IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re: EFFEXOR XR ANTITRUST LITIGATION **This Document Relates To:** **All Actions**	**Lead case no.: 3:11-cv-05479**

PLEASE TAKE NOTICE that the Federal Trade Commission will move before the Honorable Peter G. Sheridan, U.S.D.J., on September 16, 2013, for an Order granting leave to file a brief as *amicus curiae.*

PLEASE TAKE FURTHER NOTICE that in support of the motion, the Federal Trade Commission will rely on the attached memorandum of law. A proposed Order has also been submitted with this motion.

Dated: August 14, 2013

Respectfully submitted,

/s/ Kara L. Monahan

MARKUS H. MEIER
JAMIE R. TOWEY
KARA L. MONAHAN
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Telephone: (202) 326-2018
Facsimile: (202) 326-3384
kmonahan@ftc.gov

DEBORAH L. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

JONATHAN E. NUECHTERLEIN
General Counsel
Federal Trade Commission

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re: EFFEXOR XR ANTITRUST LITIGATION **This Document Relates To:** **All Actions**	**Lead case no.: 3:11-cv-05479**

FEDERAL TRADE COMMISSION'S MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

DEBORAH L. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

JONATHAN E. NUECHTERLEIN
General Counsel
Federal Trade Commission

MARKUS H. MEIER
JAMIE R. TOWEY
KARA L. MONAHAN
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Telephone: (202) 326-2018
Facsimile: (202) 326-3384
kmonahan@ftc.gov

Table of Contents

I. District Courts Have Broad Discretion to Appoint *Amicus Curiae* 2

II. This Court Should Exercise Its Discretion to Accept the FTC's *Amicus* Brief 4

Conclusion 8

Table of Authorities

Cases

Clark v. Actavis Group HF, 567 F. Supp. 2d 711 (D.N.J. 2008) 2

FTC v. Actavis, 133 S. Ct. 2223 (2013).....1

FTC v. Indiana Federation of Dentists, 476 U.S. 447 (1986).....1

Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp., 149 F.R.D. 65 (D.N.J. 1993).....2

Liberty Res., Inc. v. Phila. Hous. Auth., 395 F. Supp. 2d 206 (E.D. Pa. 2005).....3, 4

Neonatology Assocs., P.A. v. Comm'r, 293 F.3d 128 (3d. Cir. 2002).....3, 7

Order, *Prof'l. Drug. Co. Inc. v. Wyeth Inc.* (*In re Effexor XR Antitrust Litig.*), No. 11-5479, Doc. No. 187 (D.N.J. Oct. 3, 2012)..... 3, 6, 7

Sciotto v. Marple Newtown Sch. Dist., 70 F. Supp. 2d 553 (E.D. Pa. 1999).....3

United States v. Alkaabi, 223 F. Supp. 2d 583 (D.N.J. 2002) 2

Waste Mgmt. of Pa., Inc. v. City of York, 162 F.R.D. 34 (M.D. Pa. 1995) 5

Statutes

15 U.S.C. §§ 41–58.....1

Court Documents

First Amended Complaint, *FTC v. Cephalon, Inc.*, No. 08-2141, Doc. No. 40 (E.D. Pa. Aug. 12, 2009).....1

Reply Memorandum in Support of Teva Defendants' Motion to Dismiss All Direct Purchaser Complaints, No. 11-05479, Doc. No. 166 (Aug. 3, 2012).....6

Supplemental Memorandum in Further Support of Wyeth Defendants' Motions to Dismiss All Complaints, No. 11-05479, Doc. No. 231 (Aug. 7, 2013).....5

Teva Defendants' Motion to Dismiss All Direct Purchaser Complaints, No. 11-5479, Doc. No. 136 (Apr. 6, 2012).....1

Wyeth Defendants' Motion to Dismiss All Direct Purchaser Complaints, No. 11-5479, Doc. No. 138 (Apr. 6, 2012).....1

Rules

FED. R. APP. P. 29..... 2, 3, 8

Other Authorities

FTC BUREAU OF COMPETITION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012 (2013) 4

Michael K. Lowman, Comment, *The Litigating Amicus Curiae: When Does the Party Begin After the Friends Leave?*, 41 AM. U. L. REV. 1243 (1992) 3

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

The parties' filings raise issues regarding whether a branded company's commitment not to launch an authorized generic in competition with the first generic applicant (a "no-authorized-generic" commitment) can have "the 'potential for genuine adverse effects on competition'" and can be a "reverse payment" in a patent settlement agreement. *FTC v. Actavis*, 133 S. Ct. 2223, 2234 (2013) (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460 (1986)).

The FTC seeks leave to submit a brief as *amicus curiae* to assist the Court in its analysis of the antitrust implications of no-authorized-generic commitments, such as the one at issue in this case. 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, including antitrust challenges to Hatch-Waxman settlements.[3] In addition to its role as a law enforcement agency,

---

[1] *Teva Defendants' Motion to Dismiss All Direct Purchaser Complaints*, No. 11-5479, Doc. No. 136 (Apr. 6, 2012)*; Wyeth Defendants' Motion to Dismiss All Direct Purchaser Complaints*, No. 11-5479, Doc. No. 138 (Apr. 6, 2012).

[2] 15 U.S.C. §§ 41–58.

[3] *See, e.g.*, First Amended Complaint, *FTC v. Cephalon, Inc.*, No. 08-2141, Doc. No. 40 (E.D. Pa. Aug. 12, 2009).

the FTC has a congressionally-mandated role to conduct studies of industry-wide competition issues. The FTC has conducted numerous studies relating to pharmaceutical patent settlements, including one resulting in a detailed 270-page report on authorized generics.

The plaintiffs have consented to the FTC's filing of an *amicus* brief. The defendants do not consent.

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

"District courts have broad discretion to appoint amicus curiae." *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993) (citations omitted). "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 (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."[4] 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) and (e)*; see also Neonatology Assocs., P.A. v. Comm'r*, 293 F.3d 128, 130–31 (3d. Cir. 2002).

Some district courts in this Circuit have 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 v. Marple Newtown Sch. Dist.*, 70 F. Supp. 2d 553, 555 (E.D. Pa. 1999)); Order at 3, *Prof'l. Drug. Co. Inc. v. Wyeth Inc.* (*In re Effexor XR Antitrust Litig.*), No. 11-5479, Doc. No. 187 (D.N.J. 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

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

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 the brief (1) expresses both public and governmental interests not currently represented before the Court, (2) is not partial to any specific outcome in the case, and (3) proffers useful information in a timely manner.

First, the FTC is a federal agency representing public interests not currently before this Court. As outlined in the FTC's *amicus* brief, the antitrust treatment of no-authorized-generic commitments has serious long-term implications for *all* consumers, not just the private parties in this matter. Settling parties are using no-authorized-generic commitments with increasing frequency. In the FTC's most recent annual summary of brand-generic settlement agreements, no-authorized-generic commitments were included in almost half (19 out of 40) of the settlements with payment to the generic drug company and restrictions on generic entry.[5] The treatment of no-authorized-generic commitments therefore has important public policy implications.

[5] *See* FTC BUREAU OF COMPETITION, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012 at 1 (2013), *available at* http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

Moreover, as an agency charged by Congress with enforcing competition laws, and as the primary federal enforcer responsible for antitrust challenges to Hatch-Waxman patent settlements, the FTC has a special interest in the interpretation of these laws. 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). The Court's ruling and its interpretation of *Actavis* could affect potential FTC enforcement actions.

The FTC also has an interest in this case in which defendants make arguments based on misrepresentations of FTC statements and positions to support their arguments. For example, Wyeth relies on mischaracterizations of the FTC's arguments before the Supreme Court in *Actavis* to support its contentions about the meaning of "reverse payments."[6] Further, Teva dedicated an entire page of one of its briefs on an erroneous claim that "the [FTC] determined that the exclusive generic licensing of a single manufacturer did not constitute a 'payment' to the

[6] *See Supplemental Memorandum in Further Support of Wyeth Defendants' Motions to Dismiss All Complaints* at 1-2, No. 11-05479, Doc. No. 231 (Aug. 7, 2013).

generic challenger for the purpose of delaying entry."[7] The plaintiffs in this case were not involved in the FTC's decision-making in either of these instances, and they cannot competently represent what the FTC decided.

Second, while the FTC has an interest in the development of the law concerning no-authorized-generic commitments, it takes no position with regard to the ultimate outcome in this case. Concluding at this stage that the no-authorized-generic commitment may have created cognizable antitrust harm is not determinative of the outcome of this—or any—case. As the Supreme Court observed in *Actavis*, the plaintiffs still must prove their case under the rule of reason.

The FTC previously sought leave to submit an *amicus* brief in this matter, but Judge Pisano denied the motion, ruling in part that "the extent to which the FTC is partial to a particular outcome weighs against granting the agency's motion."[8] In so ruling, however, the judge failed to distinguish between two entirely different meanings of the term partial: partial in the sense of the FTC's clearly expressed interest in protecting consumers, versus partial in the sense of

---

[7] *Reply Memorandum in Support of Teva Defendants' Motion to Dismiss All Direct Purchaser Complaints* at 11, No. 11-05479, Doc. No. 166 (Aug. 3, 2012). This conclusion represents a clear mischaracterization of the FTC's analysis and errors about the underlying factual situation—the relevant agreement did not involve an exclusive license.

[8] *See* Order at 3, *Prof'l. Drug. Co. Inc. v. Wyeth Inc.* (*In re Effexor XR Antitrust Litig.*), No. 11-5479, Doc. No. 187 (D.N.J. Oct. 3, 2012).

preferring that one side ultimately prevails in the litigation. Moreover, as now-Justice Alito observed when he sat on the Third Circuit, "it is not easy to envisage an amicus who is 'disinterested' but still has an 'interest' in the case." *Neonatology Assocs.*, 293 F.3d at 131 (Alito, J.) (citing Rule 29's requirement that an *amicus* must state its interest in the case). This led then-Judge Alito to conclude that requiring an *amicus* to be impartial "became outdated long ago." *Id*.[9]

Third, the brief provides useful information based on the FTC's extensive empirical studies of pharmaceutical patent settlements—particularly those involving no-authorized-generic commitments—in a timely manner. As described in the *amicus* brief, the FTC has a unique institutional perspective—based on years of study and empirical analysis—to offer the Court in its analysis of the competitive implications of no-authorized-generic commitments. Unlike the plaintiffs, the FTC has reviewed hundreds of patent settlement agreements, most of which are non-public, and is in a singular position to discuss the potential antitrust concerns of such settlements and their possible implications for consumers. The *amicus* brief explains the FTC's findings relevant to the issues raised by this case in a manner that is more accessible to the Court than merely reading the reports.

[9] Indeed, in labeling the FTC as partial, the order denying the FTC leave to file an *amicus* brief quoted the exact language that then-Judge Alito explained was "outdated" in 2002. *Compare Neonatology Assocs.*, 293 F.3d at 131 *with* Order at 3, *Prof'l. Drug. Co. v. Wyeth Inc.* (*In re Effexor XR Antitrust Litig.*), No. 11-5479, Doc. No. 187 (D.N.J. Oct. 3, 2012).

Finally, the FTC's brief is timely because it is filed within seven days of the plaintiffs' filing on August 7, 2013. *See generally* FED. R. APP. P. 29(e).

Conclusion

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

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re: EFFEXOR XR ANTITRUST LITIGATION **This Document Relates To:** **All Actions**	**Lead case no.: 3:11-cv-05479**

FEDERAL TRADE COMMISSION BRIEF AS *AMICUS CURIAE*

DEBORAH L. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

JONATHAN E. NUECHTERLEIN
General Counsel
Federal Trade Commission

MARKUS H. MEIER
JAMIE R. TOWEY
KARA L. MONAHAN
Attorneys for Amicus Curiae
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Telephone: (202) 326-2018
Facsimile: (202) 326-3384
mmeier@ftc.gov

Table of Contents

Interest of the Federal Trade Commission.....3

I. *FTC v. Actavis* Reaffirms Application of Traditional Antitrust Principles to Agreements Between a Patentee and Its Potential Competitor.....4

A. The key defining characteristic of a reverse payment under *Actavis* is that it enables parties to share monopoly profits preserved by avoiding competition.....5

B. *Actavis* rejects the proposition that pharmaceutical patent settlements are generally immune from antitrust scrutiny.....8

II. There Is Substantial Evidence on the Economic Effects of a No-Authorized-Generic Commitment to the First Generic Applicant.....10

A. Regulatory context for authorized generics.....10

B. Typically, the brand's authorized generic competes with the first filer for generic sales during the 180-day exclusivity, resulting in lower generic drug prices.....11

C. With a no-authorized-generic commitment, the brand company forgoes revenues, the generic company gets 100 percent of generic sales, and consumers pay higher prices.....13

III. The Plaintiffs Have Alleged a Restraint With the Potential for Genuine Adverse Effects on Competition.....15

A. The no-authorized-generic commitment presents the same antitrust concern as the reverse payments the Supreme Court considered in *Actavis*.....15

B. Exclusive patent licenses are not immune from antitrust scrutiny.....17

Conclusion.....18

Table of Authorities

Cases

Benger Labs. Ltd. v. R. K. Laros Co., 209 F. Supp. 639 (E.D. Pa. 1962) 17

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670 (2012) 4

FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013)..... passim

FTC v. Watson Pharms. Inc., 677 F.3d 1298 (11th Cir. 2012) 5

Granholm v. Heald, 544 U.S. 460 (2005).....4

Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358 (3d. Cir. 1996).....17

Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).....3

Teva Pharm. Indus. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005).....11

United States v. New Wrinkle, Inc., 342 U.S. 371 (1952) 9

Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976).....4

Statutes

15 U.S.C. § 46(b) 3

15 U.S.C. §§ 41–58.....3

21 U.S.C. § 355(j)(5)(B)(iv) 11

Court Documents

First Amended Complaint, *FTC v. Cephalon, Inc.*, No. 08-2141, Doc. No. 40 (E.D. Pa. filed Aug. 12, 2009).....3

Reply Brief for the Petitioner, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416).....8

Reply Memorandum in Support of Teva Defendants' Motion to Dismiss All Direct Purchaser Complaints, No. 11-05479, Doc. No. 166 (filed Aug. 3, 2012) 17

Supplemental Memorandum of Law in Support of Pfizer's Motion To Dismiss All Complaints, *In re Lipitor Antitrust Litig.*, No. 12-2389 (D.N.J.), Doc. No. 425 (July 12, 2013) 6

Other Authorities

12 P. AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶ 2046 (3d ed. 2012) 17

Comment of Apotex Corp. in Supp. of Citizen Pet. of Mylan Pharms., Inc., No. 2004P-0075/CP1 (F.D.A. Mar. 24, 2004) 12

Drug Topics, *2009 Top 200 Branded Drugs by Retail Dollars* (June 17, 2010) 14

Drug Topics, *Top 200 Brand Drugs by Retail Dollars in 2002* (Apr. 7, 2003) 14

FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (2011) ..... passim

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2010* (2011).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2011* (2011).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012* (2013).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004* (2005).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005* (2006).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006* (2007).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007* (2008).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2008* (2009).....16

FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2009* (2010).....16

Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83 (2009).....18

Report of the American Bar Association Section of Antitrust Law, Special Committee to Study the Role of the Federal Trade Commission, 58 ANTITRUST L.J. 43 (1989).....4

TEVA PHARM. INDUS. LTD., ANNUAL REPORT (Form 20-F) (Feb. 15, 2011).....13

U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (Apr. 6, 1995).....9, 17

In *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), the Supreme Court held that antitrust concerns may arise when, in exchange for the settlement of patent litigation, a brand-name drug manufacturer pays a generic drug manufacturer to defer generic competition. The Court rejected a legal rule that conferred "near-automatic antitrust immunity" on patent settlements when the alleged anticompetitive restraints do not extend beyond the patent's expiration date. *Id.* at 2237. Instead, the Court reaffirmed that the legality of an agreement not to compete between a patent holder and a would-be rival is to be assessed using "traditional antitrust factors." *Id.* at 2231.

The pending motions to dismiss in this case present an issue with significant implications for American consumers: whether pharmaceutical patent settlements are nonetheless immune from antitrust scrutiny so long as the brand manufacturer pays for delayed entry with something other than cash. The plaintiffs allege that, in lieu of cash, Wyeth used a promise not to compete with an "authorized generic" version of the drug Effexor XR (the "no-authorized-generic commitment") to induce Teva to abandon its patent challenge and refrain from selling its generic version of Effexor XR for two years. Such deals can be a win-win for both firms: First, they can enable the brand-name drug manufacturer to forestall the date of generic entry and thus extend its enjoyment of monopoly profits; and then they can benefit the generic challenger by eliminating the only competition for sales of its

generic drug product for a significant period of time—thus creating the prospect of hundreds of millions of dollars in extra revenue for the generic company, in part from its ability to charge supracompetitive prices for its product.

Despite their settlement agreement's potential for substantial harm to consumers, both before and after generic entry, the defendants contend that *Actavis* renders the agreement immune from antitrust challenge because Wyeth allegedly paid Teva through a non-compete agreement instead of with cash. According to the defendants, this Court must dismiss this antitrust challenge without considering whether such a no-authorized-generic commitment could have functioned like the cash payments at issue in *Actavis*. They also assert that their agreement is lawful because it took the form of an exclusive license.

The defendants' arguments make neither economic nor legal sense. The allegations here raise the same type of antitrust concern that the Supreme Court identified in *Actavis*. Indeed, accepting the defendants' claim of immunity whenever patentees use vehicles other than cash to share the profits from an agreement to avoid competition elevates form over substance, and it would allow drug companies to easily circumvent the ruling in *Actavis*, at great cost to consumers.

As the federal agency with primary responsibility for protecting consumers though antitrust enforcement in the pharmaceutical industry, as well as expertise

on the economic effects of competition by authorized generics, the FTC requests leave to file this *amicus* brief to address how the antitrust concerns the Supreme Court identified in *Actavis* regarding reverse payments can be raised by the type of no-authorized-generic commitment alleged in this case.[1]

Interest of the Federal Trade Commission

The Federal Trade Commission is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws. 15 U.S.C. §§ 41–58. It exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry. The Commission has used its law enforcement authority to challenge Hatch-Waxman patent settlements involving payments to delay entry by a lower-priced generic drug ("reverse-payment" or "pay-for-delay" agreements).[2]

In addition, the FTC has a congressionally-mandated role to conduct studies of industry-wide competition issues. The agency's broad authority to compel the production of data and information, 15 U.S.C. § 46(b), gives it a unique capacity to conduct "systematic, institutional study of real-world industries and activities" that

[1] The FTC expresses no views on the ultimate disposition of this litigation.

[2] *See, e.g.*, *FTC v. Actavis*, 133 S. Ct. 2223 (2013); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); First Amended Complaint, *FTC v. Cephalon, Inc.*, No. 08-2141, Doc. No. 40 (E.D. Pa. filed Aug. 12, 2009).

"modern academic research in industrial organization rarely undertakes."[3] Courts, including the Supreme Court, have relied on FTC studies when resolving legal and policy issues.[4] The Commission has conducted a variety of empirical studies of the pharmaceutical industry, including a comprehensive empirical study of the competitive effects of authorized generics.[5] The 2011 Authorized Generic Report is based on an analysis of business documents from more than one hundred brand and generic pharmaceutical companies.

Argument

I. *FTC v. Actavis* Reaffirms Application of Traditional Antitrust Principles to Agreements Between a Patentee and Its Potential Competitor

In *Actavis*, the Supreme Court held that "reverse-payment" patent settlements—agreements in which a brand-name drug manufacturer pays a would-be competitor to abandon its patent challenge and agree not to sell its generic drug product for a number of years—are not immune from antitrust scrutiny and are to

[3] *Report of the American Bar Association Section of Antitrust Law, Special Committee to Study the Role of the Federal Trade Commission*, 58 ANTITRUST L.J. 43, 103 (1989).

[4] *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012) (FTC study on generic pharmaceuticals); *Granholm v. Heald*, 544 U.S. 460, 466–68, 490–92 (2005) (FTC study of Internet wine sales); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 754 n.11, 765 n.20 (1976) (FTC study concerning drug price advertising restrictions).

[5] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf [hereinafter Authorized Generic Report].

be evaluated under the traditional antitrust "rule of reason." The Eleventh Circuit had affirmed dismissal of an FTC complaint alleging that the manufacturer of the testosterone replacement drug AndroGel had entered two such agreements. The Eleventh Circuit did so on the ground that an agreement is "'immune from antitrust attack'" if its anticompetitive effects are all within "'the scope of the exclusionary potential of the patent.'" *Actavis*, 133 S. Ct. at 2227 (quoting *FTC v. Watson Pharms. Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012). The Supreme Court reversed, rejecting this so-called "scope-of-the-patent" approach. *Id*. at 2230 ("we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack."). The Court explained that its longstanding approach to assessing agreements between a patentee and potential competitors considers "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Id*. at 2231.

A. The key defining characteristic of a reverse payment under *Actavis* is that it enables parties to share monopoly profits preserved by avoiding competition

In *Actavis*, the Supreme Court described the nature of the antitrust concern that reverse payment settlements present. "Payment in return for staying out of the market" the Court explained, "simply keeps prices at patentee-set levels . . . while dividing that [monopoly] return between the challenged patentee and the patent

challenger." 133 U.S. at 2234-35. "[T]he payment's objective is to maintain supracompetitive prices to be shared among the patentee and the patent challenger rather than face what might have been a competitive market." *Id*. at 2235.[6]

The defendants suggest that this antitrust concern can arise only if parties use a monetary payment to share the supracompetitive returns preserved by their agreement to avoid competition. To be sure, the Supreme Court's opinion speaks in terms of "payments" and "money," as those were the allegations in *Actavis*. But nothing in the opinion suggests that the Court meant to limit its ruling to payments in cash, nor would such an artificial limitation make economic sense. Such a rule would allow settling parties to evade an antitrust challenge to a reverse payment settlement simply by transferring other valuable assets, such as gold bullion, stocks, or real estate.[7]

It is also incorrect to suggest that the only alternative to equating "payment" with cash is to treat all types of consideration to the alleged infringer as a payment. In *Actavis*, the Supreme Court distinguished among types of consideration. It

---

[6] *See also id*. at 2235 (payment may show "that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market"); *id*. at 2236 (noting "concern that the patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement").

[7] In another case, Wyeth conceded that a reverse payment can be something other than just a cash transfer to the generic company. *See* Supplemental Memorandum of Law in Support of Pfizer's Motion To Dismiss All Complaints, *In re Lipitor Antitrust Litig.*, No. 12-2389 (D.N.J.), Doc. No. 425 (July 12, 2013).

contrasted the core competitive concern of settlements that share monopoly profits with settlements in which the opposing parties merely agree to compromise on matters at stake in the litigation (such as a party accepting less than the full amount of its damage claim). *Id*. at 2233. Such a compromise of claims, the Court noted, has not been thought to raise antitrust concerns. For example, when the parties in Hatch-Waxman patent litigation settle with an agreement that merely sets a date for the generic patent challenger's market entry before patent expiration, without more, there is nothing to suggest that this familiar settlement form reflects anything other than arms-length bargaining between adverse parties based on expectations regarding the likely outcome of the litigation.

But when the inducement to settle and defer market entry includes something that the alleged infringer could not get even if it prevailed in the patent litigation, "that . . . is something quite different" and may raise antitrust concerns. *Id.* Under those circumstances, it is necessary to ask whether the inducement may be a vehicle for sharing monopoly profits. *Actavis* thus reflects a two-part framework to assess whether a settlement agreement contains a reverse payment: (1) Is the alleged payment something that a generic challenger could have obtained

had it won the litigation? and (2) Are the parties sharing monopoly profits preserved by avoiding competition?[8]

B. *Actavis* rejects the proposition that pharmaceutical patent settlements are generally immune from antitrust scrutiny

The Supreme Court's rejection of an antitrust immunity premised on the "scope-of-the-patent" approach was unequivocal. A court cannot "answer the antitrust question" merely by looking at "what the holder of a valid patent could do." *Id*. at 2230-31. The Court reviewed its precedents and explained that in none of these cases—which addressed a wide variety of restraints arising in patent-related settlement agreements and patent licenses—did it simply "measure the length or amount of restriction solely against the length of the patent's term or its earning potential." *Id*. at 2231. Instead, those prior decisions "seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition." *Id.* at 2233. It is therefore incorrect to suggest, as defendants do, that

[8] Defendants' claim that the FTC urged the Supreme Court to define "payment" as any valuable consideration is false. Indeed, the Court relied on the same principles the FTC proposed. *See* Reply Brief for the Petitioner at 9-10, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416) (stating that "the defining characteristics of a reverse payment are that it (1) is consideration from the patentee that the accused infringer could not obtain by prevailing in the litigation and (2) allows the patentee to co-opt its rival by sharing monopoly profits" and that a reverse payment includes "non-cash consideration if—but only if—these characteristics are present.").

Actavis merely created a narrow exception to an otherwise blanket antitrust immunity for patent settlements that permit entry before patent expiration.

The Supreme Court's rejection of the scope-of-the-patent test and its directive to consider traditional antitrust factors is not a special rule limited to "reverse payment" cases. As the Court emphasized, it is the approach that applies generally to antitrust cases challenging "patent-related settlement agreements" and "overly restrictive patent licensing agreements."[9] *Id*. at 2231-34. Indeed, the *Actavis* decision discusses prior cases in which agreements that provided for entry before patent expiration and involved no cash payment to the allegedly infringing licensee were found to violate the Sherman Act. *Id.* at 2232-33. That is because there was some other aspect of the agreement that raised antitrust concerns.[10] The *Actavis* decision could therefore be relevant to this Court's consideration of the pending motions to dismiss regardless of whether Wyeth's agreement not to compete through an authorized generic is labeled a "reverse payment."

---

[9] The federal enforcement agencies' 1995 *Antitrust Guidelines for the Licensing of Intellectual Property* reflect this approach. *See* U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property at 7-8 (Apr. 6, 1995).They discuss how antitrust analysis applies to a wide variety of restraints that may appear in patent license agreements, explaining that traditional antitrust principles take into account the distinctive characteristics of intellectual property.

[10] *See, e.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952) (finding that patent licenses granted under a settlement agreement could violate the antitrust laws if they are the means by which patent holders jointly regulate distribution and control prices).

II. There Is Substantial Evidence on the Economic Effects of a No-Authorized-Generic Commitment to the First Generic Applicant

An authorized generic is chemically identical to the brand-name drug, but sold by the brand company or its representative as a generic product under the same FDA approval as the brand-name drug. As discussed in detail below, the FTC's Authorized Generic Report found that: (1) introducing an authorized generic allows the brand company to offset some of the brand-name drug sales lost when generic entry occurs; (2) competition from an authorized generic during the first 180 days of generic sales substantially affects the first generic entrant's revenues and results in significantly lower prices for consumers; and (3) a brand's commitment not to launch an authorized generic will substantially increase the first generic's revenues, and also will result in higher prices for the generic product.

A. Regulatory context for authorized generics

Through enactment of the Hatch-Waxman Act, Congress established the regulatory framework under which a generic drug manufacturer may obtain approval of its product from the Food and Drug Administration. To encourage generic entry as soon as warranted, the Act establishes certain rights and procedures that apply when a company seeks FDA approval to market a generic product before expiration of the patent(s) covering the counterpart brand-name drug. In such cases, the generic applicant must certify that the patent in question is invalid or not infringed by the generic product, known as a "Paragraph IV"

certification. The Hatch-Waxman Act awards the first generic company to file an application with a Paragraph IV certification (the "first filer") 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's generic drug application. 21 U.S.C. § 355(j)(5)(B)(iv). Significantly, however, the 180-day marketing exclusivity does not preclude the brand company from marketing an authorized generic. *See Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005).

B. Typically, the brand's authorized generic competes with the first filer for generic sales during the 180-day exclusivity, resulting in lower generic drug prices

Brand companies frequently introduce authorized generics to stem the large losses that result from the rapid shift from sales of brand-name drugs to cheaper generic products. *See* Authorized Generic Report, *supra* note 5, at 12-14, 26-27. Empirical evidence from the FTC's Authorized Generic Report shows that having to compete against an authorized generic during the 180-day exclusivity period has two primary financial effects on the first-filer generic company. First, the authorized generic takes a significant share of generic sales away from the first filer. *Id*. at 57-59. Second, and most importantly for consumers, competition between generic companies drives down retail and wholesale generic drug prices. *Id*. at 41-48. The FTC's Authorized Generic Report found that average wholesale prices are 70 percent of the pre-entry brand-name drug price when the first filer

faces an authorized generic compared to 80 percent of the brand price when it does not. *Id*. at iii. Because of these two effects, "the presence of authorized generic competition reduces the first-filer generic's revenues [during the 180-day exclusivity period] by 40 to 52 percent, on average." *Id.*; *see also id.* at 33.[11]

The financial impacts of an authorized generic on the first-filer generic are well known in the pharmaceutical industry. As one generic drug company put it: "[d]ue to market share and pricing erosion at the hands of the authorized player, we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *Id*. at 81. Another generic company, Apotex, estimated that competition from an authorized generic version of the antidepressant Paxil reduced its revenues by approximately $400 million.[12] These examples demonstrate the significant financial effects that a brand company's sale of an authorized generic can have on the first-filer generic.

[11] The report notes that the effects of an authorized generic continue well after first-filer exclusivity expires, as "[r]evenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53 percent and 62 percent lower when facing an AG." *Id.* at iii.

[12] Comment of Apotex Corp. in Supp. of Citizen Pet. of Mylan Pharms., Inc., at 4, No. 2004P-0075/CP1 (F.D.A. Mar. 24, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf ("There can be no doubt that the [brand company's] authorized generic crippled Apotex' 180-day exclusivity—it reduced Apotex' entitlement by two-thirds—to the tune of approximately $400 million.").

C. With a no-authorized-generic commitment, the brand company forgoes revenues, the generic company gets 100 percent of generic sales, and consumers pay higher prices

When the brand company cedes all generic sales to the first filer by agreeing not to introduce an authorized generic, the generic drug company enjoys significantly greater sales and at higher prices. The FTC's study found that, with a no-authorized-generic commitment, on average, "the first-filer's revenue will approximately double" during the 180-day exclusivity period, compared to what the first filer would make if it faced authorized generic competition. Authorized Generic Report, *supra* note 5, at vi.

Teva has acknowledged that generic drug products such as generic Effexor XR generate "substantially increased" revenues when they do not face generic competition during the first-filer exclusivity period. As Teva explained:

> To the extent that we succeed in being the first to market a generic version of a significant product, and *particularly if we are the only company authorized to sell during the 180-day period of exclusivity* in the U.S. market provided under the Hatch-Waxman Act, our sales, profits and profitability can be *substantially increased . . . prior to a competitor's introduction of an equivalent product*.[13]

[13] *See* TEVA PHARM. INDUS. LTD., ANNUAL REPORT (Form 20-F), at 7 (Feb. 15, 2011) (emphasis added).

For a blockbuster drug like Effexor XR, the benefit from a no-authorized-generic commitment could be hundreds of millions of dollars during the exclusivity period.[14]

The brand-name drug company, as noted, forgoes the revenues it could otherwise make by selling an authorized generic. In the case of a drug like Effexor XR, these forgone revenues can also amount to hundreds of millions of dollars.[15] Consumers, meanwhile, are forced to pay supracompetitive prices for the first filer's generic product. *See* Authorized Generic Report, *supra* note 5, at 41-48.

[14] As noted above, Apotex, which faced an authorized generic version of Paxil, an antidepressant with U.S. sales roughly equal to those of Effexor XR in the year before generic entry ($2.31 billion for Paxil versus $2.39 billion for Effexor XR), reportedly lost an estimated $400 million due to competition from an authorized generic. *See* Drug Topics, *Top 200 Brand Drugs by Retail Dollars in 2002* (Apr. 7, 2003), http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=115428; Drug Topics, *2009 Top 200 Branded Drugs by Retail Dollars* (June 17, 2010), http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard/drugtopics/252010/674961/article.pdf.

[15] The payment of a royalty from the generic to the patentee may affect the amount that generic ultimately obtains and the brand ultimately loses from the no-authorization-generic commitment. The extent of the gains and losses from the no-authorized-generic commitment is a factual issue and cannot be resolved on a motion to dismiss.

III. The Plaintiffs Have Alleged a Restraint With the Potential for Genuine Adverse Effects on Competition

A. The no-authorized-generic commitment presents the same antitrust concern as the reverse payments the Supreme Court considered in *Actavis*

Applying the two-part framework for reverse payments reflected in *Actavis* to the allegations here is straightforward. First, Teva got something it could not have gotten by prevailing in the patent litigation. Even if Teva had prevailed, Wyeth would still have had the right to compete through an authorized generic during Teva's 180-day exclusivity period. A finding of patent invalidity or noninfringement would not limit Wyeth's right to market its FDA-approved product as a generic. Thus, Wyeth's commitment not to sell an authorized generic cannot be characterized as merely a compromise of claims raised in the litigation, which the Supreme Court indicated is unlikely to raise antitrust concerns.

Second, assuming the facts alleged by the plaintiffs are true, Wyeth and Teva secured monopoly profits before and after generic entry and shared those profits. Rather than a cash payment, the parties used reciprocal agreements not to compete to share monopoly returns. Wyeth obtained its share of monopoly profits during the period Teva agreed to delay its entry. Teva obtained its share during the period Wyeth agreed not to launch an authorized generic, which allowed Teva to maintain supracompetitive prices. *Cf.* Actavis, 133 S. Ct. at 2236 ("anticompetitive consequence" was "maintain[ing] supracompetitive prices to be shared among the

patentee and the challenger"). As explained above, an agreement not to launch an authorized generic could be worth hundreds of millions of dollars in additional revenues to a company in Teva's situation, including revenues resulting from the higher prices that the first filer could charge in the absence of an authorized generic.[16] In these circumstances, eliminating the threat of competition from an authorized generic can serve as the vehicle through which the patentee shares monopoly profits guaranteed by the generic drug company's agreement to abandon its patent challenge. Consequently, the no-authorized-generic commitment in the parties' agreement could serve precisely the same function as the cash payments that were before the Court in *Actavis*. A challenge to the agreement therefore states a valid antitrust claim.[17]

[16] Economic theory predicts—and empirical evidence discussed in the Authorized Generic Report confirms—that eliminating competition from the only potential competitor during the exclusivity period will increase the prices consumers pay for the generic product after generic entry occurs. *See* Authorized Generic Report, *supra* note 5, at iii.

[17] The FTC has consistently categorized such commitments as payments that can induce the generic company to end its patent challenge and stay out of the market. *See* Authorized Generic Report, *supra* note 5, at 140-142; *see also* the FTC's Bureau of Competition's annual reports summarizing filings made under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (codified at 21 U.S.C. § 355), *available at* http://www.ftc.gov/bc/healthcare/drug/index.htm.

B. Exclusive patent licenses are not immune from antitrust scrutiny

The defendants incorrectly assert that their agreement is *per se* lawful because it took the form of an exclusive patent license. As the leading antitrust treatise, which the Supreme Court cited several times in *Actavis*, has observed: "Assuming the patent is valid, the Patent Act expressly permits exclusive licenses, but this fact alone does not render them immune from antitrust scrutiny."[18] Most exclusive licenses do not raise antitrust concerns because they promote competition, such as by combining complementary assets. But as one of the cases the defendants have relied on expressly states: "Though the grant of an exclusive license is not per se a violation of the antitrust laws, it may be an instrument by which an unlawful restraint of trade or a monopoly is created."[19] The defendants provide no legal basis for this Court to hold the challenged agreement immune from antitrust scrutiny merely because the alleged restraint took the form of an exclusive license.

---

[18] 12 P. AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶ 2046 at 330 (3d ed. 2012) (footnotes omitted).

[19] *See Benger Labs. Ltd. v. R. K. Laros Co.*, 209 F. Supp. 639, 648 (E.D. Pa. 1962) cited at Reply Memorandum in Support of Teva Defendants' Motion to Dismiss All Direct Purchaser Complaints at 9, No. 11-05479, Doc. No. 166 (filed Aug. 3, 2012); *see also Antitrust Guidelines for the Licensing of Intellectual Property*, *supra* note 9, Section 3.1 ("While intellectual property licensing arrangements are typically welfare-enhancing and procompetitive, antitrust concerns may nonetheless arise."); *see generally Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1372 (3d. Cir. 1996) (subjecting exclusive licenses to rule of reason analysis).

Conclusion

Allowing pharmaceutical companies to sidestep antitrust review by using non-cash payments to purchase delayed generic entry would significantly undermine the holding in *Actavis*. Indeed, after the FTC began challenging cash-only reverse-payment agreements, pharmaceutical companies turned to other payment arrangements, in what one pharmaceutical industry observer described as a "sophisticated version of three-drug monte" designed to evade antitrust scrutiny.[20] Because this Court's ruling may have implications for potential FTC enforcement proceedings and the Commission's views may be relevant to the Court's disposition of the motions to dismiss, the FTC respectfully requests to be heard as *amicus*. In addition, the FTC would be pleased to address any questions the court may have, including by participation at the hearing when the Court considers the motion, should the Court deem it useful.

[20] Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 98 (2009) ("[B]rand firms no longer are making simple payments to generics to stay off the market. Such settlements, which appear quaint in contrast to today's sophisticated version of three-drug monte, are no longer observed in today's marketplace. Instead, a brand's promise not to introduce an authorized generic, accompanied by an ANDA generic's agreement to delay entering the market, could allow the brand to reap millions of dollars in additional profits while also benefitting the ANDA generic. At the same time, such a payment is more difficult to quantify and appears less suspicious to an antitrust court that is trained to look for monetary payments.").

Dated: August 14, 2013

Respectfully submitted,

/s/ Kara L. Monahan

DEBORAH L. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

JONATHAN E. NUECHTERLEIN
General Counsel
Federal Trade Commission

MARKUS H. MEIER
JAMIE R. TOWEY
KARA L. MONAHAN
Attorneys for Amicus Curiae
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Telephone: (202) 326-2018
Facsimile: (202) 326-3384
kmonahan@ftc.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re: EFFEXOR XR ANTITRUST LITIGATION **This Document Relates To:** **All Actions**	**Lead case no.: 3:11-cv-05479**

[PROPOSED] ORDER

Upon consideration of the Federal Trade Commission's Motion for Leave to File Brief as *Amicus Curiae*, any opposition thereto, and the applicable law, it is this _____ day of August 2013,

ORDERED, that the Federal Trade Commission's Motion for Leave to File Brief as *Amicus Curiae* is **GRANTED;** and, it is further

ORDERED, that the Clerk of the Court accept for filing within _____ days of the date of this Order the Federal Trade Commission Brief as *Amicus Curiae*; and, it is further

ORDERED, that the Clerk of the Court distribute a copy of this Order to all counsel of record.

Date: August ____, 2013

_____
The Honorable Peter G. Sheridan
United States District Court Judge

CERTIFICATE OF SERVICE

I certify that on August 14, 2013, I electronically filed the Federal Trade Commission's Motion for Leave to File Brief as *Amicus Curiae* with the Clerk of the Court using the ECF system, which sent notification to all counsel of record registered with the Court.

Dated: August 14, 2013

/s/ Kara L. Monahan

Kara L. Monahan
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, DC 20580
Tel: (202) 326-2018
Fax: (202) 326-3384
kmonahan@ftc.gov
Counsel for Amicus Curiae
Federal Trade Commission