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

WILLIAM BLUMENTHAL
General Counsel
JOHN D. GRAUBERT
Principal Deputy General Counsel
JOHN F. DALY
Deputy General Counsel for Litigation
IMAD D. ABYAD
Attorney
FEDERAL TRADE COMMISSION
600 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20580
(202) 326-2375

SUSAN A. CREIGHTON
Director
BRADLEY S. ALBERT
ELIZABETH R. HILDER
MICHAEL B. KADES
Attorneys
BUREAU OF COMPETITION

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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

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[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 the merits of the issues presented at greater length, is available at www.ftc.gov/os/2005/08/050829scheringploughpet.pdf.

[3] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

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

basic principles of antitrust law.[4] The panel's policy-based analysis is especially misguided in the Hatch-Waxman context, however, because Congress – while preserving legitimate patent rights – has specifically sought to *encourage* litigation challenging weak patent claims, in order to facilitate entry of generic drugs into the market.

Hatch-Waxman encourages patent challenges by providing the first generic applicant making a "Paragraph IV certification" – which challenges the validity or infringement of the brand-drug patent – with 180 days of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). No such economic incentive is provided for generic filings that do not challenge the brand-drug patent. Congress likewise created an incentive for the patent holder to commence the patent suit promptly. The patent holder receives an automatic 30-month stay against generic entry if, but *only* if, it sues for infringement within 45 days. 21 U.S.C. § 355(j)(5)(B)(iii). Otherwise, the FDA may approve the generic application as soon as the regulatory conditions are fulfilled. *Id.*

Congress reinforced its statutory policy to encourage litigation challenges to pharmaceutical patents through amendments to Hatch-Waxman enacted as part of the 2003 Medicare amendments. *See* 117 Stat. 2066, 2448-2464 (2003). Those amend-

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[4] The Supreme Court has long admonished that a patent owner "cannot extend his statutory grant by contract or agreement," *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942); *see United States v. Line Material Co.*, 333 U.S. 287, 308 (1948), and has applied this principle to the settlement of patent litigation, *see United States v. Singer Mfg. Co.*, 374 U.S. 174, 197-200 (1963) (White, J., concurring).

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

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[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).

opposite effect. By giving branded and generic rivals *carte blanche* to avoid competition and share the resulting profits, even where the patent claims are "fatally weak," Op. 53, successful drug patent challenges will be significantly reduced, if not eliminated.[6] In so doing, the panel gave insufficient weight to Congress's policy choices, as reflected in Hatch-Waxman, and substituted instead its own preferences and judgments about the appropriate patent policy in the pharmaceutical industry.[7]

2. The panel majority acknowledges this "troubling dynamic," Op. 50, but attempts to dismiss the practical ramifications of its ruling by assuming that branded drug sellers will be unable to buy off *all* challengers. Op. 51-52. But that assumption

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[6] The generic's anticipated profits are almost always well under those of the branded rival from the same volume of sales. Thus, absent antitrust constraints, it will almost always "make obvious economic sense," Op. 46, for the latter to buy off generics by paying them as much or (as alleged here) more than they would make by entering. Moreover, as the majority conceded, exclusion payments are most likely to be used to protect the weakest patents. Op. 50 ("The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent").

[7] The majority implies that it was somehow constrained to rule as it did because the alternative to allowing reverse-payment settlements is "to outlaw all, or nearly all, settlements of Hatch-Waxman infringement actions." Op. 52. Such dire warnings are unwarranted, however; legitimate drug patent settlements using means other than exclusionary payments continue to occur without hindrance. *See* FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (Jan. 2005), *available at* www.ftc.gov/os/2005/01/050107medicareactrpt.pdf (of the 14 settlements filed in FY 2004, resolving patent litigation between brand- and generic drug makers, *none* included an exclusionary payment from the brand to the generic).

is both economically and legally baseless. Even apart from regulatory constraints, the economics of generic drug entry dictate that settlements imposing great harm on competition and consumers will frequently be possible. Paying off the first generic company ready to enter will often delay entry for years, during which time the branded company will profit handsomely, at the expense of consumers. If, on the other hand, multiple generics are ready to enter, the prospective profits of each will be substantially lower, and each will find it advantageous to agree not to enter, even for a modest payment. In either event, the panel's ruling would allow the branded company to forestall competition even if its patent claims are weak.

More important, the impact of the panel's ruling will be magnified by the effect of Hatch-Waxman's 180-day exclusivity provision. As amended by Congress in 2003, the limited circumstances under which the exclusivity period may be forfeited depend upon resolution of an infringement or declaratory judgment suit. 21 U.S.C. § 355(j)(5)(D). A recent ruling of the Federal Circuit, moreover, makes clear that declaratory judgment is unavailable if the branded company does not threaten to sue. *See Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 473 (Oct. 11, 2005). Thus, having settled with the first challenger, a branded company can preempt all subsequent generic challenges simply by declining to sue or threaten suit against them. With declaratory judgment unavailable following *Teva*, future generic applicants will be unable to enter and compete.

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

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[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 litigation by generic firms seeking entry under Hatch-Waxman.[11] The prospect of consumer benefits from such challenges is enormous, but such benefits will be lost if branded companies are free to buy off generic challengers, regardless of the weakness of the patent or the terms of the deal, as the panel's opinion permits.

CONCLUSION

The Court should grant rehearing, to correct the panel's dangerous error.

Respectfully submitted,

WILLIAM BLUMENTHAL
General Counsel
JOHN D. GRAUBERT
Principal Deputy General Counsel

SUSAN A. CREIGHTON
Director
BRADLEY S. ALBERT
ELIZABETH R. HILDER
MICHAEL B. KADES
Attorneys
BUREAU OF COMPETITION

JOHN F. DALY
Deputy General Counsel for Litigation
IMAD D. ABYAD
Attorney
FEDERAL TRADE COMMISSION
600 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20580
(202) 326-2375

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[11] *See* Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005), *available at* www.drugtopics.com/drugtopics/data/articlestandard/drugtopics/112005/150644/article.pdf. SEC filings and public statements by their makers disclose patent challenges for the following 11 drugs: Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax, and Risperdal. *See, e.g.*, Pfizer Inc., *Form 10-Q* (Aug. 8, 2005); Wyeth, *Form 10-Q* (Aug. 5, 2005); Purdue Pharma, L.P., *Press Release* (June 8, 2005).

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:

J. Douglas Richards, Esq.
MILBERG WEISS BERSHAD & SCHULMAN
One Pennsylvania Plaza
New York, NY 10119-0165
DRichards@milbergweiss.com

Patrick E. Cafferty
MILLER FAUCHER & CAFFERTY
101 N. Main St., Suite 450
Ann Arbor, MI 48104
pcafferty@millerfaucher.com

Barbara J. Hart, Esq.
LABATON SUCHAROW & RUDOFF
100 Park Avenue, 12th Flr.
New York, NY 10017
bhart@labaton.com

Robert S. Schachter, Esq.
ZWERLING, SCHACHTER & ZWERLING
41 Madison Avenue, 32nd Flr.
New York, NY 10017
rschachter@zsz.com

Robert G. Eisler, Esq.
LIEFF CABRASER HEIMANN & BERNSTEIN
780 Third Avenue, 48th Flr.
New York, NY 10017
reisler@lchb.com

Co-Lead Counsel for Plaintiffs-Appellants

Joel Cohen
DAVIS, POLK & WARDELL
450 Lexington Avenue
New York, NY 10017
joel.cohen@dpw.com
Counsel for Defendants-Appellees Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC

George Lombardi
WINSTON & STRAWN
35 West Wacker Drive
Chicago, IL 60601
jlombardi@winston.com
Counsel for Defendant-Appellee Barr Laboratories, Inc.

IMAD D. ABYAD
Attorney
FEDERAL TRADE COMMISSION