Arkansas Carpenters Health and Welfare Fund v. Bayer AG

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At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 7th day of September, two thousand ten.

ORDER

Following disposition of this appeal on April 29, 2010, Plaintiffs-Appellants Louisiana Wholesale Drug Co., Inc.; Arthur's Drug Store, Inc.; CVS Pharmacy, Inc.; and Rite Aid Corporation filed a petition for rehearing in banc. An active judge requested a poll on whether to rehear the case in banc. A poll having been conducted and there being no majority favoring in banc review, rehearing in banc is hereby DENIED.

Judge Pooler dissents in an opinion.

ROSEMARY S. POOLER, Circuit Judge, dissenting:[2]

In 1991, Barr Labs sought to market a generic version of ciprofloxacin hydrochloride ("Cipro"). Bayer, which holds the Cipro patent, sued Barr for infringement, lost its motion for summary judgment, and subsequently settled with Barr on the eve of trial. Under the terms of the settlement agreement, Bayer paid Barr nearly $400 million and in exchange Barr agreed not to market a generic version of Cipro during the life of the patent.

The Bayer-Barr settlement agreement was unusual in a number of respects. Most obviously, under the terms of the settlement the patent holder agreed to pay the alleged infringer to settle the suit in exchange for the alleged infringer's agreement to stay out of the marketplace during the life of the patent. In the industry parlance, this is called a "reverse exclusion payment," or, more evocatively, a "pay-for-delay" settlement.[3]

This type of settlement, once unheard of, has become increasingly common. This Court has played a significant role in encouraging this unfortunate practice. In In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), a panel of this Court, over my dissent, held that exclusion payment settlements are lawful unless the branded firm's patent is "shown to have been procured by fraud, or a suit for its enforcement is objectively baseless ." Id. at 213. What followed was a dramatic surge in the practice of pharmaceutical patent holders paying potential competitors to concede the validity of their patents. In the five years before Tamoxifen was decided, there were no settlements involving

exclusion payments,[4] and even pharmaceutical industry representatives appear to have conceded the illegality of the practice, testifying before Congress that proposed amendments to the Hatch Waxman Act explicitly prohibiting exclusion payment settlements were unnecessary because such settlements "would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not."[5] In the four years since Tamoxifen, by contrast, the Federal Trade Commission has identified fifty-three pharmaceutical patent settlements involving exclusion payments.[6] The Commission estimates that such settlements cost consumers approximately $3.5 billion per year.[7] Further, such settlements serve no obvious redeeming social purpose. Put simply, what the patent holder purchases by means of an exclusion payment settlement is the continuation of a patent the patent holder must have thought had some significant probability of being declared invalid.[8]

Of course, all of this would not be this Court's concern if the Hatch-Waxman Act explicitly permitted exclusion payment settlements. However, the Act is silent on the legality of such settlements, and the Act's sponsors have openly criticized the practice.[9] Further, exclusion payment settlements seem plainly inconsistent with the stated purpose of the Hatch Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs.[10]

More significantly, the Hatch Waxman Act does nothing to change the general rule that market-sharing agreements violate the antitrust laws. See Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49 (1990) (per curiam); United States v. Sealy, Inc., 388 U.S. 350, 357-58 (1967). This is just as true when one of the parties to a market-sharing agreement happens to hold a patent. See Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49 (1990); United States v. Sealy, Inc., 388 U.S. 350, 357-58 (1967). Thus, even though we are required to presume that Bayer's patent is valid, 35 U.S.C. § 282, as the United States points out in its amicus brief, [t]he presumption of patent validity is simply a procedural device that assigns burdens in litigation challenging the validity of an issued patent. There is no basis for treating that presumption as virtually conclusive and allowing it to serve as a substantive basis to limit the application of the Sherman Act.

Br. of United States, at 6-7 (internal citations omitted).

It should not be surprising, therefore, that our Tamoxifen decision has inspired vigorous criticism from a variety of sources. The United States has described our Tamoxifen rule as "incorrect,"[11] and has supported the plaintiffs' petition for en banc rehearing in this case.[12] Also supporting the petition for rehearing are the majority of State Attorneys General,[13] the Federal Trade Commission,[14] the American Medical Association,[15] and an impressive array of consumer groups and academic commentators.[16] As amici point out, although "commentators are divided on the treatment to be accorded [exclusion payment] settlements . none take the position adopted by [] Tamoxifen."[17]

In the light of all this, I think that our Tamoxifen decision unambiguously deserves reexamination. The Tamoxifen majority recognized the "troubling dynamic" of permitting exclusion payments that

"inevitably protect patent monopolies that are, perhaps, undeserved." 466 F.3d at 211. Subsequent experience has shown that the majority was right to be "troubled." Although the "enormous importance" of the issues that this case raises is beyond dispute, Fed. R. App. P. 35(a)(2), a majority of this Court has voted against en banc rehearing. I respectfully dissent from that decision. It will be up to the Supreme Court or Congress to resolve the conflict among the Courts of Appeals. Compare In re Ciprofloxacin Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008) (exclusion payments legal), and Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (same) with In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (exclusion payments per se illegal).

1. The appeal docketed under 05-2863-cv has been transferred to the United States Court of Appeals for the Federal Circuit. See Nov. 7, 2007 Order.

2. Senior Circuit Judges Jon O. Newman and Barrington D. Parker, members of the original panel, are not authorized to participate in the en banc poll, but the panel opinion endorses the views expressed in this opinion.

3. See generally C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553 (2006).

4. See Jon Leibowitz, Commissioner, Federal Trade Commission, Prepared Statement to the Committee on the Judiciary of the United States Senate: Anticompetitive Patent Settlements in the Pharmaceutical Industry, at 13 (Jan. 17, 2007), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

5. See Hearing No. 107-1081 Before S. Comm. On Commerce, Science, and Transportation, 107th Cong. (Apr. 23, 2002), at 71 (statement of Greg Glover, Pharmaceutical Research and Manufacturers of America).

6. See Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study, at 4 (Jan. 2010), available at www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

7. Id. at 8; see also Br. of the United States, available at http://www.justice.gov/atr/cases/f259300/259325.htm, at 4 (relying on FTC Staff Study). Cf. C.Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 Colum. L. Rev. 629, 650 (2009) (estimating the exclusion payments have already cost consumers over $12 billion).

8. Nor, it should be noted, are exclusion payments a patent holder's only means of hedging against this probability. Instead, the probability of invalidation could be reflected in a settlement by means of which the patent holder agrees to some reduction in the unexpired term of the patent.

9. See 148 Cong. Rec. S7566 (July 20, 2002) (remarks of Sen. Hatch); Protecting Consumer Access to Generic Drugs Act of 2007, Hearing No. 110-39 Before H. Comm. on Energy and Commerce, 110th Cong. At 7 (May 2, 2007) (statement of Rep. Waxman).

10. H.R. Rep. No. 98-857(I), at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

11. Br. of the United States, Joblove v. Barr Labs., Inc., S.Ct. No. 06-830, available at http://www.justice.gov/osg/briefs/2006/2pet/6invit/2006-0830.pet.ami.inv.html, at 1 (2007).

12. See Br. of the United States, supra note 5.

13. See Br. of 34 State Attorneys General, available at http://www.prescriptionaccess.org/docs/Cipro_2010_May_AG_Amicus.pdf.

14. See Br. of FTC, available at http://www.ftc.gov/os/2010/05/051202amicuscarpentershealth.pdf.

15. See Br. of AARP & AMA, available at http://www.fdalawblog.net/files/cipro---aarpama.pdf.

16. See generally http://blog.prescriptionaccess.org/?cat=422 (collecting links to amicus briefs in this case).

17. Br. of 86 Law, Economics, Pub. Pol'y, & Bus. Professors, at 6-7, available at http://www.law.stanford.edu/news/details/3793/Profs%20File%20Amici%20Curiae%20Seeking%20En%20Banc%20Rehearing%20of%20Second%20Circuit%20Pharma%20Reverse%20Payment%20Antitrust%20 Decision%20/.