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

In re: WELLBUTRIN XL ANTITRUST LITIGATION **This Document Relates To:** **All Actions**	**Case no.: 2:08-cv-2431** **Case no.: 2:08-cv-2433** **NOTICE OF MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE***

PLEASE TAKE NOTICE that the Federal Trade Commission will move before the Honorable Mary A. McLaughlin, U.S.D.J., on September 26, 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: September 26, 2013

Respectfully submitted,

/s/ Markus H. Meier

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

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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 the Court's request for "briefing on the question of whether *Actavis* applies to the patent settlement agreements at issue in this litigation."[1] In addition, the Commission proposes to address the Court's earlier request for information with respect to the process for government review of pharmaceutical patent settlement agreements.[2]

Defendant's brief raises the issue 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, Inc.*, 133 S. Ct. 2223, 2234 (2013) (quoting *FTC v. Ind. Fed'n 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, and to clarify the Commission's role in the review of pharmaceutical patent settlements. The FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws.[3] It exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry, including antitrust challenges to Hatch-Waxman settlements.[4] In addition to its role as a law enforcement agency, the FTC has a congressionally mandated role to conduct studies of industry-wide

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[1] Order, *In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-2431 (E.D. Pa. July 11, 2013).

[2] Order, *In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-2431 (E.D. Pa. July 17, 2012).

[3] 15 U.S.C. §§ 41-58.

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

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." *Sciotto v. Marple Newtown Sch. Dist.*, 70 F. Supp. 2d 553, 554 (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 Appeal 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."[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

[5] 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).

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)). 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.*, 394 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 before the Court, (2) is not partial to any specific outcome in the case, and (3) proffers useful information in a timely manner. Another court in this Circuit recently approved the FTC's participation as *amicus curiae* in a similar case. *See* Order, *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479 (D.N.J. Sept. 12, 2013) (granting FTC's motion for leave to file *amicus* brief and finding that the FTC "possesses institutional expertise which may prove useful to the Court's deliberations").

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 of the settlements (19 of 40) with payment to the generic drug company and restrictions on generic entry.[6] The treatment of no-authorized-generic commitments therefore has important public policy implications.

Moreover, as an agency charged by Congress with enforcing competition laws, and 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.

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 *Actavis* applies to a case such as this one, involving a no-authorized-generic commitment, 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.

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), and experience reviewing pharmaceutical settlements filed under the Medicare

[6] *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 1 (2013), *available at* http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), 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 and the functioning of the review process for pharmaceutical patent settlements. Unlike the plaintiffs, the FTC has reviewed hundreds of patent settlement agreements, most of which are non-public, and is in the singular position to discuss the review process, the potential antitrust concerns of those settlements, and the possible implications for consumers. The *amicus* brief presents the FTC's findings and experience relevant to the questions posed by the Court in a manner that is more accessible than merely reading a collection of reports. Finally, the FTC's brief is timely because it is filed on the same day that briefs are due from the plaintiffs in this case. *See* Order, *In re Wellbutrin XL Antitrust Litigation*, No. 08-cv-2431 (E.D. Pa. Aug. 28, 2013).

Conclusion

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

Dated: September 26, 2013

Respectfully submitted,

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FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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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.

In this case the plaintiffs contend that, in lieu of cash, the patentee used a promise not to compete with an "authorized generic" version of the patented drug (the "no-authorized-generic commitment") to induce the first generic applicant to settle an infringement suit and delay selling a generic alternative. 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; second, 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 many millions of dollars in extra revenue for the generic company, in part from its ability to charge supracompetitive prices for its product.

Despite the potential for this type of settlement to cause substantial harm to consumers, both before and after generic entry, GlaxoSmithKline (GSK) contends that *Actavis* renders such an arrangement immune from antitrust challenge because the patentee paid the generic through a non-compete agreement instead of with cash. According to GSK, 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*. GSK also asserts that the challenged agreement is lawful because it took the form of an exclusive license.

GSK's arguments make neither economic nor legal sense. The type of no-authorized-generic commitment at issue here raises the same type of antitrust concern that the Supreme Court identified in *Actavis*. Indeed, accepting GSK's claim of antitrust 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 through antitrust enforcement in the pharmaceutical industry, as well as with 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] In addition, in light of this Court's previous request that the parties provide additional information about the procedures applicable to government review of patent settlement agreements between brand-name and generic drug companies, this brief also explains that process.

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

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

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 "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 FTC's 2011 Authorized Generic Report is based on an analysis of business documents from more than one hundred brand and generic pharmaceutical companies.

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[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-cv-2141 (E.D. Pa. Aug. 12, 2009).

[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].

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 period of time—are not immune from antitrust scrutiny and are to 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 into 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 ("[W]e 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 can present. "[P]ayment 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 challenger rather than face what might have been a competitive market." *Id*. at 2236.[6]

GSK contends 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, and the only two courts to have addressed the issue rejected arguments that Actavis applies only to monetary payments.[7] Such an artificial limitation would make no economic sense. The rule GSK proposes would allow settling parties to sidestep an antitrust challenge to a reverse-payment settlement simply by transferring other valuable assets, such as gold bullion, stocks, or real estate.[8]

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[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 a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement").

[7] *In re Nexium (Esomeprazole) Antitrust Litig.*, 2013 WL 4832176, at *15 (D. Mass. Sept. 11, 2013) ("This Court does not see fit to read into the [*Actavis*] opinion a strict limitation of its principles to monetary-based arrangements alone."); *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *26 (D.N.J. Sept. 5, 2013) ("[N]othing in *Actavis* strictly requires that the payment be in the form of money"). A pre-*Actavis* ruling in *In re Lamictal Antitrust Litig.*, 2012 WL 6725580 (D.N.J. Dec. 6, 2012), interpreted the Third Circuit's rule on reverse payments as limited to cash payments, but the Third Circuit decision upon which it was based has since been vacated in light of *Actavis*. *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), *vacated by* 133 S. Ct. 2849 (2013).

[8] Indeed, commentators have noted that after the FTC began challenging cash-only reverse-payment agreements, pharmaceutical companies then turned to other payment arrangements. *See, e.g.*, 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

It is also incorrect to suggest, as GSK does, that the only alternative to equating "payment" with cash is to treat all types of consideration to the alleged infringer as a payment.[9] In *Actavis*, the Supreme Court distinguished among types of consideration. It 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 not have obtained had it won the litigation? and (2) Are the parties sharing monopoly profits preserved by avoiding competition?[10]

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difficult to quantify and appears less suspicious to an antitrust court that is trained to look for monetary payments.").

[9] *See* GSK's Memorandum of Law Regarding the Applicability of *FTC v. Actavis* (filed Aug. 5, 2013) (GSK Mem.), at 14.

[10] The Supreme Court's analysis reflects the principles the FTC's brief articulated. *See* Reply Brief for the Petitioner at 9-10, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416), *available at* http://www.ftc.gov/os/caselist/0710060/130318actavisreplybrief.pdf ("[T]he defining

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 a 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 GSK does, that *Actavis* merely created a narrow exception to an otherwise blanket antitrust immunity for drug patent settlements that permit entry before patent expiration.[11]

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

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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. . . . [A reverse payment includes] non-cash consideration if—but only if—these characteristics are present.").

[11] GSK argues that the Supreme Court foreclosed any antitrust scrutiny of settlements not involving cash payments when it observed that drug companies "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." GSK Mem. at 8, 11 (quoting *Actavis*, 133 S. Ct at 2237). But this sentence does not show that "payment" can only mean cash. The Supreme Court did not purport to be conferring immunity on settlements using non-cash forms of payment. In fact, the quoted language merely reflects that entry-date-only settlements do not ordinarily raise antitrust concerns. As noted above, without more, there is nothing to suggest that this familiar settlement form reflects anything other than arms-length bargaining between adverse parties based on their expectations about the likely outcome of the litigation.

emphasized, it is the approach that applies generally to antitrust cases challenging "patent-related settlement agreements" and "overly restrictive patent licensing agreements."[12] *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.[13] The *Actavis* decision thus reaffirms the need to focus on economic substance rather than formalistic distinctions when assessing antitrust challenges to patent settlements.[14]

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

An authorized generic is a prescription drug that has been approved by the FDA as a brand-name drug but is marketed by the brand company or its representative as a generic drug product. 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

[12] The federal enforcement agencies' 1995 *Antitrust Guidelines for the Licensing of Intellectual Property* reflect this approach. *See* U.S. Dep't of Justice and Fed. Trade Comm'n, 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.

[13] *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).

[14] The Supreme Court has repeatedly emphasized that antitrust analysis turns on economic substance, not form. *See, e.g., American Needle, Inc. v. National Football League*, 130 S.Ct. 2201, 2211 (2010) ("[S]ubstance, not form, should determine should determine whether a[n] . . . entity is capable of conspiring"), quoting *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 773 n.51 (1984); *Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451, 466-67 (1992) (in assessing market power, "this Court has examined closely the economic reality of the market at issue," rather than resting on "formalistic distinctions").

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) claimed to cover 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 the first-filer generic and the authorized generic 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.[15]

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.[16] These examples demonstrate the significant financial effects that a brand company's sale of an authorized generic can have on the first-filer generic.

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[15] 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 [authorized generic]." *Id.* at iii.

[16] 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/apr04/040104/04p-0075-c00001-vol1.pdf ("There can be no doubt that the [brand company's] authorized generic crippled Apotex' 180-day

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. For a blockbuster drug like Wellbutrin XL, the benefit to the first-filer of a no-authorized-generic commitment could be substantial, potentially reach exceeding one hundred million dollars during the exclusivity period alone.[17]

The brand-name drug company, as noted, forgoes the revenues it could otherwise make by selling an authorized generic. 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.

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exclusivity—it reduced Apotex' entitlement by two-thirds—to the tune of approximately $400 million.").

[17] The FTC lacks data needed to calculate the benefit from the no-authorized-generic commitment at issue here, but the experience of Apotex, which faced an authorized generic version of the anti-depressant Paxil, may shed some light. Paxil had U.S. sales of $2.31 billion in the year before generic entry and, as noted above, Apotex reportedly lost an estimated $400 million due to competition from the authorized generic. *See* Drug Topics, *Top 200 Brand Drugs by Retail Dollars in 2002* (Apr. 7, 2003), http://drugtopics.modernmedicine.com/drug-topics/news/top-200-brand-and-generic-drugs-retail-dollars-2002. Sales of 150mg Wellbutrin XL were approximately $930 million in the year prior to generic entry, or roughly 40 percent of branded Paxil sales. Press Release, Teva Pharm. Indus. Ltd., Teva Announces Launch of Generic Wellbutrin XL Tablets, 150mg (May 30, 2008), *available at* http://www.reuters.com/article/2008/05/30/idUS158417+30-May-2008+BW20080530. Thus, the estimated loss of $400 million on Paxil could indicate that a no-authorized-generic commitment on Wellbutrin XL 150mg would be worth roughly $160 million (40 percent of $400 million).

III. 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 a no-authorized-generic commitment with the first filer generic is straightforward. First, with such a commitment the generic challenger gets something it could not get by prevailing in the patent litigation. Even if the generic prevails, the brand-name drug manufacturer still has the right to compete through an authorized generic during the first filer's 180-day exclusivity period. A finding of patent invalidity or non-infringement would not limit the patentee's right to market its FDA-approved product as a generic. Thus, the 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, such a commitment can enable the brand and the generic to secure monopoly profits both before and after generic entry and share those profits. Rather than a cash payment, the parties use reciprocal agreements not to compete to share monopoly returns. The brand-name drug company obtains its share of monopoly profits during the period the generic challenger agrees to delay its entry. The generic drug company obtains its share during the period the brand agrees not to launch an authorized generic, which allows the generic 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 lead to substantial additional revenues for a first filer generic, including revenues resulting from the higher prices that the first filer could charge in the absence of an authorized generic.[18] In these circumstances,

[18] Economic theory predicts—and empirical evidence discussed in the Authorized Generic Report confirms—that eliminating competition from the only potential competitor during the

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 at issue in this case could serve precisely the same function as the cash payments that were before the Court in *Actavis*.[19]

IV. Exclusive Patent Licenses Are Not Immune from Antitrust Scrutiny

GSK incorrectly asserts that the challenged agreement is *per se* lawful because it took the form of an exclusive patent license. *See* GSK Mem. at 14-16. 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."[20] Most exclusive licenses do not raise antitrust concerns because they promote competition, such as by combining complementary assets. But as one of the cases GSK relies on expressly states: "Though the grant of an exclusive license is not per se a

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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.

[19] 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 Bureau of Competition, Competition in the Health Care Marketplace, http://www.ftc.gov/bc/healthcare/drug/index.htm (last updated Apr. 10, 2013) (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)).

[20] 12 P. AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶ 2046 at 330 (3d ed. 2012) (footnotes omitted). *See also Antitrust Guidelines for the Licensing of Intellectual Property*, *supra* note 12, 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).

violation of the antitrust laws, it may be an instrument by which an unlawful restraint of trade or a monopoly is created."[21]

GSK is likewise incorrect when it claims that *Actavis* holds that conduct expressly authorized by the Patent Act is immune from antitrust scrutiny. *See* GSK Mem. at 15, 16. To be sure, the Patent Act authorizes patent holders to grant exclusive licenses. But the Supreme Court's analysis in *Actavis* begins with the principle that, "to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question." 133 U.S. at 2230-31. Rather, the Court explained, both patent and antitrust policies are relevant to the antitrust analysis. *Id.* at 2231, 2233. Just as the grant to corporations of the legal authority to buy and sell property does not mean they are authorized to engage in anticompetitive mergers, neither does statutory permission to use exclusive patent licenses (which are often procompetitive) mean that patent holders are entitled to use such licenses to violate the antitrust laws.[22] GSK provides 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.

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[21] *Benger Labs. Ltd. v. R. K. Laros Co.*, 209 F. Supp. 639, 648 (E.D. Pa. 1962), *cited in* GSK Mem. at 15 n.10. The other cases GSK cites likewise do not hold that exclusive licenses are immune from antitrust scrutiny. Only two are antitrust cases: one, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), applied the scope-of-the-patent approach and was effectively overruled by *Actavis*; the other case merely reflects that exclusive licenses are not per se unlawful. *See Genentech, Inc. v Eli Lilly & Co.*, 998 F.2d 931 (Fed Cir. 1993) ("[T]he decision to grant exclusive or non-exclusive licenses or to sue for infringement, and the pursuit of optimum royalty income, are not of themselves acts in restraint of trade."). Finally, *General Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175 (1938), is a patent infringement case holding that the infringer had failed to establish the factual predicate for a patent exhaustion defense.

[22] *Cf. FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003 (2013) (grant of business powers to hospital authorities did not imply authority to make anticompetitive acquisitions); *N. Sec. Co. v. United States*, 193 U.S. 197, 345-46 (1904) (general authorization for merger transactions conferred by state corporation law did not exempt mergers from antitrust scrutiny).

V. FTC Review of Settlements Under the Medicare Modernization Act

The Court previously asked the parties, in preparation for argument on the summary judgment issues associated with the challenged settlement agreements, to provide additional information on the procedures applicable to government review of those agreements. Order, Docket No. 464 (July 17, 2012). While confidentiality obligations prevent the FTC from disclosing information related to any specific filings, the Commission has substantial experience reviewing patent litigation settlement agreements in the pharmaceutical industry and welcomes the opportunity to clarify the nature of its review.

Prompted by concern over the potential anticompetitive effects of pharmaceutical patent settlement agreements, Congress included in the Medicare Modernization Act of 2003 ("the MMA" or "the Act") provisions to ensure that antitrust enforcers would have the opportunity to review those agreements. The reporting requirements of the MMA are straightforward: brand-name and generic drug companies must file copies of certain agreements involving drugs for which the generic has submitted an Abbreviated New Drug Application with the FDA, including patent litigation settlements, with the Commission and the Department of Justice ("DOJ") within ten days of execution.[23] Relevant for purposes of this matter, the Act requires drug companies to file agreements between branded and generic firms regarding "the manufacture, marketing, or sale" of either a branded or generic drug, along with any agreements "related" to a covered agreement.[24]

Reporting under the MMA simply provides the FTC and DOJ with notice and copies of covered agreements. The Act imposes no limits on the ability of the parties to implement their

[23] *See* 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) [hereinafter MMA] (requiring the filing of pharmaceutical patent settlement agreements with the FTC and the DOJ).

[24] *Id.* at § 1112(a), (c)(2).

agreements. Moreover, it contains no mechanisms or authority for the agencies to either approve or disapprove agreements, and specifies no timeframe or process for any antitrust review.[25] The MMA makes clear that failure to take action concerning a filed agreement is not a bar to a later enforcement action.[26]

The Commission has no formal regulations or processes governing the review of agreements received under the MMA. Commission staff review each agreement, and the Commission issues annual staff reports summarizing the agreements received during each fiscal year.[27] Staff may take further action in some instances, ranging from informal inquiries to clarify terms to more formal investigations that may result in an enforcement action. As with enforcement matters generally, these decisions are made on a case-by-case basis.

It is important to note that a lack of action by the Commission or its staff with respect to a specific agreement (e.g., not investigating or challenging an agreement) does not signify anything about the FTC's view of the substance of the agreement, much less implicit approval of that agreement. The Commission is aware that there may be some misunderstanding on this point. Indeed, a recent Third Circuit decision, *Mylan Inc. v. SmithKline Beecham Corp.*, after

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[25] *See, e.g., Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, http://www.ftc.gov/os/2004/01/050210pharmrules faqsection.pdf (last visited Sept. 24, 2013).

[26] *See* MMA, *supra* note 23, § 1117 ("[A]ny failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law . . . .").

[27] *See* FTC Bureau of Competition, *supra* note 19, http://www.ftc.gov/bc/healthcare/drug/index.htm (links to annual reports from 2004-2012). The annual reports describe the agreements received during a fiscal year, reporting the total number of agreements along with some of their characteristics, including how many delayed generic entry, how many involved compensation to a generic firm, and the various types of compensation used.

noting that the drug companies had submitted their patent settlement agreement to the Commission, appeared to suggest that changes the parties made to no-authorized-generic commitment in their agreement had "alleviated the FTC's exclusivity-related concerns." 723 F. 3d 413, 417 (3d Cir. 2013). The opinion leaves unclear the basis for the Third Circuit's belief and the parties' briefs in the case are sealed. The Commission wishes to make clear to this Court that in no event should the absence of Commission action with respect to an agreement filed under the MMA be interpreted as indicating FTC approval or a lack of antitrust concern.

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*. For the reasons discussed above, this Court should reject GSK's argument that *Actavis* applies only to settlement agreements including a monetary payment. Because this Court's interpretation of *Actavis* may have implications for potential FTC enforcement proceedings and the Commission's views may be relevant to the Court's consideration, 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 a hearing should the Court deem it useful.

Dated: September 26, 2013

Respectfully submitted,

/s/ Markus H. Meier

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CERTIFICATE OF SERVICE

I certify that on September 26, 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: September 26, 2013

/s/ Markus H. Meier

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

In re: WELLBUTRIN XL ANTITRUST LITIGATION **This Document Relates To:** **All Actions**	**Case no.: 2:08-cv-2431** **Case no.: 2:08-cv-2433**

[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 [September] 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:_____

_____
The Honorable Mary A. McLaughlin
United States District Court Judge