14-1243

In The

United States Court of Appeals

FOR THE THIRD CIRCUIT

In Re: Lamictal Direct Purchaser Antitrust Litigation

KING DRUG COMPANY OF FLORENCE, INC.; LOUISIANA WHOLESALE DRUG CO, INC., on behalf of itself and all others similarly situated,

Plaintiffs-Appellants,

v.

SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS,

Defendants-Appellees.

On Appeal from the United States District Court
District of New Jersey

BRIEF *AMICI CURIAE* OF 53 LAW, ECONOMICS, AND BUSINESS PROFESSORS, THE AMERICAN ANTITRUST INSTITUTE, AND CONSUMERS UNION IN SUPPORT OF APPELLANTS

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

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

Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT OF AMERICAN ANTITRUST INSTITUTE

Pursuant to Fed. R. App. P. 26.1, American Antitrust Institute states that it is a nonprofit corporation and, as such, no entity has any ownership interest in it.

CORPORATE DISCLOSURE STATEMENT OF CONSUMERS UNION

Pursuant to Fed. R. App. P. 26.1, Consumers Union states that it is a nonprofit corporation and, as such, no entity has any ownership interest in it.

Dated: April 28, 2014

Respectfully submitted,

s/Steve D. Shadowen
Steve D. Shadowen

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

INTEREST OF *AMICI CURIAE*

The academic *amici* are professors of economics, business, innovation, antitrust law, and intellectual property law. (A list of signatories is attached as Addendum A.) Their sole interest in this case is to ensure that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

Amicus 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. AAI is managed by its Board of Directors with the guidance of an Advisory Board consisting of more than 130 prominent antitrust lawyers, law professors, economists, and business leaders.

Amicus Consumers Union is the public policy and advocacy division of Consumer Reports. It works to ensure a fair, just, and safe marketplace for all consumers. It has long advocated for policies that promote the availability and affordability of generic drugs, including antitrust enforcement against anticompetitive exclusion-payment settlements.[1]

[1] All parties have consented to the filing of this brief. Pursuant to Fed. R. App. P. 29(c)(5), *amici* state that no counsel for a party has authored this brief in whole or in part; and no party, party's counsel, or any other person or entity—other than *amici* or their counsel—has contributed money that was intended to fund preparing or submitting this brief. AAI's Board of Directors has approved this

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici offer this brief because exclusion-payment settlements, by which brands provide compensation to generics to delay entering the market, are one of the most harmful forms of anticompetitive business behavior in today's economy. These agreements cause enormous harm, requiring consumers to overpay by billions of dollars and to miss dosages by splitting pills in half or not taking needed medications.

Exclusion payments today take myriad forms, including above-market-value business deals like those at issue in *FTC v. Actavis*, *Inc.*, 133 S. Ct. 2223 (2013), and numerous other types of transfers of substantial economic value. Roughly *half* of such anticompetitive transfers today take the form of "no-authorized-generic" agreements. Nothing in the Patent Act or the Hatch-Waxman Act prevents the brand from introducing its own "authorized generic" version of a drug during the first-filing generic's 180-day marketing exclusivity period. By agreeing not to launch an authorized generic during this 180-day period, the brand delivers to the generic by private pact a hiatus from competition that the law does not provide. Launching an authorized generic would dramatically reduce the generic's profits, so a brand's promise not to introduce one provides substantial value to the generic.

---

filing for AAI; individual views of members of the Board of Directors or Advisory Board may differ from AAI's positions.

These no-authorized-generic agreements, which the brand enters into 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 have long been familiar. The two parties 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, and the generic agrees to delay launching its product that would compete against the brand.

The Court in *Actavis* found that a large transfer of consideration from the brand to the generic, in exchange for the latter's delayed entry, could have "significant anticompetitive effects" and violate the antitrust laws. *Id.* at 2237. But this watershed ruling would be reduced to a dead letter if courts were to allow brands and generics to achieve the same anticompetitive ends by merely changing the form of the payment. Nor would scrutiny of agreements like the one in this case, which provides the generic with a type of consideration it could never have obtained by winning a patent case, have any effect on legitimate settlements that fall within the boundaries of patent litigation.

In holding that only cash payments are subject to antitrust scrutiny under *Actavis*, the court below applied a formalistic, stilted analysis that created a loophole large enough to accommodate an entire industry's worth of supracompetitive profits and missed dosages. And just as problematic, as explained fully below, the court's analysis purported to apply *Actavis* but was closer to

defying it, in (1) using factors the Supreme Court invoked to require *heightened* scrutiny to instead justify *reduced* scrutiny; (2) misunderstanding the valuable no-authorized-generic period; (3) deeming *procompetitive* the elimination of risk that *Actavis* held is *anticompetitive*; and (4) divining, on its mere say-so, an absence of harmful "intent."

ARGUMENT

I. A "PAYMENT" UNDER *ACTAVIS* IS NOT LIMITED TO CASH

In the landmark *Actavis* case, 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 "significant adverse effects on competition," *id.* at 2234; and "violate the antitrust laws," *id.* at 2227.

Flying in the face of this ruling, the court below concluded that "nothing in *Actavis* says that a settlement contains a reverse payment when it confers substantial financial benefits." (JA-15) (Dist. Ct. Opinion). It found that an agreement by which a brand promises not to introduce its generic version of a drug during the first-filing generic's 180-day exclusivity period is not a "payment." *Id.* It asserted that "[b]oth the majority and the dissenting opinions reek with discussion of payment of money." *Id.* And it concluded that "the Supreme Court considered a reverse payment to involve an exchange of money." *Id.*

The court below was wrong. For starters, the *Actavis* case *itself* did not involve the payment of straight cash. The Federal Trade Commission ("FTC") in the case had alleged not that the brand made a naked cash payment to the generics for delayed entry, but that the brand had overpaid the generics for services not worth the amount paid. 133 S. Ct. at 2229.

In addition, the *Actavis* majority opinion never uses the word "cash." The majority does twice use 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 value to the generic manufacturer of not facing other generic competition during the 180-day period: "[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 it possibly make economic sense to apply *Actavis* to preclude 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 not to launch an authorized generic, thereby handing the first filer "several hundred million dollars"?

Certainly not. Even the court below seemed not to believe its extreme view in conceding that it was "plausible" that *Actavis* "does not require finding a large, unjustified reverse payment of money." (JA-20) (Dist. Ct. Opinion).

What matters for antitrust analysis is not a transaction's form, but its economic substance. The Supreme Court has 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"). This Court similarly has explained that "economic realities rather than a formalistic approach must govern review of antitrust activity." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005); *see also ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 283 (3d Cir. 2012) (quoting *Kodak* case). And yet again: "Antitrust policy requires the courts to seek the economic substance of an arrangement, not merely its form." *Weiss v. York Hosp.,* 745 F.2d 786, 815 (3d Cir. 1984).

For that reason, three district courts have found that no-authorized-generic agreements are suspect "payments" under *Actavis*. *See In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-02431, slip op. at 4 (E.D. Pa. Jan. 17, 2014) (McLaughlin, J.) ("The Court is not prepared at this point to accept [defendant's] argument that only a large cash payment from the patentee to the generic is subject to antitrust analysis under *Actavis*."); *In re Nexium Antitrust Litig.*, No. 12-md-02409-WGY, 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 Litig.*, No. 3:12–cv–2389, 2013 WL 4780496, at *26 (D.N.J. Sept. 5, 2013) (Sheridan, J.) (concluding that amendment to complaint would not be futile because "nothing in *Actavis* strictly requires that the payment be in the form of money").

Actavis made clear that lower courts have an important role to play in "structuring" the antitrust litigation. 133 S. Ct. at 2238. This case calls upon this Court to continue the structuring recently begun by the *Wellbutrin XL*, *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 2231.

II. BRANDS' AGREEMENTS NOT TO LAUNCH AUTHORIZED GENERICS ARE VALUABLE TO GENERICS

Drug 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 the Act, a generic firm was required to engage in lengthy and expensive clinical trials that largely replicated the trials conducted by the brand and that the generic 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 approval process by the U.S. Food and Drug Administration ("FDA"), by which generics could enter the market during the patent term. A central element was the "Paragraph IV certification," by which a generic certifies that the brand's patents are "invalid or will not be infringed" by the generic. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). To encourage market entry via these challenges, the drafters created a 180-day period of marketing exclusivity reserved for the first generic to make a Paragraph IV filing. 21 U.S.C. § 355(j)(5)(B)(iv). The FDA cannot approve

any other generic application for the same brand drug during this 180-day period. *Actavis* explained that, because no other generic version is on the market, the exclusivity period "has proved valuable" and "indeed . . . can be worth several hundred million dollars" to the generic. 133 S. Ct. at 2235.

Courts have made clear, however, that the statute does not prohibit the brand manufacturer from introducing during the 180-day period its own generic version of its brand drug under the authority of its approved New Drug Application ("NDA"). *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005); *Mylan Pharmaceuticals v. Food & Drug Administration*, 454 F.3d 270 (4th Cir. 2006). This version, known as an "authorized generic," is approved by the FDA under the brand's own NDA but marketed—and priced—as a generic. FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at i (2011) ("FTC, *Authorized Generic Report*"). The brand firm continues to sell the brand product at high prices, but also markets the authorized generic (which is chemically identical to the brand drug) at a lower price in the generic sector of the market.[2]

[2] This strategy makes economic sense for the brand firm because a significant portion of patients (the "inelastic demanders") remain loyal to the brand product and are willing to continue paying the high price, while a larger portion of patients (the "elastic demanders") switch to a lower-priced generic version of the product. *See, e.g.*, Henry G. Grabowski & John N. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & Econ. 331, 339-40 (1992); CBO, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 29-30 (1998). Selling both a high-priced brand version and a low-priced authorized generic

In the 15 years in which anticompetitive exclusion-payment settlements have been occurring, the form of payment has dramatically evolved. Early agreements involved naked cash payments from the brand to the generic, as in *In re Ciprofloxacin Hydrochloride Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (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 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 exclusion-payment agreements reported in Fiscal Year 2012 involved no-authorized-generic pacts. FTC Bureau of Competition, *Agreements*

---

version allows the brand firm to "harvest" high prices from the inelastic demanders while also competing on price for the elastic demanders.

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). 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, then-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 significantly lowers 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.

A brand's commitment not to launch an authorized generic 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.[3] The brand's no-authorized-

[3] It is for this reason that a no-authorized-generic agreement can be even more anticompetitive than a cash payment. For a brand that pays cash "bears the entire burden of the payment," while a brand that offers a no-authorized-generic agreement "pushes some of the costs of a deal onto consumers by decreasing competition during the 180-day exclusivity period." William O. Kerr & Cleve B.

generic pledge and the generic's agreement to delay entry into the market are reciprocal non-competition agreements. 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 one 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.[4]

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

---

Tyler, *Measuring Reverse Payments in the Wake of Actavis*, 28 Antitrust 29, 34-35 (2013). The brand and generic nonetheless still have aligned interests in sharing supracompetitive profits. *See* FTC, *Authorized Generics Report*, at 141 (explaining that a brand "may agree to refrain from offering a competing [authorized generic] to maximize the net present value of both the brand[] and generic products").

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

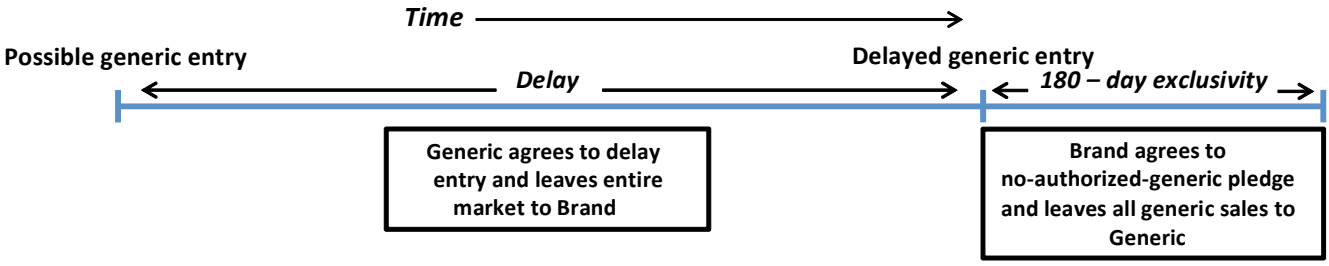
share the extra profits unlawfully extracted from consumers. As a result, courts have readily concluded that it is irrelevant whether the conspirators allocate the entire market to one of them, in exchange for payment in the form of cash or something else of value, or the conspirators allocate the market 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). *See generally* XII Hovenkamp, Antitrust Law ¶ 2030 (cataloging types of market allocation agreements and concluding that, of whatever type, "most naked market division agreements are competitively harmful").[5]

[5] Courts have long recognized the severe harms presented by market division, regardless of whether the competitors allocate the entire market to one of them, or allocate part of the market to each of them. *See, e.g., United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972) (condemning "an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition"); *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) (agreement is unlawful market allocation where "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").

In this case, the complaint alleges that Teva agreed to delay its entry into the market, which pushed back not only its own 180-day period but also other generics' entry. (JA-49-50) (Complaint). 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-seller rivalry for the Lamictal product into an extended monopoly period for GSK, while the no-authorized-generic pledge transformed the 180-day period from a three-way rivalry into a two-way 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. The exchange of non-compete pledges can be illustrated graphically:

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



Absent these reciprocal anticompetitive pledges, the entire time period depicted above could have been a period of substantial competition marked by

GSK selling the brand product, and both GSK and Teva selling generics.[6] Instead, the 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.

In short, 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 in the generic sector during the second period.

These economic facts are definitive. The agreement alleged here has the identical economic substance as the agreement in *Actavis*. Just as in *Actavis*, "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*, 498 U.S. at 49-50; *cf. United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) ("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." 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").

true point of the payments was to compensate the generics for agreeing not to compete against [GSK] until [2008].” 133 S. Ct. at 2229.

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

The court below worried that extending the concept of payment beyond cash could ensnare all settlements. It acknowledged that “[w]ithout doubt Teva received consideration in the settlement,” as “[o]therwise, there would be no incentive to settle.” (JA-17) (Dist. Ct. Opinion). And it even turned to “law student[s] in the first semester” as a reminder that “consideration is an essential element of any enforceable contract” and thus that there is “‘payment’ in every settlement.” *Id*.

The court’s concern, however, is misplaced. *Amici* do not contend that every case in which an alleged infringer receives consideration in settling a patent lawsuit presents an exclusion payment that violates the antitrust laws. After all, a generic could receive *legitimate* consideration for settling in the form of a negotiated entry date allowing entry before the end of the patent term.

Entry-split agreements provide the generic with consideration that falls within the range of what could be expected in a patent lawsuit. If the brand wins the suit, it is able to exclude competition until the end of the patent term. If the generic wins, it is able to enter immediately. A compromise allowing the generic to enter before the end of the patent term thus falls within the range of expected outcomes in patent litigation.

No-authorized-generic agreements are completely different. GSK is not providing Teva with a type of consideration that it could obtain by winning the patent litigation. Instead, GSK's promise gives the generic something valuable it could not have obtained even if it had *won* its patent challenge. Even a court ruling that the patent was invalid or not infringed only allows the generic to enter the market. Under no circumstance would the generic's victory in the patent case prevent the brand from launching an authorized generic. Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 1 (forthcoming 2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2418685 (offering test for payment based on "whether the brand conveys to the generic a type of consideration not available as a direct consequence of winning the lawsuit").

The case law leaves no doubt that 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. And by introducing an authorized generic, GSK would reduce Teva's revenues significantly (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*.

The *Actavis* opinion itself makes this crystal clear. The transaction in that case 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. 133 S. Ct. at 2231. Instead, the brand's payment was not something the generic could 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 . . . 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.

In sum, this is not a garden-variety entry-split agreement falling within the boundaries of conceivable outcomes in patent litigation. No possible result in the patent case could have prevented the brand from introducing its authorized generic.

V. THE COURT BELOW APPLIED THE RULE OF REASON IN A WAY THAT DIRECTLY CONTRAVENED *ACTAVIS*

The problems with the decision below extend not only to its formalistic, stilted interpretation of payment, but also to its application of the Rule of Reason. Though it purported to model its analysis on *Actavis*, and though some of the words were the same, the substance was completely at odds with the Supreme Court's ruling.

The court below applied five factors to dismiss plaintiffs' complaint under the Rule of Reason. But even leaving aside the court's inappropriate conclusions at

this early stage of litigation, its Rule-of-Reason analysis fails to find support in *Actavis* and often is buttressed by nothing more than speculation.

For starters, the court asserted that *Actavis* laid out "five considerations" guiding a Rule-of-Reason analysis. (JA-11) (Dist. Ct. Opinion). That is wrong. *Actavis* makes clear that the Rule-of-Reason analysis for scrutinizing exclusion-payment agreements is the familiar one that "consider[s] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations . . . ." 133 S. Ct. at 2231. *Actavis*'s five factors do not constitute a new, unique Rule-of-Reason inquiry for exclusion-payment cases. Instead, the Court said that those factors indicate why the "general legal policy favoring the settlement of disputes" does not provide immunity from a Rule-of-Reason analysis. *Id*. at 2234.

To be sure, some of these factors give strong hints, if not directives, as to how courts should structure the Rule-of-Reason inquiry. For example, the "first" factor—that an exclusion payment "has the 'potential for genuine adverse effects on competition,'" *id*. at 2234 (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460-61 (1986)), and the "third" factor—that a brand's payment to the generic suggests the presence of market power, *id*. at 2236, together indicate that a plaintiff satisfies its initial burden under the Rule of Reason by adducing evidence that the brand made a payment to the generic in exchange for delayed entry. And the "second" factor—that a payment may be "justified" if it reflects saved

litigation costs or "fair value for services," *id*. at 2236, indicates that defendants have the burden of proof on those issues. *See also id*. ("[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present"); *id*. at 2237 ("one who makes such a payment may be unable to explain and to justify it").

The district court here, however, turned these "five sets of considerations" on their heads. These factors had led the Supreme Court to "conclude that the FTC should have been given the opportunity to prove its antitrust claim." *Id.* at 2234. But they somehow led the court below to conclude that plaintiffs alleging a payment with the same anticompetitive effect as in *Actavis* should *not* be given an opportunity to prove their antitrust claim. A brief consideration of those five factors reveals how this backward analysis threatens to gut *Actavis*.

First Factor. The court somehow assumed that "the settlement does not have the potential for genuine adverse effects on competition." (JA-20) (Dist. Ct. Opinion). It defies reason to assume that an agreement by which a brand provides compensation worth millions of dollars for the generic to delay entering the market "does not have the potential for genuine adverse effects on competition." Nor are the reasons the court offered for its conclusion plausible. It found solace in the fact that "Teva was allowed six months of early entry," that "there was no payment of money," and that "the duration of the No-[authorized-generic] Agreement was a relatively brief six months."

Each of these "reasons" reveals a profound misunderstanding of plaintiffs' claim and of *Actavis*. *First*, the assertion that the agreement "allowed six months of early entry" assumes that GSK was entitled to block entry until the end of the patent term. In essence, the court resurrects the very "scope of the patent" test that *Actavis* expressly rejected: "The paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope," and therefore "to refer, as the [district court here] referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question." 133 S. Ct. at 2230-31.[7] *Second*, as discussed at length above, only a formalistic treatment of *Actavis* that ignores fundamental economics would view money as completely different from a promise worth the same amount of money. And *third*, the suggestion that the no-authorized-generic pledge covered "a relatively brief six months" ignores the well-known economics of this industry, not to mention *Actavis*'s express acknowledgement that "the vast majority of potential profits for a generic drug manufacturer materialize during the 180–day exclusivity period." 133 S. Ct. at 2229 (citation omitted).

Second Factor. The court applied similarly errant reasoning in its second factor by mystically finding that "the payment is justified." (JA-20) (Dist. Ct.

[7] The challenged agreements in *Actavis* allowed generic competition 65 months before patent expiration, yet the Supreme Court ruled that the FTC had stated a claim by alleging that the agreements had *delayed* generic entry. 133 S. Ct. at 2229.

Opinion). On this score, the court offered two reasons and a concession. The "reasons" mocked *Actavis* while the concession was telling. *First*, the court found that "the consideration which the parties exchanged in the settlement is reasonably related to the removal of the uncertainty created by the dispute." *Id.* But *Actavis* was unambiguous (indeed, redundant) in instructing that eliminating the risk that the patent would be found invalid or not infringed—the risk that competition would break out—is *anticompetitive, not procompetitive*. The payment "likely seeks to prevent the risk of competition," which "constitutes the relevant anticompetitive harm." *Actavis*, 133 S. Ct. at 2236.[8]

Second, the court speculated that "GSK may . . . have derived some ancillary benefit from Teva's licensed sales . . . in terms of distribution and marketing." (JA-20) (Dist. Ct. Opinion). But it is the defendant's burden to prove procompetitive justifications, *not the court's function to assume them*. And equally fundamentally, defendants' burden will be to show that *the payment* is procompetitive, not that some other term of the agreement (the license to Teva) is procompetitive. *Actavis*, 133 S. Ct. at 2236 ("An antitrust defendant may show . . . that legitimate

[8] The Court makes this point multiple times. *See also* 133 S. Ct. at 2233 (the antitrust violation occurs when "A, the plaintiff, pays money to defendant B purely so B will give up the patent fight"); *id.* at 2236 (the antitrust concern is "that a patentee is using its monopoly profits to *avoid the risk* of patent invalidation or a finding of noninfringement") (emphasis added); *id*. at 2233 (rejecting dissent's approach that would permit "a patent holder [] to simply 'pa[y] a competitor to respect its patent' and quit its invalidity or noninfringement claim. . .") (internal citation omitted).

justifications are present, thereby explaining the presence of the *challenged term* and showing the lawfulness *of that term* under the rule of reason.") (emphases added); *see also NCAA v. Bd. of Regents*, 468 U.S. 85, 117 (1984) (defendants must justify the "specific restraints on football telecasts that are challenged in this case"). Presumably, in obtaining Teva's agreement to delay entry, GSK would have gladly provided the license to Teva without also making the payment, so the former cannot justify the latter. *Finally*, the court's concession that the consideration "likely exceeds what the parties would have spent litigating the patent dispute" shows that *Actavis*'s "litigation costs" justification does not apply.

Third Factor. The court could not "conclude whether the brand . . . has the market power needed to bring about anticompetitive harm, but finds that this would not be dispositive." (JA-20) (Dist. Ct. Opinion). *Actavis*, however, explained that a firm without market power is not "likely to pay 'large sums' to induce 'others to stay out of its market.'" 133 S. Ct. at 2236 (citation omitted). In this case, 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 competitive levels, delayed entry would have been of no value to GSK, and a no-authorized-generic pledge would have been of no value to Teva. GSK and Teva made the reciprocal non-competition

pledges precisely because they allowed both drugmakers to obtain supracompetitive prices.

Fourth Factor. *Actavis* held that a larger-than-litigation-costs payment may provide "a workable surrogate for a patent's weakness," obviating the need for courts to, in essence, try the patent case within the antitrust case. *Id.* at 2236-37. The district court here got this completely turned around, concluding that "the sweep of the settlement d[id] not suggest that it [wa]s intended to maintain supracompetitive prices and serve as a 'workable surrogate for a patent's weakness.'" (JA-21) (Dist. Ct. Opinion). The court was wrong for several reasons:

- *Actavis* was not importing an "intent" requirement into the Rule-of-Reason inquiry. The Court was referring to *courts* using the payment as a "surrogate" for patent weakness—analyzing the payment rather than re-litigating the patent merits—not to *parties* having an intent to use the payment to mask patent weakness.

- It would seem presumptuous to assume that the parties did not intend an anticompetitive effect when they paid and received the unlawful payment *immediately after a court had ruled that a claim of the patent covering the drug's active ingredient was invalid*. (JA-49) (Complaint).

- The court's conclusion that the "sweep of the settlement" did not suggest anticompetitive intent would have been impossible absent its erroneous assumption that the 180-day exclusivity is worth only a pittance.

Fifth Factor. The court stated that "the parties settled in a way that did not involve monetary reverse payments." (JA-21) (Dist. Ct. Opinion). Referring again to "early" entry (erroneously measured against the full patent term) and a "limited"

six-month period of no authorized-generic entry (erroneously neglecting that this period delivers the "vast majority" of the generic's profits), the court sought to ensure that the settling parties had the "latitude to settle without triggering the antitrust scrutiny that large, unjustified reverse payments bring." *Id.* But again, *Actavis* taught the exact opposite lesson in its reminder that litigating parties had ways to settle that did not involve "a large, unjustified reverse payment [that] risks antitrust liability." 133 S. Ct. at 2237. Far from revealing a sole "intent" to "give patent litigants latitude to settle," the Supreme Court made clear that "the antitrust laws are likely to forbid" arrangements by which the settling parties "maintain and . . . share patent-generated monopoly profits," *id.,* as is the case where, as here, a brand and generic trade reciprocal non-compete pledges.

* * *

In short, there is an Alice-in-Wonderland quality to the district court's Rule-of-Reason analysis. It (1) uses the five *Actavis* factors not to scrutinize exclusion-payment agreements but to justify them; (2) counts as "early entry" the delayed entry that GSK bought; (3) downplays a "relatively brief" no-authorized-generic period that *Actavis* called "valuable" and worth "millions of dollars"; (4) counts as procompetitive the elimination of patent risk—the risk that competition would break out—that *Actavis* repeatedly called anticompetitive; (5) replaces courts' ability to analyze exclusion-payment settlements with a hypothesized lack of "intent" to maintain high prices; and (6) rolls out the red carpet for settlements in

which the brand conveys significant value to the generic in exchange for delayed entry—exactly the competitive danger that *Actavis* highlighted.

When antitrust scrutiny of exclusion-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 darker 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 promises that it will not introduce an authorized generic, it confers on the first-filing generic something of enormous value that it could never have obtained by winning the patent case. Under any understanding of fundamental economics, that is a payment of substantial value.

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 a patent victory and that the brand bestows in exchange for delayed generic entry. While the settling parties gain from this arrangement, consumers are left to pick up a tab of billions of dollars and missed dosages.

CONCLUSION

For the reasons above, this Court should reverse the decision of the district court granting defendants' motion to dismiss.

Dated: April 28, 2014

Respectfully submitted,

s/Steve D. Shadowen

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

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

Addendum A
List of Academic Signatories[9]

Professor John R. Allison
McCombs Graduate School of Business
University of Texas at Austin

Professor Margo Bagley
University of Virginia School of Law

Professor Ann Bartow
Pace Law School

Professor Timothy Bresnahan
Department of Economics
Stanford University

Professor Jeremy I. Bulow
Graduate School of Business
Stanford University

Professor Darren Bush
University of Houston Law Center

Professor Michael A. Carrier
Rutgers Law School

Professor Peter Carstensen
University of Wisconsin Law School

Professor Bernard Chao
University of Denver Sturm College of Law

Professor Andrew Chin
UNC School of Law

Professor Christopher Cotropia
University of Richmond School of Law

[9] The brief presents the views of the individual signers. Institutions are listed for identification purposes only.

Professor Thomas Cotter
University of Minnesota School of Law

Professor Joshua Davis
University of San Francisco School of Law

Professor Stacey L. Dogan
Boston University School of Law

Professor Aaron Edlin
Berkeley Law School
University of California at Berkeley

Professor Robin Feldman
Hastings College of the Law
University of California

Professor Eleanor Fox
NYU School of Law

Professor Shubha Ghosh
University of Wisconsin School of Law

Professor Jim Gibson
University of Richmond School of Law

Professor Thomas Greaney
Saint Louis University School of Law

Professor Bronwyn H. Hall
Department of Economics
University of California, Berkeley

Professor Jeffrey L. Harrison
University of Florida College of Law

Professor Tim Holbrook
Emory University School of Law

Professor Herbert Hovenkamp
University of Iowa College of Law

Professor Eileen Kane
Penn State Dickinson School of Law

Professor Ariel Katz
University of Toronto Faculty of Law

Professor John B. Kirkwood
Seattle University School of Law

Professor Marina Lao
Seton Hall Law School

Professor Mark A. Lemley
Stanford Law School

Professor Christopher Leslie
School of Law
University of California – Irvine

Professor Yvette Joy Liebesman
Saint Louis University School of Law

Professor Daryl Lim
The John Marshall Law School

Professor Brian Love
Santa Clara University School of Law

Professor Phillip R. Malone
Stanford Law School

Professor Jonathan Masur
University of Chicago Law School

Professor Stephen McJohn
Suffolk University Law School

Professor Joseph Scott Miller
University of Georgia School of Law

Professor Kevin Outterson
Boston University School of Law

Professor Mark Patterson
Fordham University School of Law

Professor Zia Rahman
Penn State College of Medicine

Professor Daniel B. Ravicher
Benjamin N. Cardozo School of Law
Yeshiva University

Professor William Sage
Vice Provost for Health Affairs
University of Texas at Austin

Professor Pamela Samuelson
Berkeley Law School
University of California at Berkeley

Professor Kurt Saunders
California State University, Northridge

Professor F. M. Scherer
John F. Kennedy School of Government
Harvard University

Professor Steven Semeraro
Thomas Jefferson Law School

Professor Lea Shaver
Indiana University School of Law

Professor Brenda Simon
Thomas Jefferson School of Law

Professor Aram Sinnreich
School of Communication and Information
Rutgers University

Professor Avishalom Tor
Notre Dame Law School

Professor Jennifer Urban
Berkeley Law School
University of California at Berkeley

Professor Spencer Weber Waller
Loyola University Chicago School of Law

Professor Michael P. Waxman
Marquette University Law School

COMBINED CERTIFICATIONS

Certification of Bar Membership

I hereby certify that Steve D. Shadowen, Counsel for *Amici Curiae* 53 Law, Economics, and Business Professors, the American Antitrust Institute, and Consumers Union is a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

Certification of Service

I hereby certify that on April 28, 2014, electronic copies of Brief *Amici Curiae* 53 Law, Economics, and Business Professors, the American Antitrust Institute, and Consumers Union in Support of Appellants were served on counsel via the Notice of Docket Activity generated by the Court's electronic filing system (CM/ECF). In addition, 7 hard copies of this brief were mailed to the Court.

Certification of Word Count

I hereby certify that this brief complies with the type volume limitation of Fed. R. App. P. 32(a)(7)(B), contains 6,691 words, excluding the parts exempted by Fed. R. App. R. 32(a)(7)(B))(iii) and L.A.R. 29.1(b), and has been prepared in a proportionally-spaced typeface using Microsoft in Times New Roman font, 14-point.

Certification of Identical Compliance of Briefs

I hereby certify that the PDF file and the text of the paper version of the brief are identical.

Certification of Virus Check

I hereby certify that a virus check, using Norton iAntivirus 1.1.4, was performed on the PDF file and paper version of this brief, and no viruses were found.

Dated: April 28, 2014

s/Steve D. Shadowen
Steve D. Shadowen