No. 03-7641

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

IN RE: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, *et al.*,
Plaintiffs-Appellants,

v.

BARR LABS, INC., *et al.*,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK(HON. I. LEO GLASSER, J.)

[PROPOSED] AMICUS BRIEF OF 37 BUSINESS, ECONOMICS AND LAW PROFESSORS IN SUPPORT OF PLAINTIFFS-APPELLANTS' PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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Interest of Amici

Amici are professors of business, economics and law who have written extensively on innovation, intellectual property, competition and antitrust. Amici have no stake in the outcome of this case. (A list of signatories is in Appendix A). Our sole interest in this case is that patent and antitrust law develop in a way that serves the public interest by promoting both innovation and competition. We urge the panel to reconsider its opinion, or alternatively, the Court to grant plaintiffs' request for *en banc* rehearing in this case.[1]

I. The Panel Majority Opinion Is Unprecedented

The panel majority's opinion in this case contains fundamental errors of economic reasoning and would shield many anti-competitive agreements from the reach of antitrust law, causing great harm to competition and to U.S. consumers. According to the panel majority, an agreement between a patent holder and an alleged infringer to settle their patent litigation cannot violate the antitrust laws so long as the patent litigation was not a sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the scope of the patent. Such settlements are considered *per se* legal even if, as here, the patent holder makes a substantial payment to the alleged infringer in exchange for the latter's promise not to sell the patented product independently during the patent's lifetime, and even if the patent in question is "fatally weak." (p. 53). In so holding, the panel

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[1] A co-pending appeal, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), presents similar issues, and it would seem logical to consider the two cases together.

majority has adopted a rule of near per se *legality* for conduct that seems anticompetitive on its face.

The panel's rule is far outside the mainstream of judicial and academic analysis of settlements that involve such payments and promises ("exclusionary settlements"). The Sixth Circuit considers such agreements per se *illegal*, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the Federal Trade Commission considers them presumptively anticompetitive, *see In re Schering Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), while the Eleventh Circuit applies its own test that inquires into the underlying validity of the patent before characterizing the conduct, *see Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). No circuit has applied the panel majority's approach. Similarly, academic commentators are divided. Some, including some of us, have written that settlements involving a large payment from the patent holder to the challenger should be presumptively anti-competitive.[2] Others have argued for applying the rule of reason[3] or for per se illegality.[4] Other courts and

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[2] *See, e.g.,* 1 *Herbert Hovenkamp et al., IP and Antitrust* §7.4e2, at 7-38 to 39 (2005 Supp.); Herbert Hovenkamp et al., "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minn. L. Rev.* 1719 (2003); Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 *Rand J. Econ.* 391 (2003); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in 4 *Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Mark A. Lemley & Carl Shapiro, "Probabilistic Patents," 19 *J. Econ. Perspectives* 75 (2005); Joseph Farrell & Carl Shapiro, "How Strong Are Weak Patents?" Competition Policy Center Working Paper 05-054 (2005), available at http://repositories.cdlib.org/iber/cpc/CPC05-54/.

[3] Daniel A. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 *Fla. L. Rev.* 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, "Are Settlements of Patent Disputes Illegal Per Se?", 47 *Antitrust Bull.* 491, 534-38 (2002).

commentators note that the antitrust analysis is more complex for settlements that generate offsetting benefits to consumers, e.g., those involving negotiated entry dates or patent licenses.[5] But none argue for per se legality. It is ironic that the panel majority—the first court of appeals to apply such a rule—justified its unprecedented decision by saying that "[i]t is too late in the journey for us to alter course." (p. 53). To the contrary, it is the panel majority that sets out on a new and dangerous course.

The authors differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements. In this brief we need not resolve those differences because we all agree that exclusionary settlements can state a claim under the antitrust laws. The panel majority took the unprecedented step of concluding on a motion to dismiss that exclusionary settlements can almost never be illegal. As a result, unless the opinion is reversed case law in this Circuit will never develop to distinguish pro- and anti-competitive settlements.

II. Exclusion Payments Are Generally Anticompetitive

A. The Settling Parties Have an Incentive to Preserve Monopoly Profits in Ways That Harm Consumers and Competition

Fundamental economic arguments tell us that the monopolist and any uniquely strong or early-arriving potential entrant have a strong incentive to enter into an exclusionary settlement. The settlement preserves the monopoly and thus keeps prices and profits high. In the Hatch-Waxman setting, where the first generic to file an

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4 Maureen A. O'Rourke & Joseph F. Brodley, "An Incentives Approach to Patent Settlements," 87 *Minn. L. Rev.* 1767, 1781-82 (2003).

5 *Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11^{th} Cir. 2005) (finding that a cross-license agreement did not violate the antitrust laws); 1 *Hovenkamp et al., supra* note 2, at §7.4e3 (discussing delayed entry settlements).

ANDA is entitled to a period of statutory exclusivity, the patent owner's incentive to settle with that first generic is particularly great.

The fact that the *parties* to the settlement can maximize their profits through an exclusion payment does not mean that such a settlement is in the *public* interest. That extra profit comes from somewhere. In the case of an exclusionary settlement, it comes from the pockets of consumers. Absent the settlement, the patent litigation might reveal that the patent was invalid, leading to more competition and lower prices. With an exclusion payment, the pharmaceutical patentee buys assurance that its patent will not be invalidated—something the patent law alone does not give. It uses some of this extra monopoly profit to pay off the potential competitor. Such a settlement denies consumers the benefits of enhanced competition that would result if the patent were found invalid. This is not a mere short-run consumer benefit from abrogation of a legitimate patent. On the contrary, it is a consumer benefit resulting from the discovery of the truth about the patent's validity, and thus does not threaten the rewards to truly patentable innovations.

Under the panel majority's opinion, the monopolist and potential entrant are permitted to enter into an exclusionary settlement that denies these benefits to consumers *regardless* of the contemporaneous evidence about the likelihood that the patent will be found invalid. In particular, the majority would ignore evidence in the form of a large exclusionary payment from the patent holder to the potential rival, surely an indication that the patent holder considered its patent to be weak. The panel even ignored an initial finding of invalidity in this case. The interests of consumers are given no weight at all in the majority opinion's calculus. Nor is the public interest in testing weak patents given any weight at all.

B. The Panel Majority Wrongly Assumes That Every Patent Holder Has an Absolute Right to a Monopoly

The panel majority acknowledges (p. 44) that "there is something on the face of it that does seem 'suspicious'" about a large reverse payment, but goes on (p. 45) to say: "We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is 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." (p. 45)

Here and at other key points, the majority falls back on the *assumption* that the patent holder, by virtue of the patent grant, has an absolute right to enter into an exclusionary settlement, simply because of the presumption of validity afforded to patents. But that assumption is false. A patent does not confer a certain legal right. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Rather, it reflects an initial judgment by the Patent and Trademark Office that the invention is patentable. That judgment is made after only a cursory scrutiny. When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found invalid.[6] Further, in cases such as this one, the fact that the patent owner must pay the accused infringer a large sum of money to stay out of the market – or even just to delay entry – is strong evidence that the patent owner sees the patent as likely to be held invalid. Where, as here, the case arises on a motion to dismiss, the

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6 John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 29 *Am. Intell. Prop. L. Ass'n. Q.J.* 185 (studying all patent validity litigation over an 8-year period and finding that 46% of all patents litigated to judgment were held invalid).

Court must take as true plaintiffs' allegations that the court of appeals would likely have affirmed the district court's initial finding that the patent was invalid. If the patent can be proven invalid, the settlement can certainly be anticompetitive and thus should be subject to antitrust review.

The panel majority is not merely protecting established rights of patent holders. Rather, by letting patent owners buy immunity from competition even with "fatally weak" patents, the majority is greatly expanding the patent holders' rights, turning a rebuttable (and often-rebutted) presumption into an irrebuttable one. A presumption of validity does not entitle a patentee to evade the test of patent litigation, any more than a criminal defendant's presumption of innocence entitles him to avoid trial. Allowing holders of weak patents thus to boost their profits is a poor way to encourage innovation, because by definition a weak patent often reflects no truly patentable innovation by the patentee.

C. Permitting Exclusion Payments Is Not Necessary To Encourage Settlements in the Public Interest

The panel majority recognizes that its rule shields troubling settlements from the antitrust laws, but concludes that the policy favoring settlement is so strong that it must extend even to "fatally weak" patents, "even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." (p. 50-51)

We strongly disagree with the majority's view that patent settlements must *always* be encouraged. That view confuses a general policy in favor of settlements that are in the public interest with an endorsement of a particular kind of settlement despite evidence of its anticompetitive effects. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. The social benefit of invalidating weak patents is well established in a line of Supreme Court cases. *See, e.g., United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). A successful patent challenge provides valuable benefits to third parties, including anyone who seeks to practice the patented technology and consumers via enhanced competition.[7] The majority's rule would dramatically undermine the important role of patent litigation in protecting the public from undeserved monopolies based on patents that may well prove to be invalid.

Reversing the panel majority's unprecedented and unwise rule of per se legality would by no means subject every patent settlement to an antitrust challenge. As noted above, some (including some of us) have suggested that a large exclusionary payment could be a suitable red flag, providing a limiting principle on such challenges; experience over time might suggest other approaches, but no such evolution can occur in this Circuit if the majority's holding stands. The majority is also wrong to assume that immunizing exclusion payments is necessary to encourage the many settlements that are in the public interest. Both generally and in the pharmaceutical context, patent owners and generics can and do settle patent cases without exclusion payments, by agreeing to let the generic enter in exchange for a license fee, by agreeing to delay entry without a payment, or in other ways. Indeed, the Federal Trade Commission, to

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[7] *See, e.g.,* Joseph Farrell and Robert Merges, "Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help," 19 *Berkeley Tech L.J.* 943 (2004); Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Tech. L.J.* 667 (2004).

which pharmaceutical patent settlements must now be reported, found 14 agreements settling patent litigation during 2003 and 2004, with none involving an exclusion payment. *See* http://www.ftc.gov/opa/2005/01/drugsettlement.htm. The fact that pharmaceutical companies can and do settle litigation without exclusion payments shows that there is no need to allow anticompetitive settlements in order to get the social benefits that most settlements provide.

III. Conclusion

For these reasons, we urge the panel to reverse its opinion, or in the alternative urge the full Court to rehear the case *en banc*.

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Appendix A

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