2007 PATENTLY-O PATENT LAW JOURNAL

JOSHUA D. SARNOFF*

BIO v. DC and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulation

In *Biotechnology Industry Organization v. District of Columbia,*[1] the U.S. Court of Appeals for the Federal Circuit took another big step toward assuring that a granted patent conveys immunity from market regulation. The Federal Circuit affirmed a lower-court injunction against enforcement of DC's excessive pricing prohibition for patented pharmaceuticals, holding that the DC law's pricing constraint conflicts with accomplishing the purposes and objectives of the patent law in general and of the Hatch-Waxman Act in particular, and thus is preempted by the Supremacy Clause of the U.S. Constitution (notwithstanding DC's status as a federal entity).[2]

---

* Assistant Director, Glushko-Samuelson Intellectual Property Law Clinic, Washington College of Law, American University. Professor Sarnoff was Of Counsel on the amicus brief filed by Sean Flynn on behalf of the National Legislative Association on Prescription Drug Prices, et al., in *BIO v. DC* (Fed. Cir.).

Preferred Citation: Joshua D. Sarnoff, *BIO v. DC and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulation*, 2007 Patently-O Patent L.J. 30, http://www.patentlyo.com/lawjournal/2007/08/bio-v-dc-and-th.html.

[1] No. 2006-1593 (Fed. Cir. Aug. 1, 2007).

[2] U.S. Const., Art. VI, § 2. *See Hines v. Davidowitz,* 312 U.S. 52, 67 (1941) (state laws that "stands as an obstacle to accomplishment and execution of the full purposes and objectives" of federal laws are preempted). DC is not a state but a federal territory and the DC law thus "is in some sense a federal regulation" that also is implicitly approved by Congress through a statutorily prescribed review period. Slip op. at 14; *id.* at 2 (citing D.C. Code §1-206.02(c)(1)). Nevertheless, the Federal Circuit relied on prior precedents reinforcing the inferior status of the District and its residents, and the supremacy of other federal legislative enactments to DC laws. *See* Slip Op. at 14 ("as between District statutes and superior enactments by Congress, the general principles of preemption from Supremacy Clause law apply. *See Don't Tear It Down, Inc. v. Pa. Ave. Dev. Corp.*, 642 F.2d 527, 534 n.65 (D.C. Cir. 1980) ('We need not undertake precise definition of the governmental status of the District of Columbia . . . for surely the preemption doctrine [a]ffects District of Columbia legislation no less than state enactments.')"). Thus, the principles announced here should apply to all state and local laws, even though there may be reasons to distinguish conflicts between patent laws and other federal statutes, such as the antitrust laws.

According to the Federal Circuit, "[i]nventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected 'exclusive right' to exclude others from making, using, or selling embodiments of their invention. Patentees value the right to exclude in part because … [the right to exclude] may allow them an opportunity to obtain above-market profits during the patent's term."[3] Significantly, the Court referenced its previous statement that "'[u]pon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.'"[4] The Court also cited Congressional reports explaining that under the Hatch Waxman Act, "'[p]atents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.'"[5]

The Federal Circuit concluded that the DC law impermissibly interfered with the identified federal legislative objectives, given that DC had "[b]y penalizing high prices … chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs. In the District's judgment, patents enable pharmaceutical companies to wield too much exclusive power, charging prices that are 'excessive' for patented drugs. The Act is a clear attempt to restrain those excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers."[6] Thus, the DC law was held to conflict with federal patent law even though the DC law addressed only an issue federal law does not directly regulates – the marketplace pricing of patented medicines – and notwithstanding the Federal Circuit's recognition in its opinion that the sale of patented goods is *not* protected by any right conveyed by the federal patent law.[7]

The Court's decision contains language focusing on the DC law being specifically "targeted at the patent right" in an alleged effort to alter "the proper balance between innovators' profit and consumer access" in regard to patented medicines.[8] But the Court's decision wholly fails to address considerations actually relevant for "purposes and objectives" preemption analysis. These include whether "[t]he nature of the

---

[3] Slip Op. at 15.

[4] Slip Op. at 15-16 (quoting *King Instruments Corp. v. Perego,* 65 F.3d 941, 950 (Fed. Cir. 1995)).

[5] Slip Op. at 16 (quoting H.R. Rep. No. 98-857, at 17 (1984)).

[6] Slip Op. at 18 (as modified by the errata opinion issued August 1, 2007).

[7] *See* Slip Op. at 14 ("There is no express provision in the patent statute that prohibits states from regulating the price of patented goods; indeed, 'the federal patent laws do not create any affirmative right to make, use, or sell anything.'") (quoting *Leatherman Tool Group, Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997)).

[8] Slip Op. at 18.

power exerted by Congress, the object sought to be attained, and the character of the obligations imposed by the law … preclude enforcement of state laws on the *same* subject,"[9] and whether the state law "*substantially impedes*" accomplishing the federal purpose.[10] The DC law does not address the same subject,[11] and the Federal Circuit's decision does not actually evaluate the extent of any interference that might occur with the federal objectives of providing incentives. Instead, the Court held, in the context of determining that organizational standing existed for the plaintiffs to bring their facial challenge to the DC law, only that enforcement was likely to be initiated against some of the plaintiffs' members (given legislative findings that pharmaceutical prices in the District were presumptively excessive).[12]

The Court's holding also did not address a state or local price or product regulatory law of general application, and its decision did not expressly include or exclude such laws. Potentially affected laws include not only the myriad state laws having the

---

[9] *Hines,* 312 U.S. at 70 (emphasis added). *Cf. Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947) (congressional occupation of a field is not to be presumed "in a field which the States have traditionally occupied").

[10] *Bonito Boats, Inc., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* 489 U.S. 141, 157 (1989) (emphasis added). *See id.* at 153-57 (discussing earlier preemption cases and concluding that although recent decisions "have taken a decidedly less rigid view of the scope of federal pre-emption under the patent laws … we believe that … States may not offer patent-like protection to intellectual creations which would otherwise remain unprotected as a matter of federal law."). *Cf. Hisquierdo v. Hisquierdo,* 439 U.S. 572, 581 (1979) ("State family and family-property law [areas of traditional state regulation] must do 'major damage' to 'clear and substantial' federal interests before the Supremacy Clause will demand that state law be overridden.") (citation omitted).

[11] *Cf. University of Colorado Foundation, Inc. v. American Cyanamid Co.,* 342 F.3d 1298, 1306 (Fed. Cir. 2003) (noting that "the Supremacy Clause does not [even] require full consonance between federal and state intellectual property protections" and upholding from conflicts preemption a state unjust enrichment law, because "[t]he right involved here and compensated for under a theory of unjust enrichment, however, is not 'patent-like' at all."); *Cover v. Hydromatic Packaging Co.,* 83 F.3d 1390, 1394 (Fed. Cir. 1996) (finding that state law regulating commercial warranties in patented goods was *not* preempted by federal patent law, given that federal patent law did not regulate the commercial relationships between the parties, and expressly distinguishing earlier cases because the state law at issue "does not purport to provide exclusive property rights" for subject matter unprotected by patent law).

[12] *See id.* at 10-13. As the Federal Circuit recognized, although the law creates a presumption of excessive pricing based on reference levels in other developed countries, the law only shifts the burden to the patent holder to demonstrate that its price is not excessive when considering various factors. *See id.* at 11-13 (also noting the costs of monitoring prices and one company's threat to pull out of developed country markets rather than risk having the presumption attach and thus having to defend its prices as not excessive).

object of restraining excessive prices for pharmaceutical products (e.g., state formulary "preferred drug lists"), but also laws having wholly different purposes and objectives, such as bans or restrictions on patented products and their uses or unconscionable-pricing and price-gouging laws of general application that may be applied to patented products or components. States and localities will certainly seek to distinguish the wide range of price and product regulating laws on the basis of their more general application and on the lack of any intent to recalibrate the patent law's innovation-reward balance. But given the broad dicta in the Court's decision, a flood of new litigation is likely to challenge existing and new laws that restrict the profits that can be made on any and all patented products, brought by well-funded pharmaceutical, biotechnology, and other industrial interests.

Significantly, the Court's logic and the decision's language have no clear limits. Thus, the Federal Circuit also stated that "Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use."[13] *Any* state or local regulation of market behaviors (including price regulation but also product bans and prior market approvals, anticompetitive conduct regulation, etc.) will affect the "free use" of a product by the patent holder within the marketplace, and thus will alter the commercial rewards alleged by the Court to have been contemplated by Congress as part of the federal patent law bargain. For example, the Court's reasoning in *BIO v. DC* would invalidate the "Maine Rx" law requiring drug makers to provide discounts to the uninsured in order to participate in preferential purchasing programs for Medicaid that was recently upheld against a preliminary injunction by the Supreme Court.[14] Similarly, the Court's reasoning would preempt state environmental regulations banning methods of using patented chemicals. After all, such regulations limit the profits that such products or services might otherwise generate in the market and thus the incentives purportedly assured through the patent grant. These examples demonstrate that the Court cannot reasonably have intended to mean what its decision in *BIO v. DC* actually says.

The Federal Circuit's decision, moreover, is neither warranted nor sensible. The grant of a patent obviously does not convey any right to sell (much less the right to obtain any particular level of commercial reward from the sale of) any patented invention. Nor does the Hatch Waxman Act convey such a right for pharmaceuticals for which regulatory approval must also be obtained from the Food and Drug Administration. As earlier-Federal Circuit Judge Giles Rich went to excruciating lengths to explain, patents convey only the negative right to exclude and not *any* affirmative rights (including rights to a return on investments in creating patented inventions). "No law was required to enable [the inventor] to [construct the invention]…. He sells at the highest price he can get. Still he needs no law…. It is the 'natural right' of man…. 'The franchise which the patent grants *consists altogether in the right to exclude* every one from making, using, or vending the thing patented without the permission of the

[13] Slip Op. at 17.

[14] *See Pharma v. Walsh,* 538 U.S. 644 (2003).

patentee. *This is all that he obtains by the patent.*"[15] Supreme Court precedent also makes clear that "the use of the tangible property which comes into existence by the application of the discovery is not beyond the control of State legislation, simply because the patentee acquires a monopoly in his discovery."[16] Nor did the Hatch-Waxman Act guarantee any protected expectation of commercial returns from monopoly prices. It was directed only to term extension, and not market protection: the Act intended "to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is *the restoration of some of the time lost on patent life* while the product is awaiting pre-market approval."[17]

In summary, the Federal Circuit decision creates a wholly new affirmative right from the negative right conveyed by the patent grant (at least by finding a conflict with federal legislative purpose), providing patent holders with a guarantee of commercial returns on embodiments of patented inventions wholly unrestricted by traditional state or local market regulation. In doing so, the Federal Circuit has extended immunity from market regulation to the pricing of patented products or components *outside* the scope of the exclusive patent right, as the Court did earlier for anti-competitive conduct *within* the scope of the exclusive patent right.[18] The *Bio v. DC* decision thus may add further impetus to efforts to harmonize *federal* antitrust and competition laws with patent laws by favoring patent holders at the expense of citizens, competitors, and sequential innovators. And the Federal Circuit's decision

---

[15] Giles S. Rich, *The Relation between Patent Practices and the Anti-Monopoly Laws,* 24 J. Pat. Off. Soc'y 159, 167-68 (1942) (quoting *Bloomer v. McQuewan,* 55 U.S. 539, 549 (1852)) (second emphasis added).

[16] *Patterson v. Kentucky,* 97 U.S. 501, 507 (1879).
[17] H.R. Rept. 98-857, at 15 (emphasis added).

[18] *See, e.g., Monsanto v. McFarling,* 363 F.3d 1336, 1341 (Fed. Cir. 2004) ("In the cases in which the restriction is reasonably within the patent grant, the patent misuse defense can never succeed.") (citations omitted); *In re Indep. Serv. Orgs. Antitrust Litig.,* 203 F.3d 1322, 1327-28 (Fed. Cir. 1999) (concluding that an antitrust claim "does nothing to limit the right of the patentee to refuse to sell or license in markets within the scope of the statutory patent grant"); *Virginia Panel Corp. v. MAC Panel Co.,* 133 F.3d 860, 873 (Fed. Cir. 1997) ("because we determine that the conduct underlying the allegations of misuse does not amount to patent misuse, the same conduct cannot support a judgment that [the patentee's/licensor's] conduct violated the Sherman Act."). *Cf.* U.S. Dept. of Justice and Federal Trade Commission, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (April 2007), 6 (although Congress did not create antitrust immunity for unilateral refusals to license, the right to refuse to grant a license "is a core part of the patent grant" and such refusals "will not play a meaningful part in the interface between patent rights and antitrust protection," but conditional refusals "that cause competitive harm are subject to antitrust liability"), available at http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf

wholly ignores recent Supreme Court guidance reiterating "the presumption against federal pre-emption of a state statute designed to foster public health."[19]

Although it might be hoped that the Federal Circuit's reasoning will not be followed by other courts, absent rehearing en banc or that grant of certiorari the *BIO v. DC* decision will now be the law of the land. This is because the Federal Circuit also held that such facial patent law preemption challenges to state and local laws are within its exclusive appellate jurisdiction.[20] Thus, unless the panel itself withdraws its opinion, or the Federal Circuit en banc or the Supreme Court reverse it, legislation will be needed to prevent the flood of litigation that will attack state and local price and product regulations that limit the excessive profits to be made from patented products and services, and (worse yet) may successfully prevent states and localities from protecting their citizens. Interested parties, particularly state and local governments that wield substantial power in federal legislative processes, should act now to turn the patent legislative reform bandwagon to this important issue. Reversing the *Bio v. DC* decision and protecting state and local regulation from patent law preemption should be the first of the many needed (but currently missing) public-interest reforms[21] included in the patent law bills that are taken up by the Congress when it returns from its August recess.

---

[19] *Pharma v. Walsh,* 538 U.S. at 666 (citing *Hillsborough County v. Automated Medical Labs., Inc.,* 471 U.S. 707, 715-18 (1985)).

[20] The Federal Circuit found that it possesses exclusive jurisdiction under 28 U.S.C. § 1338 to review on appeal from federal district courts any facial challenges to such laws, which challenges arise under the patent law as a necessary element of a well-pleaded Supremacy Clause claim. *See* Slip Op. at 5-9.

[21] For three of my personal favorites, Congress might also eliminate the doctrine of equivalents, strengthen the indefiniteness requirement for claims, and restore meaningful limits on patentable subject matter.