Supreme Court, U.S.
FILED
MAY 22 2009
OFFICE OF THE CLERK

No. 08-1194

IN THE

Supreme Court of the United States

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND *ET AL.*,

Petitioners,

v.

BAYER AG *ET AL.*,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION OF RESPONDENTS BARR LABORATORIES, INC., HOECHST MARION ROUSSEL, INC., WATSON PHARMACEUTICALS, INC., and THE RUGBY GROUP, INC.

DAVID E. EVERSON
HEATHER S. WOODSON
VICTORIA L. SMITH
STINSON MORRISON HECKER LLP
1201 Walnut Street
Kansas City, MO 64106
(816) 842-8600

CHRISTOPHER LANDAU, P.C.
Counsel of Record
KAREN N. WALKER, P.C.
EDWIN JOHN U
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000

May 22, 2009

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20001

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, respondents state as follows:

1. Respondent Barr Laboratories, Inc. was wholly owned by Barr Pharmaceuticals, Inc. In December 2008, Barr Pharmaceuticals, Inc. was merged into a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., which itself is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., a publicly held company. After the merger, the surviving company changed its name to Barr Pharmaceuticals LLC. No publicly held company other than Teva Pharmaceutical Industries Ltd. directly or indirectly owns 10% or more of the stock of Barr Pharmaceuticals LLC.

2. Respondent Hoechst Marion Roussel, Inc. has been merged and its pertinent assets and liabilities now reside with sanofi-aventis U.S. LLC. Sanofi-aventis U.S. LLC is owned by Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc., which are not publicly held. No other publicly held corporation owns 10% or more of its stock. Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc. are ultimately owned by sanofi-aventis, which is publicly held.

3. Respondent Watson Pharmaceuticals, Inc. is a publicly held corporation. No publicly held corporation owns 10% or more of its stock.

4. Respondent The Rugby Group, Inc. is a subsidiary of respondent Watson Pharmaceuticals, Inc. No other publicly held corporation owns 10% or more of its stock.

TABLE OF AUTHORITIES

Page(s)

Cases

Constitution, Statutes, and Rules

Other Authorities

INTRODUCTION

It is not often that a petition for certiorari acknowledges on its face that it presents a poor vehicle for this Court to address a particular legal question. The petition here, however, does just that. While the petition asks this Court to resolve a perceived tension between the federal antitrust laws and the federal patent laws in the context of patent settlement agreements, there *are* no claims under the federal antitrust laws at issue here. Petitioners are indirect purchasers who cannot obtain monetary relief under the federal antitrust laws in light of *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and cannot obtain injunctive relief under the federal antitrust laws now that the relevant patent (and hence the relevant settlement agreement) has expired. Petitioners thus have only *state-law* claims against respondents. Needless to say, a petition that does not involve any claims under the federal antitrust laws presents a poor vehicle for this Court to construe those laws.

Petitioners try to avoid this point by insisting that "there are federal injunctive and damage claims in the companion case presently pending in the Second Circuit." Pet. 18. Thus, even petitioners cannot and do not suggest that *this* case provides an appropriate vehicle for this Court's review; rather, they assert that "it would be most appropriate for this Court to *defer* ruling on this petition for certiorari until a petition is filed by the parties in the parallel portion of the case that is on appeal in the Second Circuit." *Id.* (emphasis added). But that case has only recently been argued, and there is no way to know how or when it will be resolved (or even

whether it will be resolved by the Second Circuit at all, given questions raised at oral argument about that Court's jurisdiction). There is certainly no basis for this Court to defer resolution of this petition, which does not present an issue worthy of its review, on the theory that a future petition *may* present such an issue.

Nor is there any merit to petitioners' suggestion of a conflict between the decision below and decisions by the Sixth and Eleventh Circuits. As the Federal Circuit explained, its decision is entirely consistent with the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), and the Eleventh Circuit's decision in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), not to mention the Second Circuit's decision in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005). Pet. App. 19-25a. All of those decisions comport with the holding below that an agreement to settle patent litigation does not violate the antitrust laws, as long as (1) the settlement agreement is limited to the patent's exclusionary zone, (2) the patent itself was not procured by fraud, and (3) the underlying patent litigation was not an objectively baseless sham.

At bottom, the petition essentially rests on policy arguments about the supposed adverse effects of patent settlements on competition. Putting aside the fact that these policy arguments are directed to the wrong forum, and fail to provide any reason for this Court's review, they are misguided. All of petitioners' rhetoric about the importance of competition is out of place with respect to competition within the scope of a patent, which by

definition grants an inventor freedom from competition within that limited scope for a limited time, in order to promote and reward invention. In essence, petitioners' policy arguments are simply arguments against the patent laws; in petitioners' view, the social value of competition even within the scope of a patent exceeds the social value of promoting and rewarding invention. Petitioners are certainly entitled to that view, but it assuredly is not, and never has been, the law of the land.

COUNTERSTATEMENT OF THE CASE

A. Factual Background

This case involves a challenge to a settlement of patent litigation. Respondents Bayer AG and Bayer Corp. owned and licensed the patent to the active ingredient in the prescription antibiotic ciprofloxacin hydrochloride, commonly known as Cipro. Pet. App. 4a. When respondent Barr Laboratories, a generic drug manufacturer, sought FDA approval to introduce a competing generic version of the drug pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, Bayer brought a patent infringement action, Pet. App. 5a. Barr did not deny that its proposed drug would infringe the Cipro patent, but instead challenged the validity of that patent. Because Barr did not challenge infringement and had not yet made any infringing sales, Barr's challenge to the validity of the patent was the central issue in the litigation, and for all intents and purposes Barr was the plaintiff and Bayer the defendant. Barr and Bayer litigated these patent issues against each other for five years. Pet. App. 5a, 44a.

In 1997, on the eve of trial, the parties settled the case. Pet. App. 5-6a, 44-46a. As part of the

settlement agreement, Barr and its litigation partners received both monetary consideration and a license to sell a competing ciprofloxacin product at least six months before the Cipro patent expired. Pet. App. 6-7a. Nothing in that agreement purported to preclude other parties from challenging the validity of the Cipro patent, and several other generic drug manufacturers in fact proceeded to do so—unsuccessfully. *See, e.g., Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002) (upholding validity of Bayer's Cipro patent); *see also Bayer AG v. Carlsbad Tech., Inc.*, No. 01 CV0867-B (S.D. Cal. June 7, 2002 & Aug. 7, 2002) (same); Pet. App. 7-8a. Bayer itself also sought re-examination of the Cipro patent by the U.S. Patent & Trademark Office (PTO), which reaffirmed its validity. Pet. App. 7a. The Cipro patent expired in 2003. Pet. App. 4a.

B. Procedural History

Petitioners here are indirect purchasers of Cipro, *i.e.*, they do not buy the drug directly from Bayer, but instead from intermediaries. Starting in 2000, petitioners began filing lawsuits against respondents challenging the 1997 Cipro settlement agreement as unlawfully anticompetitive. Pursuant to 28 U.S.C. § 1407, the lawsuits were transferred to the U.S. District Court for the Eastern District of New York.

After five years of discovery, the district court (Trager, J.) granted summary judgment in respondents' favor, holding that the Cipro settlement agreement passed antitrust muster because it did not "constrain[] competition beyond the scope of the patent claims." Pet. App. 94a. "Unless and until the patent is shown to have been procured by fraud, or a

suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." Pet. App. 83a. In analyzing a challenge to that settlement agreement, the district court emphasized, "it would be inappropriate to engage in an after-the-fact analysis of the patent's likely validity." Pet. App. 93a.

Petitioners appealed to the Second Circuit. That court, however, transferred their appeal to the Federal Circuit. *See* Pet. App. 36-38a. As the Second Circuit noted, *see* Pet. App. 37a, petitioners' claim alleging fraud on the PTO was one "arising under" the patent laws, *see* 28 U.S.C. § 1338, and thus within the Federal Circuit's exclusive appellate jurisdiction, *see* 28 U.S.C. § 1295(a)(1).

A unanimous panel of the Federal Circuit affirmed. *See* Pet. App. 1-35a. As the court explained, an alleged restraint on competition within a patent's exclusionary zone cannot be redressed by antitrust law, and thus "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." Pet. App. 24a. Because petitioners raised no genuine issue of material fact to show any restraint on competition beyond the exclusionary zone of the Cipro patent, and failed to establish either fraud on the PTO or sham litigation, respondents were entitled to summary judgment. Pet. App. 33-35a.

REASONS FOR DENYING THE WRIT

I. The Decision Below Is Correct And Does Not Warrant This Court's Review.

The U.S. Constitution expressly authorizes Congress "[t]o promote the Progress of Science and useful Arts" by granting inventors "the exclusive Right" to their inventions "for limited Times." U.S. Const. Art. I § 8 cl. 8. Congress exercised that authority by enacting the federal patent laws, which expressly grant patentholders "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. 35 U.S.C. § 154(a)(1).

It follows, as a matter of law and logic, that there can be no unlawful restraint of competition entirely within the scope of a valid patent. In essence, a patent is a federal license to restrain competition in a particular area for a particular time. *See, e.g.*, *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *Precision Instrument Mfg. Co. v. Automobile Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). By definition, there can be no unlawful restraint of competition within the zone of patent exclusivity. *See, e.g., United States v. General Elec. Co.*, 272 U.S. 476, 485 (1926); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 91 (1902); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1067 (11th Cir. 2005); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981). While some people may disapprove of *any* restraint

of competition as a matter of policy, no less august a document than the Constitution itself endorses the countervailing policy that giving inventors "the exclusive Right" to their inventions for "limited Times" will "promote the Progress of Science and useful Arts" for the greater good. U.S. Const. Art. I § 8 cl. 8.

Thus, as the Federal Circuit and other courts have recognized, an agreement to settle patent litigation cannot be characterized as an unlawful restraint on competition as long as (1) the settlement agreement is limited to the patent's exclusionary zone, (2) the patent itself was not procured by fraud, and (3) the underlying patent litigation was not an objectively baseless sham. *See* Pet. App. 23-24a; *Tamoxifen*, 466 F.3d at 212-16; *Valley Drug*, 344 F.3d at 1308-12; *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003) (Posner, J., sitting by designation). That approach fully and properly reconciles the federal patent laws with the federal antitrust laws. To attach antitrust liability to a settlement entirely within a patent's exclusionary zone would be to negate the lawful monopoly that lies at the heart of the patent laws.

It is no answer to argue, as do petitioners, that the patent could have been found invalid. By statute, a patent is presumed *valid* unless and until proven otherwise by clear and convincing evidence. *See* 35 U.S.C. § 282; *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004). It is thus neither necessary nor appropriate to try to second-guess the outcome of a patent validity challenge or "reverse-engineer" an agreement settling such a challenge. By their very nature,

settlements are based on imperfect information. The parties may assess the relative risks differently, and the parties may assess the relative risks incorrectly. There is simply no basis for courts to judge settlement agreements after the fact, and certainly no basis for courts to impose liability for treble antitrust damages based on any such after-the-fact assessment. Here, respondent Barr was under no legal obligation to challenge the validity of the Cipro patent in the first instance, and certainly was under no legal obligation to continue that challenge to a final judicial resolution.

Contrary to petitioners' contention, *see* Pet. 2, none of this establishes a rule of *per se* legality for patent settlements under the federal antitrust laws. To the contrary, the Federal Circuit took pains to emphasize that any such antitrust challenge must be evaluated under the traditional rule of reason. *See* Pet. App. 14-16a; *see also Tamoxifen*, 466 F.3d at 201-02. To establish a claim under the rule of reason, however, a plaintiff must allege a restraint on competition in a relevant market. *See, e.g., State Oil Co. v. Khan*, 522 U.S. 3, 10-19 (1997). By definition, there can be no "restraint" on competition within the exclusionary zone of a patent, because (as noted above) the whole point of that zone is to reward invention by protecting the patentholder from competition for a limited time.

Petitioners have failed to identify any conflict among the circuits on the standard for evaluating patent settlement agreements under the antitrust laws. Their assertion that the decision below conflicts with the Sixth Circuit's decision in *Cardizem*, 332 F.3d 896, is incorrect; indeed, the

Federal Circuit went out of its way to negate any such conflict. The agreement at issue in *Cardizem*, as the Federal Circuit explained, went *beyond* the scope of the relevant patent. *See* Pet. App. 21a (explaining that *Cardizem* is "distinguishable from this case and from the other circuit court decisions" because the agreement there "clearly had anticompetitive effects *outside* the exclusion zone of the patent") (emphasis added); *see also Tamoxifen*, 466 F.3d at 213-14 (distinguishing *Cardizem* on this ground); *Cardizem*, 332 F.3d at 908 n.13 (noting that the district court in this case distinguished the district court decision in *Cardizem* on the ground that the agreement there exceeded the scope of the patent). Indeed, the United States made this very point in its brief recommending against this Court's review in *Tamoxifen*. *See* Br. for the United States as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527 (U.S. *Tamoxifen* Br.), at 16 n.7 ("*Cardizem* involved payments to exclude competition in drugs that did *not* fall within the scope of the allegedly infringed patent, and thus it is uncertain whether the per se rule adopted by the Sixth Circuit extends beyond the unique circumstances of that case.") (emphasis in original).

Petitioners similarly miss the mark by alleging that the decision below conflicts with the Eleventh Circuit's decision in *Valley Drug*, 344 F.3d 1294. According to petitioners, *Valley Drug* mandates an "inquiry into the strength of the patent" in analyzing an antitrust challenge to a patent settlement. Pet. 14; *see also id.* at 21-22. Petitioners' reliance on *Valley Drug* is misplaced and indeed ironic. The Eleventh Circuit there *reversed* a decision imposing

antitrust liability based on a patent settlement. *See Valley Drug*, 344 F.3d at 1306, 1312-13. As the Federal Circuit pointed out below, the *Valley Drug* court focused on the inherently "anticompetitive effects of the exclusionary zone of a patent," Pet. App. 22a (citing *Valley Drug*, 344 F.3d at 1312 n.27), and simply left open "the possibility ... that an antitrust violation could be found in the extreme situation where there was evidence of fraud on the PTO or sham litigation," *id.* (citing *Valley Drug*, 344 F.3d at 1309 & n.21); *see also Valley Drug*, 344 F.3d at 1310 & n.22 (noting that "the size of the payments" could be relevant to the fraud or sham inquiry). That is, needless to say, precisely the approach adopted by the Federal Circuit below and by the Second Circuit in *Tamoxifen*. *See* Pet. App. 23-27a; *Tamoxifen*, 466 F.3d at 218. Thus, *Valley Drug*'s approach, as well as its result, is entirely consistent with the decision below.

Because they cannot identify any circuit conflict, petitioners fall back on the argument that this Court's review is warranted because the issue here has been "a 'hot button' issue in antitrust scholarship for years," and "antitrust enforcement authorities" have expressed disagreement with the approach followed below. Pet. 4, 14-15, 22-23 & n.11. But this Court would have to radically expand its docket if it ever were to get into the business of granting review of every issue that was asserted to be a "hot button" in academic circles, or where official enforcement authorities thought a legal standard was insufficiently enforcement-friendly. Presumably, that explains why neither of these factors is identified as a consideration favoring review in this Court's rules. *See* S. Ct. R. 10. If this is really such

a "hot button" issue, a circuit conflict can be expected to develop in due course as the issue percolates among the lower courts.

II. This Case Is A Poor Vehicle For Addressing The Issues Raised By The Petition.

Above and beyond the basic point that the decision below is correct and does not conflict with the decision of any other court of appeals, the fact remains that this case is a poor vehicle for this Court to address the issues raised by the petition.

In particular, while the petition purports to involve a perceived tension between the federal patent and antitrust laws, petitioners *have* no claim under the federal antitrust laws for reasons wholly unrelated to patent law. Petitioners have no federal antitrust claim for damages because they are indirect purchasers. *See, e.g., Illinois Brick*, 431 U.S. at 734-35. And petitioners have no federal antitrust claim for injunctive relief because the Cipro patent (and hence the relevant settlement agreement) has expired, and hence there is nothing to enjoin. *See, e.g. City of Los Angeles v. Lyons*, 461 U.S. 95, 101-03 (1983). Petitioners are thus left with only *state-law* claims, which obviously do not implicate any perceived tension between the federal patent and antitrust laws. Indeed, the United States recommended against review in *Tamoxifen* on just this ground. *See* U.S. *Tamoxifen* Br. 17-19.

It is no answer to assert, as do petitioners, that "an examination of the Federal Circuit's decision gives no indication whatsoever that it believed its decision stemmed from anything specific in the state laws under which the damage claims are asserted." Pet. 17-18. Regardless of how the Federal Circuit

analyzed the issue, the fact remains that there is no live federal antitrust claim in this case that would require or allow this Court to interpret and apply the Sherman Act. Petitioners' reliance on *Michigan v. Long*, 463 U.S. 1032 (1983), *see* Pet. 18, is thus misplaced: that case stands for the proposition that a state court decision will be deemed to be based on federal law if it is not clear whether the court relied on federal or state law, *see* 463 U.S. at 1040-42. Here, it is clear that there is no live federal antitrust claim, so this case is not an appropriate vehicle for this Court to address the perceived tension between federal patent and antitrust law.

At the end of the day, petitioners are thus reduced to arguing that "there are federal injunctive and damage claims in the companion case presently pending in the Second Circuit." Pet. 18. Accordingly, petitioners submit, "it would be most appropriate to *defer* ruling on this petition for certiorari until a petition is filed by the parties in the parallel portion of the case that is on appeal in the Second Circuit." *Id.* (emphasis added). But it is neither necessary nor appropriate for this Court to "defer" ruling on this petition based on a petition that *may* be filed in the future in a case that was only recently argued in the court of appeals. If and when a petition is eventually filed by the losing party in that case (which may be years from now), this Court can decide at that time whether that case warrants review. But whether such a hypothetical future petition might warrant review has no bearing on the proper disposition of this petition. Granting certiorari in another case would not change the fact that this case presents no live federal claims, and never will.

In addition, this case presents an unattractive vehicle for this Court's review because the validity of the Cipro patent actually has been adjudicated and upheld time and again. *See* Pet. App. 7-8a. The settlement agreement at issue here, after all, did not prevent other generic manufacturers from challenging the validity of the Cipro patent—and they in fact proceeded (unsuccessfully) to do just that. If anything, that underscores the insubstantial nature of petitioners' claims, which are based at bottom on the alleged invalidity of the Cipro patent. This is, in effect, the flip side of yet another ground that the United States articulated in recommending against review in *Tamoxifen*, *see* U.S. *Tamoxifen* Br. 19: there, the disputed patent had been adjudicated to be invalid at the time of the settlement, whereas here the disputed patent has been adjudicated to be valid on multiple occasions. *See* Pet. App. 7-8a. If anything, a case involving a patent that consistently has been adjudicated to be valid presents a worse vehicle for this Court to address the perceived tension between the federal patent and antitrust laws than a case (like *Tamoxifen*) in which the patent had been adjudicated to be invalid at the time of settlement.

In addition, as the United States further explained in recommending against this Court's review in *Tamoxifen*, "[c]hanges in the regulatory context have ... altered the regulatory dynamic with respect to one of the theories of competitive harm advanced by petitioners, who argued in part below that Barr's agreement to assert its exclusivity rights [under the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iv)] could preclude competition by other generics." U.S. *Tamoxifen* Br. 19. The practical

upshot of these changes, as the United States explained, was to make it more difficult for a generic drug manufacturer to restrain competition by other generic drug manufacturers in light of a patent settlement agreement. *See id.* at 20. To the extent that this Court were inclined to address the federal antitrust implications of patent settlement agreements, therefore, "it may be preferable to do so in a case that arises under the current regulatory regime." *Id.*

Finally, legislation is now pending before Congress that would alter the law governing patent settlements. *See* S. 369, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009). Needless to say, such legislation would render any decision in this case little more than an advisory opinion. If anything, a decision to grant review in this case could distort a legislative process that is now fully engaged on the underlying issues that petitioners purport to raise. Certainly, petitioners' extensive policy arguments against patent settlements, *see* Pet. 2, 12-15, 24-27, are better addressed to a legislative forum than to this Court.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for writ of certiorari.

Respectfully submitted,

DAVID E. EVERSON
HEATHER S. WOODSON
VICTORIA L. SMITH
STINSON MORRISON
HECKER LLP
1201 Walnut Street
Kansas City, MO 64106
(816) 842-8600

Counsel for Respondents Hoechst Marion Roussel, Inc., Watson Pharmaceuticals, Inc., and The Rugby Group, Inc.

CHRISTOPHER LANDAU, P.C.
Counsel of Record
KAREN N. WALKER, P.C.
EDWIN JOHN U
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000

Counsel for Respondent Barr Laboratories, Inc.

May 22, 2009