No. 15-2236

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

MYLAN PHARMACEUTICALS INC.,

Appellant,

—v.—

WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT US, LLC; MAYNE PHARMA GROUP LIMITED; MAYNE PHARMA INTERNATIONAL PTY. LTD.,

Appellees.

On Appeal From The United States District Court
For The Eastern District of Pennsylvania

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

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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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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 education, research, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI is managed by its Board of Directors, with the guidance of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders. *See* http:/www.antitrustinstitute.org.[1]

AAI filed a brief on the merits and submits this brief in support of rehearing and rehearing *en banc* because the questions raised in this appeal are important to AAI's mission, which includes the preservation of competition in prescription drug markets. AAI does not support particular companies, or types of companies or business models, or any particular result in this case. Rather, AAI seeks to ensure that the antitrust law on product hopping develops properly to ensure that the

[1] All parties have consented to the filing of this brief. Individual views of members of the Board of Directors or the Advisory Board may differ from AAI's positions. 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 AAI or its counsel—has contributed money that was intended to fund the preparation or submission of this brief. Philip Nelson, a member of AAI's Advisory Board, served as an economic expert for plaintiff, but played no role in this brief.

Hatch-Waxman Act and state drug substitution laws function as intended, and are not gamed to artificially prolong the monopoly pricing of branded drugs without offsetting benefits to consumers.

ARGUMENT

At a time when the high cost of prescription drugs is a growing national problem, the panel's forgiving approach to "product hopping" strategies of drug manufacturers to thwart generic price competition merits rehearing. Empirical research suggests that the annual consumer welfare losses from anticompetitive product hopping are on the order of some tens of billions of dollars a year. *See* Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 Rutgers L.J. 1, 3 (2009).

Mylan offered a simple and compelling anticompetitive story: Defendants were the exclusive sellers of an unpatented branded drug; when generics appeared on the horizon, they introduced a minor modification of the drug and removed the older version from the market in order to delay generic entry (and did this several times); when generic entry finally occurred against a version of the drug that Defendants could not hop away from, prices fell sharply; had the product hops not occurred, Mylan (and other generics) would have entered much sooner, prices would have fallen much sooner, and consumers (and third-party payors) would have obtained the benefits of the lower prices.

In affirming summary judgment for Defendants, the panel essentially rejected this scenario as a basis for liability under Section 2. In doing so, the panel's

analysis conflicts with basic antitrust principles and decisions of this Court, other circuits, and the Supreme Court.

I. The Panel's Ruling on Exclusionary Conduct Warrants Rehearing

This Court's rulings make clear that a monopolist need not block *all* means of distribution, just the most *cost-effective* means, in order to be held liable for engaging in exclusionary conduct. "The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005); *see United States v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001) (finding monopolistic conduct where, "although Microsoft did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones"); *accord New York ex rel. Schneiderman v. Actavis PLC* (*Namenda*), 787 F.3d 638, 656 (2d Cir. 2015); *McWane, Inc. v. FTC*, 783 F.3d 814, 838 (11th Cir. 2015). In other words, "[t]he proper inquiry is not whether [another distribution method] enable[s] a competitor to 'survive' but rather whether [it] 'poses a real threat' to defendant's monopoly." *Dentsply*, 399 F.3d at 193. In a parallel to this case, this Court in *Dentsply* rejected the district court's attempt to blame rivals' inability to attain market share on "their own business decisions," instead pegging their failure to the monopolist's "domination of dealers." *Id.* at 189.

Drug substitution laws offer "the only cost-efficient means of competing available to generic manufacturers." *Namenda*, 787 F.3d at 655-56 & n.30. Other means of competition are not "viable" since they are not "practical or feasible in the market as it exists and functions." *Dentsply*, 399 F.3d at 193. Marketing by generics is "impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by [a] generic competitor[]." *Namenda*, 787 F.3d at 656.

While acknowledging this point to a degree (Op. 36 n.79), the panel nonetheless concluded there could be no anticompetitive conduct since there was *some* entry. It asserted, "Mylan was not foreclosed from the market"; rather, it was "advantaged" by a 180-day exclusivity period and "ability to profit generously while raising prices." Op. 36-37. The panel veered even further off track by focusing on Mylan's size ("one of the largest generic pharmaceutical companies in the world") and status as an entity "difficult to perceive . . . as a 'David'" rather than "'Goliath.'" *Id.* at 36 n.79. This distraction prevented the panel from determining whether the conduct at issue "bar[red] a substantial number of rivals or severely restrict[ed] the market's ambit." *Dentsply*, 399 F.3d at 191. In essentially requiring *complete foreclosure* of the market, the panel decision directly conflicts with *Dentsply*. And it ignores the gist of the anticompetive harm resulting from Defendants' conduct: absent the product hops, Mylan (and other generics) would have entered *earlier*

and substantially brought down Doryx prices and eroded Defendants' monopoly. *Cf. McWane,* 783 F.3d at 838 (fact that targeted rival entered the market and increased its market share did not prove the absence of substantial foreclosure; "monopolists [may be] liable for anticompetitive conduct where, as here, the targeted rival gained market share—but less than it likely would have absent the conduct").

The panel opinion also conflicts with *Namenda*, the only other appellate decision on product hopping. In issuing an injunction preventing a brand from removing its drug from the market, the Second Circuit held that "the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act." *Namenda*, 787 F.3d at 659; *see id.* at 652 ("Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition."). *Namenda* was premised on the Supreme Court's admonition that "'antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue,'" *id.* at 658 (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004)), and case law providing that "efforts to manipulate aspects of the Hatch-Waxman incentive structure to exclude competition could state an antitrust claim." *Id.*

In contrast,[2] the panel adopted a sharply constricted approach to the role of the antitrust laws in policing anticompetitive manipulation of the pharmaceutical regulatory regime, advising lower courts to "be wary" of "second-guessing Congress's legislative judgment." Op. 40.[3] It held that product hopping involving coercion of consumers (as evidenced here by Defendants' removal of the product from the market and buying up and destroying remaining inventory) was insufficient to raise competitive concerns; rather, the panel advised lower courts to be on the lookout for "extreme coercion" or "blatant misrepresentations." *Id.* at 41.

The panel reached out to define narrowly the contours of liability for product hopping though this case was not a "close call" because Mylan was not foreclosed from the market and therefore failed to satisfy even the first step in the *Microsoft* framework (anticompetitive harm). *Id.* And although the panel

[2] The panel distinguished *Namenda* on the basis that "there were no patent cliffs on the horizon" here. Op. 38. However, the Hatch-Waxman Act and state drug substitution laws seek to promote generic competition whether or not a brand drug was ever patented. And unpatented drugs can have significant monopolies, due in part to the regulatory restrictions on entry. Moreover, insofar as a generic in this case entered prior to Defendants' withdrawal of its capsules from the market, whatever "freedom" consumers had to request that their physician write a prescription for the generic product was short lived if, as Mylan suggests, Defendants' withdrawal of the capsule from the market caused the generic capsule entrant to abort its entry. *Cf. Namenda*, 787 F.3d at 648 (finding coercion even though "withdrawn" drug was still available if doctor filled out form stating it was medically necessary).

[3] *See id.* at 40 n.88 (noting that "Congress could have chosen to bar or significantly restrict name-brand manufacturers from making changes that would delay generic entry, but it did not do so").

acknowledged that the "District Court found . . . that Defendants had indeed made the Doryx 'hops' primarily to 'delay generic market entry,'"[4] it inexplicably went out of its way to resolve *against Mylan* disputed issues of fact as to whether Defendants' justifications were pretextual.[5] Indeed, having decided there was no monopoly power, the entire discussion of exclusionary conduct is unnecessary dicta that will serve only to provide cover to anticompetitive product-hopping strategies.[6]

II. The Panel's Ruling on Monopoly Power Warrants Rehearing

Courts, legal commentators, and economists agree that while a violation of Section 2 requires both monopoly power and exclusionary conduct, proof that a defendant has engaged in exclusionary conduct *that raises prices above the level that*

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[4] Op. 18. The panel also noted that "documents may imply that Defendants were motivated by an intent to *compete* with generics," by which the panel apparently meant *prevent competition* from generics. *Id.* at 37 n.80 (emphasis added).

[5] The panel asserted that Defendants offered "strong evidence of non-pretextual purposes for their various product changes." Op. 37. It is not clear how the court resolved the conflicting evidence of Defendants' anticompetitive intent and purported justifications. In any event, the panel failed to connect the justifications with Defendants' destruction and buying back of their products, behavior that makes no economic sense absent the harm to generic competition. *See Trinko*, 540 U.S. at 408 (profit sacrifice establishes anticompetitive intent); Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 91 Notre Dame L. Rev. (forthcoming 2016) (manuscript at 54-55), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2747526 (explaining why Doryx product hops fail "no economic sense" test).

[6] The exclusionary conduct ruling also was not necessary to resolve Mylan's Section 1 and tortious interference claims and therefore should be withdrawn.

would have prevailed absent the conduct is sufficient to establish a violation of Section 2. That is because proof of such conduct and its effect establishes not only the conduct element of Section 2, but also the defendant's monopoly power, which is "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956); *see Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 477 (1992) ("It is clearly reasonable to infer that Kodak has market power to raise prices and drive out competition in the aftermarkets, since respondents offer direct evidence that Kodak did so."); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 292 (6th Cir. 1898) ("The most cogent evidence that [defendants] had [market] power is the fact . . . that they exercised it."); *cf. FTC v. Actavis*, 133 S. Ct. 2223, 2236 (2013) ("where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring about that harm in practice").[7]

[7] *See also* Steven C. Salop, *The First Principles Approach to Antitrust,* Kodak*, and Antitrust at the Millennium*, 68 Antitrust L.J. 187, 188 (2000) ("market power and market definition . . . are not valued for their own sake, but rather for the roles they play in an evaluation of market effects"); Phillip Areeda, *Market Definition and Horizontal Restraints*, 52 Antitrust L.J. 553, 565 (1983) ("Once we know that significant price enhancement has occurred . . . we know that the defendant has substantial market power. At that point market definition would be superfluous and irrelevant. . . . [M]arket definition and market shares are second best to direct measurement.").

The panel ignored these basic principles by invoking dicta that direct evidence of monopoly power is "rarely available" and by failing to consider the evidence offered by Mylan that when it (and other generics) were finally able to enter on a large scale with an AB-rated generic, average prices of Doryx dropped significantly. Op. 25. Among other errors, the panel also committed the well-known "*Cellophane* fallacy" by assuming that Defendants' lost sales from price increases revealed a lack of monopoly power instead of a monopolist's inability to charge more than the monopoly price. *See Kodak*, 504 U.S. at 471.

CONCLUSION

The petition for rehearing *en banc* should be granted. At the very least, in the alternative, the panel should withdraw that part of the opinion addressing exclusionary conduct.

Respectfully submitted,

s/ Richard M. Brunell

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October 19, 2016

CERTIFICATE OF COUNSEL

I, Richard M. Brunell, hereby certify that:

1. Pursuant to Local Appellate Rule 46.1, I am member of the bar of this court;

2. This brief complies with the page limitations of Fed. R. App. P. 29 because the brief contains 7.5 pages, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Local Appellate Rule 29.1(b).

3. This brief complies with the type-face requirements of Fed. R. App. P. 32(a)(5) and type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

4. Pursuant to Local Appellate Rule 31.1(c), this document was scanned by Microsoft Defender, Version 1.22.1929.0 created on September 8, 2016, and no viruses were detected.

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Richard M. Brunell

October 19, 2016

CERTIFICATE OF SERVICE

I hereby certify that on October 19, 2016, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. To the best of my knowledge, all parties to this appeal are represented by counsel who are registered CM/ECF users and will be served electronically by the appellate CM/ECF system.

s/ Richard M. Brunell
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