IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., et al., *Plaintiffs,* v. WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., *Defendants.*	**Civil Action No. 12-3824** **CONSOLIDATED**

MEMORANDUM IN SUPPORT OF THE FEDERAL TRADE COMMISSION'S MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

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The Federal Trade Commission respectfully moves for leave to file an *amicus curiae* brief in the above-captioned matter in connection with defendants' pending motions to dismiss.[1]

The complaints in this case allege that defendants introduced reformulations of their branded Doryx product that offered little or no apparent medical benefit to consumers and constitute an exclusionary tactic known as "product switching." According to plaintiffs, each reformulation prevented meaningful generic competition and preserved defendants' monopoly profits not on the merits of the reformulations, but by manipulating the pharmaceutical regulatory system. A central issue in this case is whether the alleged product switching violates Section 2 of the Sherman Act for unlawful monopolization. The plausibility of plaintiffs' monopolization claims must be considered in light of the economic and regulatory context of the pharmaceutical marketplace, an industry in which the FTC has substantial expertise.

The FTC seeks leave to submit a brief as *amicus curiae* to assist the Court in its analysis of plaintiffs' monopolization claims. The FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws.[2] It exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry and has substantial experience concerning the balance between antitrust and intellectual property laws[3] and the impact of the Hatch-Waxman Act on competition in the

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[1] Def. Warner Chilcott's Mot. to Dismiss Mylan's Complaint and the Direct Purchasers' Consol. Am. Class Action Compl., No. 12-3824, Doc. No. 83 (filed Oct. 1, 2012); Def. Mayne's Mot. to Dismiss Mylan's Complaint and the Direct Purchasers' Consol. Am. Class Action Compl., No. 12-3824, Doc. No. 82 (filed Oct. 1, 2012).

[2] 15 U.S.C. §§ 41–58.

[3] *See, e.g.*, Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011), available at http://www.ftc.gov/os/2011/03/110307patentreport.pdf; U.S. Department of Justice & Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* (2007), available at http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf; Federal Trade Commission, *To Promote Innovation: The Proper*

pharmaceutical industry.[4] In addition to its role as a law enforcement agency, the FTC has a congressionally-mandated role to conduct studies of industry-wide competition issues. The FTC has conducted numerous studies covering the pharmaceutical industry, including reports on drug product selection and generic substitution, which are particularly relevant to the issues before this Court.

Plaintiff Mylan consents to the FTC's filing of an *amicus* brief. Defendants Warner Chilcott and Mayne do not consent.

I. District Courts Have Broad Discretion to Appoint an *Amicus Curiae*

"District courts have broad discretion to appoint amicus curiae." *Sciotto v. Marple Newtown Sch. Dist.*, 70 F. Supp. 2d 553, 555 (E.D. Pa. 1999) (quoting *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993)); *see also Avellino v. Herron*, 991 F. Supp. 730, 732 (E.D. Pa. 1998). "Although there is no rule governing the appearance of an *amicus curiae* in the United States District Courts," *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002), some district courts in the Third Circuit have looked to the Federal Rules of Appellate Procedure for guidance in exercising their broad discretion. *See, e.g.*, *id*. (citation omitted). Rule 29 distinguishes between *amicus* briefs filed by federal government agencies and those filed by private parties. *Amicus* briefs from federal agencies are accepted by Courts of Appeals as a matter of right, *see* FED. R. APP. P. 29(a), and have been accepted by some district courts solely on this basis. *See, e.g.*, *Clark v. Actavis Group HF*, 567 F. Supp. 2d 711, 718 n.11

Balance of Competition and Patent Law and Policy (2003); available at www.ftc.gov/os/2003/10/innovationrpt.pdf; U.S. Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) www.usdoj.gov/atr/public/guidelines/0558.htm.

[4] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified at various sections of Titles 15, 21, and 35 of the U.S. Code).

(D.N.J. 2008) (*amicus* brief filed by U.S. Department of Justice). *Amici* from federal agencies offer a distinctive perspective because "governmental bodies, acting as amicus curiae, possess unparalleled institutional expertise and constitute a valuable means of determining how the court's decision may affect the world outside its chambers."[5] In contrast, for private *amici*, Rule 29 requires that, unless all parties consent to its filing, the *amicus curiae* obtain leave of the court after showing that its brief is timely and expresses an interest relevant to the disposition of the case. FED. R. APP. P. 29(a), (b), (e)*; see also Neonatology Assocs., P.A. v. Comm'r of Internal Revenue*, 293 F.3d 128, 130–31 (3d Cir. 2002).

District courts in this Circuit have also applied a four-part standard that incorporates principles similar to Rule 29 as well as other factors, including one considering the "partiality" of the would-be *amicus*. *See, e.g.*, *Liberty Res., Inc. v. Phila. Hous. Auth.*, 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005) (citing *Sciotto*, 70 F. Supp. 2d at 555); *Prof. Drug. Co. Inc. v. Wyeth Inc.* (*In re Effexor XR Antitrust Litig.*), No. 11-5479, Doc. No. 187 (D.N.J. filed Oct. 3, 2012). These courts grant leave to participate as *amicus curiae* when: "(1) the petitioner has a 'special interest' in the particular case; (2) the petitioner's interest is not represented competently or at all in the case; (3) the proffered information is timely and useful; and (4) the petitioner is not partial to a particular outcome in the case." *See, e.g.*, *Liberty Res.*, 395 F. Supp. 2d at 209.

II. This Court Should Exercise Its Discretion to Accept the FTC's *Amicus* Brief

This Court should exercise its discretion to accept the FTC's *amicus* brief because (1) the brief expresses both public and governmental interests of a federal agency charged with protecting consumers from unfair competition; (2) these interests are not currently represented

[5] Michael K. Lowman, *The Litigating Amicus Curiae: When Does the Party Begin After the Friends Leave?*, 41 AM. U. L. REV. 1243, 1261–62 (1992).

before the Court; (3) the information proffered is useful and timely; and (4) the FTC is not partial to any specific outcome in the case.

First, the FTC is a federal agency representing the public interest with the goal of preserving competition and protecting consumers from violations of the antitrust laws. As outlined in the FTC's *amicus* brief, the issue of whether a brand firm's drug product reformulation is an exclusionary tactic designed to impede generic entry has serious long-term implications for *all* consumers, not just the private parties in this matter. Moreover, as an agency charged by Congress with enforcing competition laws, and as the primary antitrust enforcer in the pharmaceutical industry, the FTC has a special interest in the interpretation of laws impacting generic drug competition. District courts consider these interests when granting motions for leave to federal agencies to participate as *amicus curiae*. *See, e.g.*, *Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 37 (M.D. Pa. 1995) (stating as a basis for accepting an *amicus* brief that "the EPA has a special interest in this litigation as it is the primary body responsible for administering and enforcing" the relevant law).

Second, the FTC's interest, and the corresponding interest of consumers in general cannot be adequately represented by the private parties to this litigation because each of the parties is charged with representing its own interests. The FTC's unique perspective as a government agency will aid the court in its analysis of the issues in this case. *See, e.g., Avellino*, 991 F. Supp. at 732 (granting leave for motion to file *amicus* brief because it "will aid the Court in its understanding of the issues before it").[6]

[6] In two recent cases involving a different subject matter, district courts in the Third Circuit have reached divergent conclusions regarding whether to allow the FTC to file an *amicus* brief. *Compare In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-CV-00995, Doc. No. 100 (D.N.J. Nov. 7, 2012) (Walls, J.) (granting the FTC's motion for leave to file an *amicus* brief) *with Prof. Drug Co., Inc. v. Wyeth Inc. (In re Effexor XR Antitrust Litig.)*, No. 11-5479, Doc. No.

Third, the brief provides useful information based on the FTC's extensive empirical studies of generic drug competition in a manner that is timely and allows defendants sufficient opportunity to respond. As described in the *amicus* brief, the FTC has a unique institutional perspective—based on years of study and empirical analysis of pharmaceutical markets—to offer the Court in its analysis of the competitive implications of product reformulations. The *amicus* brief presents data from comprehensive studies conducted by the FTC on the federal and state regulation of prescription drugs and the effects of generic substitution on prescription drug prices. The *amicus* brief explains and applies the FTC's conclusions to the issues raised by this case in a manner that is both easier to understand and more accessible to the Court than merely reading the reports, and can aid the Court in understanding the effects of its decision on consumer welfare. Additionally, the FTC's brief is timely because it is filed within seven days of plaintiffs' filing on November 15, 2012, and provides ample time for defendants to respond. *See generally* FED. R. APP. P. 29(e).

Fourth, while the FTC is interested in the development of the law concerning drug product reformulations, it takes no position on the ultimate outcome in this case. Indeed, a finding that plaintiffs' antitrust claims withstand defendants' motions to dismiss is not determinative of the ultimate outcome of this case. Such a holding would merely give all parties the opportunity to support their claims and defenses with evidence. Thus, while the FTC is partial in the sense of its clearly expressed interest in protecting consumers, it is not partial in the sense of expressing a view on which party should ultimately prevail in the litigation. As Justice Alito observed when he sat on the Third Circuit, "it is not easy to envisage an amicus who is

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187 (D.N.J. Oct. 3, 2012) (Pisano, J.) (denying the FTC's motion for leave to file an *amicus* brief).

'disinterested' but still has an 'interest' in the case." *Neonatology Assocs.*, 293 F.3d at 131 (citing Rule 29's requirement that an amicus must state its interest in the case). Then-Judge Alito concluded that requiring an *amicus* to be fully impartial "became outdated long ago." *Id.*

III. Conclusion

For the foregoing reasons, the Commission respectfully requests that the Court grant leave to file an *amicus curiae* brief.

Dated: November 21, 2012

Respectfully submitted,

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