

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

No. 03-7641

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.)

**BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION
IN SUPPORT OF PLAINTIFFS-APPELLANTS' PETITION
FOR PANEL REHEARING AND REHEARING EN BANC**

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INTEREST OF THE AMICUS CURIAE

The Federal Trade Commission is an independent federal agency, charged with promoting the efficient functioning of the marketplace and protecting consumer interests. 15 U.S.C. §§ 41 *et seq.* It has significant expertise regarding the proper balance between antitrust and intellectual property,¹ and has brought several law enforcement actions targeting the very type of agreement at issue here – *i.e.*, one in which the holder of a challenged drug patent harms competition by unjustifiably paying a would-be generic entrant to stay off the market.² The Commission also has performed a comprehensive empirical study of generic drug entry,³ and, since January 2004, has reviewed all drug patent settlements filed pursuant to specific congressional direction in Pub. L. No. 108-173, 117 Stat. 2066 (2003). In light of the importance

¹ See, e.g., Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (October 2003), available at www.ftc.gov/os/2003/10/innovationrpt.pdf; Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (April 1995), available at www.usdoj.gov/atr/public/guidelines/0558.htm.

² See, e.g., *Schering-Plough Corp.*, FTC Dkt. No. 9297 (Dec. 8, 2003), vacated, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), petition for cert. filed, (U.S. Aug. 29, 2005) (No. 05-273); *Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (April 14, 2003); *Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001). The Commission's petition for *certiorari* in *Schering*, which addresses

of the issues here to its mandated mission, and the risk to consumer welfare, the Commission submits this brief as *amicus curiae* in support of rehearing *en banc*.

ARGUMENT

As plaintiffs-appellants have shown in their petition for rehearing, the panel’s majority opinion conflicts with basic principles of antitrust law in numerous respects, the most egregious example of which is condoning agreements that harm competition and consumers on the ground that they make “economic sense” to the parties who profit from them. Pet. for Rehearing at 13-14; *cf.* Op. 44-47. The Commission will focus, however, on two areas with which it has particular familiarity, and that provide compelling reasons for further review — the panel’s disregard for the policies and incentives of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), and the practical ramifications of the panel’s ruling. A proper analysis of these issues shows that the panel failed to give proper consideration to the Hatch-Waxman Act, and, as a result, adopted a rule that will greatly harm the health and economic well-being of American consumers. This Court should therefore rehear the case *en banc*.

1. The panel majority’s analysis proceeds from the misconceived premise that the general judicial policy favoring the settlement of litigation, Op. 31, commands such force that it precludes condemnation of private agreements even if they ensure “the survival of monopolies created by what would otherwise be fatally weak patents.” Op. 53. The panel cites no authority for this *ipse dixit*, which contravenes

ments, largely prompted by congressional concern over the competitive effects of agreements such as those at issue here, sought in part to stamp out the “abuse of the Hatch-Waxman law” resulting from “pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market.” S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).⁵

The panel majority noted that Hatch-Waxman altered the litigants’ bargaining positions, but the panel drew entirely the wrong lesson from Congress’s modification of the respective rights of patentees and challengers in the pharmaceutical context – characterizing it as an “unintended consequence.” Op. 40. In fact, as evident from its 2003 amendments, Congress made those alterations for the very purpose of facilitating successful patent challenges and permitting the early entry of generics. Thus, viewed in their proper statutory context, exclusionary or “reverse” payments cannot be summarily excused as “a natural by-product of the Hatch-Waxman process,” *id.*, when they may be more of an artifice to subvert its intended policies.

In the face of Congress’s efforts to create incentives for patent challenges that result in early generic entry, the panel has adopted a rule that will have precisely the

⁵ Among the corrective measures enacted to address such abuses, the amendments require brand drug companies and generic applicants who enter into patent litigation settlements to file those settlement agreements with the Commission and the Department of Justice for antitrust review. Pub. L. No. 108-173, § 1112. If such an agreement is found to violate the antitrust laws, the generic party forfeits any 180-day marketing exclusivity period it may have. 21 U.S.C. § 355(j)(5)(D)(i)(V).

Indeed, a troubling trend by branded companies towards employing just such a strategy is increasingly evident.⁸ Under the panel ruling, pharmaceutical companies are now free to pursue this anticompetitive ploy without fear of antitrust liability.

3. Once the legal and regulatory ramifications of the panel ruling are properly understood, the economic effects are staggering. Consumers and health plans spend over a hundred billion dollars per year on prescription drugs.⁹ Facilitated by the Hatch-Waxman incentive structure, numerous generics have successfully challenged listed patents, including those of a number of “blockbuster” drugs with annual sales in the billions.¹⁰ Moreover, of the twenty top-selling prescription drugs in the United States today, eleven, with annual sales of nearly \$25 billion, currently are the subject

⁸ See, e.g., *Teva Pharms. USA, Inc. v. FDA*, 2005 WL 2692489 (D.D.C. Oct. 21, 2005); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp.2d 187 (S.D.N.Y. 2005); *Glaxo Group Ltd. v. Dr. Reddy’s Labs., Ltd.*, 325 F. Supp.2d 502 (D.N.J. 2004); *Mutual Pharm. Co., Inc. v. Pfizer Inc.*, 307 F. Supp.2d 88 (D.D.C. 2004).

⁹ In 2002 alone, for example, Americans spent over \$160 billion for prescription drugs. The Henry J. Kaiser Family Foundation, *Prescription Drug Trends*, at 1 (Oct. 2004). See also Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures, 2003*, at 1 (January 11, 2005) (prescription drug spending rose 14.9 percent in 2002 and 10.7 percent in 2003).

¹⁰ The FTC examined all patent litigations initiated between 1992 and 2000 between branded drug manufacturers and generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products. *Generic Drug Study*, *supra* note 3, at 19-20. Generic competition to Prozac, Zantac, Taxol, and Plantinol alone is estimated to have saved consumers more than \$9 billion. See *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (April 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Association), at 12.

of

CERTIFICATE OF SERVICE

I, Imad Abyad, certify that on this 30th day of November, 2005, I caused a copy of the foregoing brief of *amicus curiae* Federal Trade Commission to be served by first-class mail, postage prepaid, and electronically, on each of the following counsel:

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