No. 15-2236

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

MYLAN PHARMACEUTICALS INC.,
Plaintiff-Appellant,

v.

WARNER CHILCOTT PLC, ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court
For the Eastern District of Pennsylvania (No. 2:12-cv-03824-PD)

BRIEF FOR AMICUS CURIAE FEDERAL TRADE COMMISSION IN SUPPORT OF PLAINTIFF-APPELLANT MYLAN PHARMACEUTICALS INC.'S PETITION FOR REHEARING AND REHEARING *EN BANC*

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INTRODUCTION

The Federal Trade Commission works to ensure that consumers benefit from generic drug competition, which saved them $239 million in 2013 alone.[1] These savings are driven in part by state laws that permit or require pharmacists to substitute a typically cheaper generic drug for the more expensive brand-name drug when they fill prescriptions.[2] Efforts to obstruct the operation of generic substitution laws can raise significant competitive concerns. This case involves allegations of one such way to defeat substitution laws called "product hopping" — the practice of making trivial and non-therapeutic changes to existing drugs that make generic substitution laws inapplicable to the new formulation.

The panel generally acknowledged that product hopping could amount to anticompetitive conduct, *see* slip op. at 40-41, but several aspects of the decision's analysis are not consistent with established antitrust precedent, including decisions of this Circuit, and could be relied on by litigants to make it harder to prove future product hopping cases, to consumers' detriment. Indeed, one litigant has already invoked language in the opinion to defend against alleged anticompetitive conduct. The FTC therefore urges the Court to clarify or amend its decision to correct those

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[1] Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.*, at 1 (6th ed. 2014).

[2] FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010) ("Pay-for-Delay Report"), https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff.

misstatements of law. Although we support the petition for rehearing or rehearing *en banc*, we take no position on the ultimate merits of this case.

First, the Court should clarify that a plaintiff may seek to prove monopoly power with any type of evidence that directly shows monopoly power, not only the kinds of evidence the panel found absent here. Although the panel was correct that direct evidence demonstrating monopoly power includes proof of high price-cost margins or restricted output, under established law it also can include evidence of actual detrimental effects, such as a showing that a defendant's conduct blocked the entry of a generic product that would have decreased price significantly. Monopoly power can also be inferred from conduct that would be irrational for a firm lacking such power.

Similarly, indirect proof of monopoly power through examination of market structure is not limited to evidence showing that products are functionally interchangeable or evidence of price cross-elasticity. As this Court recently recognized in *FTC v. Penn State Hershey Medical Center*, 2016 U.S. App. LEXIS 17525 (3d Cir. Sept. 27, 2016), relevant markets should be defined to reflect evolving economic understanding, which can include frameworks such as the hypothetical monopolist test.

Second, the Court should correct the panel's analysis of exclusionary conduct. Antitrust analysis is concerned with effects on competition, not effects on

competitors. But the panel incorrectly analyzed whether Warner Chilcott engaged in exclusionary conduct by focusing on its effect on Mylan, as a competitor, rather than the effect of Warner Chilcott's alleged product hopping on competition (and ultimately consumers), which occurs through automatic substitution at the pharmacy. Further, in analyzing the exclusionary conduct at issue here, the Court should confirm that "total foreclosure" is not required to prevail on a monopolization claim.

INTEREST OF THE FEDERAL TRADE COMMISSION

The FTC is an independent agency charged with promoting a competitive marketplace and protecting consumer interests. *See* 15 U.S.C. § 41 *et seq*. As exemplified by *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013), the Commission exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry. The Commission participated as an amicus in this proceeding before both the district court and the panel.

ARGUMENT

I. THE COURT SHOULD CLARIFY THAT IT DID NOT INTEND TO LIMIT THE KINDS OF EVIDENCE USED TO ANALYZE MONOPOLY POWER

The panel concluded that, based on the factual record before it, Mylan failed to establish disputed facts that Warner Chilcott possessed monopoly power. First, it found that Mylan had failed to provide direct evidence of monopoly power. Slip

op. 28. Second, it concluded that Mylan had not shown indirect evidence of monopoly power through Warner Chilcott's share of a relevant market. The panel concluded that the market comprised all oral tetracylines, not just Doryx and its generic substitutes, and that Warner Chilcott had an approximately 18 percent share in that market. Slip op. 29-30. The FTC is not privy to the sealed evidence that underlies the panel's conclusion. Nevertheless, we are concerned that specific statements in the decision could be read — and already are being used — to prevent plaintiffs from using sound economic analysis to demonstrate monopoly power.

A. Direct Evidence of Monopoly Power

Addressing proof of monopoly power through direct evidence, the decision states that "a plaintiff must often provide an analysis of the defendant's costs, showing both that the defendant had an 'abnormally high price-cost margin' and that the defendant 'restricted output.'" Slip op. at 25-26 (quoting *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 500 (2d Cir. 2004)). It continues that "we must examine whether the record includes any proof of Defendants' market power based on supracompetitive pricing or restricted output." Slip op at 26; *see also id.* at n. 53 (declining to review Mylan's expert testimony "in the absence of clear evidence of supracompetitive prices or restricted output"). These statements suggest that only supracompetitive pricing or restricted output qualify as evidence

of direct effects, and that other evidence of direct effects will not suffice to establish monopoly power.

Under established principles of antitrust law, however, direct evidence of monopoly power is not so limited. For example, monopoly power also may be shown through direct evidence of detrimental effects. "Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (quoting 7 Phillip E. Areeda, *Antitrust Law* ¶ 1511, at 429 (1986)). As Justice Breyer observed in *California Dental Association v. FTC*, 526 U.S. 756, 793 (1999) (Breyer, J., concurring in part, dissenting in part), the ultimate purpose of the monopoly power inquiry is to determine whether the conduct at issue makes a "real world difference" to consumers.

Thus, where a plaintiff alleges competitive harm from a brand-name drug manufacturer's eliminating or limiting generic competition through product hopping or other exclusionary conduct, direct evidence of monopoly power could include evidence showing that prices would have dropped had the drug not been excluded from the market. Before generic entry, a branded drug may compete to a

limited degree on price or some other basis with other products used to treat the same condition. But prices drop radically once generics enter the market — 85 percent on average, and generics capture about 90 percent of unit sales. *See* Pay-for-Delay Report at 8. The competitive effect of generic entry shows that generics are uniquely close competitors to their brand-name counterpart and that other drugs on the market were less close competitors. Indeed, if other drugs had offered the same degree of competition as the generic, prices would already have been driven down and generic entry would not have such an enormous impact on price and market share. Product strategies precluding or reducing generic competition therefore can make a "real world difference" to consumers by allowing the brand to sustain higher prices.

The brand-name manufacturer's own conduct may also provide direct evidence of monopoly power. For example, in *Actavis*, the Supreme Court observed that the willingness of a branded drug manufacturer to pay would-be generic competitors to stay out of the market is by itself a "strong indicator of power" over prices. 133 S. Ct. at 2236 (quoting 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046, at 351 (3d ed. 2012)); *see also King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015).

The same logic applies to product hopping. A company making trivial and therapeutically insubstantial changes merely to prevent or delay generic entry

would not benefit from that behavior unless it had monopoly power that it was trying to protect. *See* 2B Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 520b2, at 214 (4th ed. 2014) ("Market power can sometimes be inferred from an exclusionary practice that would not be a rational act for a firm lacking significant power."). The most natural explanation for product hopping is that the brand-name manufacturer wants to maintain profits that a generic would undermine and no *alternative* drug had yet disciplined.

To minimize the risk that the panel decision will be misunderstood, the Court should clarify that a party may establish direct evidence of monopoly power not only by showing supracompetitive prices or restricted output, but also by demonstrating other actual detrimental effects or conduct that would be irrational absent monopoly power.

B. Indirect Evidence of Monopoly Power

The decision correctly recognized that monopoly power may also be proven through indirect evidence, including high market shares in a defined relevant market. Slip op. at 28-29. It continued that this analysis involves an assessment of "the reasonable interchangeability of use between a product and its substitute" and the products' "cross-elasticity of demand." *Id.* at 29 (quotations and citations omitted). The FTC is concerned that these statements can be read, and are being

used, to place unwarranted emphasis on the role of product interchangeability in defining relevant markets.[3]

Interchangeability is relevant to market definition, but it does not end the analysis. *See, e.g.*, *Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 58 (D.D.C. 2009) (functional interchangeability probative but "certainly not dispositive"). The critical question is whether interchangeability disciplines prices. Where it does not, the relevant market must exclude even functionally interchangeable products. *See Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (relevant market limited to generic version of brand-name drug); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064-65 (3d Cir. 1978) (despite some functional interchangeability among antibiotics, specific class of antibiotics represented a separate product market based on a lack of cross-elasticity); *United States v. Archer-Daniels-Midland Corp.*, 866 F.2d 242, 248 (8th Cir. 1988) (functionally interchangeable sweeteners were in separate product markets because "a small change in the price of [one] would have little or no effect on the demand for [the other]").

[3] For example, the defendants in *In re Asacol Antitrust Litigation* have cited the decision to suggest that a brand-name and generic product market cannot be a relevant market and that the district court should focus solely on interchangeability. *In re Asacol Antitrust Litig.*, Memorandum of Law in Support of Defendants Motion to Dismiss, No. 1:15-cv-12730 (D. Mass. Oct. 11, 2016).

More generally, an exclusive focus on product interchangeability is contrary to this Court's recent recognition in *Penn State Hershey Medical Center*, that antitrust analysis of a practice must account for its economic and competitive consequences. 2016 U.S. App. LEXIS 17525, at *11. In *Hershey*, for example, the Court defined the relevant market using the hypothetical monopolist test, "a common method employed by courts and the FTC" as part of its competitive effects analysis. *Id.* at *15. Under that test, a proposed market is properly defined "if a hypothetical monopolist could impose a small but significant non-transitory increase in price ('SSNIP') in the proposed market." *Id.* at *14-*15. Thus, in the context of evaluating the competitive impact of conduct preventing or limiting generic competition, evidence that a hypothetical monopolist could profitably raise prices if it controlled the brand and generic versions of a drug would be relevant to defining the relevant market.

The Court should clarify that market definition can be shown not only through evidence of interchangeability and cross-price elasticity of products but also in other economically sound ways.

II. THE PANEL IMPROPERLY FOCUSED ON THE EFFECT OF PRODUCT HOPPING ON MYLAN RATHER THAN ITS OVERALL EFFECT ON COMPETITION

The panel concluded that "Mylan was advantaged in the generic market" and "reaped generous profits from its sales of the generic tablet, in the amount of $146.9 million." Slip op. at 36-37 & n. 79. Extrapolating from those sales, the

panel held that Warner Chilcott's product hopping was not exclusionary because Mylan was not foreclosed from the market. Slip op. at 36. That analysis suffers from two flaws.

First, the principal concern in a case under Section 2 of the Sherman Act is whether the complained-of conduct harms competition, not whether it harms a competitor. *Aspen Skiing v. Aspen Highlands Skiing*, 472 U.S. 585, 602 (1985); *Brown Shoe Co., Inc. v. United States*, 370 U.S. 294, 308 (1962); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005). The panel erred because, instead of examining the effect of Warner Chilcott's product hopping on *competition*, it focused on the impact of that behavior on *Mylan*.

Second, the panel misunderstood the degree of foreclosure necessary to prove exclusionary conduct. A monopolist acts anticompetitively if, "through something other than competition on the merits," it protects its monopoly by "significantly reducing usage of rivals' products." *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (*en banc*); *see also Broadcom*, 501 F.3d at 308; *Dentsply Int'l, Inc.*, 399 F.3d at 187, 191. Such exclusion may occur when the monopolist forces rivals into less efficient distribution channels, materially raises their costs of doing business, and thereby maintains its own monopoly power. *See, e.g.*, *Dentsply*, 399 F.3d at 191; *McWane, Inc. v. FTC*, 783 F.3d 814, 832-33 (11th

Cir. 2015); *Microsoft*, 253 F.3d at 69-71; *see also Lorain Journal Co. v. United States*, 342 U.S. 143, 149-50 (1951). In those circumstances, "[c]onsumer injury results from the delay that the dominant firm imposes on the smaller rival's growth" and thus the rival's ability to discipline the monopolist's prices. *Dentsply*, 399 F.3d at 191 (quoting Herbert Hovenkamp, *Antitrust Law* ¶ 1802c, at 64 (2d ed. 2002)).

The panel failed to examine whether Warner Chilcott competed on the merits in barring Mylan from its most cost-efficient means of competing — automatic substitution. Slip op. at 18. Mylan's sales of some amount of its generic product do not disprove that Warner Chilcott harmed competition by thwarting far greater sales via automatic substitution. Under *Dentsply* "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Dentsply* 399 F.3d at 191. As the Second Circuit has explained, "generics need not be barred 'from all means of distribution' if they are 'bar[red] ... from the cost-efficient ones.'" *New York v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015) (quoting *Microsoft*, 253 F.3d at 64, and citing *Dentsply*, 399 F.3d at 191). This Court similarly explained in *Dentsply* that the question is not whether a monopolist's conduct forecloses all "possible" distribution options, but

whether the remaining options are "practical or feasible" in the market "as it exists and functions." 399 F.3d at 193.

The panel's analytical approach cannot be squared with *Denstply*, *Microsoft* and the other foreclosure cases. The Court found that Warner Chilcott's conduct was not anticompetitive because Mylan could have undertaken costly and inefficient marketing of its generic once Warner Chilcott thwarted automatic substitution. Slip op. at 36 n.79. In other words, the panel held that a brand company cannot face antitrust liability when it destroys the overwhelmingly most efficient means of generic distribution — automatic substitution — so long as generics could theoretically still pursue more costly distribution alternatives. That determination ignores the commercial reality of the pharmaceutical marketplace and lacks grounding in antitrust law.

CONCLUSION

The Court should grant the petition for rehearing.

Respectfully submitted,

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October 19, 2016

COMBINED CERTIFICATES – CASE 15-2236
BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMMISSION IN SUPPORT OF PETITION FOR REHEARING AND REHEARING *EN BANC* OF PLAINTIFF-APPELLANT MYLAN PHARMACEUTICALS INC.

I hereby certify that:

1. This brief complies with the type-volume limitation of Amended Fed. R. Civ. P. 29(b) and L.A.R. 29.1(b). It has 2,564 words as counted by Microsoft Word 2010.

2. The electronic version of this brief is in PDF and was scanned using Symantec Endpoint Protection Version 12.1.6 with virus definitions updated October 19, 2016. No viruses were detected.

3. I filed the electronic version of this brief with the Court via the CM/ECF system. The Notice of Docket Activity generated by CM/ECF system constitutes service upon all Filing Users in this proceeding. The docket for this proceeding indicates that all parties are Filing Users.

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

/s/ Mark S. Hegedus
Mark S. Hegedus

DATE: October 19, 2016