriation of Intellectual Property by State and Municipal Governments Before and After Seminole Tribe: The Eleventh Amendment and Other Immunity Doctrines*, 55 WASH. & LEE L. REV. 849, 871–72 (1998); Seamon, *supra* note 9, at 1072 n.19 (listing several other academic articles that make similar assertions regarding *First English*).

²⁶⁰ See Seamon, *supra* note 9, at 1101–10.

²⁶¹ 382 F.3d 1324 (Fed. Cir. 2004). After discussing the limitations of state immunity for patent infringement, Judge Newman concluded that:

The circumstances of this case illustrate that when a state is charged with contravention of federal law in a way that directly affects private property, and if no remedy is indeed available within the state’s tribunals—whether by the state’s invocation of immunity or by federal preemption of the cause of action—there can arise an affront to the fundamentals of due process. Respect for the principles of federalism does not automatically immunize the state from due process considerations.

Id. at 1335.

²⁶² See, e.g., *Tennessee v. Lane*, 541 U.S. 509 (2004) (upholding congressional abrogation of state immunity in Title II of the Americans with Disabilities Act under the Fourteenth Amendment).

state could attempt to avoid liability by claiming the act of infringement is merely regulatory in nature—a justified use of the state’s police powers—and not compensable if it leaves a reasonable economic use of the patent property in question (a very likely result in the case of pharmaceutical importation takings).²⁶³ On the other hand, if takings law as it pertains to physical occupations of, or interference with, tangible property is applied to drug importation, just compensation must be paid no matter what use of the property remains.²⁶⁴ While there is no explicit guidance in the case law as to which approach applies to intellectual property, the proper method can be derived through analogies to tangible property as well as the implicit treatment by the courts.

It is well established that, in the context of real property, slightly different legal rules apply depending on which of two primary types of appropriation have occurred. There is the open and notorious “physical occupation,” wherein a government entity physically intrudes upon a property owner’s curtilage.²⁶⁵ A government entity achieves this by taking real property (land or buildings) for its exclusive use on either a temporary or permanent basis.²⁶⁶ More recently, the courts have recognized that government regulation can effectuate a second type of taking when the regulation severely limits a property owner’s use of the land through some type of police power derived restriction.²⁶⁷

²⁶³ See *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1019 (1992) (“We think, in short, that there are good reasons for our frequently expressed belief that when the owner of real property has been called upon to sacrifice all economically beneficial uses in the name of the common good, that is, to leave his property economically idle, he has suffered a taking.”).

²⁶⁴ See *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg’l Planning Agency*, 535 U.S. 302, 322–24 (1999) (“When the government physically takes possession of an interest in property for some public purpose, it has a categorical duty to compensate the former owner, *United States v. Pewee Coal Co.*, 341 U.S. 114, 115 (1951), regardless of whether the interest that is taken constitutes an entire parcel or merely a part thereof.”).

²⁶⁵ See *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 427–28 (1982) (discussing the difference between physical takings and regulatory takings, noting that the latter relates to use restrictions only).

²⁶⁶ See *United States v. Gen. Motors Corp.*, 323 U.S. 373, 378–79 (1945) (finding a taking when the government temporarily occupied a building for a public purpose); *United States v. Petty Motor Co.*, 327 U.S. 372, 374–75 (1946) (finding a taking when the government temporarily occupied a building under lease to another).

²⁶⁷ See *Lucas*, 505 U.S. at 1019.

Generally, the owner's ability to exclude the physical presence of others—including the government—is not affected.²⁶⁸ Unlike physical occupations, regulatory takings must be quite onerous to be compensable. Essentially all economically beneficial use of the property must be forestalled by the government regulation before the act is transformed from merely an exercise of police power to a compensable appropriation.²⁶⁹ The rules related to real property appear fairly well characterized, at least conceptually, but the application is not always cogent or consistent.

The scheme for addressing government intrusions on personal property is similar, though the manner in which a government entity “occupies” such property is obviously different. A physical intrusion on personal property occurs when that property is either temporarily confiscated, or permanently taken or destroyed.²⁷⁰ In either case, the property owner's rights must be substantially affected. Theoretically, the government can also regulate one's use of personal property so strictly as to prevent reasonable future economic use. However, the case law suggests that such incidents are rare.²⁷¹ Moreover, even when the facts arguably support such an allegation, plaintiffs have had little success against government entities.²⁷²

How does the legal structure for tangible property fit intellectual property rights? As an intangible, intellectual property obviously cannot be physically occupied, captured or damaged (though it can be destroyed or eliminated).²⁷³ Additionally, since intellectual property rights do not include the right to use what is

²⁶⁸ *Id.* at 1044 (Blackmun, H., dissenting).

²⁶⁹ *Id.*

²⁷⁰ *See General Motors*, 323 U.S. at 383–84 (determining that compensation was owed for destruction or devaluation of trade fixtures—a type of personal property—during a temporary occupation of a building).

²⁷¹ *See, e.g., E. Enters. v. Apfel*, 524 U.S. 498, 523 (1998) (noting only one regulatory case involving personal property); *Am. Pelagic Fishing Co. v. U.S.*, 49 Fed. Cl. 36, 46 (2001) (failing to note more than one case of the application of regulatory takings law to personal property), *rev'd*, 379 F.3d 1367 (Fed. Cir. 2004).

²⁷² *See, e.g., Andrus v. Allard*, 444 U.S. 51 (1979).

²⁷³ *See, e.g., DVD Copy Control Ass'n v. Bunner*, 10 Cal. Rptr. 3d 185, 192–93 (Ct. App. 2004) (noting, in the context of the Internet, that disclosure of a trade secret destroys it).

covered,²⁷⁴ regulatory intrusion would also seem to be impossible. But there must be some link between traditional eminent domain law and intellectual property rights, or the “property” nomenclature is misdescriptive. The solution to this conundrum lies in the fact that, at base, physical intrusions on tangible property are nothing more than infringements on the property owner’s right to exclude others (including the government) from the property.²⁷⁵ Interfering with this right is the essence of a physical occupation, and various physical interactions are simply different flavors of the same cuisine. In fact, real property takings have been found when a government merely prohibits the property owner from keeping outsiders away, even if the government makes no direct use of the property.²⁷⁶ Although intellectual property rights differ in what activities the owner may prevent others from undertaking,²⁷⁷ a breach of any of these rights of exclusion necessarily diminishes the value of the property in a similar fashion to a physical occupation of tangible property.²⁷⁸

²⁷⁴ While the act of invention itself “vests an inventor with a common law or ‘natural’ right to make, use and sell his or her invention absent conflicting patent rights in others,” *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1578 (Fed. Cir. 1991), a patent conveys the additional right to exclude others from making, using, selling or offering to sell the invention. *Id.* (citing *Six Wheel Corp. v. Sterling Motor Truck Co.*, 50 F.2d 568, 571 (9th Cir. 1931)).

²⁷⁵ See *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979) (“In this case, we hold that the ‘right to exclude,’ so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation.” *But see* *Boise Cascade Corp. v. United States*, 296 F.3d 1339, 1350 (Fed. Cir. 2002) (holding that the right to exclude spotted owls, as eliminated by government regulation, is not a permanent physical occupation), *cert. denied*, 538 U.S. 906 (2003).

²⁷⁶ See *Kaiser Aetna*, 444 U.S. at 176 (finding that a servitude on landowner’s navigable waterway took the landowner’s right to exclude, “one of the most essential sticks in the bundle of rights that are commonly characterized as property”).

²⁷⁷ See 35 U.S.C. § 271(a), (g) (2003).

²⁷⁸ Note that courts have found this to be the case even if minimal monetary damages accrue. See *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996) (“The right to exclude others from a specific market, no matter how large or small that market, is an essential element of the patent right. As we have stated, ‘because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole.’”) (citing *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1456–57 (Fed. Cir. 1988)).

Therefore, infringement of an intellectual property owner's rights of exclusion should be treated as a physical occupation.²⁷⁹

Another way to conceptualize the nature of government takings of intellectual property is to consider the parallels between the government acts that constitute takings, and the acts of private parties that violate an owner's rights. Physical takings of tangible property are akin to trespass to real or personal property.²⁸⁰ Both involve intentional acts²⁸¹ that lead to the breaching of one's property boundaries. Tangible takings and trespass are largely co-extensive.²⁸² The same should be true of intellectual property. In other words, the same acts that would constitute the parallel to trespass—infringement—should theoretically constitute a taking.²⁸³

Although a definitive connection between tangible and intangible takings is not laid out in either state or federal statutory law, there is a relatively clear delineation in the common law of the

²⁷⁹ As straightforward as this analysis may seem, creating a proper analogy for intellectual property takings is no simple task. If the government intrusion is like a physical taking, compensation is relatively automatic, and the degree of the intrusion is a question relevant for determining damages only. However, if government intrusion is like a regulatory takings, a much more complicated assessment must be undertaken. *See Yee v. Escondido*, 503 U.S. 519, 523 (1992) (“The first category of cases [physical taking] requires courts to apply a clear rule; the second [regulatory taking] necessarily entails complex factual assessments of the purposes and economic effects of government actions.”).

²⁸⁰ Also known as “trespass to chattels.”

²⁸¹ Trespass to land and chattels are considered “intentional torts.” *See Sheehan v. United States*, 896 F.2d 1168, 1172 n.6 (9th Cir. 1990) (noting that some intentional torts like trespass are not excluded from the Federal Torts Claims Act). This means that the act undertaken was intentional knowing that certain harm is substantially certain to result. *See W. KEETON ET AL., PROSSER AND KEETON ON LAW OF TORTS* §§ 13, 14 (5th ed. 1984). One need not have intended to “trespass.”

²⁸² The exception may be where the government trespass/taking is transitory and caused by actions removed from the property (such as causing a flood). *See Sanguinetti v. United States*, 264 U.S. 146, 149 (1924) (to be a taking, flooding must “constitute an actual, permanent invasion of the land, amounting to an appropriation of, and not merely an injury to, the property”); *United States v. Kan. City Life Ins. Co.*, 339 U.S. 799, 809–10 (1950).

²⁸³ *See RICHARD EPSTEIN, TAKINGS: PRIVATE PROPERTY AND THE POWER OF EMINENT DOMAIN* 35–36 (1985). Epstein draws parallels between private tort and eminent domain law, and states that the relevant question in determining the existence of a taking is: “Would the government action be treated as a taking of private property if it had been performed by some private party? If so, there is a taking of private property” *Id.*

most relevant judicial fora. Recent cases involving patent takings by the federal government are in line with the analogy to physical takings due to the application of compensation without proceeding through a regulatory analysis.²⁸⁴ In fact, most court decisions fail to address the issue, simply referring to the government taking or infringement as an eminent domain exercise. Conversely, it is perhaps more instructive that no courts have found copyright or patent takings to be “regulatory takings.” The physical occupation scheme intuitively seems most appropriate.

If there is any argument to be made for the application of a regulatory takings scheme, it would likely be based in the Supreme Court’s rather curious decision in *Ruckelshaus v. Monsanto*.²⁸⁵ In that case, the Court considered Monsanto’s allegation that the U.S. Environmental Protection Agency disclosed and thus destroyed trade secret information that Monsanto provided to the agency in confidence as part of its regulatory obligation.²⁸⁶ While finding that such an effect on even an intangible property right constituted a Fifth Amendment taking, the Court also stated that the determination as to whether a taking occurred must consider whether “a governmental action has gone beyond ‘regulation’” by looking to such factors as “the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations.”²⁸⁷ In other words, the Court applied a regulatory takings analysis. Importantly, the Court did not suggest that such a test should be exclusively employed in all cases, or even that it applied to all types of intellectual property.²⁸⁸ However, it does stand out as the Supreme Court’s only decision on the treatment of such intangible takings. Considering the Federal Circuit’s handling of patent takings, the closer analogy to tangible property physical occupations, and the openings left in *Ruckelshaus* in terms of available legal theory, is reasonable to treat the case as distinguishable or inapplicable. This approach has

²⁸⁴ See, e.g., *Gargoyles, Inc. v. United States*, 113 F.3d 1572 (Fed. Cir. 1997). However, it should be recognized that the government infringement statute is written to compensate automatically, so a conclusion is hard to draw. See 28 U.S.C. § 1498 (2000).

²⁸⁵ 467 U.S. 986 (1984).

²⁸⁶ *Id.* at 1000–01.

²⁸⁷ *Id.* at 1005.

²⁸⁸ *Id.*

been acknowledged in the context of litigation and academic theory.²⁸⁹

3. “Just Compensation” for Patent Infringement

If states are, in fact, liable in their own courts under a takings theory, what is the appropriate measure of just compensation? Though this may appear to be a secondary issue compared to the establishment of liability, it is in many ways just as important: a patent property right requiring a minor licensing fee for an importation taking is a mere road bump, whereas one that implicates compensation for all of the patentee’s losses is a veritable brick wall. As with the compensation trigger discussed above, the answer is not entirely clear due to the nature of this type of intellectual property taking. If an entire patent right is appropriated or eliminated by the state, an accounting method similar to that used for the sale of the intellectual property would reasonably be employed to determine the value of the property lost.²⁹⁰ However, a taking that infringes only part of the right, while leaving the remainder, is less straight forward. Again, an analogy to patent infringement actions provides the best guidance.

The federal Patent Act is fairly clear in outlining the source of remedies for private party infringement, if not the precise method of calculation.²⁹¹ However, it does not necessarily follow that all of these measures are available in a suit against a government entity. In fact, to the extent that certain remedies are intended to punish an infringer for tortious behavior like willfulness,²⁹² they would seem in conflict with the principles of the Fifth and

²⁸⁹ See *Zoltek Corp. v. United States*, 58 Fed. Cl. 688, 706 (2003) (“[A]s [*Ruckelshaus v. Monsanto*] does not preclude the recognition of other forms of takings, Plaintiff could allege a taking of a different sort from either [regulatory taking or physical taking] categories.”); Cotter, *supra* note 9, at 558–65 (arguing that there are strong reasons for limiting *Ruckelshaus* to its facts and finding that unauthorized government use of intellectual property always effectuates a taking).

²⁹⁰ See GORDON V. SMITH & RUSSELL L. PARR, *VALUATION OF INTELLECTUAL PROPERTY & INTANGIBLE ASSETS* 170 (3d ed. 2000) (“The income approach is best suited for the appraisal of . . . patents, trademarks, and copyrights . . .”).

²⁹¹ See 35 U.S.C. §§ 281–85 (2000).

²⁹² See *id.* § 284 (stating that a damages award may be increased up to three times the actual amount at the discretion of the court).

Fourteenth Amendments, which do not seek to dissuade the intentional use of eminent domain powers so long as just compensation is paid.²⁹³ Nevertheless, there are parallels between some aspects of patent infringement damages and eminent domain.

In eminent domain jurisprudence, the object of compensation is to provide the property owner with the “fair market value” of the property taken.²⁹⁴ While it is understood that this may not compensate the property owner to complete indifference (as the complete right to exclude can never be reconstructed), the intent is to put the owner in the same position as existed before the taking.²⁹⁵ Similarly, the basic forms of damages available under the Patent Act are intended to compensate the patent owner for the effects of the infringement. If it can be shown, with reasonable probability, that a patent owner lost sales due to infringement, the profits from those sales can be obtained to compensate the owner to indifference.²⁹⁶ Alternatively, if the patent owner cannot demonstrate lost profits, a reasonable royalty guarantees some compensation for the breach of the right to exclude others from the invention.²⁹⁷

While it seems logical to use the existing lost profits and reasonable royalty framework to measure eminent domain

²⁹³ See *Leesona Corp. v. United States*, 599 F.2d 958, 969–79 (Ct. Cl. 1979) (en banc) (“An aggrieved party is entitled to receive only reasonable and entire compensation, not more than that Unlike his counterpart in a private infringement suit, he is not entitled to be the recipient of increased damages heaped on other parties as punishment or deterrence.”) (citations omitted).

²⁹⁴ *City of New York v. Sage*, 239 U.S. 57, 61 (1915) (“But what the owner is entitled to is the value of the property taken, and that means what it fairly may be believed that a purchaser in fair market conditions would have given for it in fact”); see also *United States v. Reynolds*, 397 U.S. 14, 16 (1970).

²⁹⁵ *Reynolds*, 397 U.S. at 16; see also EPSTEIN, *supra* note 283, at 182 (“In principle the ideal solution is to leave the individual owner in a position of indifference between the taking by the government and retention of the property.”).

²⁹⁶ See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964) (plurality opinion) (The statutory measure of damages is “the difference between [the patent owner’s] pecuniary condition after the infringement, and what his condition would have been if the infringement had not occurred.”); accord *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999).

²⁹⁷ See *State Indus. v. Mor-Flo Indus.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989) (award of damages may be split between lost profits as actual damages to the extent they are proven and a reasonable royalty for the remainder).

compensation, not everyone agrees. In particular, the government has argued in the course of several federal patent takings cases that a reasonable royalty is generally all that is required.²⁹⁸ This has been echoed by commentators²⁹⁹ as well as a few early court decisions.³⁰⁰ According to this line of reasoning, if lost profits are ever to be awarded, a plaintiff must demonstrate their appropriateness in accordance with a more difficult to achieve “clear and convincing” standard of proof.³⁰¹ However, a recent decision from the Federal Circuit in *Gargoyles, Inc. v. United States*³⁰² casts doubt on the distinction between eminent domain compensation and patent damages by suggesting that the latter is applicable in its current form.³⁰³ Since the matter has yet to be firmly resolved,³⁰⁴ state governments would be wise to consider the worst case scenario of lost profits in their risk assessments.

If state governments are on the hook for lost profits damages in many importation cases, the damages may well preclude the viability of the programs. As described above, because the measure of damages could be the difference in the U.S. sales price versus the foreign price, it may be a zero sum (or worse) game.

²⁹⁸ See, e.g., *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1572 (Fed. Cir. 1996) (emphasis added).

²⁹⁹ See, e.g., Lionel Marks Lavenue, *Patent Infringement Against the United States and Government Contractors Under 28 U.S.C. § 1498 in the United States Court of Federal Claims*, 2 J. INTELL. PROP. L. 389 (1995). *But see* David M. Schlitz & Richard J. McGrath, *Patent Infringement Claims Against the United States Government*, 9 FED. CIR. B.J. 351, 365 (2000) (Concluding that lost profits should be recoverable in many more cases than most people realize, the authors observe that “there are potentially large rewards in meritorious suits against the government, which for the most part have not been pursued.”).

³⁰⁰ See, e.g., Cahoy, *supra* note 7, at 155–61 (reviewing several cases from the Federal Claims Court and the Federal Circuit that seem to indicate a preference for a reasonable royalty in § 1498 damages assessments).

³⁰¹ See *Tektronix, Inc. v. United States*, 552 F.2d 343, 348–49 (Ct. Cl. 1977) (“But even if we assume that lost profits is still a viable measure of recovery under 28 U.S.C. § 1498, we cannot adopt that standard in this case because it has not been sufficiently shown by clear and convincing evidence that plaintiff . . . would have made and kept the profits it now demands.”).

³⁰² 113 F.3d 1572 (Fed. Cir. 1997).

³⁰³ *Id.* at 1576 (“We also note that the announcement of the ‘strictest proof’ standard in *Tektronix* is supported only by general references to the Fifth Amendment and the court’s reticence to award lost profits against the government . . .”).

³⁰⁴ See Cahoy, *supra* note 135, at 160.

The barrier provided by constitutional takings law may be, in effect, insurmountable.

D. The Impact of the Constitution on Federal Liability is in Flux

In view of the problems facing private entities, as well as state and municipal drug importation programs, one might assume that the federal government would step in as a player. Although its current position has been to discourage drug importation and it is currently poised to do no more than lightly regulate imports,³⁰⁵ the government could become a more active participant. For example, an administrative agency such as Health and Human Services could engage in active importation, or at least actively facilitate the importation by private parties through Web portals and other directing resources. At the very least, it could do so for government-funded purchases through programs like Medicare.³⁰⁶ Of course, the federal government can also be liable for infringing patents, even though it is the sovereign source of the grant.³⁰⁷ Would this effectively preclude this importation route as well? Curiously, the answer depends on unsettled law regarding whether a plaintiff has the right to pursue a remedy for this particular type of infringement.

Since 1910, patent owners have had an explicit right of action against the federal government if it is found to have “used or manufactured [a patented invention] by or for the United States without license of the thereof or lawful right to use of manufacture the same.”³⁰⁸ This right, detailed in the U.S. Code, provides a method for obtaining compensation based on either direct government use or the government’s authorization of another’s

³⁰⁵ See Rowland, *supra* note 4.

³⁰⁶ See *supra* note 67 and accompanying text.

³⁰⁷ See 28 U.S.C. § 1498(a) (2000).

³⁰⁸ That predecessor statute to § 1498 was enacted in 1910, and it contained essentially the same language as the current version with respect to rights infringed and compensation required. Act of June 25, 1910, ch. 423, 36 Stat. 851, *amended by* Act of July 1, 1918, ch. 114, 40 Stat. 705. The prior statute was originally codified as part of the Patent Act at 35 U.S.C. § 68 (1940), and reorganized as § 1498 of Title 28 in 1948. Act of June 25, 1948, ch. 646, 62 Stat. 941.

use.³⁰⁹ While the statute uses neither the phrase “infringement” nor “taking,” it appears to bridge the gap between the two concepts by providing for liability for informal and inadvertent intellectual property infringements, while using language similar to the Constitution in articulating the remedy for unlawful use of inventions.³¹⁰

Despite the constitutional overtones in § 1498, the federal government has occasionally argued that it does not actually exercise eminent domain power over patents when it intrudes on the rights of the owner. Rather, the government contends that it actually exercises a license option that is included within the original patent grant.³¹¹ A few courts have entertained this notion, most particularly the trial-level United States Court of Federal Claims in the case of *De Graffenried v. United States*,³¹² which stated that the government has a statutory right to use all patented inventions.³¹³ However, more recent decisions from the Federal

³⁰⁹ See 28 U.S.C. § 1498(a) (2000) (“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.”).

³¹⁰ See *id.*

³¹¹ See, e.g., *Zoltek Corp. v. United States*, 58 Fed. Cl. 688, 692 (2003) (reviewing U.S. government’s argument that § 1498 cases are not infringements but merely the exercise of a type of inherent licensing authority on the part of the government). In effect, this would be a compulsory license. In more specific contexts, the federal government does retain recognized compulsory licensing rights. See 35 U.S.C. §§ 200–11 (2000) (Bayh-Dole Act provisions that give private parties the right to own patents in federally-funded inventions, but reserves in the federal government a nonexclusive, nontransferable, irrevocable, paid-up license for the invention to practice it or have it practiced for or on the government’s behalf throughout the world); 42 U.S.C. § 2183 (2000) (providing for compulsory licensing of patents having “primary importance in the production or utilization of special nuclear material or atomic energy”); 42 U.S.C. § 7608 (2000) (providing for compulsory licensing of patents necessary to enable any person to comply with the implementation of Clean Air Act requirements).

³¹² 29 Fed. Cl. 384 (1993).

³¹³ *Id.* at 387–88 (“[T]he government does not have to resort to exercising its sovereign power of eminent domain to utilize a patent owner’s patented invention because the

Circuit as well as other opinions from the Claims Court suggest that this analysis is erroneous.³¹⁴ Additionally, it has been noted that if this theory were true, jurisdiction for compensation grounded in the “unlawful” use or manufacture of a patented invention would be nonsensical; all use would theoretically be lawful.³¹⁵ This is logically inconsistent with the legislative intent in providing such a mechanism for plaintiffs.

As a straightforward reading suggests, § 1498 has a number of limitations that would specifically impact the importation debate. First and foremost, the statute does not provide for liability for contributory infringement/takings or inducement of another’s infringement.³¹⁶ Only acts by or under the authority of the government are covered.³¹⁷ More importantly, the statute appears to cover only the acts of direct infringement that were recognized at the time the statute was first enacted in 1910. Since then, the Patent Act has evolved to contain additional rights, and it has been found that these rights were not automatically incorporated into §

statutory framework that defines a patent owner’s property rights gives the government the authority to use all patented inventions.”)

³¹⁴ See, e.g., *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1572 (Fed. Cir. 1996) (recovery is based on eminent domain); *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 756 (1999) (“Use by the government of a patented invention without an express license from the patentee is properly viewed as a taking of property under the Fifth Amendment to the Constitution through the government’s exercise of its power of eminent domain.”); *Leesona Corp. v. United States*, 599 F.2d 958, 967 (Ct. Cl. 1979) (en banc) (“This court has traditionally searched the law of eminent domain for legal precedents and principles to apply in determining the ‘reasonable and entire compensation’ to be granted in a valid infringement action against the government.”); *Calhoun v. United States*, 453 F.2d 1385, 1391 (Ct. Cl. 1972) (“The theory underlying a patent suit in this court pursuant to [§ 1498] is that the Government, when a patent device or invention is made or used by or for the United States, *ipso facto* takes by eminent domain a compulsory compensable license in the patent; the patentee obtains his Fifth Amendment just compensation for that taking through his action here under § 1498.”).

³¹⁵ See *Zoltek Corp.*, 58 Fed. Cl. at 700.

³¹⁶ *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1581 (Fed. Cir. 1997) (“[T]he government has not waived sovereign immunity for collateral acts like inducement and contributory infringement.”); *Motorola, Inc. v. United States*, 729 F.2d 765, 768 n.3 (Fed. Cir. 1984) (“Further, the Government can only be sued for any direct infringement of a patent (35 U.S.C. § 271(a)), and not for inducing infringement by another (section 271(b)) or for contributory infringement (section 271(c)).”).

³¹⁷ *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980).

2005] *PROPERTY BARRIERS TO PHARMACEUTICAL IMPORTATION* 689

1498.³¹⁸ For example, the right to exclude imports, added in to the Patent Act in 1994, cannot be the basis of a § 1498 claim.³¹⁹

In view of the § 1498 limitations, one could imagine a government program to purchase and distribute (or even sell) imported pharmaceuticals that would not infringe a patent owner's rights under the statute. At the very least, it could provide a significant negotiating tool that drives down prices. All of this, of course, is premised on the notion that § 1498 provides the exclusive means for obtaining relief for U.S. government patent takings. A recent case has brought this into question by concluding that a plaintiff's right to receive compensation may not be so limited.³²⁰

The logic for looking outside of §1498 starts from the proposition that patents are personal property rights and government infringement is a type of taking.³²¹ This, in turn, suggests that the same jurisdiction implicated to resolve disputes regarding tangible property should apply to intellectual property. Specifically, since the end of the Nineteenth Century, plaintiffs have been able to pursue a remedy against the federal government under the Tucker Acts. The so-called Little Tucker Act is reserved for cases that amount to less than \$10,000 and confers concurrent original jurisdiction in federal district courts and the Court of Federal Claims.³²² The Big Tucker Act³²³ concerns greater monetary amounts and confers exclusive jurisdiction in the Court of Federal Claims.³²⁴ Both statutes give their respective federal courts the ability to "render judgment upon any claim against the United States founded . . . upon the Constitution."³²⁵ Among the

³¹⁸ *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 837 (2002) ("Because nothing in the legislative history indicates that Congress intended for the meaning and effect of section 1498 to change in congruence with changes in 35 U.S.C. § 271, the Court is constrained to hold that section 1498 does not apply to all forms of direct infringement as currently defined in 35 U.S.C. § 271.").

³¹⁹ Uruguay Round Agreements Act, Pub. L. 103-465, § 532, 108 Stat. 4809, 4983 (1994).

³²⁰ *Zoltek Corp. v. United States*, 58 Fed. Cl. 688 (2003), discussed in detail *infra*.

³²¹ See *supra* notes 271-79 and accompanying text.

³²² 28 U.S.C. § 1346(a)(2) (2000); see also *Preseault v. I.C.C.*, 494 U.S. 1, 12 (1990).

³²³ Hereinafter, both Acts will be collectively referred to as "the Tucker Act."

³²⁴ 28 U.S.C. § 1491 (2001); see also *Preseault*, 494 U.S. at 12.

³²⁵ 28 U.S.C. §§ 1346(a)(2), 1491 (2001).

recognized types of claims founded on the Constitution are Fifth Amendment-based takings of property.³²⁶ If patent takings fit into this category, this is no reason why Tucker Act jurisdiction should not apply.

The importance of allowing patent plaintiffs to use the Tucker Act is that the jurisdiction is bounded only by constitutional liability. This would extend to all aspects of the property right as opposed to a few specific articulations; the Tucker Act should cover what has been left out of § 1498. However, there is a bit of a legal puzzle concerning the integration of § 1498 and the Tucker Act that complicates the analysis. The Tucker Act was passed many years before the first iteration of § 1498.³²⁷ How can its coverage be broader and inclusive of a later-enacted statute? In other words, did § 1498 impliedly supersede and eliminate some jurisdiction under the Tucker Act, or was § 1498 simply redundant and unnecessary? If the latter is the case, the federal government cannot escape liability for direct pharmaceutical importation or sales on grounds of sovereign immunity.

To put this issue in perspective, one must take a trip back in time to the Nineteenth Century when the Tucker Act was passed. Even at that point in history, it is clear that courts and legislators believed that intellectual property rights like patents should be treated like any other type of property, including in terms of eminent domain law. For example, in the 1881 case of *James v. Campbell*,³²⁸ the Supreme Court noted:

That the government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the

³²⁶ See *United States v. Causby*, 328 U.S. 256, 267 (1946) (“If there is a taking, the claim is ‘founded upon the Constitution’ and within the jurisdiction of the [Court of Federal Claims] to hear and determine.”).

³²⁷ See ch. 359, 24 Stat. 505 (1887) (codified as amended in scattered sections of 28 U.S.C., but primarily in 28 U.S.C. §§ 1346(a)(2), 1941); Gregory C. Sisk, *The Tapestry Unravels: Sovereign Immunity and Money Claims Against the United States*, 71 GEO. WASH. L. REV. 602, 606–11 (2003) (“Prior to 1855, individuals with contract or other monetary claims against the federal government were barred by sovereign immunity from seeking redress in court and thus were left to petition Congress to enact legislation—in the form of ‘private bills’—appropriating funds to pay those claims.”).

³²⁸ 104 U.S. 356 (1881).

patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.³²⁹

When the Tucker Act was enacted in 1887, one would think it would be read to encompass any taking of property rights, including one involving patents. But in a strange and contradictory move, in 1894, the Supreme Court declared in *Schillinger v. United States*³³⁰ that the unauthorized use of a patent sounded in tort rather than eminent domain, and plaintiffs had no recourse through the Tucker Act.³³¹ This effectively put intellectual property into a different category from tangible property. Congress enacted the predecessor statute to § 1498 specifically in response to *Schillinger* in order to provide jurisdiction for government patent infringement “torts.”³³² Confusingly, Congress apparently believed this to be justified and necessary in consideration of federal government’s responsibilities under the Fifth Amendment.³³³ Regardless, as of 1910, patent owners could only use the specific jurisdictional statute enacted by Congress to obtain relief.

The law became murkier following the Supreme Court’s subsequent decision in *Crozier v. Fried Krupp Aktiengesellschaft*.³³⁴ In that case, which related to the U.S. Army’s unauthorized use of a patent on artillery design, the Court interpreted and considered the application of § 1498’s predecessor

³²⁹ *Id.* at 357–58.

³³⁰ 155 U.S. 163 (1894).

³³¹ *Id.* at 168–69 (“It is true also that to jurisdiction over claims founded ‘upon any contract, express or implied, with the government of the United States,’ is added jurisdiction over claims ‘for damages, liquidated or unliquidated,’ but this grant is limited by the provision ‘in cases not sounding in tort.’”).

³³² H.R. Rep. No. 1288, at 3 (1910) (report accompanying the bill which became the predecessor statute to § 1498) (“Our only purpose is to extend the jurisdiction of that court so that it may entertain suits and award compensation to the owners of patents in cases where the use of the invention by the United States is unauthorized and unlawful; in short, to give the court in patent cases, in addition to the jurisdiction it now has in matters of contract, jurisdiction in cases of tort.”).

³³³ *Id.* at 2–3.

³³⁴ 224 U.S. 290 (1912).

shortly after it was enacted. Following a discussion of *Schillinger* that noted its denial of tort jurisdiction under the Tucker Act, the Court held that the new statute effectively filled this gap.³³⁵ However, the Court went on to specifically describe the government's unauthorized use or manufacture of an invention as an act of eminent domain as opposed to a tort.³³⁶ The Court remarked that the statute's clear intent was to provide a remedy for takings.³³⁷ The *Crozier* decision appears to merge the concepts of infringement and eminent domain in the context of patent disputes. Though it did not suggest Tucker Act jurisdiction was available in such a case, it was not ruled out either.

In 2003, Chief Judge Damich of the U.S. Court of Federal Claims considered the availability of remedies outside of the § 1498 structure in *Zoltek Corp. v. United States*.³³⁸ Zoltek sued the U.S. government for infringing/taking its patent rights relating to a process for manufacturing silicon carbide fiber sheets used in fighter aircraft.³³⁹ The government allegedly imported fibers manufactured in a foreign country, which would violate Zoltek's rights under a specific provision of the patent act.³⁴⁰ Because this relatively recent addition to U.S. patent rights was not incorporated into § 1498, the court, in an earlier decision, determined that compensation could not be obtained through this statute.³⁴¹ However, Zoltek contended that the act of importation was nonetheless a taking of property, cognizable under the broader

³³⁵ *Id.* at 303–07.

³³⁶ *Id.* at 305–07.

³³⁷ *Id.* at 307 (“[W]e think there is no room for doubt that the statute makes full and adequate provision for the exercise of the power of eminent domain for which, considered in its final analysis, it was the purpose of the statute to provide.”).

³³⁸ 58 Fed. Cl. 688 (2003).

³³⁹ *Id.* at 689.

³⁴⁰ 35 U.S.C. § 271(g) (2003) (“Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. . . .”).

³⁴¹ *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 837 (2002) (“Because nothing in the legislative history indicates that Congress intended for the meaning and effect of section 1498 to change in congruence with changes in 35 U.S.C. § 271, the Court is constrained to hold that section 1498 does not apply to all forms of direct infringement as currently defined in 35 U.S.C. § 271.”).

Tucker Act. In a decision involving some delicate legal maneuvering, the court agreed.³⁴²

The basis of the court's decision was that *Crozier* overruled *Schillinger's* narrow interpretation of the Tucker Act.³⁴³ The court determined that *Crozier* held government patent infringement to be an act of eminent domain, and that the predecessor to § 1498 was a remedial measure necessary only during those intervening years following *Schillinger*.³⁴⁴ Despite the current redundancy of § 1498, the court found that it could be integrated with the Tucker Act by allowing the latter to extend jurisdiction to acts of infringement not covered under the former.³⁴⁵ The court noted that remedies for both cases would be restricted to those described under § 1498 (which, if based on eminent domain, should not be different than those available under the Tucker Act).³⁴⁶

The analysis in *Zoltek* could be a bit harder to reconcile in consideration of Congress's clear beliefs throughout the Twentieth Century, a period when it enacted not only the predecessor statute to § 1498, but also an amendment that provided jurisdiction for copyright infringement/takings.³⁴⁷ The copyright amendment was added much more recently, in 1960, and it is clear from the legislative history of that move that Congress believed that jurisdiction was not otherwise available.³⁴⁸ Thus, to follow the

³⁴² *Zoltek Corp. v. United States*, 58 Fed. Cl. 688, 704 (2003).

³⁴³ *Id.* at 702 (“Thus, *Crozier* effectively overruled *Schillinger* sub silentio and reinstated the theory of *James v. Campbell* “[t]hat the government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.”) (quoting *James v. Campbell*, 104 U.S. 356, 357–58 (1881)).

³⁴⁴ *Id.* at 700–02.

³⁴⁵ *Id.* at 702–03 (“Thus, regarding rights created by the Patent Act other than use or manufacture, the Tucker Act can provide jurisdiction to this Court without conflicting with § 1498.”).

³⁴⁶ *Id.* at 704.

³⁴⁷ Pub. L. 86-726, §§ 1, 4, 74 Stat. 855, 856 (1960) (codified as 28 U.S.C. § 1498(c) (2000)).

³⁴⁸ *See, e.g.*, S. REP. NO. 1877, at 3 (1960):

When the Government deliberately publishes a copyrighted article, without obtaining the prior consent of the copyright proprietor, the general assumption

reasoning of *Zoltek*, one must accept that Congress was so mistaken regarding Tucker Act jurisdiction that it enacted two separate, completely unnecessary statutes. If so, it is a little surprising that no court has raised the issue until the turn of this century.

Despite the prior confusion surrounding intellectual property and eminent domain law, the most reasonable position is that adopted by the *Zoltek* court. Odd as it may seem, it appears that both Congress and the Supreme Court have been periodically confused as to the relationship between property torts and takings.³⁴⁹ The fact is, as described above,³⁵⁰ they are not different in nature, but only in context. A physical intrusion on private property, violating the owner's right to exclude, is a tort when it occurs between two private individuals.³⁵¹ However, when the trespasser is a government entity, the very same infringement may be an act of inverse condemnation based on eminent domain powers.³⁵² This is entirely clear in the law concerning tangible property, but for some reason has become muddled when intellectual property is involved.

would be that the holder, pursuant to the principles of "just compensation" under the Fifth Amendment of our Constitution should be entitled to an action against the Government for infringement. Yet no such infringement cases have been reported so far as this committee can determine. The reason appears to be that the Government, under still another established concept, i.e., "sovereign immunity," must consent to be sued for this particular type of wrong, and as yet has not so consented.

³⁴⁹ See, e.g., *id.*; *Schillinger v. United States*, 155 U.S. 163, 169 (1894). It is interesting to note that, in the Senate Report on the copyright amendment to § 1498, the belief that the federal government enjoyed immunity from copyright suits appears to be based largely on the empirical fact that none had been attempted, rather than a thoughtful legal analysis. S. REP. NO. 1877, at 3; see *supra* note 348.

³⁵⁰ See *supra* Part IV.C.2.

³⁵¹ See RESTATEMENT, *supra* note 233, § 158; KEETON ET AL., *supra* note 281, §§ 13, 14.

³⁵² See *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 436 (1982) (drawing parallels between the special kind of damage a property owner incurs when a stranger physically invades his or her property, and the government's obligations under the Fifth Amendment); *Drury v. United States*, 902 F. Supp. 107, 110 (E.D. La. 1995); *Palm v. United States*, 835 F. Supp. 512, 516 (N.D. Cal. 1993) (stating that "because of this gray area, the same set of facts may, under certain circumstances, constitute viable claims under both legal theories"), *aff'd sub. nom. Bartleson v. United States*, 96 F.3d 1270 (9th Cir. 1996).

Some commentators have argued that there is a distinction, but it is not tort law versus eminent domain, but rather non-intentional torts versus authorized acts of intrusion.³⁵³ Patent infringement is generally recognized as an unintentional tort,³⁵⁴ whereas acts of eminent domain must occur with the authority of the sovereign to be constitutional.³⁵⁵ In truth, referring to patent infringement as a no-intent harm is probably an artifact of some early ill-reasoning—it could be argued that patent infringement requires general intent (as opposed to specific intent) in the same way that trespass to personal property or chattels does³⁵⁶—but this notion exists in the law nonetheless. However, even if one may be “strictly liable” for patent infringement without any intent,³⁵⁷ many infringers are well aware of the implications of their acts.³⁵⁸ And to the extent a patent infringement/taking is intentional (such as importing a pharmaceutical explicitly covered by a patent)³⁵⁹ there would seem

³⁵³ See, e.g., Jed Silversmith, *Takings, Torts & Turmoil: Reviewing the Authority Requirement of the Just Compensation Clause*, 19 UCLA J. ENVTL. L. & POL’Y 359, 389–94 (2001).

³⁵⁴ See, e.g., *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring) (“Similarly, because intent is irrelevant to patent infringement, an experimental use excuse cannot survive.”); *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (Fed. Cir. 1996).

³⁵⁵ See Silversmith, *supra* note 353, at 368–72.

³⁵⁶ RESTATEMENT, *supra* note 233, § 217(b) (“A trespass to a chattel may be committed by intentionally . . . using or intermeddling with a chattel in the possession of another . . .”); *id.* § 158(a) (“One is subject to liability to another for trespass, irrespective of whether he thereby causes harm to any legally protected interest of the other, if he intentionally . . . enters land in the possession of the other. . .”).

³⁵⁷ See, e.g., *Jurgens*, 80 F.3d at 1570 n.2 (“Infringement itself, however, is a strict liability offense . . .”).

³⁵⁸ This is the primary reason that courts enhance damages as permitted by 35 U.S.C. § 284. See *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992) (“While no statutory standard dictates the circumstances under which the district court may exercise its discretion, this court has approved such awards where the infringer acted in wanton disregard of the patentee’s patent rights, that is, where the infringement is willful.”).

³⁵⁹ Information regarding which patents, if any, a manufacturer believes cover a particular drug is publicly available—now even through the Internet—via the FDA’s Orange Book. See *Electric Orange Book*, *supra* note 26. While knowledge of a patent is not, in and of itself, enough to create a finding of willfulness, it does obligate a party to investigate further the potential for infringement. See *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1190 (Fed. Cir. 1998). The Federal Circuit recently addressed the obligation to investigate potential infringement, affirming the “affirmative duty of due care to avoid infringement,” but eliminating the negative inference for not

to be no basis for distinguishing between eminent domain takings and private infringement (except in terms of remedies). Thus, in the current context, this distinction is not important.

The liability for direct federal government involvement in importation appears to substantially lessen the attractiveness of this option. In combination with the barriers facing states and municipalities, such large scale programs to ensure safety follows low prices may be foreclosed. Of course, the foregoing analysis addresses existing law at it affects importation. However, one could reasonably ask, if the legal rights afforded pharmaceutical patent owners present such daunting liability concerns for importers, why not just change the law? Indeed, Congress is considering bills that would do just this. However, the Constitution ensures that such measures are not so easily enacted.

IV. A CATCH-22: CONSTITUTIONAL ROADBLOCKS IN REVISING PATENT RIGHTS TO PERMIT IMPORTATION

A revision of the current rules could be accomplished by relatively simple legislative action. Of course, when established property rights are limited or eliminated by Congress, there are constitutional hurdles that must be addressed for such changes in the law to stand. In the case of patent property rights on important pharmaceuticals, it appears that the benefits of legal change would either be offset by the costs, or delayed for an intolerable amount of time. A review of current legislative proposals suggests that this may be an intractable issue that Congress cannot simply draft away.

A. Legislation that Negatively Impacts Established Property Rights

Because the boundaries of the patent right are defined by the Patent Act's infringement provision³⁶⁰ as well as a few common law rules such as national exhaustion, Congress can eliminate an

seeking the advice of outside counsel. *See* Knorr-Bremse Systeme Fuer Nutzpahrzeuge GmbH v. Dana Corp., 383 F.3d 1337, 1345–47 (Fed. Cir. 2004).

³⁶⁰ 35 U.S.C. § 271 (2000).

unwanted category of infringement very directly. In the case of international exhaustion, the legislature could simply rewrite the statute to overrule *Jazz Photo* and impose exhaustion following an authorized international sale. Such a revision could even be targeted to a specific field, such as pharmaceuticals. How this is accomplished with respect to existing property rights, however, determines whether such a revision will be upheld, or declared unconstitutional.

1. Constitutional Obstacles to Revising Property Rights

Although extensions rather than reductions of patent rights have typically been the rule over recent years,³⁶¹ rights have been explicitly excised at times. In many cases, reductions are coupled with extensions, and the net effect of a particular law is a bit unclear. For example, provisions in 1984's Hatch-Waxman Act that resulted in the loss of a pharmaceutical patent owner's right to sue infringers for using the patented invention to conduct research in preparation for a FDA application³⁶² were arguably offset by the patent owner's ability to obtain extensions of patent rights for regulatory delay.³⁶³ The argument that a legal revision has a neutral economic effect can be very important in terms of constitutional considerations, as described below.³⁶⁴

There have, however, been instances wherein patent rights were simply eliminated. Often, such measures appear to have been provoked by a political problem rather than a legal (or economic) one. Perhaps the best example is the 1996 act entitled *Limitations on Patent Infringements Relating to a Medical Practitioner's*

³⁶¹ See FEDERAL TRADE COMMISSION, *supra* note 16, ch. 2, pp. 18–22 (referring to a general strengthening of the patent system through Congress and the courts).

³⁶² 35 U.S.C. § 271(e) (2000) (amended 2003) (note that the 2003 amendment now expressly grants subject matter jurisdiction to the federal courts for a declaratory judgment of non-infringement where the patent holder fails to bring an action within 45 days after notice under 21 U.S.C. § 355).

³⁶³ 35 U.S.C. §§ 155, 156 (2003); see also Mossinghoff, *supra* note 28, at 190.

³⁶⁴ See, e.g., H.R. Rep. No. 98-857, pt.2, at 27–30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711–14 (considering whether the Hatch-Waxman Act would result in an unconstitutional taking of intellectual property and determining that it does not).

Performance of a Medical Activity.³⁶⁵ This law eliminated infringement liability for medical practitioners who infringe patents in the course of their medical activities.³⁶⁶ It was passed as part of the Department of Defense Appropriations Bill for that year³⁶⁷ with the poignant implication that medical practitioners were suffering under burdensome patent infringement liability.³⁶⁸ The law abolished these patent rights due to a perception that such enforcement would be socially unacceptable³⁶⁹ and merely added to health care costs.³⁷⁰ After some initial protest in the patent community, the revision has now been accepted, or at least tolerated.

The greatest obstacle the legislature faces in curtailing patent rights is the Fifth Amendment.³⁷¹ The courts have been clear that a legislative act that harms or eliminates existing property rights may constitute a taking, triggering the Constitution's just compensation requirement.³⁷² This characterization applies even when the act affects only a small part of a broad property right.³⁷³ If a statute making such a change does not provide a means for obtaining just

³⁶⁵ See Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616 (1996).

³⁶⁶ 35 U.S.C. § 287(c)(1) (2000).

³⁶⁷ See Courtenay C. Brinckerhoff, *Medical Method Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking?*, 4 U. BALT. INTELL. PROP. L.J. 147, 154-57 (1996).

³⁶⁸ See Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 789, 789-90 (1996) (reviewing the background behind the adoption of the limitation).

³⁶⁹ *Id.*

³⁷⁰ See 142 Cong. Rec. S. 12024 (1996) (statement of Sen. Frist).

³⁷¹ U.S. CONST. amend. V.

³⁷² See *E. Enters. v. Apfel*, 524 U.S. 498, 532-34 (1998) ("Retroactivity is generally disfavored in the law In *Calder v. Bull*, 3 Dall. 386, 1 L.Ed. 648 (1798), this Court held that the *Ex Post Facto* Clause is directed at the retroactivity of penal legislation, while suggesting that the Takings Clause provides a similar safeguard against retrospective legislation concerning property rights.").

³⁷³ See *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 429-30 (1982) ("Later cases, relying on the character of a physical occupation, clearly establish that permanent occupations of land by such installations as telegraph and telephone lines, rails, and underground pipes or wires are takings even if they occupy only relatively insubstantial amounts of space and do not seriously interfere with the landowner's use of the rest of his land.").

compensation, it is unconstitutional and will be struck down by a court, at least in part.³⁷⁴

Faced with the constitutional impediment, Congress has two choices: (1) create a mechanism for paying just compensation or (2) draft the law so as to only apply prospectively. The former is usually impractical for reasons described above, but the latter is commonly utilized.³⁷⁵ Unfortunately, in the fight to curb drug costs, prospective application of the law would render it useless in the near term.

Prospective application of a revision to the Patent Act means that only patents issuing after the law takes effect would be subject to the reduced rights.³⁷⁶ Existing patent rights would remain the same. This is significant because patents are usually obtained for products years before they traverse the complex and time consuming procedures for FDA marketing approval.³⁷⁷ Thus, a prospective patent right restriction would not only fail to impact products that are currently on the market, but new products arriving on the market for several years would be free of the new

³⁷⁴ See *E. Enters.*, 524 U.S. at 538 (invalidating a provision of Coal Industry Retiree Health Benefit Act that required a former operator to fund health benefits for retired miners who had worked for the operator before it left the coal industry). Theoretically, if a statute constitutes a taking and is unclear regarding Congress's intent to provide compensation, a plaintiff must first seek compensation from the Court of Federal Claims. See *Preseault v. ICC*, 494 U.S. 1, 11 (1990). However, the Supreme Court has recognized that, in situations wherein it would be a practical impossibility for the federal government to compensate, it can be presumed that Congress did not intend to provide compensation. See *E. Enters.*, 524 U.S. at 520–22. This must be the case in the context of an elimination of patent rights, which would require Congress to compensate for each incident of infringement in many separate, continuing actions; injunctive relief is the only realistic solution.

³⁷⁵ The Supreme Court has even noted that legislative decisions that affect property are presumed to be prospective unless they are specifically noted to apply retroactively. See, e.g., *United States v. Sec. Indus. Bank*, 459 U.S. 70, 79 (1982) (“The principle that statutes operate only prospectively, while judicial decisions operate retrospectively, is familiar to every law student.”).

³⁷⁶ For example, the law limiting medical practitioner liability states that it applies only to patents issuing on applications filed after the enactment date of the statute, September 1996. 35 U.S.C. § 287(c)(4) (2000). This is probably a bit of overkill, as patents become property rights only upon issuance, not application.

³⁷⁷ See also *Mossinghoff*, *supra* note 28, at 193 (chart using data from PhRMA depicting a typical timeline for the development of a new drug wherein patent rights are obtained ten years before the drug is approved).

rules. Thus, such a provision would not benefit consumers in the near future.

2. Legislative Initiatives Will Not Pass Muster Unless Diluted to Ineffectiveness

A legislative effort to open the borders to pharmaceutical importation is not merely hypothetical; at least six bills introduced in the 109th Congress seek to do so primarily by revising the FDA's regulatory and oversight mission.³⁷⁸ One of the most interesting of these legislative initiatives is the Pharmaceutical Market Access and Drug Safety Act of 2005 (hereinafter "PMADSA").³⁷⁹ The bill, sponsored by Senator Byron Dorgan and co-sponsored by a large, bi-partisan group of senators,³⁸⁰ is notable in that it tackles many of the most difficult issues involved in creating an effective importation system, going quite far in its impact on established property rights. For example, the PMADSA would have explicitly created an international exhaustion rule that is specific to pharmaceuticals:

(f) EXHAUSTION-

(1) IN GENERAL- Section 271 of title 35, United States Code, is amended—

(A) by redesignating subsections (h) and (i) as (i) and (j), respectively; and

(B) by inserting after subsection (g) the following:

(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food,

³⁷⁸ See, e.g., Affordable Health Care Act, S. 16, 109th Cong.; Prescription Drug Affordability Act, H.R. 578, 109th Cong.; Pharmaceutical Market Access Act of 2005, S. 109, 109th Cong.; Safe IMPORT Act of 2005, S. 184, 109th Cong.; Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong.; Prescription Drug Affordability Act of 2005, H.R. 563, 109th Cong.

³⁷⁹ Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th Cong.

³⁸⁰ See *id.* at 1 (listing co-sponsors such as Senators Trent Lott, Edward Kennedy and John McCain).

Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.³⁸¹

In doing so, the bill implicitly recognizes the existence of a national exhaustion rule for all other patented inventions and that a change to the Patent Act is required for a pharmaceutical importation plan to be effective.³⁸² The PMADSA also contains numerous provisions to address safety concerns and the proper role of the FDA in overseeing imports.

It is significant from the perspective of constitutional protections for patent rights that the bill contains no statement that the Patent Act revision is to apply prospectively, nor does it suggest that rights are not harmed.³⁸³ Additionally, it does not provide a compensation mechanism for patent rights taken by eminent domain. Thus, this provision appears to be a relatively clear unconstitutional legislative taking of property.

As with many of the other bills currently pending, the PMADSA is a reincarnation of a bill originally introduced during the 108th Congress. Interestingly, the part of the former PMADSA³⁸⁴ that received the most attention with respect to property rights was a section that would prohibit any attempt to restrict or deny supplies of drugs to registered exporters who import back into the United States.³⁸⁵ The same language exists in

³⁸¹ *Id.* § 4(d) (emphasis added).

³⁸² At least two other bills contain almost identical language: Affordable Health Care Act, S. 16, 109th Cong.; Pharmaceutical Market Access Act of 2005, S. 109, 109th Cong.

³⁸³ The bill does state that “[n]othing in the amendment made by [the paragraph revising the patent importation right] shall be construed to affect the ability of a patent owner or licensee to enforce their patent, subject to such amendment.” Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, §4(d) 109th Cong. This obviously does not account for the harm to the rights taken by the amendment.

³⁸⁴ Pharmaceutical Market Access and Drug Safety Act of 2004, S. 2328, 108th Cong.

³⁸⁵ See *Key Differences Between Kennedy-Dorgan & Gregg-Smith-Collins*, available at http://www.appwp.org/documents/safe_import_gregg-v-dorgan.pdf (last visited Feb. 12, 2005) (This document, which appeared on Senator Judd Gregg’s Website for several weeks in 2004, states that S. 2328 requires drug manufacturers to sell unlimited quantities of their drugs to foreign retailers at whatever price that foreign country stipulates, likely violating both the Takings Clause of the Fifth Amendment and the Patent Clause of Article I of the U.S. Constitution.).

the current bill.³⁸⁶ The reason for the provision was the fear that pharmaceutical companies would respond to an importation system by simply restricting the quantity of drugs that are exported to foreign countries to ensure an excess is not available for re-importation.³⁸⁷ Arguably, it would also constitute a taking in that it apparently compels pharmaceutical companies to make and sell whatever quantities of drugs are requested by licensed exporters.³⁸⁸ Such forced sales could be constitutional if initiated as a remedial measure to a finding of illegal activity, such as a violation of the antitrust laws.³⁸⁹ However, no such finding has been made with respect to international sales that would apply to the entire pharmaceutical industry. Thus, it is doubtful that this provision also would pass constitutional muster.

For the reasons identified above, the PMADSA will likely be quite controversial. Competing bills that are less stringent (and more industry friendly) have been proposed,³⁹⁰ and are likely to be proposed in the future. Unfortunately, it is doubtful that any compromise in approach will be both effective and constitutional. Anything less than a reduction of established patent rights will give branded pharmaceutical manufacturers the power to eliminate the benefits of any importation program. If there is any last hope among public policy advocates that these issues can be resolved without engaging pharmaceutical companies in negotiation, it is through legal revision by the courts.

³⁸⁶ Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, § 4(a), 109th Cong.

³⁸⁷ See 150 Cong. Rec. S4229 (2004) (“Our legislation also includes strict rules to close the loopholes that drug companies may use to evade the law.”) (statement of Senator Kennedy).

³⁸⁸ See Pharmaceutical Market Access and Drug Safety Act of 2004, S. 2328, 108th Cong. § 27(a).

³⁸⁹ See, e.g., *Xerox Corp.*, 86 F.T.C. 364, 373 (1975) (ordering compulsory licenses for patents relating to office copiers).

³⁹⁰ See, e.g., Safe IMPORT Act of 2005, S. 184, 109th Cong. It is a reincarnation of a bill introduced by Senator Judd Gregg in July of 2004, the Safe IMPORT Act of 2004, S. 2493, 108th Cong., apparently in response to Senator Dorgan’s S. 2328.

B. Rewriting the Rules through the Courts: An Exception to Constitutional Protections

Perhaps the most surprising aspect of eminent domain law is that the incredibly high constitutional hurdles that exist for the legislature are entirely absent when legal rules are changed by the courts. If a court decides to make a change to a common law rule that has a retroactive effect on existing property rights, no Fifth or Fourteenth Amendment concerns arise.³⁹¹ While the Supreme Court has toyed with the idea that new principles of law should be interpreted to apply prospectively only,³⁹² that view has been rejected in recent decisions.³⁹³ In light of this, it would appear that the *Jazz Photo* decision, the platform upon which so much of the controversy regarding importation and intellectual property rights rests, could be revised far more easily and with fewer implications than an act of Congress.³⁹⁴

To overrule *Jazz Photo*, another case and controversy obviously must arise, as certiorari has long been denied in that case.³⁹⁵ Even if this were to occur, to be effective, the decision

³⁹¹ The just compensation clause has never been applied to judicial decision making. See Daniel R. Cahoy, *Changing the Rules in the Middle of the Game: How the Prospective Application of Judicial Decisions Related to Intellectual Property Can Promote Economic Efficiency*, 41 AM. BUS. L.J. 1, 21 n.75 (2003) (noting this fact and the likely rationale).

³⁹² See *Chevron Oil Co. v. Huson*, 404 U.S. 97, 107 (1971) (“We should not indulge in the fiction that the law now announced has always been the law and, therefore, that those who did not avail themselves of it waived their rights.”) (citing *Griffin v. Illinois*, 351 U.S. 12, 26 (1956) (Frankfurter, J., concurring in judgment)).

³⁹³ See *Harper v. Va. Dept. of Taxation*, 509 U.S. 86, 97 (1993):

When this Court applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review and as to all events, regardless of whether such events predate or postdate our announcement of the rule.

The notion that a court could avoid *Harper* by fashioning a *remedy* that essentially rendered it ineffective to all but prospective cases was rejected in *Reynoldsville Casket Co. v. Hyde*, 514 U.S. 749, 753–54 (1995).

³⁹⁴ However, a revision of *Jazz Photo* would have a much greater economic effect, as it would affect patent rights in all industries, as opposed to being restricted to the pharmaceutical industry as in S. 2328.

³⁹⁵ See *Jazz Photo Corp. v. Int’l Trade Comm’n*, 536 U.S. 950 (2002). As noted previously, this assumes that the decision in *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368 (Fed. Cir. 2005), is merely a clarification of the earlier opinion.

must either be made by an *en banc* panel of the Federal Circuit³⁹⁶ or appeal of a three-judge-panel decision to the Supreme Court. While the Federal Circuit has been willing to make decisions *en banc* from time to time, they are relatively rare events. The Supreme Court, for its part, has generally allowed the Federal Circuit to operate on its own as the expert specialty court on patent law.³⁹⁷ The Court has been known to step in on occasions when the patent bar is particularly distressed about a ruling that has a particularly strong negative effect on patent rights.³⁹⁸ In the case of the exhaustion doctrine after *Jazz Photo*, however, no such outrage was evident (presumably because it is said to favor patent owners) and the case became dormant. It could be some time before another exhaustion case arises in the context of a typical patent infringement case.

On the other hand, if a patent provision like that in S. 334³⁹⁹ is enacted, it is possible that the issue will emerge in the course of a constitutional challenge to the statute by the owner of a pharmaceutical-related patent. Regardless of whether the case is initiated in federal or state court as described above, the issue of the proper boundaries of the patent right could eventually be addressed by the Supreme Court.⁴⁰⁰ The fact that an international exhaustion rule exists in other countries could influence certain members of the Court who have voiced an interest in looking to

³⁹⁶ An *en banc* panel of the Federal Circuit is required to change the precedent set forth by a three-judge panel. A subsequent three-judge-panel decision that differs is not binding on a subsequent panel or lower court. *See Newell Cos. v. Kenny Mfg. Co.* 864 F.2d 757, 765 (Fed. Cir. 1988) (“This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc*.”).

³⁹⁷ *See generally* Mark D. Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001 U. ILL. L. REV. 387 (2001).

³⁹⁸ *See, e.g., Festo Corp. v. Shoketsu Kinzoki Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), *vacated and remanded*, 535 U.S. 722 (2002). Over thirty-five amicus briefs were filed in the appeal before the Supreme Court. *See Festo*, 535 U.S. 722 (2002) (No. 00-1543).

³⁹⁹ *See supra* notes 379–89 and accompanying text.

⁴⁰⁰ In a takings case, one of the predicate issues a court must address is the scope and validity of the property right. *See United States v. Causby*, 328 U.S. 256, 260–61 (1946) (determining the boundaries of air rights associated with land in the modern world).

approach of other nations in forming legal doctrine.⁴⁰¹ And given the pharmaceutical industry's current status in the public eye—which appears on-par with tobacco companies—the *Jazz Photo* rule could be ripe for reversal. However, such a decision could be years in the future.

CONCLUSION

The preceding sections detail the conflict between health policy and patent property rights and note the legal obstacles that exist for pharmaceutical importation plans which envelope acts of infringement. A broad consideration of relatively novel Fifth and Fourteenth Amendment-based arguments suggests that there is no easy way to escape the protections accorded established property rights by the Constitution without creating special rules. If the law is straightforwardly enforced, unauthorized importers of patented pharmaceuticals will face liability under the Constitution even if there is immunity from prosecution under the Patent Act. This suggests that almost impenetrable barriers exist for importation initiatives. One might ask if this is really the proper result. From a philosophical standpoint, will we accept intellectual property rights that are so strong? The visceral issues in the drug import context provide a good test of society's convictions.

There are of course important reasons for granting full property rights for the creation of desirable information—principally, to create an incentive to invest money and effort.⁴⁰² However, lesser powers could be recognized for intangibles while still providing some incentives. For example, if infringement of intellectual

⁴⁰¹ See *Lawrence v. Texas*, 539 U.S. 538, 573 (2003) (looking to a decision by the European Court of Justice on the validity of laws prohibiting consensual homosexual conduct).

⁴⁰² See, e.g., *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (“The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’”); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 993–95 (1997) (“In a private market economy, individuals will not invest in invention or creation unless the expected return from doing so exceeds the cost of doing so—that is, unless they can reasonably expect to make a profit from the endeavor.”).

property were determined to be wholly distinct from eminent domain takings of the same property, thus removing the constitutional remedies, a less potent property right would result. Such a regime would, in essence, create a second-class form of property for patents, trademarks, copyrights and trade secrets. Though permissible under the law (assuming the legal revision is made by courts), there could be an economic cost. Each “stick” that one removes from the property bundle reduces the value of the whole to some extent;⁴⁰³ at some point, if enough sticks are disregarded, a few investors may be dissuaded and their innovations may never come to fruition.⁴⁰⁴ This is especially significant where the innovations in question are directly applicable to health and safety problems.⁴⁰⁵

In addition to economic incentives, there are public policy reasons for limiting the power of the government in its interactions with private property in the stream of commerce. In a market economy, government use of eminent domain power to control supply and demand in the market place would be an abuse of power if the government were not forced to fully compensate the injured party. Commentators have recognized that this power is

⁴⁰³ See, e.g., *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979) (describing the harm when a property owner loses “one of the most essential sticks in the bundle of rights that are commonly characterized as property—the right to exclude others”).

⁴⁰⁴ See, e.g., Sunil Kanwar & Robert Evenson, *Does Intellectual Property Protection Spur Technological Change?* 18 (June 2001) (Center Discussion Paper No. 831 (unpublished), Economic Growth Center, Yale University) (concluding that intellectual property protection has a strong positive association with research and development investment), available at <http://www.econ.yale.edu/~egcenter/research.htm>. One measure of the success of a patent system is the number of innovations it induces over the number that would have existed anyway. See NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, *A PATENT SYSTEM FOR THE 21ST CENTURY* 46 (Stephen A. Merrill et al. eds., 2004) (using “high quality patents” as an assessment criteria and stating that “[p]atents on known or only trivially modified inventions would confer potential market power . . . without providing incentives for making genuine advances or disclosing such advances to the public”), available at <http://www.nap.edu/books/0309089107/html>.

⁴⁰⁵ See, e.g., Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 247–50 (1999) (asserting that a legal change that allows parallel importation of pharmaceuticals will have a negative effect on research and development).

purposely limited to resolving the holdout problem.⁴⁰⁶ Eminent domain law ensures that the public costs are not borne solely by a few private property owners.

Of course, whether this private property-based model is the only one capable of producing the optimal amount of innovation is a fair question. The model seems primed for conflict, as it suggests that more income is always necessary for producing more innovation. Any reduction in income could result in fewer important treatments in the future than would otherwise be discovered.⁴⁰⁷ In the context of pharmaceuticals, research suggests that the pressures on the system are only likely to increase because the return on research and development investment appears to be decreasing.⁴⁰⁸ Other methods of encouraging innovation have been suggested,⁴⁰⁹ and some already run in parallel with the

⁴⁰⁶ See THOMAS J. MICELI, *ECONOMICS OF THE LAW* 138 (1997) (reviewing several theories regarding the rationale for eminent domain power and concluding that “[t]he justification for eminent domain, then, is the need to prevent hold-outs, which is a form of transaction costs”); see also RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 58–59 (4th ed. 1992); B. Hermalin, *An Economic Analysis of Takings*, 11 *J.L. ECON. & ORG.* 64, 64–86 (1995); William Michael Treanor, *The Origins and Original Significance of the Just Compensation Clause of the Fifth Amendment*, 94 *YALE L.J.* 694, 711–12 (1985). Theoretically, a legitimate public use of the taken property must also be shown, but courts have relaxed this requirement significantly. See *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 240 (1984) (“There is, of course, a role for courts to play in reviewing a legislature’s judgment of what constitutes a public use, even when the eminent domain power is equated with the police power. But the Court in *Berman* made clear that it is ‘an extremely narrow’ one. . . .”) (quoting *Berman v. Parker*, 348 U.S. 26, 32 (1954)). But see *County of Wayne v. Hathcock*, 684 N.W.2d 765, 782–88 (Mich. 2004) (overruling the decision in *Poletown Neigh. Council v. Detroit*, 304 N.W.2d 455 (Mich. 1981), and finding that, under the Michigan Constitution, a public use must be found in the condemnation itself).

⁴⁰⁷ See PhRMA, *supra* note 41, at 1 (arguing that “[i]f we focus too much on cutting the costs of medicines, we may lose sight of their value and we may jeopardize the value of pharmaceuticals that could be developed in the future”).

⁴⁰⁸ See DiMasi et al., *supra* note 42, at 154 fig.1 (demonstrating that the discovery of new chemical entities does not appear to be increasing at the same rate as R&D expenditure).

⁴⁰⁹ See, e.g., Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 *Q.J. ECON.* 1137 (1998) (proposing a system wherein property rights for important innovations are purchased by the public and freely available for developmental research). But see Michael Abramowicz, *Patent Prizes*, 56 *VAND. L. REV.* 115, 170–71 (2003) (introducing a detailed discussion as to why such “patent prize” systems are inherently flawed).

current intellectual property system.⁴¹⁰ Though they may not render the concept of intellectual property obsolete in the near future, such alternatives may provide a measure of relief in areas of great tension like health care.

For the immediate future, it is important to note that protecting patent property rights and providing effective health care (or any other public service) are not necessarily mutually exclusive. There are other methods for allocating resources that do not depend on rewriting property rules. Three intelligent steps toward resolving the health care crisis in this manner include: (1) using the negotiating power of government entities and large private purchasers (such as insurers) to extract lower prices; (2) undertaking and reporting rational assessments of the effectiveness of new medicines to enable purchasers to decide which new, patented products are worth high prices; and (3) providing the public with an honest assessment of the trade-offs that must be made when the best health care is limited by economic realities. In view of the barriers to pharmaceutical importation composed of patent fences supported by durable constitutional fence posts, elected officials would be wise to consider the alternatives before setting out on a journey that is likely to end in public disenchantment.

⁴¹⁰ See, e.g., David McGowan, *Legal Implications of Open Source Software*, 2001 U. ILL. L. REV. 241, 287–88 (2001) (describing the interaction between the tenets of the open source software movement and copyright intellectual property law).