05-2851-cv(L)

05-2852-cv(CON), 05-2863-cv(CON)*

United States Court Of Appeals

FOR THE SECOND CIRCUIT

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, MARIA LOCURTO, PAPER, ALLIED-INDUS, UNITED FOOD AND COMMERCIAL WORKERS UNION-EMPLOYER, LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.

Plaintiffs-Appellants,

SOL LUBIN, ANN STUART, LINDA K. MCINTYRE,

Plaintiffs,

-against-

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF OF AMICUS CURIAE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITION FOR REHEARING IN BANC OF PLAINTIFFS-APPELLANTS SEEKING REVERSAL OF THE PANEL DECISION

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* 05-2863-cv has been transferred to the Federal Circuit Court of Appeals. *See* Order filed 11/7/07

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STATEMENT OF IDENTITY OF AMICUS CURIAE

The American Antitrust Institute ("AAI") is an independent non-profit education, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws.[1] AAI is managed by its Board of Directors with the guidance of an Advisory Board consisting of over 100 prominent antitrust lawyers, law professors, economists and business leaders.[2] AAI, which filed an amicus brief before the Panel, submits that in banc determination should be ordered because the holding in *Tamoxifen*, which is the foundation for *Cipro*, is flawed and seriously threatens competition. If left standing, *Tamoxifen* will allow weak or narrow patents to block generic entry, reduce competition and encourage and permit pharmaceutical patentees to pay generic competitors to keep their cheaper generic drugs off the market.

INTRODUCTION

In *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"), a pharmaceutical patentee paid a generic manufacturer $21 million not

[1] All parties have consented to the filing of this brief. The author of the brief has received no compensation for its preparation and has no financial interest in the outcome of this case. No person other than AAI and its counsel has authored any part of this brief or made a monetary contribution to fund its preparation or submission.

[2] AAI's Board of Directors alone has approved this filing for AAI. The individual views of members of the Advisory Board may differ from AAI's positions.

to challenge the validity of the Tamoxifen patent or enter the market until the patent expired. This reverse payment settlement agreement was entered into after the patent was held invalid at trial. *Id*. at 193-94.

Direct purchasers of the patented drug subsequently sued the patentee and the generic manufacturer alleging that the reverse payment agreement restrained competition in violation of the Sherman Act. The trial court granted the defendant's motion to dismiss. This Court affirmed, holding that the plaintiffs had failed, as a matter of law, to state a claim. Specifically, this Court stated (1) that so long as the patent litigation was not a sham, the patentee was merely "seeking to arrive at a settlement in order to protect *that to which it is presumably entitled*: a lawful monopoly over the manufacture and distribution of the patented product" and (2) that unless the patent was procured by fraud "*there is no injury to the market cognizable under existing antitrust laws as long as competition is restrained only within the scope of the patent*." *Id*. at 208-09, 213 (emphasis added).

Thus, *Tamoxifen* holds that if a patent is neither procured by fraud nor the basis of a bad faith infringement suit, then, as a matter of law, no cognizable injury to competition results when a potential market entrant is paid (1) not to challenge a potentially invalid patent, and (2) not to enter the market. In so holding, this Court acknowledged that reverse payment agreements allow the patentee to continue earning

monopoly profits, which it can then share with the generic manufacturer, and that as a result consumer prices are likely to be higher than if market entry had occurred. *Id*. Nonetheless, this Court believed that reverse payment agreements were beyond the reach of the antitrust laws because the patentee was "presumably entitled" to its "monopoly over . . . the patented product." *Id*. In effect, the Court presumed that the patent was valid and that the resulting monopoly was, therefore, lawful.

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (2d Cir. April 29, 2010), the defendant patentee, Bayer, owned the patent to ciprofloxacin hydrochloride ("Cipro"), one of the most prescribed antibiotics in the world. The generic manufacturer defendant, Barr, was a potential entrant into the Cipro market. In 1991, twelve years before the Cipro patent expired, Barr filed an Abbreviated New Drug Application ("ANDA") and a paragraph IV certification which indicated that it would enter the Cipro market and assert that the Cipro patent was either invalid or not infringed by Barr's generic version. Slip Op. at 3-4. In response, Bayer sued Barr for infringement, as is permitted by 35 U.S.C. § 271(e)(2)(A). Slip Op. 4.

Two weeks before trial, Bayer and Barr agreed to a reverse payment settlement. *Id*. at 6. Bayer – which faced no risk of a money judgment against it – agreed to pay the accused infringer $398 million. In return, Barr promised not to enter the Cipro market until the patent expired and stipulated that the patent was valid. *Id*.

Direct purchasers of Cipro filed an antitrust suit alleging that the reverse payment agreement allocated the Cipro market to Bayer and allowed it to charge anticompetitively high prices. *Id*. at 7. The trial court granted summary judgment for the defendants. It held that whether the reverse payment agreement adversely affected competition was not "the crux of the matter." *Id*. The *only* pertinent question was whether the injury to competition was within the scope of the Cipro patent. *Id*. The trial court reasoned that any other "approach would undermine the presumption of validity of patents in all cases." *Id*.

The Panel affirmed the grant of summary judgment. It stated that the holding in *Tamoxifen* – that reverse payment agreements, as a matter of law, do not violate the antitrust laws – "is dispositive of plaintiffs' claims." *Id*. at 2, 11-12. The Panel also stated, however, that the antitrust implications of *Tamoxifen* are of "exceptional importance" and that there are "compelling reasons" for the full court to revisit that decision. The Panel therefore "invite[d] the plaintiff-appellants to petition for rehearing in banc." *Id*. at 2, 19.

ARGUMENT

Rehearing In Banc Should Be Granted Due to the Exceptional Importance of Attempted Market Entry into Prescription Drug Markets

AAI respectfully submits that *Tamoxifen*'s erroneous view of the legal significance of potential market entry seriously undermines the proper enforcement of

the antitrust laws in prescription drug markets. *Tamoxifen* is based on two interrelated and incorrect propositions. First, *Tamoxifen* confuses the right of a patentee to exclude others from making the patented device with a supposed right to pay potential competitors not to test the validity of the patent. Second, *Tamoxifen* misapprehends the presumption of patent validity. The presumption of validity is a procedural rule that merely determines who has the burden of proof when a patent is challenged. It is not a substantive rule of validity and is not irrebuttable – as *Tamoxifen* appears to hold.

The antitrust laws protect both actual and potential competition. Thus, the Sherman Act prohibits not only agreements that restrain competition, but also those that restrain market entry. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (agreement between competitor and potential entrant that the potential entrant would not attempt to enter the market, held to unlawfully restrain competition); *U.S. v. Topco Associates, Inc.*, 405 U.S. 596 (1972) (agreement between competitors not to attempt entry into each other's market held to be anticompetitive and unlawful).

When a market is dominated by a competitor with a blocking patent, a potential entrant must establish either that its device does not infringe the patent or that the patent is invalid in order to enter the market. The necessity of establishing either proposition is analytically no different than the need for a new entrant to build a plant or procure access to scarce materials. In each case, the new entrant must invest time, effort and capital in the pursuit of a goal that might or might not be achieved. No one

would suggest, however, that an agreement to pay the potential entrant millions of dollars not to build a plant or attempt to enter the market would be lawful. To the contrary, the Supreme Court has repeatedly held that an agreement precluding a potential competitor from entering a competitor's market is "unlawful on its face." *Palmer*, 498 U.S. at 50; *Topco*, 405 U.S. at 608 (agreement precluding potential competitors from entering a co-conspirator's market held *per se* unlawful).[3] As the United States stated to the Panel, the Sherman Act does not permit patent holders "to contract their way out of the statutorily imposed risk that the patent litigation could lead to invalidation of the patent [and therefore entry] while claiming antitrust immunity for that private contract." Slip Op. 16.

Tamoxifen's holding that reverse payment agreements do not injure competition because the patentee is "presumably entitled" to its patent monopoly (466 F.3d 208-09, 213) is also incorrect. The patent law provides no such iron-clad presumption in favor of validity. Indeed, Congress specifically provided for judicial review of patent

[3] *See also* 12 Phillip E. Areeda and Herbert Hovenkamp, *Antitrust Law*, §2030(b) at 213 (2d ed. 2005) ("the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition"); *U.S. v. Microsoft Corp.*, 253 F.3d 34, 78-79 (D.C. Cir. 2001) (rejecting the contention that no injury to competition could be shown unless the new entrant, in fact, would have successfully developed its new product); *Microlux Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680, 685-86 (D. Md. 2000) (agreement preventing plaintiff from obtaining needed materials held to be "obvious[ly]" anticompetitive even though the plaintiff would have needed to overcome numerous obstacles to successfully enter the market).

validity. The presumption of validity is only "a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). It merely assigns burdens to patent litigants and does not "acquire an independent evidentiary role in any [other] proceeding." *In re Berwyn E. Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Indeed, far from providing that drug patents must be presumed valid, the Hatch-Waxman Act explicitly encourages generic manufacturers to challenge those patents and protect the public interest by testing them in Court.[4]

AAI does not here address the question of what substantive rule should be employed to determine whether a reverse payment agreement unreasonably injures competition[5] or whether the plaintiffs have suffered antitrust injury. AAI submits that those questions should be addressed on the merits by the full Court. For current purposes, AAI submits only that the holding in *Tamoxifen* is incorrect and raises questions of exceptional importance to the proper role of market entry, and in

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[4] *See, e.g., Blonder-Tongue Labs, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 344 (1971) (patent law "encourage[s] authoritative testing of patent validity"); *U.S. v. Glaxo Group, Ltd.*, 410 U.S. 52, 58 (1973) ("it is . . . important to the public that competition should not be repressed by worthless patents").

[5] The United States has suggested that reverse payment agreements be deemed presumptively unlawful unless the exclusionary payment does not greatly exceed the cost of the litigation. Slip Op. at 17. The FTC has also proposed that reverse payment agreements be deemed presumptively unlawful. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC, Dec. 8, 2003), *rev'd.* 402 F.3d 1056 (11th Cir. 2005).

particular entry into prescription drug markets, and should be re-examined in banc.

CONCLUSION

Tamoxifen makes at least two mistakes. First, it ascribes too little importance to market entry and therefore holds, as a matter of law, that a competitor may pay a potential entrant not to attempt market entry. Secondly, it ascribes too much importance to the presumption of patent validity. That presumption is not absolute. Numerous patents are found invalid or not infringed. The critical question here is whether a patentee can pay off a would-be market entrant in order to insure that its patent will not be tested and its monopoly remains intact. AAI respectfully submits *Tamoxifen* answers that question incorrectly and should be revisited in banc.

Dated: May 20, 2010

Respectfully submitted,

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PROOF OF SERVICE

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