Nos. 15-2875/3559/3591/3681/3682

IN THE
UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

In Re: Wellbutrin XL Antitrust Litigation

On Appeal from the United States District Court for the Eastern District of Pennsylvania

Case Nos. 08-cv-2431, 08-cv-2433
District Judge: Hon. Mary A. McLaughlin

BRIEF OF THE AMERICAN ANTITRUST INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR REHEARING AND REHEARING *EN BANC*

Richard M. Brunell
AMERICAN ANTITRUST INSTITUTE
1025 Connecticut Ave., NW
Suite 1000
Washington, D.C. 20036
Tel: (202) 600-9640
rbrunell@antitrustinstitute.org

Steve D. Shadowen
HILLIARD & SHADOWEN LLP
2407 S. Congress Ave.
Suite E 122
Austin, TX 78704
Tel: (855) 344-3298
steve@hilliardshadowenlaw.com

Counsel for Amicus Curiae

CORPORATE DISCLOSURE STATEMENT

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

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INTEREST OF AMICUS CURIAE

The American Antitrust Institute ("AAI") is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI enjoys the guidance of an Advisory Board consisting of more than 130 prominent antitrust lawyers, law professors, economists, and business leaders.[1]

AAI has a keen interest in the law regarding reverse payments, having filed *amicus curiae* briefs in more than a dozen such cases. Most recently, this Court cited and relied upon the AAI brief in *In re Lipitor Antitrust Litig.*, ___ F.3d ___, 2017 WL 3585180 at *18 n.14, *19 n.15 (3d Cir. May 19, 2017).

INTRODUCTION

AAI agrees with the Petition for Rehearing and Rehearing En Banc and the arguments made by the Amici Curiae Professors. We write here to elaborate on the first ground for rehearing set forth in the petition involving "risk aversion."

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[1] 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 amicus or its counsel—has contributed money that was intended to fund preparing or submitting this brief. Individual views of members of the Board of Directors or Advisory Board may differ from AAI's positions. Certain members of AAI's Board of Directors and Advisory Board or their law firms are among the counsel for the plaintiffs and were recused from involvement in AAI's deliberations with respect to the brief.

The Panel's error regarding risk aversion affected this case, but, more broadly, it threatens to undermine the analytical framework undergirding the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2233 (2013). As we explain in detail below, *Actavis*' conclusion that a large reverse payment is a "surrogate for" the patent's weakness necessarily rejected the assumption of risk aversion that the Panel adopted. By resuscitating the risk-aversion hypothesis that *Actavis* rejected, the Panel's decision would leave in doubt one of the pillars on which *Actavis* was built.

Moreover, the Supreme Court was right to reject the assumption of risk aversion because it is bad economics. The Panel adopted the assumption because it believed that "most *people*" are risk-averse. Op. at 73 (emphasis added). But corporations are not people. Foundational economics says that, whatever the risk tolerances of *people*, large *corporations* are risk-neutral because their shareholders are able to diversify their risks: "[c]orporations are generally assumed to be risk neutral since any riskiness involved in the corporation's business can be eliminated by the shareholders." Richard A. Posner, *Antitrust Law* 269 n.2 (2d ed. 1976).

The Panel's embrace of the risk-aversion assumption is bad law and bad economics. Left uncorrected, it could lead to the undoing of the enormous gains that healthcare consumers have made in the wake of *Actavis*.[2]

ARGUMENT

On the question whether GSK's payment to Anchen caused injury to Plaintiffs, the Panel rejected Plaintiffs' factual assertion that Anchen "would have prevailed against Andrx in litigation" over the '708 patent. Op. 68. Plaintiffs argued that the Court could use the size of the payment as a "surrogate for the patent's weakness," *id*. at 72, as *Actavis* held.

The Panel was instead "persuaded by an argument raised in the amicus brief filed by a group of antitrust economists." Op. 73. Those economists, who were not addressing the causation issue, urged that "a brand company" might make a reverse payment due to risk aversion rather than to delay entry beyond the date warranted by a rational, risk-neutral evaluation of the patent's merits.[3] Those economists

[2] The latest FTC report shows that, after *Actavis*, patent litigation settlements have continued at the same rate but have taken the pro-consumer form of early-generic-entry licenses rather than anticompetitive reverse payments. FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2014* (Jan. 2016).

[3] Brief of Antitrust Economists as Amici Curiae in Support of Defendants-Appellees at 11, filed May 10, 2016 [hereinafter "Econ. Amici Br."].

offered, and the Panel accepted, an example of "[m]ost people" being willing to accept $20 million in exchange for a 50% chance of obtaining $100 million. *Id*. at 73-74. The Panel deemed this an "effective rebuttal" to Plaintiffs' argument that the payment reflected GSK's rational evaluation of the patent's weakness. *Id*. at 74.

The Panel's acceptance of that risk-aversion argument was erroneous and threatens to do great mischief in reverse-payment cases.

I. *Actavis* Rejected the Premise of Risk Aversion

The Supreme Court held in *Actavis* that the existence of a reverse payment is "a workable surrogate for a patent's weakness." 133 S. Ct. at 2236-37. The necessary premise for that conclusion is that corporations are risk-neutral. The Panel suggested that a risk-averse manufacturer might make a large payment despite the patent's strength, in which case the payment would *not* be a surrogate for the patent's weakness. Op. at 72-73. The Supreme Court, however, concluded that the existence of a reverse payment *is* a surrogate for the patent's weakness, so the Supreme Court *necessarily* rejected the premise of risk aversion. Moreover, the Court's conclusion that a large payment (in excess of litigation savings or other benefits) delays generic entry and is anticompetitive, whatever the strength of the patent, is also premised on an assumption of risk-neutrality.

The Supreme Court rejected the risk-aversion premise despite its having been vigorously argued by the defendant[4] and various amici[5] and accepted by the dissent. 133 S. Ct. at 2244 (Roberts, C.J., dissenting). Even the argument's proponents admit that the Supreme Court "consider[ed] the possible implications of risk aversion" and "brushed the concern aside."[6] And pharmaceutical manufacturers and their amici subsequently made the risk-aversion argument again in *Lamictal*[7] and *Loestrin*.[8] Those Courts also refused to accept it. *King Drug Co. of Florence v. Smithkline Beecham Corp*., 791 F.3d 388, 403-09 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551-52 (1st Cir. 2016).

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[4] Brief for Respondent Solvay Pharms., Inc., No. 12-416 (S. Ct.), at 33, filed Feb. 21, 2013.

[5] *E.g*., Br. of Antitrust Economists as Amici Curiae in Support of Respondents, No. 12-416 (S. Ct.), at 19-21, filed Feb. 28, 2013; Br. for Shire PLC as Amicus Curiae Supporting Respondents, No. 12-416 (S. Ct.), at 11, filed Feb. 28, 2013.

[6] Addanki & H. Butler*, Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements*, 15 Minn. J.L. Sci. & Tech. 77, 83 n.37 (2014).

[7] Br. of Antitrust Economists as *Amicus Curiae*, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 14-1243 (3d Cir.), at 4-5, filed June 3, 2014.

[8] Br. National Association of Manufacturers as *Amicus Curiae*, *In re Loestrin Antitrust Litig*., No. 14-2071 (1st Cir.), at 22-23 & n.44, filed August 27, 2015.

The Panel here accepted the risk-aversion assumption in the context of causation, rejecting Plaintiffs' argument that the reverse payment reflected GSK's view that Anchen likely would have won the patent litigation. The Panel's risk-aversion assumption is troubling enough if limited only to *causation* issues. If left undisturbed, however, the Panel's risk-aversion analysis could infect the law regarding whether reverse payments are *anticompetitive* and thus unlawful. Under the Panel's reasoning, reverse payments do not generally cause harm because they are merely payments that brand manufacturers make because they are risk-averse. But if that is so, why are reverse payments anticompetitive? Indeed, the economists' amicus brief on which the Panel relied offered the risk-aversion argument as a ground for concluding that reverse payments are *not anticompetitive*. Econ. Amici Br. at 11-12.

The Panel's risk-aversion decision, if left standing, could undermine a pillar of *Actavis*' reasoning—that reverse payments are anticompetitive because they buy the absence of competition that was otherwise likely to occur. 133 S. Ct. at 2236.

II. A Foundation of Mainstream Economics Is that Corporations Are Not Risk-Averse

The Panel's decision is also bad economics. It is foundational economics that large corporations like GSK are *not* risk-averse. Economic theory of the firm relies on the insight that the purpose of a corporation is to maximize profits.

Dennis W. Carlton & Jeffrey M. Perloff, *Modern Industrial Organization* 12 (4th ed. 2005) ("They exist to make money."). Antitrust law adopts that insight. *See Matsushita v. Zenith Radio Corp*., 475 U.S. 574, 595 (1986).

Firms maximize profits by *not* being risk-averse. Some individual persons are risk-averse, "preferring a sure thing to uncertain levels of consumption." Paul A. Samuelson & William D. Nordhaus, *Economics* 193 (16th ed. 1998). But publicly traded corporations avoid risk aversion because stock ownership is a "form of risk sharing" that allows "the financial ownership of physical capital [to] be spread among many owners." *Id*. at 194. Accordingly, in standard economics "[c]orporations are generally assumed to be risk neutral since any riskiness involved in the corporation's business can be eliminated by the shareholders, each of whom can combine his shares in the corporation with other shares . . . to create a portfolio that will be as risky or as risk free as he desires." Posner, *supra*, at 269 n.2.

In a nutshell, corporations are not individuals; they are not afflicted with the risk aversion to which some individuals succumb. So they will *not* accept $20 million in exchange for a 50% chance of winning $100 million.

This standard economic assumption of risk-neutrality predominates throughout the pharmaceutical industry. For example, the Federal Trade Commission uses it to interpret drug-firm decisions regarding the introduction of

authorized generics.[9] Likewise, a study commissioned by the Pharmaceutical Researchers and Manufacturers of America analyzed behavior of potential Paragraph IV challenges on the assumption that firms seek to maximize expected profits.[10]

Prominent economists conclude that the standard economic theory of corporation risk-neutrality applies in analyzing reverse payments. For example:

> Of course, basic capital market theory would say that if the litigation risk is non-systematic and the firms' managers act as fiduciaries for well-diversified stockholders, then the firms should be risk-neutral regarding the litigation. As an empirical matter, risk aversion should not be terribly relevant in most cases. The market values of large pharmaceutical companies (pharmas) are enormous relative to the amount at stake in most of these cases, even if the absolute dollars may be in the hundreds of millions.[11]

And again:

> Although individuals might sometimes prefer to avoid variation in profits by accepting certain profits with lower expected value, this is unlikely to be relevant for a publicly held corporation, which generally has incentives

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[9] FTC, *Authorized Generics: Short-Term Effects and Long-Term Impact* 56 (Aug. 2011).

[10] Howrey, LLP, *The Short-Term and Long-Term Competitive Impact of Authorized Generics: A Report for the Federal Trade Commission* 1-32 at 20-28 (October 28, 2009).

[11] Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, *in Innovation Policy and the Economy* 145, 162 (2004).

> to maximize expected profits on behalf of a diversified set of shareholders.[12]

GSK is, of course, the epitome of a large, publicly traded corporation whose shareholders can diversify their portfolios to incur whatever level of risk they desire.

To be sure, a minority of economists argue that individual managers can make decisions for firms based on their personal aversion to risk. But that is not standard economics. "Various forces keep managers from deviating from profit-maximizing behavior." Carlton, *Modern Industrial Organization* 13. These include "[i]ncentives, such as stock ownership and other bonuses," not to mention the threat of being "fired for inefficiency." *Id*. In short, "[m]anagers who do not maximize expected profits increase the risk that their conduct will be punished by product markets, capital markets, labor markets, takeover threats, shareholder voting, and lower valuation of their stock options."[13]

The amici economist brief on which the Panel relied elided the critical distinction between people who may be risk-averse and corporations that are not. The brief said *nothing* about whether GSK and other pharmaceutical corporations are risk-averse. The brief instead put the rabbit in the hat, giving the Panel an

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[12] Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 312 (2012).

[13] Elhauge & Kreuger, *supra*, at 312.

example of how "most *people*" and how "a *person*" would respond to risk. Econ. Amici Br. at 11. But the Panel accepted that example to assert how *GSK* would act. Op. at 73-74. This was a fundamental error.

And even if a court were to permit the *theory* that individual managers may be risk-averse—despite *Actavis* and standard economics—that would be the beginning of the analysis, not the end. The question would become whether these particular managers were *in fact* risk-averse. But GSK never raised the issue in the district court in any brief or argument at any stage of the litigation.

III. The Panel's Acceptance of the Risk-Aversion Argument Has Adverse Implications for Reverse-Payment Cases Generally

As noted above, the risk-aversion argument made by defendants' amici economists did not address the causation issue here. They instead submitted it as an explanation for why a large reverse payment is not anticompetitive *at all*. The theory is that brand firms might make a reverse payment not to buy the absence of competition, but to assuage their managers' aversions to risk. Thus, the payment would not result in generic entry any later than the objectively "expected" entry date based on the patent's strength. The Panel's ruling opens the door to this type of argument in *every* reverse payment case.

As shown above, *Actavis* rejected this contention. We note, however, that the argument, even on its own terms, is not supportable. If accepted, the theory that

GSK's managers were risk-averse could account for their giving Anchen more *in consideration* than warranted by the objectively expected value of the litigation. But it could not account for that consideration taking the form of a reverse payment (worth some $233 million), rather than *taking the form of earlier agreed entry* into the market.

A risk-averse manager could provide additional consideration to the generic—the "premium" for the manager's being risk-averse—in the form of agreeing to entry earlier than a risk-neutral patent evaluation would warrant. This of course would make it easier to settle the case without a reverse payment. So accepting the theory of manager risk aversion would make a reverse payment *more* competitively suspicious, not less.

In short, the theory that managers are risk-averse could affect "how [the parties] are willing to compromise the entry date," but reverse payments "distort[] the calculus that would otherwise obtain—based on whatever risk preferences the parties might have."[14]

[14] *In the Matter of Schering-Plough Corp*., 136 F.T.C. 956, 1060, 2003 WL 25797209 (2003), *rev'd*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (reversing based on "scope of the patent" test), *abrogated by FTC v. Actavis, Inc*., 133 S. Ct. 2223 (2013).

CONCLUSION

For the foregoing reasons, and those stated by the Plaintiffs and their academic amici, this Court should grant the petition for rehearing and rehearing en banc.

Dated: September 7, 2017

Respectfully Submitted,

/s/ *Steve D. Shadowen*

Steve D. Shadowen
HILLIARD & SHADOWEN LLP
2407 S. Congress Ave., Suite E 122
Austin, TX 78704
Tel: (855) 344-3298
steve@hilliardshadowenlaw.com

Richard M. Brunell
AMERICAN ANTITRUST INSTITUTE
1025 Connecticut Ave., NW
Suite 1000
Washington, D.C. 20036
Tel: (202) 600-9640
rbrunell@antitrustinstitute.org

Counsel for Amicus Curiae American Antitrust Institute

CERTIFICATE OF COMPLIANCE AND OTHER CERTIFICATIONS

I, Steve D. Shadowen, certify that:

1. On September 7, 2017, a true and correct copy of the foregoing motion was served on all parties to this appeal, via CM/ECF, pursuant to 3rd Cir. L.A.R. 25.1(b), because, to the best of my knowledge, counsel for all parties are registered CM/ECF users and will be served electronically by the appellate CM/ECF system.

2. The attached motion complies with the page limitation set forth in Fed. R. App. P. 29(b)(4) because it does not exceed 2,600 words, excluding those elements set forth in L.A.R. 29.1(b). The number words in the document is 2330.

3. The attached motion has been scanned for viruses using Kapersky VirusDesk, released on Sept. 7, 2017, and according to this program is free from viruses.

4. I am a member of the bar of this court.

Dated: September 7, 2017

Respectfully Submitted,

/s/ *Steve D. Shadowen*
Steve D. Shadowen