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Patents play a role in drug-importation debate

A patent owner's rights may not be exhausted by a first sale of the drug.

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MANY CONTEND that American consumers would pay less for medicines if the U.S. market were opened to imported drugs. Indeed, the Medicine Equity and Drug Safety Act of 2000 purported to open the U.S. market to drug importation from 25 countries if the secretary of Health and Human Services certified that there would be no risk to public health or safety and that there would be a significant cost reduction. While the secretary has provided no such certification, the Food and Drug Administration (FDA) has adopted a policy of not enforcing, against individuals, the standing law that only FDA-approved manufacturers may import drugs. As a result, cross-border sales of pharmaceuticals have now risen to well above $1 billion annually.

PATENT

Public health and safety concerns aside, drug importation may violate the patent rights of U.S. drug companies in two instances. In the first, the U.S. patent holder manufactures the drug in the United States and exports it for sale abroad. There, a third party buys the drug and imports it into the United States. In the second instance, the U.S. patent holder or its authorized representative manufactures and sells the drug outside of the United States. A third-party purchaser then imports the drug into the United States for resale.

A patent permits the owner to exclude others from making, using, offering to sell, selling or importing the patented subject matter without permission for a specified period of time—typically 20 years from the patent's filing date. Thus, if a prescription drug or its method of manufacture or use falls within the scope of a U.S. patent, the owner can exclude a third party from importing, selling or using the drug in the United States. On the face of it, then, a third party cannot import a patented pharmaceutical into the United States without the permission of the patent owner.

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Whether a patent owner can actually enforce its patent rights against the drug importer, however, depends on whether the patent owner's activities in connection with the imported product have exhausted those rights. For example, has the patent owner's manufacture of the drug in the United States and sale of the drug outside the United States exhausted its rights under the U.S. patent? Has the manufacture and sale of the drug outside the United States by the patent owner or under its authority exhausted its U.S. rights?

Patent exhaustion

Patent exhaustion, or the "first sale" doctrine, terminates a patentee's rights if it has sold the patented product without restriction. For example, the purchaser of the patented product in the United States may resell it without running afoul of a U.S. patent claiming the product. See *Mitchell v. Hawley*, 83 U.S. (16 Wall.) 544, 548 (1872); *Intel Corp. v. ULSI Sys. Tech.*, 995 F.2d 1566, 1568-70 (Fed. Cir. 1993). In the context of the drug importation debate, U.S. courts have limited the doctrine of patent exhaustion in two ways that are important.

A drug sale may also be under explicit and lawful restrictions.

First, legal sales of products outside of the United States do not exhaust the patent owner's rights under a U.S. patent. For example, in *Boesch v. Graff*, 133 U.S. 697, 702 (1890), a third-party sale in Germany, under prior-user rights, did not exhaust a patentee's rights under the U.S. patent. More recently, the U.S. Court of Appeals for the Federal Circuit extended this rule to non-U.S. sales, even under the authority of the U.S. patentee. *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1376-77 (Fed Cir. 2005). But see *Sanofi S.A. v. Med-Tech Veterinarian Prods. Inc.*, 565 F. Supp. 931, 937-38 (D.N.J. 1983) (unrestricted foreign sales exhaust U.S. patent rights).

In *Jazz Photo*, Fuji, the U.S. patent owner, had authorized the foreign sale of its disposable cameras. Jazz had obtained many of those cameras, refurbished them, and imported them for sale in the United States. It argued that Fuji's unrestricted sales outside of the U.S. exhausted Fuji's U.S. patent rights. Jazz's theory was that the patentee Fuji had received the benefit of its patent. See *United States v. Masonite Corp.*, 316 U.S. 265, 277-82 (1942): "The test [is] whether or not there has been such a disposition of the article that it may fairly be said that the patentee has received his reward for the use of the article." Id. at 278. The Federal Circuit, however, ruled against Jazz: "The patentee's authorization of an international first sale does not affect exhaustion of that patentee's rights in the United States." *Fuji Photo*, 394 F.3d at 1376.

Second, the sale of a product under explicit and lawful restrictions may preclude the purchaser from subsequent resale both as a matter of contract law and patent law. See, e.g., *B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997) (sales of patented valve limited to particular uses precluded resale for other uses). The issue is the scope of the sale restriction, or "label license," and whether those restrictions are unlawful or anti-competitive. For example, restrictions on resale price are typically unlawful.

Courts, however, have held that many restrictions accompanying the sale of patented articles are not illegal, either as patent misuse (an unfair extension of the patent grant) or as a violation of the antitrust laws. For example, a restriction limiting a patented medical device to a single use did not exhaust the patentee's remedies for infringement against a third party that reconditioned and resold the device for subsequent use. *Mallinckrodt Inc. v. Medipart Inc.*, 976 F.2d 700, 708-09 (Fed. Cir. 1992). Similarly, a label license limiting the resale of seed corn only to end users or to

authorized dealers was an enforceable restriction such that a third party's resale of the seed corn was not immunized from liability for patent infringement. *Pioneer Hi-Bred Int'l Inc. v. Ottawa Plant Food*, 283 F. Supp. 2d 1018, 1031-35 (N.D. Iowa 2003). See also *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1297-98 (Fed. Cir. 2002) (restriction limiting the use of patented herbicide-resistant seed to use in a single growing season and for growing commercial crops, not seeds, held enforceable).

Wholly apart from the patent laws, courts have found that legal restrictions on subsequent sale or use in label licenses on products are enforceable contracts between the seller and the third-party purchaser. For example, a label license restricting the use of corn seed was enforceable against the purchasers of the seed. The evidence showed that the purchaser had knowledge of the restrictions and did not object to them within a reasonable time after the sale. *Monsanto Co. v. Scruggs*, 342 F. Supp. 2d 568 (N.D. Miss. 2004, now on appeal).

Proposed law would hold that importation is not infringement.

Proposed legislation

As described above, the law of patent exhaustion would effectively preclude drug importation and its perceived benefits. Thus, proponents of drug importation have for the last several years introduced bills in Congress to remedy the problem. The pending 2005 bills, H.R. 328 and S. 334, would amend 35 U.S.C. 271, the patent statute addressing infringement, as follows: "(h) It shall not be an act of infringement to use, offer for sale, or sell within the United States or to import into the United States any patented invention under Section 804 (21 U.S.C. § 384) 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." See H.R. 328, § 8; S. 334, § 4(d).

These pending bills and their patent provisions raise a significant constitutional "takings" issue. In the United States, the protection of intellectual property rights begins with Article 1, § 8 of the U.S. Constitution. That clause grants to Congress the power to promote the progress of "Science and useful Arts." Congress has done so by enacting the patent statutes. To now amend those long-standing protections so as to ex post facto remove from patent protection certain acts—the importation of a drug product sold outside the United States under authority of the U.S. patent holder—raises constitutional issues of a taking without due process of law. See *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 600-03 (Fed. Cir. 1985).

Patents are property, albeit intellectual. As such, they are just like real or personal property. No person may be deprived of property without due process of law. If Congress were to change the definition of patent infringement to exclude imported drugs, patent owners undoubtedly would challenge the new law as unconstitutional.

Second, the pending bills also restrict the contractual rights of the patent owner that result from a label license or other legal restriction on the future use or sale of a marketed product. These contract rights exist wholly apart from patent rights. Thus, the patent owner still may be able to prevent the drug importation by enforcing the appropriate resale restrictions under contract law. However, the pending legislation would preclude the exercise of those rights.

State and local activities

In attempting to secure the hoped-for benefit of lower drug prices for their citizens, state and local governments are in some cases now becoming involved in drug importation. Some have set up Web sites linked to Canadian pharmacies. Others are including Canadian imported drugs in employee health plans. Still others are brokering the direct purchases of imported drugs for sale and distribution to their residents. These government activities raise several issues under the patent laws.

Bill would also limit contractual rights of a patent owner.

While the 11th Amendment grants states immunity from suits in federal courts, including suits for patent infringement, states may still be liable for damages in state court actions. *Fla. Prepaid Post Secondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 642-45 (1999).

Further, the sovereign immunity from suits for patent infringement enjoyed by a state does not extend to state officials responsible for the infringing activities. Rather, under the doctrine set out in *Ex parte Young*, 209 U.S. 123 (1908), state officials may be enjoined from acting in a way that directly or indirectly infringes the patent. *Seminole Tribe of Fla. v. Fla.*, 517 U.S. 44, 72 n.16 (1996). In addition, sovereign immunity does not extend to nonstate third parties that induce or contribute to the state's infringing activities. *Applera Corp. v. MJ Research Inc.*, 311 F. Supp. 2d 293, 298 (D. Conn. 2004).

Finally, sovereign immunity may not extend at all to local governments or to municipalities, which are not "arms of the state." *Mt. Healthy City Sch. Dist. v. Doyle*, 429 U.S. 274, 280-81 (1977) (a local school board was not an arm[s] of the State).

There are a variety of factors that determine when a local government or authority is an arm of the state entitled to 11th Amendment sovereign immunity from suit in federal courts:

- How the entity is referred to in the documents that created it.
- How the governing members of the entity are appointed.
- How the entity is funded.
- Whether the entity's function is traditionally one of local or state government.
- Whether the state has a veto power over the entity's activities.
- Whether the entity's obligations are binding upon the state. See *Lake County Estates v. Tahoe Reg'l Planning Agency*, 440 U.S. 391, 401-02 (1979).

Under these factors, the New York State Thruway Authority, a toll road operator, was held not to be an arm of the state and thus not immune from suits in federal courts. *Mancuso v. N.Y. State Thruway Auth.*, 86 F.3d 289, 296 (2d Cir. 1996). By contrast, the Idaho Potato Commission, a state agency charged with promoting the sale of Idaho potatoes, was found to be an arm of the state. *Idaho Potato Comm'n v. M&M Produce Farms*, 95 F. Supp. 2d 150, 154 (S.D.N.Y. 2000); aff'd sub nom. *Hapco Farms Inc. v. Idaho Potato Comm'n*, 238 F.3d 468 (2d Cir. 2001).

Thus, the liability of a state agency or local government for patent infringement as a result of its activities in providing imported drugs to its employees and citizens may well depend on the organization that arranges for and participates in the importation.

Any debate about the importation of drugs to achieve a hoped-for reduction in drug prices must consider patent rights, any exhaustion of those rights by an authorized sale outside of the United States, the enforceability of label licenses against the drug importer, the immunity of states and local governmental agencies and their employees from suits for patent infringement in federal courts, and the damages that may accrue to governments participating in activities that amount to an unlawful taking of the intellectual property of the branded pharmaceutical company. NLJ