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 (Direct) Case No. 2:08-cv-2433 (Indirect) **Hon. Mary A. McLaughlin**

BRIEF *AMICI CURIAE* OF THE AMERICAN ANTITRUST INSTITUTE AND CONSUMERS UNION

MICHAEL A. CARRIER
Distinguished Professor
Rutgers Law School
217 North Fifth Street
Camden, NJ 08102
(856) 225-6380

STEVE D. SHADOWEN*
Hilliard & Shadowen LLC
39 West Maine Street
Mechanicsburg, PA 17055
(717) 903-1177
steve@hilliardshadowenlaw.com
*Counsel of Record

Counsel for *Amici Curiae*

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Antitrust Institute ("AAI") is an independent and non-profit education, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. The AAI is managed by its Board of Directors, with the guidance of an Advisory Board that consists of more than 125 prominent antitrust lawyers, law professors, economists, and business leaders.[1] The AAI has been an active participant in the "reverse payment" controversy over the past decade, having filed nine *amicus curiae* briefs on the issue, including one favorably cited by the Supreme Court in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

Consumers Union is the public policy and advocacy division of Consumer Reports. It is an independent nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves. Since its founding in 1936, it has advocated for consumers on a variety of issues, including health care policy and competition policy. Consumer Reports is the world's largest independent product-testing organization. It has over 8 million subscribers to its magazine, website, and other publications. Both

[1] No person other than *amici curiae* or their counsel authored this brief in whole or in part or made a monetary contribution intended to fund its preparation or submission. A majority of the AAI's Board of Directors has approved this filing for the AAI; individual views of members of the Advisory Board may differ from the AAI's positions. Eric Cramer, who is counsel to Plaintiffs, sits on the Board of Directors of the AAI. Mr. Cramer was recused from this matter and played no role in the Directors' deliberations or the preparation or drafting of the brief.

through its advocacy and through its publications, Consumer Reports has long supported policies that promote the availability and affordability of generic drugs, including appropriate antitrust enforcement against anticompetitive reverse-payment settlements.

Amici AAI and Consumers Union are represented here by, in addition to practitioner co-counsel, Michael A. Carrier, who is a Distinguished Professor at Rutgers University School of Law and Co-Director of the Rutgers Institute for Information Policy and Law. Professor Carrier has spent his career analyzing the intersection of the intellectual property and antitrust laws and has written extensively on these topics, authoring nine articles on drug-patent settlements and co-authoring the AAI's *amicus curiae* brief in *Actavis*.

Amici offer this brief because reverse-payment settlements, by which brands pay generics to delay entering the market, are one of the most harmful forms of anticompetitive business conduct occurring in today's economy. These agreements cost consumers billions of dollars and lead to patients splitting pills in half or not taking needed medications.

Reverse payments today take myriad forms, including above-market-value business deals like those at issue in *Actavis*, the forgiveness of debt, and many other types of transfers of substantial economic value. Roughly *half* of such anticompetitive transfers today take the form of agreements by which brands

promise not to introduce their own versions of generic drugs during the 180-day marketing exclusivity period that the Hatch-Waxman Act provides to the first generic manufacturer that challenges the patent. Such "authorized generics" dramatically reduce generic profits, so a brand's promise not to introduce one provides substantial economic value to the generic.

These no-authorized-generic agreements, made by the brand in exchange for the generic's agreement to delay entry into the brand's market, are simply a variation on a type of unlawful market-allocation agreement with which courts are very familiar. The two manufacturers make reciprocal agreements not to compete in the other's allocated portion of the market: the brand agrees not to launch an authorized generic that would compete against the generic firm, and the generic firm agrees to delay launching its product that would compete against the brand.

The Court in *Actavis* found that a large payment from the brand to the generic, in exchange for the latter's delaying entry, could have "significant anticompetitive effects" and violate the antitrust laws. *Actavis*, 133 S. Ct. at 2237. This watershed ruling would be reduced to a dead letter if courts were to allow brand and generic firms to achieve the same anticompetitive ends by merely changing the form of the payment. As we explain in detail below, the anticompetitive effects do not change – and the antitrust analysis should not change – merely because the generic delays entry in exchange for payment in the

form of a reciprocal non-competition pledge rather than, as in *Actavis*, payment in the form of an above-market-value business deal.

As a leading antitrust organization and a leading consumer advocacy organization that have long been involved in promoting generic drug competition, and in consultation with Professor Carrier, who is a leading academic expert on drug-patent settlements, AAI and Consumers Union respectfully submit this *amici curiae* brief.

ARGUMENT

In *Actavis*, the Supreme Court for the first time considered the antitrust legality of agreements by which brands pay generics to delay entering the market. The Court forcefully held that such agreements could be "unjustified," 133 S. Ct. at 2235-36, have the "potential for genuine adverse effects on competition," *id.* at 2234, and could "violate the antitrust laws," *id.* at 2227.

Several appellate courts (though not the Third Circuit, see *In re K–Dur Antitrust Litigation,* 686 F.3d 197 (3d Cir. 2012), vacated, 133 S. Ct. 2849 (2013)), had held just the opposite, finding that the agreements were immune from the antitrust laws as long as their anticompetitive effects fell within the nominal scope of the patent. The Supreme Court, in contrast, made clear that the "scope of the patent" test was not appropriate because it "would be incongruous to determine

antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy." *Actavis*, 133 S. Ct. at 2231.

The essence of the Court's analysis in *Actavis* is that a payment from the brand to the generic, in exchange for the latter's agreement to delay entry into the market, can be anticompetitive. *Id.* at 2237. Defendant GSK[2] here tries to neuter this landmark decision, asserting that the Court's antitrust analysis applies only if the brand pays the generic in cash.

As we explain in detail below, GSK's formalistic argument restricting the type of payment encompassed by the Court's analysis in *Actavis* misses the mark. First, the Hatch-Waxman Act does not prevent brand firms from launching an "authorized generic" product during the first-filing generic's 180 days of exclusivity. And the brand's agreement not to launch an authorized generic during that period can transfer tens or hundreds of millions of dollars to the generic manufacturer. Brands are increasingly making these types of payments in exchange for generic firms' reciprocal agreements to drop patent challenges and delay entry into the market.

Second, both *Actavis*' language and fundamental antitrust law prevent GSK from distinguishing *Actavis* based on the form of payment that the brand makes in

[2] For ease of reference, *Amici* refer to "GSK" rather than to GlaxoSmithKline plc, Valeant Pharmaceuticals International, Inc., Biovail Corporation, and their related entities.

exchange for the generic's delayed entry. A payment by means of a no-authorized-generic agreement, no less than by means of an above-market-value business deal (by which the brand overpays for unrelated services provided by the generic), can have significant anticompetitive effects. Antitrust law and *Actavis*' rule-of-reason analysis are based not on the form of the payment, but on the payment's economic effect, whatever its form.

Third, GSK and the generics with the 180-day exclusivity (Anchen and its business partner Teva, hereafter referred to collectively as "Teva") allocated the market between themselves by exchanging non-competition pledges. Teva agreed to delay entry, and in exchange, GSK agreed not to launch an authorized generic during Teva's 180-day exclusivity period. In all material respects, this transaction has the same economic structure and effect as the agreement in *Actavis*.

Fourth, *Actavis* held that the payment there – an above-market-value business deal – was suspect because it transferred value to the generic that it could not have obtained even if it had won the patent case. Similarly, in this case, Teva could not have blocked GSK from entering with an authorized generic even if Teva had won the patent case. In both *Actavis* and this case, the brand firm bought an additional delay in generic entry, beyond any delay legitimately reflecting a compromise on disputed patent rights, by granting to the generic valuable consideration that even a patent win could not have delivered.

Lastly, GSK cannot avoid antitrust scrutiny by invoking the label "exclusive license." GSK did not merely grant to Teva the right to enter free from competition from an authorized generic (what GSK is calling an exclusive license); it granted that right in exchange for Teva's reciprocal agreement to drop the patent challenge and delay entry. Thus, a proper antitrust analysis must consider the "exclusive license" not in abstract isolation, but in its real economic context as one part of the two drug firms' reciprocal agreements not to compete.

I. THE HATCH-WAXMAN ACT DOES NOT PREVENT BRANDS FROM LAUNCHING AUTHORIZED GENERICS, AND BRANDS' AGREEMENTS NOT TO DO SO CAN BE WORTH HUNDREDS OF MILLIONS OF DOLLARS TO GENERICS

Pharmaceutical patent settlements involving authorized generics must be considered in the context of the Hatch-Waxman Act, which Congress enacted in 1984 to increase generic competition and foster innovation in the pharmaceutical industry. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Before Hatch-Waxman, a generic manufacturer was required to engage in lengthy and expensive clinical trials that largely replicated the trials conducted by the brand firm and that the generic firm could not begin during the patent term. As a result, roughly 150 drugs had no generic equivalent even after the brands' patent terms had expired. H.R. Rep. No. 98-857, pt. 1, at 17 (1984).

The Hatch-Waxman Act created a new legal framework, with a more expedited FDA approval process, by which generic firms could enter the market during the patent term. A central element of this framework was the "Paragraph IV certification," by which a generic firm certifies that the patents covering the brand drug are "invalid or will not be infringed" by the generic. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). To encourage the filing of Paragraph-IV certifications, the drafters of the Hatch-Waxman Act created a 180-day period of marketing exclusivity reserved for the first generic to make such a filing. 21 U.S.C. § 355(j)(5)(B)(iv).

As the Court explained in *Actavis*, this exclusivity period "has proved valuable" and "indeed . . . can be worth several hundred million dollars" to the generic. 133 S. Ct. at 2235. Importantly, however, although the exclusivity period is designed to encourage generic entry, the brand firm is free to introduce its own generic version during the period. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005). This version, known as an "authorized generic," is approved by the U.S. Food and Drug Administration (FDA) as a brand drug, but is marketed as a generic. FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, at i (2011) ("Authorized Generic Report"). Although the authorized generic is chemically identical to the brand drug, the brand firm lowers the price to sell it in the generics sector of the market.

In the 15 years during which anticompetitive reverse-payment settlements have been occurring, the form of payment has dramatically evolved. Early agreements involved the brand paying cash to the generic, as in *In re Ciprofloxacin Hydrochloride Litigation*, 544 F.3d 1323 (Fed. Cir. 2008), abrogated by *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (cash payment of more than $398 million). But more recent settlements are more complicated, with the brand overpaying for services provided by the generic (such as supplying materials or promoting products) or the generic underpaying for the brand's product line or service offerings. *See, e.g.*, C. Scott Hemphill, *The Aggregate Approach to Antitrust: Using New Data and Agency Rules to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-68 (2009).

In one recent variation, the one involved in this case, the brand pays the first-filing generic by agreeing not to launch an authorized generic to compete against it during its 180-day exclusivity period. A comprehensive study conducted by the Federal Trade Commission ("FTC") found that of 39 agreements involving a no-authorized-generic promise and delayed entry between 2004 and 2010, 15 took place in 2010 alone. FTC, Authorized Generic Report, at 145.

This number continues to increase. In its most recent report, the FTC found that 19 of 40 potential reverse-payment agreements reported in Fiscal Year 2012 involved no-authorized-generic pacts. 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), http://www.ftc.gov/os/2013/01/130117mmareport.pdf. This was a "record number" that was "significantly greater" than that in previous years. *Id.* at 2.

In his statement accompanying the release of the FTC's earlier Interim Report on Authorized Generics, Chairman Jon Leibowitz noted the essential equivalence of cash payments and no-authorized-generic promises:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG [authorized generic] is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."

Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics, June 2009, http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf.

Competition from an authorized generic has a significant adverse impact on the first-filing generic's sales and profits. The FTC's comprehensive study showed that the first-filing generic loses significant market share when it competes with an

authorized generic during the exclusivity period, and suffers revenue reductions of 40% to 52% on average. FTC, Authorized Generic Report, at 57, 58-59. These effects result from "increased pricing pressure" from authorized generics as well as reduced quantities. *Id.* at 59. Even after the exclusivity period, these effects continue, with revenues of the first-filing generic 53% to 62% lower in the 30 months following exclusivity. *Id.* at iii.

For these reasons, a brand's promise not to introduce an authorized generic during the 180-day exclusivity period is enormously valuable to the first-filing generic. That promise grants to the first-filing generic a hiatus from competition that neither the Patent Act nor the Hatch-Waxman Act provides. This restraint on competition can deliver hundreds of millions of dollars in extra profits to the first-filing generic – all at the expense of consumers.

On the other side of the coin, brands that launch an authorized generic during the 180-day exclusivity period increase their own profits by 6% to 21%. *Id.* at 62. Brands recognize that authorized generics "can generate incremental revenue when a branded product loses exclusivity." *Id.* at 68. And even after the end of the 180-day period, the brand continues to benefit. *Id.* at 93.

Giving up these benefits during and after the exclusivity period makes sense only if the brand gets something in return. That something is the first-filing generic's reciprocal agreement to delay entry into the market. The brand's no-

authorized-generic pledge and the generic's agreement to delay entry into the market are reciprocal non-competition agreements.

We show next that GSK cannot distinguish *Actavis* on the ground that the brand's payment there was an above-market-value business deal, while the brand's payment here is a reciprocal pledge not to compete.

II. *ACTAVIS*' ANTITRUST FRAMEWORK APPLIES TO ALL PAYMENTS FROM BRANDS TO GENERICS

GSK asserts that the Court in *Actavis* "repeatedly tied its concerns about anticompetitive effects to substantial cash payments made by brand-name manufacturers." GSK Br. at 1. In fact, however, *Actavis* itself did not involve the payment of straight cash – the FTC alleged there that the brand overpaid the generics for services that were not worth the amount paid. *Id.* at 2229.

Indeed, the *Actavis* majority opinion never uses the word "cash." True, the majority twice uses the phrase "millions of dollars" – once in describing a hypothetical example of a payment from "A" to "B," *id.* at 2227; and once in describing the overpayment from the brand in that case to the generics, *id.* at 2229. But the Court also twice uses that same phrase in referring to *the very thing that GSK secured for Teva here*: "[T]his 180–day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Id.* at 2229 (citation omitted). And again: "[T]he special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product . . . can be worth several hundred

million dollars." *Id.* at 2235 (citation omitted). Indeed, emphasizing that substance, not form, matters, the Court noted that in challenging the above-market-value business deal, the FTC "alleges that, *in substance*, the plaintiff agreed to pay the defendants many millions of dollars . . . ." *Id.* at 2231 (emphasis added).

Can GSK really argue, with a straight face, that *Actavis* precludes antitrust scrutiny where, instead of overpaying for services, the brand pays the generic with Kreugerands or real estate, or gives the generic a lucrative business deal for free, or agrees not to compete with the generic in some other market, or agrees to preserve the generic's 180-day exclusivity "worth several hundred million dollars"?

Suppose that in *Actavis* the brand, rather than substantially *over*paying for services provided *by* the generics, had instead provided services *to* the generics for which they substantially *under*paid. Under GSK's form-over-substance logic, these two forms of payment – with identical economic effect – would receive radically different antitrust treatment. GSK has no basis to impute such silly formalism to the Supreme Court.

What matters for antitrust analysis is not a transaction's form, but its economic substance. The Supreme Court and the Third Circuit have consistently required that antitrust analysis "be based upon demonstrable economic effect rather than . . . upon formalistic line drawing." *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58-59 (1977); *see also Eastman Kodak Co. v. Image Tech.*

Servs., Inc., 504 U.S. 451, 466-67 (1992) ("formalistic distinctions" are "generally disfavored in antitrust law"); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 283 (3d Cir. 2012) (actual market impact, not formalism, matters); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) ("economic realities rather than a formalistic approach must govern review of antitrust activity").

For that reason, both of the courts that have considered no-authorized-generic agreements post-*Actavis* have held that they may be unlawful under the mandated rule-of-reason analysis. *See In re Nexium Antitrust Litigation*, 2013 WL 4832176, at *15 (D. Mass. Sept. 11, 2013) ("Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment," and "[a]dopting a broader interpretation of the word 'payment' . . . serves the purpose of aligning the law with modern-day realities"); *In re Lipitor Antitrust Litigation*, 2013 WL 4780496, at *26 (D.N.J. Sept. 5, 2013) (concluding that amendment to complaint would not be futile because "nothing in *Actavis* strictly requires that the payment be in the form of money").

The *Actavis* Court made clear that lower courts have an important role to play in "structuring" the antitrust litigation. *Actavis*, 133 S. Ct. at 2238. This case calls upon this Court to continue the structuring recently begun by the *Nexium* and *Lipitor* courts by making clear that whether a payment invokes antitrust scrutiny

under *Actavis* depends not on its form, but on its economic substance. And there can be no doubt that here, as in *Actavis*, the antitrust plaintiffs have alleged that "in substance, the [brand] agreed to pay the [generic] many millions of dollars." *Id.* at 133 S. Ct. at 2231.

We address that economic substance next.

III. GSK AND TEVA ALLOCATED THE MARKET BY EXCHANGING RECIPROCAL NON-COMPETITION PLEDGES

No "demonstrable economic effect" separates this case from *Actavis*. Colluding firms have two basic ways to unlawfully allocate a market and split the resulting ill-gotten profits. The first way, as in *Actavis*, is for the two firms to agree to allocate the entire market to one of them, with the firm that receives the market paying the other firm a share of the excess profits that the agreement unlawfully extracts from consumers. A second way is for the two firms to allocate a part of the market to each of them, with their reciprocal agreements not to compete in each other's part of the market serving as a payment from each to the other. Each conspiring firm keeps the excess profits that unlawfully accrue to it from the sales it makes in its allocated part of the market.[3]

[3] Market division among competitors is considered perhaps the most pernicious from of anticompetitive business behavior since it completely eliminates *all* competition between the parties on *all* grounds. Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 2031 (3d ed. 2012).

Both ways of unlawfully allocating a market (1) create or preserve prices above competitive market levels and (2) provide a means for the conspirators to share the extra profits unlawfully extracted from consumers. Consequently, courts have readily concluded that it is irrelevant whether the conspirators allocate the entire market to one of them, in exchange for payment in the form of cash or something else of value, or the conspirators allocate the market between themselves, with their exchange of consideration consisting of reciprocal non-competition pledges. In the words of the leading case, twice cited in *Actavis*, 133 S. Ct. at 2227, 2230, "[s]uch agreements are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other." *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 47, 49-50 (1998).[4]

[4] Courts have long recognized the severe harms presented by market division. *See, e.g., United States v. Topco Associates, Inc.*, 405 U.S. 596, 608 (1972) ("an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition" is plainly anticompetitive); *United States v. Addyston Pipe & Steel Co.*, 175 U.S. 211, 241 (1899) ("If dealers in any commodity agreed among themselves that any particular territory . . . should be furnished with such commodity by certain members only of the combination, and the others would abstain from business in that territory, would not such an agreement be regarded as one in restraint of interstate trade?"); *Engine Specialties, Inc. v. Bombardier, Ltd.*, 605 F.2d 1, 11 (1st Cir. 1979) ("Bombardier is free of Agrati's competition in both sales and manufacturing in North America and Agrati is free of Bombardier's competition in manufacturing outside North America. This, we think, rises to the level of a territorial allocation of markets."); *Garot Anderson Agencies, Inc. v. Blue Cross & Blue Shield United*, 1993 WL 78756, at *13 (N.D. Ill. Feb. 26, 1993) ("Assuming Blue Cross entered an agreement whereby it agreed to stay out of the Illinois health insurance market, but Health Care did not reciprocally agree to stay out of the Wisconsin health insurance market, the net effect is an anticompetitive effect on the Illinois health insurance market.").

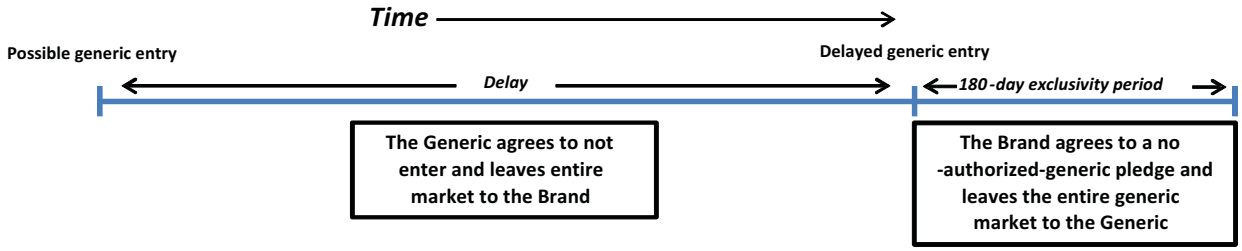
Here, Teva agreed to delay its entry into the market, pushing back not only the 180-day period for itself but also entry by other generics. In exchange, GSK agreed not to introduce a generic version of its product that would have competed against Teva during its 180-day exclusivity period. The agreement thus has a sinister symmetry: Teva's delayed-entry pledge transformed a period of two-product rivalry for the Wellbutrin XL molecule into an extended monopoly period for GSK, while the no-authorized-generic pledge transformed the 180-day period from a three-product rivalry into a two-product rivalry (with a monopoly for Teva in the generics sector).

GSK and Teva thus allocated the market *in time* by means of reciprocal non-compete pledges. Like all anticompetitive market allocation agreements, this increased their joint profits at consumers' expense.[5]

[5] As noted by the FTC: "Material produced in connection with the FTC's study of authorized generics confirms that a brand-name company may agree to refrain from offering a competing AG to maximize the net present value of both the brand-name and generic products." FTC, Authorized Generics Report, at 141.

The exchange of non-compete pledges can be illustrated graphically:

Reciprocal Non-Compete Pledges in a No-Authorized-Generic Agreement



The deferred-entry pledge prevented Teva from entering the market earlier, allocating the entire market to GSK for an extended period of time. And the no-authorized-generic pledge prevented GSK from entering the generics sector during the 180-day exclusivity period, allocating the entire generics sector to Teva during that time. Absent these reciprocal anticompetitive pledges, the entire time period depicted above could have been a period of substantial competition, with GSK selling the brand product, and both GSK and Teva selling generics.[6] Instead, the

[6] Of course, in determining the lawfulness of the agreement, it does not matter that it was uncertain whether the generic would have entered earlier, or whether GSK would have launched an authorized generic. It is unlawful to allocate a market with a *potential* competitor as well as with an actual competitor. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 47, 49-50 (1998); *cf. United States v. Microsoft*, 253 F.3d 34, 79 (D.C. Cir. 2001) ("the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power"). The Court in *Actavis* made unmistakably clear that a non-compete agreement is anticompetitive if it avoids "even a small risk of [patent] invalidity" because it thereby "prevent[s] the risk of competition" – which is "the relevant anticompetitive harm." *Actavis*, 133 S. Ct. at 2236; *see also id.* ("maintain[ing] supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market . . . [is] the very anticompetitive consequence that underlies the claim of antitrust unlawfulness").

reciprocal pledges neatly and illegally led to an extended period of brand-only sales, followed by 180 days of sales of the brand and only one generic.

GSK and Teva agreed to limit competition during each other's allocated time period, with GSK's reciprocal non-compete pledge serving as a payment to Teva in exchange for its delayed entry. Consumers picked up the tab, paying higher prices than they otherwise would have during both of the time periods depicted above: GSK collected and kept the supracompetitive profits generated during the first period, while Teva collected and kept the supracompetitive profits generated during the second period.

These economic facts are definitive. The agreement here has the identical economic substance as the agreement in *Actavis*. Just as in *Actavis*, "the true point of the payments was to compensate the generics for agreeing not to compete against [GSK] until [2008]." *Actavis*, 133 S. Ct. at 2229.

IV. GSK'S NO-AUTHORIZED-GENERIC PLEDGE PROVIDED VALUE TO TEVA THAT IT COULD NOT HAVE RECEIVED BY WINNING THE PATENT CASE

GSK argues that prohibiting all consideration from the brand to the generic – including a simple split of the patent term – would outlaw all settlements. GSK Br. at 13-14. This argument is a red herring. It willfully ignores that what makes the payments here and in *Actavis* suspect is that they provide something of value *beyond* what the generic could have received by winning the patent litigation. In

other words, the brand is not merely compromising its disputed patent rights. Instead, it is supplementing the exclusionary force of its disputed patent with extraneous, non-patent-derived economic power.

Pursuant to reverse-payment settlements, brands pay generics to drop patent challenges and delay entering the market. Central to the *Actavis* Court's understanding of why the payment in that case was suspect was that the generic was receiving consideration it could not have obtained by winning the patent case.

The Court noted, for example, that the brand and generic can simply divide the remaining patent term. The greater the likelihood that the patent is valid and infringed, the later in the period generic entry would occur. For example, if there are 10 years remaining in the patent term, and the parties conclude that there is a 60% likelihood that the patent is valid, the parties could agree that generic entry would occur in 6 years. Such an agreement by the brand firm provides the generic firm nothing more than it could have received had it won the patent case, and this type of consideration generally poses no antitrust concern. *Actavis*, 133 S. Ct. at 2234.

It is when the brand seeks to pay the generic for additional delay that antitrust concerns arise. Continuing the example above, the brand might pay the generic to delay entering the market from Year 6 until Year 9. The quid pro quo for the payment is the generic's agreement to stay out of the market beyond Year 6

– *i.e.*, beyond the date that otherwise reflects the parties' assessment of the patent's strength and the likely outcome of the patent litigation.

The problem with these payments is that they give the generic something valuable that it could not have obtained even if it had *won* its patent challenge and *entered* the market. Even if a court ruled that the patent was invalid or not infringed, there is no reasonable scenario under which the brand firm would also pay the generic firm. By paying the generic what it could not obtain even if it won the patent case, the brand entices the generic to delay entry beyond the date that the parties' views of the patent's strength would otherwise have yielded. A brand's payment – consideration in the form of something of value that the generic could not have obtained by winning the patent case – results in a longer delay in generic entry beyond what would have otherwise occurred. This "pay for delay" is the anticompetitive agreement that *Actavis* holds is subject to the antitrust laws.

Actavis makes this clear. The transaction in *Actavis* was "unusual" in that it did not reflect a mere compromise on the generic entry date, permitting the generic to enter some time before the patent expired. *Actavis*, 133 S. Ct. at 2231. Instead, the brand's payment to the generic was something that it could not have received even if it had won the patent case: "the [patent] plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for

damages." *Id.*; *see also id.* at 2233 ("In reverse payment settlements, in contrast, a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market."). Agreements of this nature "tend to have significant adverse effects on competition." *Id.* at 2231.

The same is true here. Even by winning the patent case Teva could not thereby obtain the right to prevent GSK from entering with an authorized generic during the 180-day exclusivity period. GSK would be perfectly free to launch its own authorized generic. And by doing so, GSK would have reduced Teva's revenues significantly (by roughly 50%, assuming effects similar to those discussed in the FTC report). GSK's payment to Teva in the form of agreeing to forgo an authorized generic, in exchange for Teva's reciprocal agreement to delay entry, has exactly the same "significant adverse effects on competition" as the payment in *Actavis*.

Likewise, the *Actavis* Court's analysis of each of the five anticompetitive aspects of brand payments, discussed in Part IIB of its opinion, is also squarely applicable here.

First, the antitrust plaintiff in *Actavis* alleged that the "payment in return for staying out of the market . . . simply keeps prices at patentee-set levels, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee

and the challenger gain; the consumer loses." *Id.* at 2234-35. Just so here. Teva delayed entry into the market in exchange for GSK's payment in the form of a reciprocal agreement not to enter with an authorized generic. That payment "provide[s] strong evidence 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 2235.

Second, just like the above-market-value business deals in *Actavis*, GSK's promise not to launch an authorized generic bestowed supracompetitive profits on the generic far in excess of "litigation costs or fair value for services." *Id.* at 2236.

Third, GSK's promise not to launch an authorized generic, and Teva's acceptance of that promise in exchange for delayed entry, reflect "higher-than-competitive profits – a strong indication of market power." *Id.* If existing competition were constraining prices to marginal cost, delayed entry would have been of no value to GSK, and a no-authorized-generic pledge would have been of no value to Teva. The reciprocal non-competition pledges make sense precisely because they allow both GSK and Teva to obtain supracompetitive prices.

Fourth, if "otherwise unexplained," a payment by means of an above-market-value business deal "likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm." *Id.* The same is true of a payment by means of a reciprocal non-compete pledge.

Teva received that non-compete pledge in exchange for dropping its patent challenge, which could have opened the market up to competition. If left unexplained, the natural inference is that GSK's agreement to forgo an authorized generic "likely [sought] to prevent the risk of competition." *Id.*

Fifth, just like the patent litigants in *Actavis*, GSK and Teva could have settled the case by splitting the patent term "without the patentee paying the challenger to stay out prior to that point." *Id.* at 2237. Although GSK and Teva might have had reasons for requiring that GSK not launch an authorized generic, "the relevant antitrust question is: What are those reasons?" *Id.* If, as alleged here, the reason was to allocate the market and divide the supracompetitive profits, "the antitrust laws are likely to forbid the arrangement." *Id.*

In sum, just as in *Actavis*, the "large and unjustified payment" – GSK's reciprocal non-competition pledge – "can bring with it the risk of significant anticompetitive effects." *Id.* GSK's extensive exalting of form over substance cannot change that economic reality.

V. THE LABEL "EXCLUSIVE LICENSE" ADDS NOTHING TO THE ANALYSIS

GSK asserts that "at most" it granted a so-called "exclusive license" (the no-authorized-generic pledge) to Teva, that the license was a "perfectly legitimate form[] of consideration," and that the Patent Act, 35 U.S.C. § 261, expressly permits such licenses. GSK Br. at 14-15. Not so.

GSK did not "at most" grant an exclusive license that was a "perfectly legitimate form of consideration" to Teva. GSK granted that "license" *in exchange for Teva's agreeing to defer entry into the market*. In short, *Amici* are not concerned about the fact that GSK gave Teva a license; *Amici* are concerned that GSK gave the license in exchange for Teva withdrawing its patent challenge and deferring entry into the market. It is not GSK's mere grant of a license that draws antitrust scrutiny, but its grant of that license in exchange for deferred entry.

The *Actavis* Court repeatedly emphasized that antitrust analysis focuses not on a transaction's form, but on its economic context and its purpose and effect. Specifically, "to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question." *Actavis*, 133 S. Ct. at 2230-31. The key economic fact here, as in *Actavis*, is that the generic manufacturer had been actively attempting to enter the market without any license at all (and, with respect to one dosage strength, did so), by asserting that the patent was invalid and not infringed. As *Actavis* made clear: "The patent here may or may not be valid, and may or may not be infringed . . . . The paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope." *Id.* at 2231; *see also id.* at 2232 ("both within the settlement context and without, the Court has struck down overly restrictive patent licensing agreements"); *id.* at 2231 (it "would be incongruous to determine antitrust legality by measuring the

settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well"); 12 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 2046 at 330 (3d ed. 2012) ("the Patent Act expressly permits exclusive licenses, but this fact alone does not render them immune from antitrust scrutiny").

Teva was an active, potent competitor who asserted a right to enter the market license-free. Regardless of whether GSK otherwise had a right to grant or withhold a license from Teva, Teva could not have obtained the absence of an authorized generic from the market even by winning the patent litigation. Teva was an aggressive competitor, and GSK eliminated that competitive threat by providing to Teva a reciprocal hiatus from competition that Teva could not have obtained in the patent litigation. These indisputable facts must inform the antitrust inquiry.

Of course, nothing in *Actavis* prevents GSK from trying to justify the so-called "exclusive license." GSK can try to show "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Actavis*, 133 S. Ct. at 2236. The usual justification for a legitimate exclusive license is that the patentee has concluded that the licensee has certain distribution-efficiency advantages over the patentee and other potential distributors and can therefore most profitably

distribute the product for the patentee. *See, e.g.,* U.S. Dep't of Justice & FTC, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition 79-80 (2007), http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf. GSK may have difficulty explaining here, among other things, why GSK suddenly realized Teva's superior distribution skills in 2007, years after the brand product was first marketed, just after Teva entered the market at risk with its 300mg generic Wellbutrin XL, and just as Teva was preparing to compete against the brand with a 150mg generic Wellbutrin XL, and why GSK also apparently believed that Teva's superior distribution skills would then lapse after only 180 days.

The point is this: GSK is entitled under the *Actavis* rule-of-reason analysis to try to justify the no-authorized-generic pledge as a legitimate exclusive license. They are not entitled to invoke the label "exclusive license" as a talisman to preclude antitrust inquiry into whether GSK granted that no-authorized-generic pledge in exchange for Teva's reciprocal agreement to defer entry.

CONCLUSION

When antitrust scrutiny of reverse-payment agreements burst onto the scene 15 years ago, brands were paying cash to generics to delay entering the market. Times have changed. Settling parties are now cleverly stashing the payments in

more obscure corners such as the above-market-value business deals in *Actavis* and the reciprocal no-authorized-generic pledge here.

None of this should dissuade courts from calling a payment what it is. When a brand sacrifices its right to enter with an authorized generic, it confers on the first-filing generic more profits and more market share than it otherwise would have obtained. That is a payment of substantial value. And it is value that the first-filing generic could not have obtained even by winning its patent litigation.

Above-market-value business deals and no-authorized-generic promises may not appear as blatant as cash payments. But their anticompetitive bite is just as strong. And even though settling parties are engaging in ever-more-sophisticated versions of "three-drug monte," courts must keep their eye on the ball. Whether that ball is cash, an above-market-value deal, or a no-authorized-generic pledge, the effect is the same: a bounty of substantial value to the generic that it could not have obtained through litigation and that the brand bestows in exchange for delayed generic entry. And while the settling parties each gain from this arrangement, it is consumers who pick up the tab.

Dated: September 26, 2013

Respectfully submitted,

s/ Steve D. Shadowen

MICHAEL A. CARRIER
Distinguished Professor
Rutgers Law School
217 North Fifth Street
Camden, NJ 08102
(856) 225-6380

STEVE D. SHADOWEN*
Hilliard & Shadowen LLC
39 West Maine Street
Mechanicsburg, PA 17055
(717) 903-1177
steve@hilliardshadowenlaw.com
*Counsel of Record

ALBERT A. FOER
President
RANDY M. STUTZ
Senior Counsel
American Antitrust Institute
2919 Ellicott Street NW
Washington, DC 20008
(202) 905-5420

GEORGE P. SLOVER
Senior Policy Counsel
Consumers Union
1101 17th Street, NW
Washington, DC 20036
(202) 462-6262

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 (Direct) Case No. 2:08-cv-2433 (Indirect) **Hon. Mary A. McLaughlin**

[PROPOSED] ORDER

Upon consideration of the Motion of the American Antitrust Institute and Consumers Union for Leave to File Brief as *Amici Curiae,* any opposition thereto, and the applicable law, it is this _____ day of September, 2013,

ORDERED, that the Motion of the American Antitrust Institute and Consumers Union for Leave to File Brief as *Amici Curiae* is GRANTED; and it is further

ORDERED, that the Clerk of the Court accept for filing within ___ day(s) of the date of this Order, the Brief *Amici Curiae* of the American Antiturst Institute and Consumers Union*;* 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

CERTIFICATE OF SERVICE

I, Steve D. Shadowen, hereby certify that I caused to be electronically filed the foregoing Motion of The American Antitrust Institute and Consumers Union for Leave to File Brief as *Amici Curiae*; Memorandum in Support of Motion of The American Antitrust Institute and Consumers Union for Leave to File Brief as *Amici Curiae*; Brief *Amici Curiae* of the American Antitrust Institute and Consumers Union; and Proposed Order with the Clerk of Court via CM/ECF. Those attorneys who are registered with the Court's electronic filing system may access this filing through the Court's system, and notice of this filing will be sent to these parties by operation of the Court's electronic filing system.

Dated: September 26, 2013

Respectfully Submitted,

/s/ Steve D. Shadowen
Steve D. Shadowen