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CRS Report for Congress

Patents and Drug Importation

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Patents and Drug Importation

Summary

Prescription drugs often cost far more in the United States than in other countries. Some consumers have attempted to import medications from abroad in order to realize cost savings. The practice of importing prescription drugs outside the distribution channels established by the brand-name drug company is commonly termed "parallel importation." Parallel imports are authentic products that are legitimately distributed abroad and then sold to consumers in the United States, without the permission of the authorized U.S. dealer.

Parallel importation may raise significant intellectual property issues. Many prescription drugs are subject to patent rights in the United States. In the *Jazz Photo* decision, the U.S. Court of Appeals for the Federal Circuit confirmed that the owner of a U.S. patent may prevent imports of patented goods, even in circumstances where the patent holder itself sold those goods outside the United States. The *Jazz Photo* opinion squarely declined to extend the "exhaustion" doctrine — under which patent rights in a product are spent upon the patent owner's first sale of the patented product — to sales that occurred in foreign countries. The court's ruling will in some cases allow brand-name pharmaceutical firms to block the unauthorized parallel importation of prescription drugs through use of their patent rights.

Several state and local governments are either themselves importing, or encouraging others to import, patented medications from foreign jurisdictions. The Eleventh Amendment of the U.S. Constitution provides that a federal court may not adjudicate a lawsuit by a private person against a state, except under certain limited circumstances. The ability of a private party to obtain a remedy for patent infringement against a state government is therefore uncertain. Eleventh Amendment immunity may in some cases extend to political subdivisions of a state as well.

In addition to any patent rights they possess, brand-name drug companies may place label licenses on their medications. It is possible to draft a label license restricting use of a drug to the jurisdiction in which it was sold. As a result, in addition to a charge of patent infringement, an unauthorized parallel importer may potentially face liability for breach of contract.

Two bills introduced before the 109th Congress, S. 109 and H.R. 328, each addressed the importation of prescription drugs. Each titled the Pharmaceutical Market Access Act of 2005, these bills would have amended the Patent Act of 1952 to provide that importation into the United States of a regulated pharmaceutical sold abroad by a patent proprietor or its representative is not a patent infringement. Introduction of an "international exhaustion" rule restricted to pharmaceuticals does not appear to be restricted by the provisions of the so-called TRIPS Agreement, which is the component of the World Trade Organization (WTO) agreements concerning intellectual property. Another possible legislative response is the immunization of specific individuals, such as pharmacies or importers, from patent infringement liability. Alternatively, no legislative action need be taken if the current possibility of an infringement action against unauthorized importers of patented pharmaceuticals is deemed satisfactory.

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Patents and Drug Importation

The pricing of prescription drugs has become a significant concern for many U.S. consumers. As spending on health care has risen in recent years,[1] so too has consumer interest in purchasing more affordable medications. Overseas markets provide one possible source of less costly prescription drugs. Some comparative studies of prescription drug prices in the United States and foreign nations have concluded that prices for specific drugs may be significantly lower abroad.[2] These price disparities in some instances have encouraged individuals and firms, as well as state and local governments, to attempt to import comparable medications from abroad in order to realize cost savings.[3]

The practice of importing patented prescription drugs outside the distribution channels established by the brand-name drug company is commonly termed "parallel importation."[4] Parallel imports are authentic products that are legitimately distributed abroad and then sold to consumers in the United States, without the permission of the authorized U.S. dealer. These goods are legitimate in that they are produced by the brand-name drug company or its authorized representative. In particular, parallel imports are not generic versions of a brand-name drug distributed by a different manufacturer, nor are they pirated copies that form part of the "black market." Because parallel imports disrupt the marketing arrangements established by the brand-name drug company, however, they are sometimes called "grey market goods."[5]

Current debate surrounding the parallel importation of prescription pharmaceuticals has largely addressed the safety and efficacy of the imported medications.[6] This practice may also raise significant intellectual property concerns,

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[1] See CRS Report RL31094, *Health Care Spending: Past Trends and Projections*, by Paulette C. Morgan.

[2] See, e.g., Farin Khosravi, "Price Discrimination in the United States: Why Are Pharmaceuticals Cheaper in Canada and Are Americans Seizing the Opportunities Across the Border?," 9 *Law and Business Review of the Americas* (2003), 427.

[3] See, e.g., Shubha Ghosh, "Pills, Patents and Power: State Creation of Gray Markets as a Limit on Patent Rights," 14 *Florida Journal of International Law* 217 (2002).

[4] See, e.g., Warwick A. Rothnie, *Parallel Imports* (Sweet & Maxwell 1993); Simon Horner, *Parallel Imports* (Blackwell Science 1987).

[5] See, e.g., Seth E. Lipner, *The Legal and Economic Aspects of Gray Market Goods* (Quorum Books, Westport, Connecticut 1990).

[6] See CRS Report RL32271, *Importation of Prescription Drugs Provisions in P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, by Susan Thaul & Donna U. Vogt.

however. Many prescription drugs are subject to patent rights in the United States. Indeed, because patented drugs usually have no exact generic equivalent available in the marketplace,[7] economic incentives for parallel importation may be strongest for patented medications. Among the rights granted by an issued patent is the ability to exclude others from importing the patented product into the United States.[8] As a result, even if a foreign drug is judged safe and effective for domestic use, brand-name firms may nonetheless be able to block the unauthorized importation of prescription drugs through use of their patent rights.

In the 109th Congress, two bills titled the Pharmaceutical Market Access Act of 2005, S. 109 and H.R. 328, would have accounted for the patent implications of the parallel importation of pharmaceuticals. In particular, section 8 of these bills would have amended the Patent Act of 1952 to provide that it is not an act of patent infringement to import into the United States a drug that was first sold abroad by or under authority of the owner or licensee of such patent. The effect of these bills would have been to introduce a doctrine known as "international exhaustion" into the U.S. patent law.[9]

The parallel trade of patented pharmaceuticals involves a fundamental trade-off within the intellectual property law: encouraging the labors that led to technological innovation, on one hand, and promoting access to the fruits of those labors, on the other. The patent system is built upon the premise that patents provide individuals with an incentive to innovate by awarding inventors exclusive rights in their inventions for a limited period of time.[10] Some observers believe that a diminishment of patent rights will decrease incentives to develop new pharmaceuticals in the future.[11] Yet there is growing concern that drug prices are too high in the United States as compared to other nations. Some commentators believe that the patent system should not be used to regulate the movement of legitimate, lawfully purchased products through the global marketplace.[12]

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[7] See, e.g., Melissa K. Davis, "Monopolistic Tendencies of Brand-Name Drug Companies in the Pharmaceutical Industry," 15 *Journal of Law and Commerce* (1995), 357.

[8] See 35 U.S.C. § 271(a) (2006) (providing patent proprietors with the right to exclude others from importing patented inventions into the United States).

[9] See Rebecca S. Eisenberg, "Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development," 72 *Fordham Law Review* (2003), 477.

[10] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989).

[11] Claude E. Barfield & Mark A. Groombridge, "Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy," 10 *Fordham Intellectual Property, Media and Entertainment Law Journal* (1999), 185.

[12] William Davis, "The Medicine Equity and Drug Safety Act of 2000: Releasing Grey Market Pharmaceuticals," 9 *Tulane Journal of International and Comparative Law* (2001), 483.

This report explores the intellectual property laws and policies concerning the parallel importation of patented pharmaceuticals into the United States.[13] It begins with a review of patent policy and procedures. The report then discusses the current legal framework for analyzing the permissibility of the parallel importation of patented pharmaceuticals, including both the domestic and international exhaustion doctrines. Special consideration is given to state and local governments that have either themselves imported, or have encouraged others to import, patented medications from foreign jurisdictions; the potential use of label licenses on patented drugs; and the implications of international trade rules established by World Trade Organization. This report closes with a review of legislative issues and alternatives as they relate to intellectual property issues and parallel importation.

Fundamentals of Pharmaceutical Patents

Patent Policy

The patent system is animated by a number of policy objectives designed to promote the production and dissemination of technological information. Many commentators have argued that the patent system is necessary to encourage individuals to engage in inventive activity.[14] Proponents of this view reason that, absent a patent system, inventions could easily be duplicated by free riders, who would have incurred no cost to develop and perfect the technology involved, and who could thus undersell the original inventor. The resulting inability of inventors to capitalize on their inventions would lead to an environment where too few inventions are made. By providing individuals with exclusive rights in their inventions for a limited time, the patent system allows inventors to realize the profits from their inventions. Further, these rights are grounded in the U.S. Constitution, which authorizes Congress to delineate them.[15]

The courts have also suggested that absent a patent law, individuals would favor maintaining their inventions as trade secrets so that competitors could not exploit them. Trade secrets do not enrich the collective knowledge of society, however, nor do they discourage others from engaging in duplicative research. The patent system attempts to avoid these inefficiencies by requiring inventors to consent to the disclosure of their inventions in issued patent instruments.[16]

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[13] This report does not address other mechanisms to lower the prices of pharmaceuticals. For one view on whether allowing the parallel importation of pharmaceuticals would in fact lower prices, see Congressional Budget Office, Economic and Budget Issue Brief, *Would Prescription Drug Importation Reduce U.S. Drug Spending?*, by Colin Baker (April 29, 2004).

[14] E.g., Dan L. Burk & Mark A. Lemley, "Policy Levers in Patent Law," 89 *Virginia Law Review* (2003), 1575.

[15] U.S. Constitution, Article I, § 8, cl. 8.

[16] See, e.g., Grant v. Raymond, 31 U.S. 218, 247 (1832).

There are still other explanations for the patent laws. For instance, the Patent Act of 1952[17] is thought by supporters to stimulate technological advancement by inducing individuals to "invent around" patented technology. Issued patent instruments may point the way for others to develop improvements, exploit new markets or discover new applications for the patented technology.[18] The patent system may encourage patentees to exploit their proprietary technologies during the term of the patent. Proponents believe the protection provided by a patent's proprietary rights increases the likelihood a firm will continue to refine, produce and market the patented technology.[19] Finally, the patent law has been identified as a facilitator of markets. Absent patent rights, an inventor may have scant tangible assets to sell or license, and even less ability to police the conduct of a contracting party. By reducing a licensee's opportunistic possibilities, the patent system lowers transaction costs and makes technology-based transactions more feasible.[20]

The current patent system has a great number of critics. Some assert that the patent system is unnecessary due to market forces that already suffice to create an optimal level of invention. The desire to gain a lead time advantage over competitors, as well as the recognition that technologically backward firms lose out to their rivals, may well provide sufficient inducement to invent without the need for further incentives.[21] Some commentators observe that successful inventors are sometimes transformed into complacent, established enterprises that use patents to suppress the innovations of others.[22] Others assert that the inventions that have fueled some of our most dynamic industries, such as early biotechnologies and computer software, arose at a time when patent rights were unavailable or uncertain.[23]

While these various justifications and criticisms have differing degrees of intuitive appeal, none of them has been empirically validated. No conclusive study broadly demonstrates that we get more useful inventive activity with patents than we would without them. The justifications and criticisms of the patent system therefore remain open to challenge by those who are unpersuaded by their internal logic.[24]

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[17] P.L. 82-593, 66 Stat. 792 (codified at Title 35 United States Code).

[18] R. Polk Wagner, "Information Wants to Be Free: Intellectual Property and the Mythology of Control," 103 *Columbia Law Review* (2003), 995.

[19] F. Scott Kieff, "Property Rights and Property Rules for Commercializing Inventions," 85 *Minnesota Law Review* (2000), 697.

[20] See Robert P. Merges, "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," 93 *Michigan Law Review* (1995), 1570.

[21] See Frederic M. Scherer & David Ross, *Industrial Market Structure and Economic Performance* (Rand McNally & Co., 3d ed. 1990).

[22] See Robert P. Merges and Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *Columbia Law Review* (1990), 839.

[23] See, e.g., Pamela Samuelson, Benson *Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program — Related Inventions*, 39 *Emory Law Journal* (1990), 1025.

[24] See CRS Report RL31951, *Innovation, Intellectual Property, and Industry Standards*, by (continued...)

U.S. Patent Acquisition and Enforcement

As mandated by the Patent Act of 1952,[25] U.S. patent rights do not arise automatically. Inventors must prepare and submit applications to the U.S. Patent and Trademark Office ("USPTO") if they wish to obtain patent protection.[26] USPTO officials, known as examiners, then assess whether the application merits the award of a patent.[27] The patent acquisition process is commonly known as "prosecution."[28]

In deciding whether to approve a patent application, an USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[29] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[30] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must be useful, novel and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[31] To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other knowledge within the public domain.[32] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[33]

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[34] The term of the patent is ordinarily set at twenty years from the date the patent application was filed.[35] Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits the inventor to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market.

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[24] (...continued)
John R. Thomas.

[25] P.L. 82-593, 66 Stat. 792 (codified at Title 35 United States Code).

[26] 35 U.S.C. § 111 (2006).

[27] 35 U.S.C. § 131 (2006).

[28] John R. Thomas, "On Preparatory Texts and Proprietary Technologies: The Place of Prosecution Histories in Patent Claim Interpretation," 47 *UCLA Law Review* (1999), 183.

[29] 35 U.S.C. § 112 (2006).

[30] *Ibid.*

[31] 35 U.S.C. § 101 (2006).

[32] 35 U.S.C. § 102 (2006).

[33] 35 U.S.C. § 103 (2006).

[34] 35 U.S.C. § 271(a) (2006).

[35] 35 U.S.C. § 154(a)(2) (2006).

Patent rights are not self-enforcing. A patentee bears responsibility for monitoring its competitors to determine whether they are using the patented invention or not. Patent owners who wish to compel others to observe their intellectual property rights must usually commence litigation in the federal district courts. The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") possesses exclusive national jurisdiction over all patent appeals from the district courts,[36] while the U.S. Supreme Court possesses discretionary authority to review cases decided by the Federal Circuit.[37]

Pharmaceutical patents are subject to special provisions created by the Drug Price Competition and Patent Restoration Act of 1984.[38] This legislation, which was subject to significant legislative revisions in 2003,[39] is commonly known as the Hatch-Waxman Act.[40] This statute establishes special rules for enforcement of certain patents on certain drugs and medical devices by brand-name firms against generic competitors. The Hatch-Waxman Act includes provisions extending the term of a patent to reflect regulatory delays encountered in obtaining marketing approval by the Food and Drug Administration (FDA);[41] exempting from patent infringement certain activities associated with regulatory marketing approval;[42] establishing mechanisms to challenge the validity of a pharmaceutical patent;[43] and creating a reward for disputing the validity, enforceability, or infringement of a patented and approved drug.[44] The 1984 Act also provides the FDA with certain authorities to offer periods of marketing exclusivity for a pharmaceutical independent of the rights conferred by patents.[45]

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[36] 28 U.S.C. § 1295(a)(1) (2006).

[37] 28 U.S.C. §1254(1) (2006).

[38] P.L. 98-417, 98 Stat. 1585 (1984).

[39] The Medicare Prescription Drug and Modernization Act of 2003, P.L.. 108-173, Title XI (Dec. 8, 2003). See CRS Report RL32377, *The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents*, by Wendy H. Schacht and John R. Thomas.

[40] See CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas.

[41] 35 U.S.C. § 156 (2006).

[42] 35 U.S.C. § 271(e)(1) (2006).

[43] 21 U.S.C. § 355(j) (2006).

[44] 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

[45] 21 U.S.C. § 355(j)(4)(D) (2006).

The Exhaustion Doctrine

Patent rights are subject to a significant restriction that is termed the "exhaustion" doctrine. Under the exhaustion doctrine, an authorized, unrestricted sale of a patented product depletes the patent right with respect to that physical object.[46] As a result of this doctrine, the purchaser of a patented good ordinarily may use, charge others to use, or resell the good without further regard to the patentee. The courts have reasoned that when a patentee sells a product without restriction, it impliedly promises its customer that it will not interfere with the full enjoyment of that product.[47] The result is that the lawful purchasers of patented goods may use or resell these goods free of the patent.[48] Because it is the first sale of a patented product that extinguishes patent rights with respect to the item that is sold, some authorities refer to the exhaustion doctrine as the "first sale rule."[49]

For example, suppose that a consumer purchases an appliance at a hardware store. The appliance is subject to a patent that is owned by the manufacturer. Later, the consumer sells the appliance to a neighbor at a garage sale. Ordinarily, the patent laws provide the manufacturer with the ability to prevent others from selling an appliance that uses its patented design.[50] In this case, however, the patent right in that particular appliance was exhausted when the manufacturer made its first sale to the consumer. That consumer, as well as any subsequent purchasers of that individual appliance, may freely sell it without concern for the manufacturer's patent.[51]

International Aspects

U.S. patents provide their owners with rights only within the United States.[52] The grant of a U.S. patent provides its owner with no legal rights in any foreign nation. If inventors desire intellectual property protection in another country, they must specifically procure a patent in that jurisdiction. Ordinarily the foreign patent acquisition process begins with the submission of a patent application to a foreign patent office.[53]

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[46] See Intel Corp. v. ULSI System Technology, 995 F.2d 1566, 1568 (Fed. Cir.1993).

[47] See B. Braun Medical, Inc. v. Abbott Laboratories, 124 F.3d 1419, 1426, (Fed. Cir.1997).

[48] See Intel Corp. v. ULSI System Technology, 995 F.2d 1566 (Fed. Cir.1993).

[49] See, e.g., Alan O. Sykes, "TRIPS, Pharmaceuticals, Developing Countries, and the Doha 'Solution'," 3 *Chicago Journal of International Law* (2002), 47.

[50] 35 U.S.C. § 271(a) (2006).

[51] See Roger E. Schechter & John R. Thomas, *Intellectual Property: The Law of Copyrights, Patents and Trademarks* § 1.2.3 (2003).

[52] *Quality Tubing, Inc. v. Precision Tube Holdings Co.*, 75 F.Supp.2d 613, 619 (S.D. Tex. 1999).

[53] See CRS Report RL31132, *Multinational Patent Acquisition and Enforcement: Public Policy Challenges and Opportunities for Innovative Firms*, by John R. Thomas.

As a practical matter, multinational corporations often obtain a set of corresponding national patents for each of their significant inventions. Although these patents concern the same invention — for example, the same chemical compound that possesses pharmacological properties — they often do not have precisely the same legal effect in each jurisdiction. Divergent wordings of the patents' claims, translations into various languages, and distinctions between national patent laws and practice are among the factors that lead to these differences.[54]

Under an important international agreement concerning patents, the Convention of Paris for the Protection of Industrial Property ("Paris Convention"),[55] each issued national patent is an independent legal instrument. One significant consequence of the independence of national patents is that they must be enforced individually.[56] For example, suppose that an inventor owns patents directed towards the same invention in both the United States and Canada. Following litigation in Canada, a court rules that the Canadian patent is invalid. Even though the Canadian patent may be similar or identical to the U.S. patent, the U.S. patent may still be freely enforced. Although a U.S. court may find the reasoning of the Canadian court persuasive as it reaches its own judgment regarding the validity of the U.S. patent, the Canadian court decision has no direct effect upon the validity or enforceability of the U.S. patent.[57]

The Parallel Importation of Patented Pharmaceuticals

In some circumstances, widely divergent drug prices between the United States and other nations have encouraged parallel importation. Price disparities between the United States and other nations create incentives for individuals to purchase medications from abroad, and import them into the United States, in order to lower health care costs or undercut the U.S. distributor.[58] In this context, the term "parallel imports" refers to patented products that are legitimately distributed abroad, and then sold to consumers in the United States without the permission of the authorized U.S. dealer. Although these "grey market goods" are authentic products that were sold under the authorization of the brand-name drug company, they entered the U.S. market outside the usual distribution channels for that drug.

The legal situation regarding the parallel importation of patented pharmaceuticals remains somewhat clouded. In such circumstances, the U.S. patent

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[54] See Margaret A. Boulware et al., "An Overview of Intellectual Property Rights Abroad," 16 *Houston Journal of International Law* (1994), 441.t

[55] 13 U.S.T. 25 (1962).

[56] See John R. Thomas, "Litigation Beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement," 27 *Law & Policy in International Business* (1996), 277.

[57] *Ibid.*

[58] See, e.g., Shubha Ghosh, "Pills, Patents and Power: State Creation of Gray Markets as a Limit on Patent Rights," 14 *Florida Journal of International Law* 217 (2002).

proprietor may be able to use its patent rights to block the importation of grey market pharmaceuticals. Because this scenario involves the distribution of a patented product that initially sold under the authorization of the patent proprietor, it raises issues concerning the exhaustion doctrine.[59]

One position, favorable to the patent proprietor, is that the U.S. patent is fully enforceable against imports despite the exhaustion doctrine. Under this line of reasoning, the fact that the sale by the patent proprietor or its representative took place outside the United States is significant. This line of reasoning relies on the fact that U.S. patents exist independently of foreign patents,[60] and that U.S. patents are effective only within the United States.[61] As a result, this reasoning continues, a foreign sale cannot result in exhaustion of a U.S. patent. This legal doctrine — which restricts the exhaustion doctrine to domestic sales only — allows the U.S. patent to be used to block unauthorized imports of a patented pharmaceutical.[62]

A competing view is that the exhaustion doctrine is not limited to domestic sales by the patentee or its representative, but to all sales regardless of their location. This position is commonly referred to as "international exhaustion."[63] Under this view, because the importer lawfully purchased authentic goods from the patent holder or its representative, the U.S. patent right is subject to "international exhaustion" due to the sale, despite the fact that the sale technically took place under a foreign patent.[64]

In its 2001 decision in *Jazz Photo Corp. v. United States International Trade Commission*,[65] the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") rejected the "international exhaustion" position and instead limited the exhaustion doctrine to sales that occur within the United States. There the Federal Circuit issued a succinct statement explaining:

> United States patent rights are not exhausted by patent rights 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, 10 S.Ct. 378, 33 L.Ed. 787 (1890).[66]

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[59] Nanao Naoko et al., "Decisions on Parallel Imports of Patented Goods," 36 *IDEA: The Journal of Law and Technology* (1996), 567.

[60] See supra notes 56-58 and accompanying text.

[61] See supra note 53 and accompanying text.

[62] 35 U.S.C. § 271(a) (2006).

[63] See Bruce A. Lehman, "Intellectual Property Rights as a Trade, Health, and Economic Development Issue," 17 *St. John's Journal of Legal Commentary* (Spring 2003), 417.

[64] See Jamie S. Gorelick & Rory K. Little, "The Case for Parallel Importation," 11 *North Carolina Journal of International Law and Commercial Regulation* (1986), 205.

[65] 264 F.3d 1094 (Fed. Cir. 2001).

[66] 264 F.3d at 1105.

Some commentators have criticized the Federal Circuit's reasoning in the *Jazz Photo* case, and in particular the court's reliance on the *Boesch v. Graff* decision.[67] In *Boesch v. Graff*, the plaintiff owned a U.S. patent for a lamp burner. An individual named Hecht, who was not a party to the litigation, enjoyed a "prior user right" pertaining to the lamp burners under German law. The German patent statute allowed individuals who had used an invention prior to the date of another's patent application the privilege of continuing to exploit the invention commercially, without regard to the patent. Hecht had met the conditions for this prior user right to apply, and as a result could sell the burners in Germany. Hecht eventually sold some burners to the defendants, who in turn imported them into the United States and commenced sales. The plaintiff brought suit to enjoin the sale of the imported burners in the United States. In opposing the injunction, the defendants argued that they had lawfully purchased the burners and that the U.S. patent should be subject to the exhaustion doctrine. The Supreme Court rejected the defendant's arguments, holding:

> The right which Hecht had to make and sell the burners in Germany was allowed him under the laws of that country, and purchasers from him could not be thereby authorized to sell the articles in the United States in defiance of rights of patentees under a United States patent. ... The sale of articles in the United States under a United States patent cannot be controlled by foreign laws.[68]

The facts and holding of *Boesch* have suggested to some commentators that its precedential reach is quite limited. In *Boesch*, it was a prior user, rather than the patentee or its licensee, which made the foreign sale. The patentee neither consented to the sale of the invention nor received compensation for that sale. According to some observers, this is a much different state of affairs than the typical parallel importation case, where either the patentee or an authorized overseas distributor makes a sale as part of an arm's-length commercial transaction.[69]

Given this precedential foundation, as well as the limited consideration of the issue in *Jazz Photo*, some legal commentators have questioned whether this apparent absolute ban on parallel importation will survive further judicial scrutiny.[70] The Federal Circuit has maintained this holding in subsequent case law,[71] however, so the Federal Circuit's statement in the *Jazz Photo* case remains the controlling patent law precedent. In particular, the federal district courts are bound by the *Jazz Photo* decision unless the Federal Circuit or Supreme Court alters the rule.[72]

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[67] Daniel Erlikhman, "*Jazz Photo* and the Doctrine of Patent Exhaustion: Implications to TRIPS and the International Harmonization of Patent Protection," 25 *Hastings Communications and Entertainment Law Journal* (2003), 307.

[68] 133 U.S. at 703.

[69] Erlikhman, *supra* note 68.

[70] *Ibid.*

[71] *See* Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d 1368, 1376-77 (Fed. Cir. 2005).

[72] See Matthew F. Weil & William C. Rooklidge, "State Un-Decisis: The Sometimes Rough Treatment of Precedent in Federal Circuit Decision-Making," 80 *Journal of the Patent and* (continued...)

To summarize current law, the Federal Circuit has taken the position that patent exhaustion applies only to sales that occurred in the United States. This rule squarely rejects the principle of "international exhaustion." As a result, brand-name drug companies may potentially block imports of patented medications into the United States even if the imported good is the patent owner's own product, legitimately sold to a customer in a foreign jurisdiction.[73]

Related Issues

In addition to the issue of patent infringement, the parallel importation of patented pharmaceuticals potentially raises a number of other complex issues. This report next considers three of these issues: the status of state and local governments that have either themselves imported, or have encouraged others to import, patented medications from foreign jurisdictions; the potential use of label licenses on patented drugs; and the implications of international trade rules established by World Trade Organization (WTO).

State and Local Governments

Several state governments are currently considering plans to import or facilitate the importation of prescription drugs. California, Illinois, Iowa, Minnesota, New Hampshire, North Dakota, Vermont and Wisconsin are among those that have considered importation programs.[74] If a state government or agency of a state encourages the importation of a patented medication in a manner that would infringe a patent, then the patentee's ability to obtain relief is at present time uncertain.

Observers have questioned whether the states should be subject to the patent rights of private parties.[75] The U.S. Constitution places a significant jurisdictional hurdle before a patentee seeking to vindicate its rights against a state. The Eleventh Amendment provides that a federal court is without power to entertain a suit by a private person against a state, except under certain limited circumstances.[76] Because

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[72] (...continued)
Trademark Office Society (1998), 791.

[73] See Catalin Cosovanu, "Piracy, Price Discrimination, and Development: The Software Sector in Eastern Europe and Other Emerging Markets," 31 *American Intellectual Property Law Association Quarterly Journal* (2003), 165.

[74] See CRS Report RL32191, *Prescription Drug Importation and Internet Sales: A Legal Overview*, by Jody Feder.

[75] See, e.g., Jennifer Polse, "Holding the Sovereign's Universities Accountable for Patent Infringement After *Florida Prepaid* and *College Savings Bank*," 89 *California Law Review* (2001), 507; Kenneth S. Weitzman, "Copyright and Patent Clause of the Constitution: Does Congress Have the Authority to Abrogate State Eleventh Amendment Sovereign Immunity After *Pennsylvania v. Union Gas Co.*?," 2 *Seton Hall Constitutional Law Journal* (1991), 297.

[76] The Eleventh Amendment to the U.S Constitution stipulates: "The judicial power of the (continued...)

the federal courts possess exclusive jurisdiction over patent infringement litigation,[77] this situation creates a dilemma for patentees — the only statutorily authorized forum is constitutionally unavailable, and the only constitutional forum is statutorily unavailable, at least for the assertion of a conventional patent infringement claim. This means that a patentee's only option would be a state court suit charging the state government with a taking, or asserting general unfair competition principles, in order to vindicate its patent rights.[78]

The Supreme Court established one notable exception to the Eleventh Amendment prohibition against federal court litigation against a state. In *Ex parte Young*,[79] the Court allowed private citizens to petition a federal court to enjoin state officials acting in their official capacity from engaging in future conduct that would violate the Constitution or a federal statute. The doctrine is based on a premise that state officers who violate federal law in the course of discharging the duties of their positions are acting outside the authority of their office, and therefore do not qualify as the state or its agent for Eleventh Amendment purposes.[80] The only remedy available under the *Ex parte Young* ruling is prospective injunctive relief, however, rather than a monetary judgment that would compensate for past harms.[81] Further, some uncertainty exists over the application of the *Young* exception to patents. Although the federal patent statute establishes the conditions under which inventors may obtain patents, an individual patent is effectively the grant of a private right, not a federal law.

Congress attempted to abrogate the Eleventh Amendment immunity of states to patent infringement suits in 1992. The Patent and Plant Variety Protection Remedy Clarification Act introduced section 271(h) into the Patent Act of 1952.[82] That provision specified not only that the states were subject to patent infringement suits in the federal courts, but that they were liable for any remedies that could be had against a private party.[83] However, the 1999 opinion of the Supreme Court in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank* found that Congress had not properly abrogated state immunity to patent

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[76] (...continued)
United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by citizens of another state, or by citizens or subjects of any foreign state."

[77] 28 U.S.C. § 1338(a) (2006) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . . Such jurisdiction shall be exclusive of the courts of the states in patent . . . cases.")

[78] See, e.g., Jacobs Wind Electric Co. v. Florida Dep't of Transportation, 919 F.2d 726 (Fed. Cir. 1990).

[79] 209 U.S. 123 (1908).

[80] *Cardenas v. Anzai*, 311 F.2d 929, 935 (9th Cir. 2002).

[81] See *Edelman v. Jordan*, 415 U.S. 651, 667-69 (1974).

[82] P.L. 102-560, 106 Stat. 4230 (Oct. 28, 1992).

[83] 35 U.S.C. § 271(h) (2006).

infringement litigation in the federal courts in keeping with the requirements of the Eleventh Amendment.[84]

In *Florida Prepaid* and other opinions, the Supreme Court did leave open the possibility that a state could waive its Eleventh Amendment immunity by submitting to federal jurisdiction.[85] In addition, Congress may in some cases overcome state Eleventh Amendment immunity through legislation pursuant to another constitutional authority, such as the Fourteenth Amendment.[86] Several bills have been introduced before Congress since the Supreme Court issued the *Florida Prepaid* decision that would take this approach, but none has been enacted.[87]

The immunity to federal suit provided by the Eleventh Amendment is restricted to state governments, and does not ordinarily apply to local governments.[88] As a result, a city or county government is generally not entitled to claim Eleventh Amendment immunity and avoid a suit for patent infringement in a federal court. However, some judicial opinions have reasoned that a political subdivision of a state can qualify for Eleventh Amendment immunity where the locality is only nominally the actor, and the state itself is the real party in interest in the litigation.[89] This determination depends on the precise relationship between the state and its political subdivision under the circumstances of a particular case.[90]

Label Licenses

As noted previously, the theory behind the exhaustion doctrine is that when a patent proprietor makes an unrestricted sale of a product to a consumer, the proprietor impliedly promises its customer that it will not use its patent rights to interfere with the full enjoyment of that product.[91] As a result, lawful purchasers of patented goods should be able to use or resell these goods free of the patent.[92]

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[84] 527 U.S. 627, 119 S.Ct. 2199, 144 L.Ed.2d 575 (1999).

[85] *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 238 (1985).

[86] *Welch v. Department of Highways and Public Transportation*, 483 U.S. 468, 477 (1987).

[87] Jeffrey W. Childers, "State Sovereign Immunity and the Protection of Intellectual Property: Do Recent Congressional Attempts to 'Level the Playing Field' Run Afoul of Current Eleventh Amendment Jurisprudence and Other Constitutional Doctrines?," 82 *North Carolina Law Review* (2004), 1067.

[88] See, e.g. Mount Healthy School District v. Doyle, 429 U.S. 274 (1977). *See also* Melvyn R. Durschlag, "Should Political Subdivisions Be Accorded Eleventh Amendment Immunity?," 43 *DePaul Law Review* (1994), 577; Anthony J. Harwood, "A Narrow Eleventh Amendment Immunity for Political Subdivisions: Reconciling the Arm of State Doctrine with Federalism Principles," 55 *Fordham Law Review* (1986), 101.

[89] See, e.g., Belanger v. Madera Unified School District, 963 F.2d 248, 254 (9th Cir. 1992).

[90] Donald L. Boren, "Congressional Power to Grant Federal Courts Jurisdiction Over States: The Impact of *Pennsylvania v. Union Gas*," 24 *Akron Law Review* (1990), 13.

[91] See B. *Braun Medical, Inc. v. Abbott Laboratories*, 124 F.3d 1419, 1426 (Fed. Cir.1997).

[92] See *Intel Corp. v. ULSI System Technology*, 995 F.2d 1566 (Fed. Cir.1993).

In some circumstances, however, the patent owner may attempt to restrict a customer's use of a good. Sales contracts are the typical mechanism for imposing such limitations. Contractual provisions that are placed on the product or its packaging are sometimes termed "label licenses" or "bag tags."[93] A commonly observed label license is "Single Use Only," as applied to printer cartridges or other goods that the manufacturer does not intend for consumers to reuse.[94] Other patent proprietors have attempted to impose geographical limitations upon the use of their products. A label stating "For Use in Canada Only" is representative of such a restriction.

Whether such label licenses are enforceable, or are instead nullified by the exhaustion principle, is a complex legal issue. However, the prevailing view of the Court of Appeals for the Federal Circuit is that absent exceptional circumstances — such as an antitrust violation or misuse of the patent by its proprietor — these restrictions will be upheld.[95] The legal theory is that the patent right gives proprietors the ability to exclude others from using the patented product, they may also impose lesser restrictions when they choose to sell the patented product.[96] In addition, customers are presumed to have entered into binding sales contracts that are presumptively valid.[97] As the law currently stands, then, a customer who violates a label license could be liable both for breach of contract and for patent infringement.[98]

The TRIPS Agreement

As a member of the World Trade Organization (WTO), the United States is a signatory to the so-called TRIPS Agreement, or Agreement on Trade-Related Aspects of Intellectual Property Rights.[99] Under Part III of the TRIPS Agreement, all member countries agreed to enact patent statutes that include certain substantive provisions. In particular, Article 27 stipulates that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology

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[93] See, e.g., Daniel R. Cahoy, "Oasis or Mirage? Efficient Breach as a Relief to the Burden of Contractual Recapture of Patent and Copyright Limitations," 17 *Harvard Journal of Law and Technology* (2003), 135; Michael J. Madison, "Reconstructing the Software License," 35 *Loyola University of Chicago Law Journal* (2003), 275.

[94] See *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992).

[95] See *Monsanto Co. v. McFarling*, 363 F.3d 1336 (Fed. Cir. 2004); *Bowers v. Baystate Technologies, Inc.*, 320 F.3d 1317 (Fed. Cir. 2003).

[96] See Richard Stern, "Post-Sale Restrictions After *Mallinckrodt* — An Idea in Search of a Definition," 5 *Albany Law Journal of Science and Technology* (1994), 1.

[97] See Merritt A. Gardiner, "*Bowers v. Baystate Technologies:* Using the Shrinkwrap License to Circumvent the Copyright Act and Escape Federal Preemption," 11 *University of Miami Business Law Review* (Winter/Spring 2003), 105.

[98] See Raymond Nimmer, "Issues in Software Licensing," 576 *Practising Law Institute/Pat.* (1999), 399.

[99] See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994) [hereinafter "TRIPS Agreement"].

and whether products are imported or locally prevented."[100] Article 27 ordinarily requires that all classes of invention receive the same treatment under the patent laws, subject to certain minor exceptions. It would generally be impermissible under Article 27, for example, for a country to accord patents on pharmaceuticals a lesser set of proprietary rights than is available for patents on automobile engines, computers, or other kinds of inventions.[101]

The TRIPS Agreement places lesser obligations upon signatory states with regard to the exhaustion doctrine, however.[102] Article 6 of the TRIPS Agreement states:

> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 above nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.[103]

The referenced Articles 3 and 4 of the TRIPS Agreement impose obligations of national treatment and most-favored-nation status respectively. As a result, a TRIPS Agreement signatory may not permissibly establish more favorable exhaustion rules for its own citizens than for citizens of other WTO countries.[104] In addition, if a TRIPS Agreement signatory provides for favorable treatment with respect to the exhaustion doctrine to one WTO member state, then the same treatment must be extended to all WTO member states.[105] Other than these basic national treatment and most-favored-nation obligations, the TRIPS Agreement does not impose other restrictions regarding the exhaustion doctrine. In particular, the TRIPS Agreement does not appear to require that all types of inventions be treated equally with regard to the exhaustion doctrine.[106]

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[100] TRIPS Agreement, Article 27(1).

[101] See J.H. Reichman, "Universal Minimum Standards of Protection Under the TRIPS Component of the WTO Agreement," 29 *International Lawyer* (1995), 345.

[102] See Lana Kraus, "Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry," 37 *Vanderbilt Journal of Transnational Law* (2004), 527.

[103] TRIPS Agreement, Article 6.

[104] See, e.g., Shubha Ghosh, "Pills, Patents and Power: State Creation of Gray Markets as a Limit on Patent Rights," 14 *Florida Journal of International Law* 217 (2002).

[105] *Ibid.*

[106] The United States has also entered into Free Trade Agreements with certain of its trading partners. Certain of these agreements may also bear upon the parallel importation of patented pharmaceuticals. For further discussion of this issue, see CRS Report RL33205, *Intellectual Property and the Free Trade Agreements: Innovation Policy Issues*, by John R. Thomas.

Legislative Issues and Alternatives

Should congressional interest continue in this area, a variety of options are available. If the possibility of an infringement action against unauthorized importers of patented pharmaceuticals is deemed sound, then no action need be taken. Alternatively, Congress could confirm the Federal Circuit's decision in *Jazz Photo*, which rejects the doctrine of international exhaustion and confines the exhaustion principle to sales that occurred within the United States.[107]

If legislative activity is deemed appropriate, however, another possibility is the introduction of some form of international exhaustion doctrine into U.S. patent law. The TRIPS Agreement does not seem to require that a country adopt the international exhaustion doctrine as an all-or-nothing proposition, applying either to all patented products or to none.[108] As a result, if Congress chose to limit application of the international exhaustion doctrine to patented pharmaceuticals, or some other specific type of invention, then no ramifications appear to arise with respect to the TRIPS Agreement obligations of the United States. It should be noted, however, that there appears to be no precedent, either domestically or abroad, for establishing an international exhaustion doctrine that is specific to pharmaceuticals.

At least two statutory mechanisms exist for implementing the international exhaustion doctrine into U.S. patent law. One possible approach would be to declare that importation into the United States of goods sold abroad by a patent proprietor or its representative is not a patent infringement. The two bills introduced as the Pharmaceutical Market Access Act of 2005 in the 109th Congress would have taken this approach with respect to patented pharmaceuticals, specifying that:

> 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, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.[109]

In addition to codifying the international exhaustion doctrine with respect to pharmaceuticals, the amendment proposed in S. 109 and H.R. 328 may have conversely led to the implication that the international exhaustion doctrine does not apply to patented inventions other than pharmaceuticals. This provision could potentially fortify the ruling in the *Jazz Photo* case for inventions outside of the pharmaceutical field.

Another statutory mechanism for promoting the importation of patented drugs is to immunize specific individuals from infringement liability. The Patent Act takes this approach in the area of patented medical methods, exempting licensed medical practitioners and certain health care entities from patent infringement in certain

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[107] See notes 66-73 and accompanying text.

[108] See supra notes 99-05 and accompanying text.

[109] § 8.

circumstances.[110] In the case of drug importation, potential patent infringers include importers, distributors, wholesalers, pharmacies, and individual consumers. Should Congress wish to promote parallel trade in patented pharmaceuticals, an explicit statutory infringement exemption could encourage individuals to engage in drug importation.

In considering these or other legal changes to the patent laws, the possibility of label licenses should be kept in mind. Even if Congress exempted drug importation practices or practitioners from patent infringement liability, firms may still be able to stipulate through the contract law that a drug sold in a foreign jurisdiction is for use exclusively within that jurisdiction.[111] If a purchaser instead imported that medication into the United States, then the seller may have a cause of action for breach of contract. As a result, any legal changes may need to account for the ability of firms to use contractual provisions as something of a substitute for patent protection in the area of prescription drug importation.

In addition, the issue of drug importation may provide an impetus for clarification of the patent infringement liability of state governments.[112] Some states, as well as political subdivisions of the states, have either seriously considered or commenced the practice of drug importation. To the extent that these authorities continue this trend, their potential Eleventh Amendment immunity to a patent infringement case in federal court may present another significant issue concerning patents and drug importation.

Controlling the costs of prescription drug spending, on one hand, and encouraging the development of new drugs, on the other, are both significant goals. These aspirations may potentially conflict, however. Although introducing international exhaustion into U.S. patent law may initially lower the price of patented drugs, it might also decrease the incentive of firms to engage in the research and development of new pharmaceuticals, as well as to shepherd new drugs through time-consuming and costly marketing approval procedures. Consideration of patent law reforms would likely be put into the larger context of drug costs, which may be influenced by the pricing policies of foreign nations, profits earned by wholesalers and other intermediaries, the physical costs of shipment into the United States, and other diverse factors.[113] Striking a balance between increasing access to medications and ensuring the continued development of new drugs by our nation's pharmaceutical firms is a central concern of the current drug importation debate.

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[110] 35 U.S.C. § 287(c) (2006).

[111] See supra notes 91-98 and accompanying text.

[112] See supra notes 74-90 and accompanying text.

[113] See Congressional Budget Office, Economic and Budget Issue Brief, *Would Prescription Drug Importation Reduce U.S. Drug Spending?*, by Colin Baker (April 29, 2004).