United States Court of Appeals for the Federal Circuit

2006-1593

BIOTECHNOLOGY INDUSTRY ORGANIZATION,

Plaintiff-Appellee,

and

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellee,

v.

DISTRICT OF COLUMBIA,
Adrian M. Fenty, MAYOR OF THE DISTRICT OF COLUMBIA,
OFFICE OF THE ATTORNEY GENERAL FOR THE DISTRICT OF COLUMBIA,
Robert Spagnoletti, ATTORNEY GENERAL OF THE DISTRICT OF COLUMBIA,
OFFICE OF DOCUMENTS AND ADMINISTRATIVE ISSUANCES
OF THE DISTRICT OF COLUMBIA,
Arnold R. Finlayson, ADMINISTRATOR, OFFICE OF DOCUMENTS AND
ADMINISTRATIVE ISSUANCES OF THE DISTRICT OF COLUMBIA,

Defendants-Appellants.

David W. Ogden, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC, argued for all plaintiffs-appellees. With him on the brief for Pharmaceutical Research and Manufacturers of America were Randolph D. Moss, Anne K. Small, Catherine M.A. Carroll, and Thomas G. Saunders. On the brief for Biotechnology Industry Organization were Daniel E. Troy and Eric A. Shumsky, Sidley Austin LLP, of Washington, DC.

William J. Earl, Assistant Attorney General, Office of Attorney General for the District of Columbia, of Washington, DC, argued for defendants-appellants. With him on the brief were Linda Singer, Acting Attorney General, District of Columbia, Todd S. Kim, Solicitor General, and Edward E. Schwab, Deputy Solicitor General.

Sean M. Fiil-Flynn, Program on Information Justice and Intellectual Property, Washington College of Law, American University, of Washington, DC, for amici curiae, National Legislative Association on Prescription Drug Prices, et al. With him on the brief was Joshua D. Sarnoff, Glushko-Samuelson Intellectual Property Law Clinic.

Jeffrey L. Handwerker, Arnold & Porter LLP, of Washington, DC, for amicus curiae The AIDS Institute. With him on the brief was Matthew H. Solomson.

Richard A. Samp, Washington Legal Foundation, of Washington, DC, for amici curiae Washington Legal Foundation, et al. With him on the brief was Daniel J. Popeo.

Appealed from: United States District Court for the District of Columbia

Judge Richard J. Leon

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Defendants-Appellants.

DECIDED: August 1, 2007

Before BRYSON, Circuit Judge, PLAGER, Senior Circuit Judge, and GAJARSA, Circuit Judge.

GAJARSA, Circuit Judge.

This is a pre-enforcement challenge to a statute of the District of Columbia, before this court after transfer from the United States Court of Appeals for the District of Columbia Circuit. Defendants, the District of Columbia and various of its departments and officers (collectively, "the District" or "D.C."), appeal from a judgment of the United

States District Court for the District of Columbia declaring the District's Prescription Drug Excessive Pricing Act of 2005, codified at D.C. Code § 28-4551 to 28-4555 ("the Act"), preempted by the federal patent laws and enjoining its enforcement. We affirm the judgment of the district court and the injunction.

I. BACKGROUND

A. The challenged legislation

The D.C. City Council has adopted specific legislation which prohibits any patented drug from being sold in the District for an excessive price. The operative section of the Excessive Pricing Act reads:

> It shall be unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.

D.C. Code § 28-4553. The legislation was adopted after the Council determined that:

> The excessive prices of prescription drugs in the District of Columbia is threatening the health and welfare of the residents of the District as well as the District government's ability to ensure that all residents receive the health care they need, and these excessive prices directly and indirectly cause economic harm to the District and damage the health and safety of its residents. . . . [I]t is incumbent on the government of the District of Columbia to take action to restrain the excessive prices of prescription drugs.

Id. § 28-4551. The Council's response to that finding was passage of the challenged legislation. Following signature by the Mayor and the expiration of the statutorily prescribed period for Congress to review D.C. statutes, see D.C. Code § 1-206.02(c)(1), the Act took effect on December 10, 2005. The statutory term "excessive price" is not specifically defined. The statute states that "[a] prima facie case of excessive pricing shall be established where the wholesale price of a patented prescription drug in the District is over 30% higher than the comparable price in any high income country in

which the product is protected by patents or other exclusive marketing rights." Id. § 28-4554(a). If such prima facie excessive pricing is shown, the burden shifts to the defendant to prove:

> that a given prescription drug is not excessively priced given demonstrated costs of invention, development and production of the prescription drug, global sales and profits to date, consideration of any government funded research that supported the development of the drug, and the impact of price on access to the prescription drug by residents and the government of the District of Columbia.

Id. § 28-4554(b). A "high income countr[y]" is defined as one of "the United Kingdom, Germany, Canada, or Australia." Id. § 28-4552(2). The Act provides for both public and private enforcement: "Any affected party, including the District of Columbia, shall have standing to file a civil suit in a court of competent jurisdiction for a violation of this chapter and to seek a remedy, including declaratory and injunctive relief." Id. § 28-4555(a). The term "affected party" is itself broadly defined as "any person directly or indirectly affected by excessive prices of patented prescription drugs, including any organization representing such persons or any person or organization representing the public interest." Id. § 28-4552(1). The Act provides for a wide array of remedies:

> (1) Temporary, preliminary, or permanent injunctions to enjoin the sales of prescription drugs in the District at excessive prices;
> (2) Appropriate fines for each violation;
> (3) Damages, including treble damages;
> (4) Reasonable attorney's fees;
> (5) The cost of litigation; or
> (6) Any other relief the court deems proper.

Id. § 28-4555(b).

B. Procedural history

On October 12, 2005, plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") filed suit in the United States District Court for the District of Columbia, alleging that the Act was invalid in light of the Commerce Clause of the Constitution and that it was preempted by the federal patent laws. Fifteen days later, plaintiff Biotechnology Industry Organization ("BIO") filed a similar suit. Both plaintiffs are industry organizations whose membership includes manufacturers of patented pharmaceuticals. The district court consolidated the two actions, heard oral argument, and on December 22, 2005 issued an opinion and order finding the Act to be preempted by the patent laws and enjoining its enforcement. Pharm. Research & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56 (D.D.C. 2005).

The district court concluded that the plaintiffs had established their standing since they represented members who complained of "realistic and imminent" injuries. Id. at 62-63. Noting that "Congress' regulation of our nation's pharmaceutical industry is grounded in large part in a complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation, research, and development of new drugs," id. at 65, the district court concluded that the Act did not "square with the congressional purpose and objectives" of the patent laws, id. at 66. Accordingly, the district court found that "the D.C. Act is preempted and therefore facially unconstitutional." Id. at 67. It also found that the Commerce Clause of the Constitution invalidated the Act as applied to transactions between parties not located within the District's borders, id. at 71, a conclusion which the District does not appeal. Finally, the district court rejected the plaintiffs' claim that the Foreign Commerce Clause

of the Constitution facially preempted the Act as a whole, finding it valid only "to the extent that future plaintiffs are able to establish a prima facie case to the satisfaction of a Superior Court judge without any reference to the wholesale price of the same drug in any foreign country." Id. at 72.

The District timely appealed to the United States Court of Appeals for the District of Columbia Circuit. On August 23, 2006, that court granted the District's unopposed motion to transfer the case to the Federal Circuit.

II. DISCUSSION

A. Statutory subject matter jurisdiction

Any appeal taken to a federal appeals court must be within its jurisdiction. Because this case does not pose the typical questions of patent law—infringement, validity, enforceability, and the like—which this court normally reviews under our jurisdictional statute (28 U.S.C. § 1295), and because the parties' briefing on our jurisdiction was limited, we raised the issue of whether our statutory grant of jurisdiction encompasses this case sua sponte at oral argument. See Bender v. Williamsport Area Sch. Dist., 475 U.S. 534, 541 (1986) ("Federal courts are not courts of general jurisdiction; they have only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress pursuant thereto. For that reason, every federal appellate court has a special obligation to satisfy itself . . . of its own jurisdiction." (citation omitted)).

This court has exclusive jurisdiction to review cases which arise under the patent laws. Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 807 (1988). Our jurisdiction is created and constrained by statute. Congress has granted this court

"exclusive jurisdiction . . . of an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on [28 U.S.C. § 1338]," with exceptions not applicable here. 28 U.S.C. § 1295(a)(1). Section 1338 vests district courts with "original jurisdiction of any civil action arising under any Act of Congress relating to patents." Thus, we have jurisdiction if and only if the plaintiffs' preemption claim is one "arising under" the patent laws, under the meaning of that phrase in § 1338.

The Supreme Court, resolving a jurisdictional dispute between this court and a sister Circuit, has held that:

> [Section] 1338(a) jurisdiction . . . extend[s] only to those cases in which a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.

Christianson, 486 U.S. at 808-09. Patent law does not "create" the plaintiffs' cause of action here, because there is no language in the patent statute explicitly authorizing preemption claims. The absence of lawsuit-enabling language does not end the jurisdictional inquiry, though, since patent law may be a "necessary element" of an action authorized under some other provision.

Patent law is indeed a necessary element of the claim here. If the plaintiffs are able to show that the patent laws preempt the Act, the Act will be declared unenforceable and enjoined, but if they cannot, their preemption claim will fail and their members may be required to defend against suits under the Act. In other words, "some right or privilege will be defeated by one construction, or sustained by the opposite construction of [the patent] laws." Id. at 807-08 (quoting Pratt v. Paris Gas Light & Coke Co., 168 U.S. 255, 259 (1897)).

Two prior cases of this court confirm that in certain circumstances patent law may be a "necessary element" of an otherwise nonpatent claim. In Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318 (1998), overruled en banc on other grounds, Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356, 1358-59 (Fed. Cir. 1999), we addressed our jurisdiction over a California state-law claim for injurious falsehood. The plaintiff alleged that the defendant patentee had claimed to hold exclusive rights in certain patents with "willful and wanton disregard" for the fact that the patent claims at issue were invalid and unenforceable. Id. at 1322. Since proof of a false statement was a necessary element of the state-law tort and in this case the statement's truth or falsity turned on the resolution of a patent issue, we held the claim to arise under the patent laws. Id. at 1329. Likewise, in Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc., 986 F.2d 476, 478 (Fed. Cir. 1993), we held that a Texas business disparagement claim arose under the patent laws where the alleged false statement was the defendant's claim that the plaintiff infringed its patent. In Hunter Douglas and Additive Controls, state tort law created the cause of action, but the pleadings at issue required patent-law questions to be resolved. The same analysis applies here: though the plaintiffs' claim is created by principles of supremacy law, its resolution necessarily requires us to construe the patent statutes.

In an "arising under" analysis, the focus must remain on the well-pleaded complaint. A claim does not arise under the patent laws merely if a patent issue appears in a defense to that claim, Thompson v. Microsoft Corp., 471 F.3d 1288, 1292 (Fed. Cir. 2006), or if the claim is asserted in the defendant's answer as a counterclaim, Holmes Group, Inc. v. Vornado Air Circulation Sys., 535 U.S. 826, 831 (2002). Here,

the preemption issue is raised in the plaintiffs' complaint. However, we noted in Speedco, Inc. v. Estes that "we determine whether federal court jurisdiction exists in a case seeking a declaratory judgment by applying the well-pleaded complaint rule not to the declaratory judgment complaint, but to the action that the declaratory defendant would have brought." 853 F.2d 909, 912 (Fed. Cir. 1988). Speedco cited to the Supreme Court's decision in Franchise Tax Board v. Construction Laborers Vacation Trust for Southern California, 463 U.S. 1, 16 (1983), for the proposition that "if, but for the availability of the declaratory judgment procedure, the federal claim would arise only as a defense to a state created action, jurisdiction is lacking." (internal citations omitted). If we were to follow the mirroring rule laid down in Speedco and consider the hypothetical action that might be brought by the District against one or more of the plaintiffs' members, the relevant complaint would be one requesting relief under the challenged Act. The issue of preemption by the patent laws would appear, if at all, only as a defense in the answer to that complaint. Such an action would not arise under the patent laws, and this court would not be the correct forum to decide this appeal.

However, the Supreme Court has expressly distinguished Franchise Tax Board as to cases where the plaintiff seeks to enjoin enforcement of the allegedly preempted provision:

> The Court's decision today in Franchise Tax Board . . . does not call into question the lower [federal] courts' jurisdiction to decide these cases. . . . A plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is pre-empted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, thus presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve.

Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 96 n.14 (1983). The phrase "arising under" has the same meaning in § 1338 as it does in § 1331, the general federal-question

provision. Vornado, 535 U.S. at 829-30 (citing Christianson, 486 U.S. at 808-09). Since this case presents a request for injunction of the Act's enforcement in addition to a declaratory judgment, it is controlled by Shaw, not Franchise Tax Board and Speedco. Accordingly, the mirroring rule does not apply and the relevant well-pleaded complaints are the ones actually filed by plaintiffs BIO and PhRMA. As noted above, construction of the patent laws is a necessary element of the preemption cause of action appearing in those complaints. Therefore, the preemption action here "aris[es] under [an] Act of Congress relating to patents," the district court had "jurisdiction based . . . in part[] on section 1338," and this case falls within our exclusive jurisdiction under § 1295. We conclude that this appeal is properly before us and should not be transferred back to the D.C. Circuit.[1]

B. Standing

Resolution of the statutory issue above does not end our jurisdictional inquiry, since the District also alleges that the two plaintiff organizations lacked standing to bring this action. Standing is, of course, a constitutional prerequisite for our own jurisdiction and that of the district court:

> Article III of the Constitution limits the federal judicial power to "Cases" or "Controversies," thereby entailing as an irreducible minimum that there be (1) an injury in fact, (2) a causal relationship between the injury and the challenged conduct, and (3) a likelihood that the injury will be redressed by a favorable decision.

[1] We acknowledge that Christianson directs appellate courts to apply the law of the case doctrine and defer to sister Circuits' jurisdictional determinations upon a transfer. 486 U.S. 816. However, we note that the transfer order here was issued by the D.C. Circuit's Clerk after an unopposed motion and without a decision by the judges of that court. Because we independently agree that jurisdiction properly lies in this court, we do not decide whether a clerk-signed transfer order has "decided upon a rule of law," id. at 817, and therefore merits deference under Christianson.

United Food & Commercial Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 550 (1996) ("United Food") (internal quotations omitted). We decide questions implicating this court's jurisdiction under our own circuit law. Pause Tech. LLC v. TiVo Inc., 401 F.3d 1290, 1293 (Fed. Cir. 2005) ("On matters relating to this court's jurisdiction, we apply Federal Circuit law, not that of the regional circuit from which the case arose."); Nystrom v. TREX Co., 339 F.3d 1347, 1349-50 (Fed. Cir. 2003); State Contracting & Eng'g Group v. Florida, 258 F.3d 1329, 1334 (Fed. Cir. 2001); Woodard v. Sage Prods., 818 F.2d 841, 844 (Fed. Cir. 1987) (en banc).

Neither plaintiff here manufactures patented prescription drugs itself or otherwise engages in activities likely to fall within the ambit of the Act. However, "an organization may sue to redress its members' injuries, even without a showing of injury to the association itself." United Food, 517 U.S. at 552.

> [A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

Id. at 553 (quoting Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977)); see also Inv. Co. Inst. v. Camp, 401 U.S. 617, 620-21 (1971) (finding that association of investment companies had standing to challenge federal regulation which harmed its members). The two plaintiffs here are both industry organizations who seek to shape policy in a manner favorable to member pharmaceutical and biotechnology companies, so the subject matter of this case is highly germane to their respective purposes. For the purposes of this facial challenge seeking only an injunction against a generally applicable statute, none of the plaintiffs' members need be joined directly in the action. The standing question therefore collapses into an inquiry as to whether

some member of each organization would have standing to bring a similar action itself. One such member will suffice. See United Food, 517 U.S. at 552 ("The association must allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit." (emphasis added) (quoting Warth v. Seldin, 422 U.S. 490, 511 (1975)).

Standing requires "at an irreducible minimum an injury in fact; that is, there must be some threatened or actual injury resulting from the putatively illegal action." Virginia v. Am. Booksellers Ass'n, 484 U.S. 383, 392 (1988). That injury must be "(a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180 (2000) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)). The injury need not have been already manifested. "A plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement. But one does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending that is enough." Babbitt v. United Farm Workers Nat'l Union, 442 U.S. 289, 298 (1979) (internal citations and quotations omitted).

The findings and legislative history of the Act demonstrate a strong likelihood that the District is imminently likely to enforce it against plaintiffs' members. The Act itself contains a finding that the prices of prescription drugs in the District of Columbia are presently "excessive," the same word as the standard for an illegal price. D.C. Code § 28-4551(a). The findings section also declares that "it is incumbent on the

government of the District of Columbia to take action to restrain the excessive prices of prescription drugs." Id. § 28-4551(c). When the Act was debated in the D.C. City Council, its sponsor singled out two companies by name:

> Once a lawsuit is filed the prescription drug manufacturer will be afforded an opportunity to explain why its prices are not excessive. . . . For instance, under the new law Merck may have the opportunity to explain why District residents pay 166 percent more for the cholesterol drug Zocor than the citizens of Germany. Or Pfizer could defend its reasoning for charging District residents 323 percent more for its arthritis drug Celebrex than the residents of Australia.

Remarks of D.C. Councilmember Catania, Sept. 20, 2005. Merck and Pfizer are members of both BIO and PhRMA. The District "has not suggested that the newly enacted law will not be enforced, and we see no reason to assume otherwise. We conclude that plaintiffs[' members] have alleged an actual and well-founded fear that the law will be enforced against them." Am. Booksellers, 484 U.S. at 393.

Whether the Act is enforced or not, its presence is highly likely to cause pharmaceutical manufacturers, including plaintiffs' members, to incur costs in an effort to avoid running afoul of its broadly-worded provisions. The Act does not directly regulate manufacturers' wholesale prices—instead, liability attaches if the pharmaceutical seller's activity "results in the prescription drug being sold in the District for an excessive price." D.C. Code § 28-4553. If the prices in the District exceed the price in any "high income country" by over 30 percent, the manufacturer is presumed to be in violation. Id. § 28-4554(a). The Act provides that the presumption is rebuttable, but other than listing a variety of factors to be considered, does not explain how that rebuttal might occur. Id. § 28-4554(b). Prudent pharmaceutical manufacturers seeking to comply with the Act must therefore monitor the retail prices of their drugs in the District, and correlate those with the prices in four foreign countries designated as "high

income" benchmarks for the Act's prima facie analysis. One member of plaintiff PhRMA, Valeant Pharmaceuticals International, has declared that if the Act is not enjoined, it will forgo selling one of its drugs in the Canadian and Australian markets rather than risk having the presumption of excessiveness attach. Wyeth Pharmaceuticals, a member of both BIO and PhRMA, has declared that in light of the Act it "will need to consider the impact of its decisions as to the timing and pricing of launches in [the four benchmark] markets on domestic prices." Even if Wyeth and other similarly situated pharmaceutical manufacturers ultimately choose not to change their global pricing structure, the need to monitor and consider that structure in light of the Act will necessarily impose upon them actual administrative costs.

Members of both plaintiff organizations have therefore demonstrated that the Act threatens them with a concrete, imminent injury, since they have shown "a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." United Farm Workers, 442 U.S. at 298. The remaining elements of standing are causation ("the injury is fairly traceable to the challenged action of the defendant," Friends of the Earth, 528 U.S. at 180) and redressability ("it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision," id. at 181). In light of our discussion above, both of those elements are satisfied, because the injury flows directly from the Act, and if the Act is enjoined, the injury will not occur. All of the elements of standing are satisfied. Accordingly, we have jurisdiction to hear this appeal, and turn now to the merits of the plaintiffs' preemption case.

C. Preemption

The plaintiffs argue that the Act cannot stand because it is preempted by superior federal law. While this case implicates supremacy principles, we note that it does not deal with an alleged conflict between a state regulation and a federal law requiring the application of the Constitution's Supremacy Clause. See U.S. Const. art. VI, § 2; Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 479 (1974). The District of Columbia is federal territory whose self-governance is authorized by Congress, so the Act is in some sense a form of federal regulation. Nevertheless, 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."). Accordingly, references in our discussion to states, state law, or the like apply to the District law at issue here.

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." Leatherman Tool Group, Inc. v. Cooper Indus., Inc., 131 F.3d 1011, 1015 (Fed. Cir. 1997). Nevertheless, state law must yield to congressional enactments if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941). The plaintiffs urge that the Act conflicts with

Congress's intention to provide their members and other pharmaceutical patent holders with the pecuniary reward that follows from the right to exclude granted by a patent.

Our conflict inquiry is a searching one that ranges beyond the literal text of the statute. "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000). "[T]he entire scheme of the statute must of course be considered and that which needs must be implied is of no less force than that which is expressed." Id. (quoting Savage v. Jones, 225 U.S. 501, 533 (1912)). We analyze this question under our own circuit law. Midwest Indus., Inc. v. Karavan Trailers, Inc. 175 F.3d 1356, 1358-59 (Fed. Cir. 1999) (en banc in relevant part).

We have noted that "the essential criteria" for determining whether a state law is preempted are "the objectives of the federal patent laws." Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1333 (1998). The fundamental goal of the patent law is spelled out in the Constitution: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Inventors 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 ability to foreclose competitors from making, using, and selling the invention may allow them an opportunity to obtain above-market profits during the patent's term.

This court has repeatedly recognized as important the pecuniary rewards stemming from the patent right:

> We have long acknowledged the importance of the patent system in encouraging innovation. Indeed, "the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." . . . Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts.

Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006) (quoting Patlex Corp. v. Mossinghoff, 758 F.2d 594, 599 (Fed. Cir. 1985)).

> [T]he Patent Act creates an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.

King Instruments Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995).

This court's past statements about the patent law's incentive structure are illuminating, but our inquiry must be focused on Congress's purposes. Congress, too, has acknowledged the central role of enhanced profits in the statutory incentive scheme it has developed. In the legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984 (popularly known as the "Hatch-Waxman Act"), the House Committee on Energy and Commerce observed:

> Patents 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.

H.R. Rep. No. 98-857, at 17 (1984); see also id. at 15 ("The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development.").

Of course, the patent laws are not intended merely to shift wealth from the public to inventors. Their purpose is to "promote the Progress of . . . useful Arts," U.S. Const. art. I, § 8, cl. 8, ultimately providing the public with the benefit of lower price through unfettered competition. That goal is underscored by the Constitutional command that periods of exclusivity be for "limited Times." Id. Once the patent expires and the inventor's exclusive rights terminate, others may enter the market with products based on the teachings of the patent, which must "enable any person skilled in the art . . . to make and use the [invention]." 35 U.S.C. § 112 ¶ 1. If the market functions properly, this new participation will bring down the formerly elevated price of the patented product to competitive levels. These two objectives—to reward innovators with higher profits and to keep prices reasonable for consumers—are in dialectic tension. The Supreme Court has noted that "[t]he tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152 (1989); see also Hunter Douglas, 153 F.3d at 1333 ("[T]he objectives of the federal patent laws . . . . are in some tension with one another, and Congress struck a balance between them."). Congress, as the promulgator of patent policy, is charged with balancing these disparate goals. The present patent system reflects the result of Congress's deliberations. 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.

It is unquestioned that the District has general police power within its borders and that "[w]hatever rights are secured to inventors must be enjoyed in subordination to this

general authority of the State over all property within its limits," Webber v. Virginia, 103 U.S. 344, 348 (1880). But general state power must yield to specific Congressional enactment: "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." Felder v. Casey, 487 U.S. 131, 138 (1988) (quoting Free v. Bland, 369 U.S. 663, 666 (1962)). Furthermore, this Act is in no way general, affecting only patented products. The Act's operation stands largely—indeed, exclusively—within the scope of the patent laws, and its effect is to shift the benefits of a patented invention from inventors to consumers.

By penalizing high prices—and thus limiting the full exercise of the market power that derives from a patent—the District has 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 market 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. This may be a worthy undertaking on the part of the District government, but it is contrary to the goals established by Congress in the patent laws. The fact that the Act is targeted at the patent right is apparent on its face. It applies only to patented drugs. D.C. Code § 28-4553. The District has thus seen fit to change federal patent policy within its borders. The underlying determination about the proper balance between innovators' profit and consumer access to medication, though, is exclusively one for Congress to make. As the Supreme Court has noted, "[w]here it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-

guess." Bonito Boats, 489 U.S. at 152; see also Webber, 103 U.S. at 347 (noting that sale of patented articles "cannot be forbidden by the State, nor can the sale of the article or machine produced be restricted except as the production and sale of other articles, for the manufacture of which no invention or discovery is patented or claimed, may be forbidden or restricted").

The Act stands as an obstacle to the federal patent law's balance of objectives as established by Congress. Accordingly, we conclude that it is preempted by federal patent law.

III. CONCLUSION

Because the federal patent laws preempt the Act, we affirm the district court's injunction against the Act's enforcement. Since patent-law preemption invalidates the Act entirely, we do not need to consider the Foreign Commerce Clause argument advanced by plaintiffs as an alternative ground for affirmance.

AFFIRMED

Each party shall bear its own costs.