# 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.

William J. Earl, Senior Assistant Attorney General, Office of Attorney General for the District of Columbia, of Washington, DC, filed a combined petition for panel rehearing and rehearing en banc for defendants-appellants. With him on the petition were Linda Singer, Attorney General, Todd S. Kim, Solicitor General, and Edward E. Schwab, Deputy Solicitor General.

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

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

Judge Richard J. Leon

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Defendants-Appellants.

ON PETITION FOR PANEL REHEARING
AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, Circuit Judges, PLAGER, Senior Circuit Judge,[*] LOURIE, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges.

PER CURIAM.

GAJARSA, Circuit Judge, concurs in the denial of the petition for rehearing en banc in a separate opinion. DYK, Circuit Judge, dissents in the denial of the petition for rehearing en banc in a separate opinion.

[*] Senior Judge Plager, who was on the original panel, participated only in decision on the petition for panel rehearing.

O R D E R

A combined petition for panel rehearing and rehearing en banc was filed by the Appellants, and a response thereto was invited by the court and filed by the plaintiffs-appellees. The petition for rehearing was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue on November 6, 2007.

FOR THE COURT

October 30, 2007

__s/Jan Horbaly___
Jan Horbaly
Clerk

cc: William J. Earl, Esq.
Daniel E. Troy, Esq.
David W. Ogden, Esq.
Sean Michael Fiil-Flynn, Esq.
Jeffrey L. Handwerker, Esq.
Richard Samp, Esq.

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Defendants-Appellants.

GAJARSA, Circuit Judge, concurring in the denial of the petition for rehearing en banc.

I concur in the court's denial of rehearing en banc in this case. There is no need for en banc consideration as the decision is not inconsistent with any prior decisions of the United States Supreme Court or this Circuit. The panel decision reached the correct result on the proper legal basis. I write briefly to respond to the dissent to the denial of the rehearing en banc.

The dissent acknowledges that the panel was correct to hold that the District of Columbia's Prescription Drug Excessive Pricing Act of 2005 (the "D.C. Act") is preempted by the federal patent laws. As it notes, the D.C. Act impermissibly seeks to "establish patent policy" by requiring "the D.C. courts to determine what price is necessary to spur innovation." Dissent, slip op., at 3. But the dissent, nevertheless, faults the panel for deciding the issue on "conflict preemption" grounds rather than "field preemption" grounds. The dissent is grounded in sophistry. As the Supreme Court has cautioned, these categories are not "rigidly distinct." English v. General Elec. Co., 496 U.S. 72, 79 n.5 (1990); see also id. ("Indeed, field pre-emption may be understood as a species of conflict pre-emption . . . ."). That the D.C. Act could also be considered preempted by "field preemption" because it impermissibly establishes new patent policy, only strengthens the panel's determination that there is a direct conflict between the D.C. Act and the objects and purposes of the federal patent laws.

The dissent reaches the opposite conclusion by ignoring, for the purposes of its conflict analysis, the D.C. Act's statutory language and its clear invasion of the patent policy field. Instead, the dissent considers only the Act's alleged purpose of preventing price discrimination. See, e.g., dissent, slip. op. at 4 ("Despite the poor drafting of the D.C. Act, which inadvertently invades the field of patent policy, the main thrust of the D.C Act is designed to prevent price discrimination . . . . To the extent that the D.C. Act is designed to prohibit price discrimination, I see no conflict with federal policy."). This bifurcated approach is improper. Regardless of whether D.C.'s interference with patent policy was "inadvertent[]" or purposeful, we cannot change the language of the statute, but must instead base our preemption analysis on the entire statute as written.

Moreover, by focusing only on "price discrimination," the dissent distorts the holding of the panel, which relied on a consideration of the D.C. Act as a cohesive whole, and which was based in significant part on the panel's conclusion that the D.C. Act was a direct attempt "to change federal patent policy" within the District of Columbia. Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

As the dissent correctly points out, the heightened presumption of validity for state statutes in fields of traditional state regulation can only be overcome by a showing that "the clear and manifest purpose of Congress" is to preempt the state law. N.Y. State Conference of Blue Cross & Blue Shield Plans, 514 U.S. 645, 655 (1995). But finding a clear and manifest purpose does not require an express statement of preemption. Rather preemption is warranted when the challenged state law clearly "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000). And the Supreme Court has cautioned that "[w]hat is a sufficient obstacle" is to be determined not only by the express language of the federal statutory enactments, but also by "examining the federal statute as a whole and identifying its purpose and intended effects." Id.; see also id. ("[T]he entire scheme of the statute must of course be considered and that which needs must be implied is of no less force that that which is expressed."). Here, the direct conflict between the D.C. Act and the objects and purposes of the federal laws regarding pharmaceutical patents makes clear Congress' intention to preempt the D.C. law.

It is, of course, well-established that the patent laws, including the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub.

L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 156), do not "create any affirmative right to make, use, or sell anything." Leatherman Tool Group v. Cooper Indus., 131 F.3d 1011, 1015 (Fed. Cir. 1997). But the right that the patent laws do confer upon patent holders—the right to "exclude others from making, using, or selling a claimed invention for a limited period of time," id.—is not granted in a vacuum or for its own sake. Rather, as the Constitution itself establishes, the purpose of granting the patentee the right to exclude is "to promote the Progress of Science and useful Arts," U.S. Const. art I, § 8 cl. 8. And the primary mechanism by which the right to exclude promotes such innovation is by providing the patentee with the opportunity to obtain greater profits than it could have obtained without such a right to exclude. The Hatch-Waxman Act which extended the patent term for pharmaceutical products to account for the costs and delays of the FDA approval process, and its legislative history, make this link especially clear for patented drugs. As the House Committee on Energy and Commerce Report explained:

> 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 15 (1984); see also 130 Cong. Rec. 24,427 (1984) (statement of Representative Waxman) ("A patent is a monopoly, and when anyone holds a monopoly that person has the ability or that company has the ability to charge the highest price because there is no one else in competition, and as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product. But at some point

public policy calls for the free market system competition which will bring about the result of a lower price for the consumer. That is the purpose of the legislation."); 130 Cong. Rec. 15846 (statement of Senator Hatch) ("[T]he Drug Price Competition and Patent Term Restoration Act of 1984 . . . add[s] stimulus for research on new drugs and medical devises . . . through an extension of patent life to help recover the costs of obtaining FDA approval."). Congress' clear purpose to spur innovation by providing a right to exclude can, thus, be obstructed not only by directly preventing an inventor from excluding others, but also by systematically preventing a patentee from reaping the increased profits that would otherwise come from its exclusionary rights.[1]

Moreover, while there is particularly acute tension in the pharmaceutical context between promoting innovation by increasing the profit reward of patents and the public interest in affordable drugs, it was precisely the balance between these two interests that Congress intended to carefully calibrate when it passed the Hatch-Waxman Act, which not only extended the patent term for pharmaceutical products but also simplified the process of approval for generic products. 98 Stat. 1585. The legislative history of the Hatch-Waxman Act demonstrates that the Act's readjustment of the scope of the patent right for pharmaceutical products represented the culmination of a "long . . . effort to combine and balance these two objectives" of innovation and cost. 130 Cong. Rec.

[1] This does not mean that any state regulation that affects a patentee's profits so undermines the goals of the patent system as to be preempted. It is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption, even if this regulation incidentally affects the profits a patentee gains from its patent. See, e.g., Patterson v. Kentucky, 97 U.S. 501 (1878). But that states have broad leeway to regulate patented products does not mean that they have unlimited ability to do so in situations in which the regulation significantly and directly impedes Congress's purpose in providing the federal patent right.

23058 (statement of Representative Madigan); see also, e.g., 130 Cong. Rec. 23058-59 (statement of Representative Synar) ("This bill accomplishes two important goals: It provides incentives for research on new drugs by restoring a portion of the patent life that is lost during the FDA approval processes; and [i]t increases price competition in the drug marketplace by simplifying the approval process for generic drugs. Together, these two will bring about cheaper drugs today and better drugs tomorrow . . . This bill is an important compromise that improves research and development and increases price competition in the drug marketplace."); id. at 23058 (statement of Representative Madigan) ("Under the provision of this legislation, patent protection can be extended up to 5 years, as long as the extension when added to the patent time remaining, does not exceed 14 years. We must provide this extension to guarantee the continued commitment of resources for the development of innovative drugs to address the changing health needs of our citizens. At the same time, I am concerned with the containment of health care costs. [The bill] will allow the marketing of generic counterparts . . . following the expiration of the original patent term . . . The contribution of medications to overall cost of health care can be reduced drastically if these generic equivalents are brought to the marketplace in a timely fashion.").

The D.C. Act is not simply about preventing "price discrimination," but directly targets and undermines this careful balance between innovation and drug costs. The D.C. Act's prohibition on "excessive prices" for patented drugs (and patented drugs only), is purposefully aimed at adjusting the scope and reward of the federal patent right. It would replace Congress's deliberate balance with (a) the different balance reached by other foreign governments (such as Australia, Germany, or the United

Kingdom), which although providing exclusivity, temper the benefits of that right with various forms of government price control, and (b) jury determinations of how pharmaceutical companies should be compensated for their innovation. See D.C. Code §§ 28-4552,-4554. In doing so, the D.C. Act clearly "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," Crosby, 530 U.S. at 373. And in light of this conflict, the panel correctly determined that the D.C. Act was preempted. See id.; see also Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 152 (1989) ("Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess.").

The dissent alludes to the price discrimination impact of the D.C. Act not being in conflict with federal patent law. This is an erroneous syllogism, since the issue before the panel was not premised on whether D.C. has the authority to impose price discrimination restrictions in general; the issue presented was whether or not the specific D.C. Act was preempted by federal patent drug statutes, e.g., 35 U.S.C. §§ 154-57. The panel correctly determined that it was.

Similarly, I note that the dissent overstates the breath of the panel opinion to the extent that it suggests that the opinion would require the preemption of "any state law regulating the prices of patented pharmaceutical products." See dissent, slip. op., at 2. The panel opinion's analysis rests, as all preemption analysis must, on the specifics of the D.C. statute, considered as a whole. See, e.g., Biotechnology Indus. Org., 496 F.3d at 1374 ("The fact that the Act is targeted at the patent right is apparent on its face. It applies only to patented drugs. The District has thus seen fit to change federal patent policy within its borders."). Whether future efforts of states to regulate drug prices,

which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day.

Thus, for the foregoing reasons and those stated in the panel decision, this Court correctly declined to consider this case en banc.

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Defendants-Appellants.

DYK, Circuit Judge, dissenting from denial of rehearing en banc.

I respectfully dissent from the court's denial of rehearing en banc in this case. In my view the panel's decision in this case presents an important issue of broad significance beyond the District of Columbia, warranting our en banc attention. As the panel opinion noted, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1371-72 (Fed. Cir. 2007), the District of Columbia stands on the same footing as any state with respect to preemption analysis, and our jurisdiction is exclusive. Therefore,

any state law regulating the prices of patented pharmaceutical products would likely be preempted as a result of the panel's holding. While the D.C. statute in this case appears to be invalid because of its poor drafting, the panel's opinion suggests that even legitimate price regulation is invalid.

The panel held that the District of Columbia's Prescription Drug Excessive Pricing Act of 2005 (the "D.C. Act") is preempted by federal patent law. The D.C. Act prohibits the sale of patented pharmaceuticals at excessive prices, and includes a presumption that prices more than 30% above the prices charged for the same drug in the United Kingdom, Germany, Canada, or Australia are excessive if the drug "is protected by patents or other exclusive marketing rights" in that country. See D.C. Code §§ 28-4552, -4554. The D.C. Act also provides that a pharmaceutical manufacturer can refute the resulting presumption by showing, by a preponderance of the evidence, that the price charged in the District is not excessive in light of several factors:

> 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).

The panel agrees that the patent statutes contain no provision expressly preempting state regulation of the price of patented goods. Biotechnology Indus. Org., 496 F.3d at 1372. Under these circumstances, a state law is preempted only if it either (1) regulates in an area where federal regulation is exclusive (so-called field

preemption) or (2) regulates in a way that conflicts with federal policy (so-called conflict preemption). See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).[1]

In Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989), the Supreme Court held that a state law providing intellectual property protection similar to patent protection was preempted by federal patent law. Id. at 144. In holding the state law preempted, the Court appears to have found both field and conflict preemption.[2] With respect to field preemption, the Supreme Court found that "[t]he patent statute's careful balance between public right and private monopoly to promote certain creative activity is a 'scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.'" Id. at 167 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, (1947)).

The problem with the D.C. Act, in my view, is that in a misguided effort to accommodate the patent statutes, it seeks to establish patent policy and thus is subject to field preemption. This is so because the statute requires the D.C. courts (in addressing the defense to excessive pricing) to determine what price is necessary to spur innovation, see D.C. Code § 28-4554(b), a policy determination that Congress surely did not intend to leave to the states. This is not, however, the ground for the panel decision here, which rests on conflict preemption. In my view, a price discrimination provision presents no conflict with the purpose of the federal patent law.

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[1] Conflict preemption is also appropriate when "compliance with both federal and state law is in effect physically impossible," La. Public Serv. Comm'n v. Fed. Commc'ns Comm'n, 476 U.S. 355, 368 (1986), but there is no allegation that this is the case here.

[2] The Supreme Court found conflict preemption, concluding that the state law "conflicts with the federal policy 'that all ideas in general circulation be dedicated to

Despite its poor drafting, which inadvertently invades the field of patent policy, the main thrust of the D.C. Act is designed to prevent price discrimination between sales of patented pharmaceutical products in the District and in certain other countries that confer exclusivity. See D.C. Code § 28-4554. In this respect, the D.C. Act reflects the significant public concern about the disparity between drug prices in the United States and other industrialized nations with pharmaceutical patent protection. See generally, U.S. Dep't of Commerce, Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation (2004). The District determined that it was important to regulate this price discrimination to protect public health, due to concern that such price discrimination would deny access to important pharmaceutical products to some District residents who are unable to afford needed medicines. D.C. Code § 28-4551. It is limited to patented drugs because that is the area in which the price discrimination and access issues exist.

To the extent that the D.C. Act is designed to prohibit price discrimination, I see no conflict with federal policy. Clearly, there is no conflict with federal antitrust law, such as the Robinson-Patman Act, which prohibits, under certain circumstances, "discriminate[ion] in price between different purchasers of commodities of like grade and quality . . . where the effect of such discrimination may be substantially to lessen competition or tend to create a monopoly . . . ." 15 U.S.C. § 13(a). The Supreme Court has rejected an argument, under comparable circumstances, that federal price discrimination statutes preempt state price discrimination prohibitions that are in some respects more demanding. Exxon Corp. v. Governor of Md., 437 U.S. 117, 131 (1978).

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the common good unless they are protected by a valid patent.'" Id. at 159-60 (quoting

The panel finds no conflict with the antitrust laws; rather, it finds a conflict with the patent laws. The panel concluded that the D.C. Act would "penaliz[e] high prices . . . and . . . limit[] the full exercise of the exclusionary power that derives from a patent . . . [thus] re-balanc[ing] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." Biotechnology Indus. Org., 496 F.3d at 1374. In other words, the panel finds a conflict between the D.C. Act and a supposed policy of the patent law to allow patent holders to reap maximum profits during the term of the limited monopoly on use of the invention.

This seems to me incorrect. First, the patent laws are not designed to confer immunity from antitrust-type regulation. Congress has not conferred any right on a patentee "to enlarge the scope of the patent monopoly by using the [exclusionary] power it confers to restrain competition" except to the extent that the patent law confers exclusivity. Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 37 (2006) (quoting Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 16 (1984)); see also Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 49 (1912). Thus, for example, sellers of patented products have no special right to fix the price at which the patented products are sold. United States v. Gen. Elec. Co., 272 U.S. 476, 493-94 (1926) (citing cases).

Second, the panel errs in suggesting that the purpose of the patent statutes is to allow a patentee to reap maximum profits during the exclusivity period because "the only limitation on the size of the carrot [the patentee's profit during the exclusivity period] should be the dictates of the marketplace." Biotechnology Indus. Org., 496 F.3d at 1372 (quoting King Instruments Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995)).

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Lear, Inc. v. Adkins, 395 U.S. 653, 668 (1969)).

A patent grant is designed not to allow the patent holder to exploit the grant for the maximum profit that the market will bear, but merely to confer a right of exclusivity. The panel's assertion to the contrary is inconsistent with longstanding Supreme Court precedent.

It is well established that Congress intended patents to confer upon their holders only "a limited right to exclude others from making, using, or selling a claimed invention for a limited period of time," but not to "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); see 35 U.S.C. § 154(a). The Supreme Court has frequently applied this principle to conclude that patent law does not preempt or conflict with state and federal statutes regulating or prohibiting the sale of patented products. See, e.g., Webber v. Virginia, 103 U.S. 344, 347-48 (1880) (finding state tax not preempted as applied to sale of patented products); Patterson v. Kentucky, 97 U.S. 501 (1878) (holding patent rights subordinated to state statute governing safety requirements for lighting oil); see also Standard Sanitary, 226 U.S. at 49 (holding patent rights do not apply to preempt price-fixing restrictions imposed by the Sherman Act). There is no indication that the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, changed this clearly established legal principle. The legislative history of the Hatch-Waxman Act shows no more than a desire to allow exclusivity because it would result in higher profits. See, e.g., H.R. Rep. No. 98-857, at 17 (1984) ("Patents are designed to promote innovation by providing the right to exclude . . . enable[ing] innovators to obtain greater profits than could have been obtained if direct competition existed."). A law that does nothing to

interfere with exclusivity also does nothing to interfere with this purpose. There is not a word in the cited legislative history of the Hatch-Waxman Act suggesting any concern about state price regulation of patented pharmaceutical products. The D.C. Act does not conflict with the purposes of federal patent law because the D.C. Act's limitations on price discrimination do not in any way interfere with any patent holder's right to exclusivity. The D.C. Act does not authorize any other person to make, use, or sell any patented products.

Finally, in finding a conflict between price discrimination regulation and federal patent policy, I think that the panel failed to give adequate consideration to the presumption against preemption. See N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654-55 (1995). This presumption is particularly strong with respect to state regulations pursuant to the states' police power in "fields of traditional state regulation," such as laws protecting health and safety. Id. at 655. To overcome the presumption against preemption under these circumstances, the party asserting preemption must demonstrate that "the clear and manifest purpose of Congress" supports preemption. Id. It is clear that, to the extent that the D.C. Act prohibits price discrimination to ensure public access to important medications, it falls within the core of the states' traditional powers, triggering a strong presumption against preemption. The patent laws were not designed to immunize patent holders from legitimate state regulation in the states' traditional legislative spheres.

A prohibition on price discrimination may or may not be desirable legislation. But the decision of whether to preempt such legislation is for the Congress to make, and not this court. While I agree that the panel correctly invalidated this particular statute, I

dissent from the panel's apparent holding that the prevention of price discrimination is inconsistent with the clear and manifest purpose of the patent statutes, and I dissent from the denial of en banc review.