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 SUPPORTING PLAINTIFF-APPELLANT

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INTRODUCTION

Generic competition saves American consumers hundreds of billions of dollars in prescription drug costs each year. Brand-name drug companies use various strategies—some lawful and some not—to avoid such competition and maintain high profits. In one such strategy, called "product-hopping," a brand-name manufacturer makes minor changes to a drug and, to thwart generic substitution at pharmacies, takes calculated steps to damage the market for the original formulation before generic entry. The defendants here are alleged to have engaged in such a strategy in violation of the Sherman Act. As the nation's main antitrust enforcer for the pharmaceutical industry, the Federal Trade Commission submits this brief to highlight the distinct economic and legal dimensions of product-hopping disputes. This brief takes no position on the ultimate merits of this case but explains that, in the FTC's view, the district court made significant analytical errors in ruling for the defendants on summary judgment.

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. It also makes use of its broad statutory authority to

gather market-wide information directly from businesses and other market participants to prepare "systematic, institutional stud[ies] of real-world industries and activities."[1] Of particular relevance here, the Commission has issued a variety of empirical studies addressing the competitive dynamics of generic substitution for brand-name drugs.[2] Because of its enforcement responsibilities and deep background in generic drug competition, the Commission filed an amicus brief in the district court proceedings, opposing defendants' motion to dismiss.

STATEMENT OF THE CASE

1. Prescription Drugs and Generic Competition

Before marketing a new drug, a pharmaceutical manufacturer must file a "new drug application" ("NDA") with the Food and Drug Administration and

[1] *Report of the ABA Section of Antitrust Law Special Committee*, 58 Antitrust L.J. 43, 103 (1989); *see* 15 U.S.C. § 46(b). The Supreme Court and this Court have frequently relied on such FTC studies. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 n.21 (3d Cir. 2015).

[2] *See* FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011) ("*AG Report*"), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf; Allison Masson & Robert L. Steiner, FTC, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* at 8-13 (1985) ("*Masson & Steiner*"), https://www.ftc.gov/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection; FTC, *Drug Product Selection*, Staff Report, Bureau of Consumer Protection (1979) ("*Drug Product Selection*"), http://catalog.hathitrust.org/Record/000258518.

obtain FDA approval. 21 U.S.C. § 355(b). A drug approved under the NDA process is often called a "brand-name" drug.

Before 1984, a generic drug manufacturer had to undertake the same NDA process as a brand-name drugmaker. That requirement deterred generic entry because the NDA process is costly and can take many years to complete. To address that concern, Congress enacted legislation in 1984, known informally as the Hatch-Waxman Act, that promotes competition while continuing to encourage innovation.[3] Among its other provisions, the Hatch-Waxman Act enables generic manufacturers to use a streamlined process to obtain FDA approval for generic versions of previously introduced brand-name drugs. Specifically, the Act allows generic manufacturers to file Abbreviated New Drug Applications ("ANDAs") that rely on brand manufacturers' existing safety and efficacy studies, reducing the costs of generic drug development and expediting the FDA approval process. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iii), (iv); *see also* note 9, *infra* (discussing other Hatch-Waxman provisions).

Because of regulatory constraints on the distribution of prescription drugs to individual consumers, FDA approval by itself does not allow generic drugs to compete efficiently with brand-name prescription drugs. In most other markets,

[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified at various sections of Titles 15, 21, 28, and 35 of the U.S. Code).

consumers select, pay for, and use the products of their choice, and competition for their business keeps prices competitive. That dynamic is absent in the prescription drug marketplace. By law, a consumer cannot obtain prescription drugs without the approval of a third party—a prescribing physician. And the physician typically has little incentive to consider the price of those drugs: she does not pay for them, and indeed payment is often the principal responsibility of yet another third party, such as an insurance company.

In short, "the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescriptions." *Drug Product Selection* at 2-3; *accord New York v. Actavis PLC*, 787 F.3d 638, 645-46 (2d Cir. 2015) ("*Namenda*"). Empirical studies confirm that physicians are often poorly informed about drug prices and the availability of cheaper alternatives.[4] And even though generic drug companies could seek to change physicians' prescription behavior by marketing to them, the marketing of generic drugs is often "impractical and ineffective" (*Namenda*, 787 F.3d at 656) for reasons specific to the pharmaceutical

[4] Fiona Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the U.S. Pharmaceutical Industry*, 18 Int'l J. Indus. Org. 1085, 1086-87 (2000); *see also* G. Michael Allen et al., *Physician Awareness of Drug Cost: A Systematic Review*, 4 PLOS Med. 1486, 1486 (2007).

marketplace. *See* pp. 24-25, *infra*. Moreover, deploying resources to marketing activities could undermine the generic companies' ability to offer lower-priced alternatives to brand drugs. *See Namenda*, 787 F.3d at 656 n.30.

Since the late 1970s, state legislatures throughout the country have sought to address the prescriber-payor pricing disconnect by enacting laws that enable (and sometimes require) a pharmacist to substitute a therapeutically equivalent generic drug (known as an "AB-rated" drug) when presented with a prescription for a brand-name drug, unless a physician directs or the patient requests otherwise.[5] These substitution laws foster price competition by allowing parties "who have financial incentives to make price comparisons—the pharmacist and the patient—to select drug products on the basis of price." *Drug Product Selection* at 7. For example, retail pharmacies have financial incentives to make efficient generic substitutions because they compete with other pharmacies on price and because they earn greater profits on generics than brand-name drugs. *See Masson & Steiner* at 7.

[5] The FDA grants a generic drug an "AB rating" if the drug contains the same active pharmaceutical ingredient as the branded drug, has the same dosage and form, and exhibits a similar rate and extent of absorption as the brand product. As a practical matter, that FDA determination triggers state automatic-substitution laws for particular drugs. *See Namenda*, 787 F.3d at 645. Today, all states and the District of Columbia have such laws. *See id.* at 644-45.

Once unleashed, generic competition sharply lowers drug prices. In 2014, brand-name drugs accounted for 12 percent of total prescriptions but nearly 72 percent of total consumer spending ($374 billion) on prescription drugs. IMS Inst. for Healthcare Informatics, *Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014*, at 5, 15 (Apr. 2015). That disparity arises from, *inter alia*, the monopoly prices that pharmaceutical companies charge for certain brand-name drug products and the much lower prices that prevail once generics enter.

As FTC studies reveal, the first generic version of a given drug on the market is priced, on average, nearly 15 percent lower than the brand-name drug. *See AG Report* at ii-iii. After additional generic competitors enter, generic prices ultimately end up 85 percent lower on average than the brand-name manufacturers' original prices.[6] And, because of automatic substitution at the pharmacy, a brand-name drug ultimately loses on average about 90 percent of its market share (by unit sales) to its generic competitors. *Pay-for-Delay Report* at 8. The Congressional

[6] 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; *see also* William H. Shrank et al., *The Consequences of Requesting "Dispense as Written,"* 124 Am. J. Med. 309, 311 (2011).

Budget Office and other researchers have reached similar conclusions.[7] In short, consumers benefit enormously from generic competition, saving about $239 billion in 2013 alone.[8]

This is not to say that competition policy should focus single-mindedly on lowering prices. For example, patent law creates incentives for innovation by granting inventors rights of exclusivity and enabling them to earn high profits during the patent term. But Congress limited patent rights to a fixed period of years because it concluded that, beyond that period, consumers' interests in competitive pricing outweigh whatever incremental innovation incentives a longer patent term would create. And because Congress also understood that some drug patents are weak or narrow, the Hatch-Waxman Act contains provisions that encourage generic manufacturers to challenge the patents claimed for brand-name drugs. *See Actavis*, 133 S. Ct. at 2228-29; *see also id.* at 2233 (recognizing "patent-related policy of eliminating unwarranted patent grants so the public will

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[7] *See* CBO, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii, 28 (Jul. 1998); Murray L. Aitken et al., *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity*, National Bureau of Economic Research (Oct. 2013); Henry G. Grabowski and John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J. L. & Econ. 331 (1992).

[8] Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.*, at 1 (6th ed. 2014); *see also* U.S. Gov't Accountability Off., *Report No. GAO-12-371R, Savings from Generic Drug Use* 9-11 (2012), http://www.gao.gov/assets/590/588064.pdf.

not 'continually be required to pay tribute to would-be monopolists without need or justification'") (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).[9]

2. Efforts to Impede Generic Entry Through "Product Hopping"

This case involves allegations that a drug company unlawfully suppressed generic competition and maintained its monopoly power through a strategy called "product hopping." A typical product-hopping scheme works as follows. A brand-name pharmaceutical company expects generic rivals to win FDA approval to compete with the company's profitable brand-name drug using automatically substitutable AB-rated equivalents. To thwart such substitution, the brand-name company introduces minor changes to the drug's formulation, such as therapeutically insignificant tweaks to dosage levels or to the form of administration (*e.g.*, capsules vs. tablets).

Before generic equivalents have a chance to enter, the brand-name manufacturer then takes various steps to extinguish demand for the original version. For example, the manufacturer might restrict or eliminate the supply of the original formulation, increase its effective price to patients, or flood physician

[9] The Hatch-Waxman Act provides procedural mechanisms that apply when a company seeks FDA approval to market a generic product before expiration of patents claimed to cover the counterpart brand-name drug. *See Actavis*, 133 S. Ct. at 2228-29. For example, if the brand-name manufacturer promptly files a patent suit, the FDA generally may not approve the generic company's ANDA for 30 months.

offices with free samples of the revised formulation but not the original to divert prescriptions to the revised formulation. That shift in prescriptions is generally a one-way street: once doctors prescribe a medicine and find that it works, they are generally reluctant to switch users back to the original formulation even if a cheaper generic version of it later becomes available.[10] Theoretically, third-party payors (*e.g.*, insurers) should have incentives to persuade physicians to switch patients back to generic versions of the original drugs—for example, by announcing that they will deny coverage when a patient shows up at the pharmacy with a prescription for the more expensive new formulation. Empirical research suggests, however, that such efforts have been generally ineffective in influencing physicians' responses to product-hopping behavior.[11]

Shifting the market to the reformulated product in this manner can thwart generic entry. As noted, effective generic competition generally depends on

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[10] *See Namenda*, 787 F.3d at 656 (because switching back to prior formulations presents "high transaction costs," it can be "very unlikely" to occur); *see also* Susan L. Coyle, *Physician-Industry Relations, Part I: Individual Physicians*, 136 Annals of Internal Med. 396, 398 (2002). ("[O]nce a patient exhausts a free supply of medication, the physician typically writes a prescription for the same brand.").

[11] *See* Aaron Gal, *Why Does Lifecycle Management Still Work?* Bernstein Research (Jun. 14, 2013) (available on request) (reformulated drugs "have consistently maintained their script levels after generics to the first generation drugs launched … despite very minor clinical difference between the two drugs and substantial difference in prices. It thus appears that while care managers have the ability to influence 'forward switches', they are unable to 'back-switch' drug markets."); *see also Namenda*, 787 F.3d at 656.

automatic substitution at the pharmacy. But automatic substitution ordinarily requires an FDA determination of therapeutic equivalence—an "AB rating." In general, because an AB rating is specific to dosage and form, a pharmacist cannot automatically substitute a generic drug that differs even slightly from the dosage or form of the prescribed brand-name drug.[12] Thus, if a brand-name manufacturer tweaks its brand-name product shortly before anticipated generic entry and begins eliminating the market for the original formulation, it can impede competition from would-be generic entrants, which have sought FDA approval to sell a generic version only of the original formulation and not the replacement. The foiled generic entrant can try to make conforming changes to its own product, but it cannot sell its reformulated version without restarting the FDA approval process (and under certain circumstances provoking patent litigation and automatic regulatory stays (*see* note 10, *supra*)). The brand-name manufacturer's well-timed tweaks to its drugs can thus create an ever-retreating horizon of generic competition at the expense of consumers.

[12] *See*, *e.g.*, Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 Houston J. Health & Pol'y 379, 398 (2007).

3. Warner Chilcott's Alleged Product-Hopping and the District Court Decision

The product-hopping scheme alleged in this case involves delayed-release doxycycline hyclate, a prescription drug used primarily to treat severe acne. JA.17. Defendant Warner Chilcott markets a brand-name form of the drug sold under the name Doryx; plaintiff Mylan sought to market a generic version.

Mylan alleges that, before generic entry, Warner Chilcott engaged in an anticompetitive product-hopping scheme by curtailing the availability of the original formulation in order to shift the market to three successive product reformulations that, according to Mylan, offered little or no therapeutic benefit to consumers. *See* Mylan Br. 8-17. Mylan claims that this conduct impeded meaningful generic competition and preserved Warner Chilcott's monopoly profits, not because the market valued the reformulations on the merits, but because Warner Chilcott had successfully manipulated the pharmaceutical regulatory system.

After discovery, the district court granted summary judgment to Warner Chilcott. The court first concluded that no reasonable juror could find on this record that Warner Chilcott had monopoly power, given what the court deemed "uncontradicted evidence" of "the interchangeability of Doryx with other oral tetracyclines." JA.31. The court further held that, even if Warner Chilcott had monopoly power, the product-hopping scheme would not have violated the

Sherman Act. The court accepted *arguendo* Mylan's claims that Warner Chilcott "made the Doryx 'hops' … primarily to defeat generic competition" and that the hops "prevented Mylan from taking advantage of more profitable means of distributing its generic Doryx." JA.25, 40. But the court nonetheless held that Mylan could have competed against Warner Chilcott through means other than automatic substitution and faulted Mylan for not promoting its generic versions of Doryx through, for example, advertising and marketing. JA.38-39. The court further characterized automatic substitution as a "regulatory windfall" to generic manufacturers and concluded that Warner Chilcott's efforts to deny Mylan the benefits of that mere "windfall" were "hardly predatory." JA.47.

SUMMARY OF ARGUMENT

1. The district court's analysis of the threshold monopoly-power question foundered on a basic misunderstanding of the special characteristics of the pharmaceutical marketplace. Generics are unique sources of competition for brand-name prescription drugs. Without automatic substitution, the disconnect between prescribing physicians and payors often insulates brand-name prescription drugs from effective price competition, and a given drug may be priced at monopoly levels even if other drugs are therapeutically similar. The district court here thus erred when, in granting summary judgment, it relied heavily on evidence that Doryx is therapeutically similar to other antibiotics.

The court further contradicted established antitrust doctrine when it concluded that evidence of price-related substitution among these drugs showed that Doryx was priced at competitive levels. As courts have long understood, even when a product is priced at a profit-maximizing *monopoly* level, further price increases from that level will nonetheless trigger substitution to other, increasingly distant products. Warner Chilcott's high profit margins make that possibility, if anything, more likely.

Finally, the very fact of product-hopping can itself be evidence of monopoly power. The manufacturer of a brand-name drug generally undertakes a product hop to preserve high profits that generic versions of the same drug would undercut but that no alternative drug, competing in the same market, has yet disciplined. If such a broader market existed, competition from those alternative drugs should already have driven down the price for the brand-name drug, and a brand company would thus normally have little incentive to make minor product changes solely to defeat generic entry.

2. The district court also erred in its analysis of exclusionary conduct. Under established Sherman Act precedent, a monopolist's conduct is unlawful if, without countervailing procompetitive justifications, it raises rivals' costs by depriving them of their most efficient distribution mechanisms and thus harms

consumers by impeding the rivals' competitive ability to discipline monopoly prices.

As the Second Circuit recently held in *Namenda*, that principle applies to anticompetitive product hops, which deprive generics of their most—indeed, often their only—efficient distribution mechanism: automatic substitution at the pharmacy. The district court here was wrong to dismiss automatic substitution as a mere "regulatory windfall" undeserving of antitrust protection. State and federal laws facilitate automatic substitution as an efficient solution to the regulation-induced disconnect between the physicians who choose drugs and the market actors who pay for them. And a monopolist may not avoid antitrust liability simply because the efficient distribution mechanism it destroys was created in part by procompetitive government action.

Contrary to the district court's suggestion, policies favoring innovation do not categorically preclude antitrust liability for product-hopping. In well-functioning markets, a modified product's success is typically evidence that consumers value the innovation. A similar inference is not always warranted in the pharmaceutical marketplace, however, because the physicians who choose prescription drugs do not pay for them and thus do not internalize the economic costs of anticompetitive product modifications. As the Second Circuit held in *Namenda*, pharmaceutical innovation is also unlikely to be chilled simply because

antitrust law holds brand-name manufacturers liable when they make minor product tweaks to avoid automatic substitution and take calculated steps to damage or destroy the market for the original formulation.

ARGUMENT

A plaintiff alleging unlawful monopolization under Section 2 of the Sherman Act must prove two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power" through anticompetitive means, as distinct from competition on the merits. *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). This brief addresses those two elements in turn. The FTC offers no views on how a factfinder should ultimately resolve this case but explains why the district court's grant of summary judgment rested on fundamentally flawed reasoning.

I. THE DISTRICT COURT ERRED BY IGNORING THE UNIQUE CHARACTERISTICS OF PHARMACEUTICAL MARKETS IN ITS ANALYSIS OF MONOPOLY POWER

"Monopoly power is 'the power to control prices or exclude competition.'" *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 380 (3d Cir. 2005) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956)). Monopoly power may be established through direct evidence, such as "prices substantially above the competitive level," *United States v. Microsoft*

Corp., 253 F.3d 34, 51 (D.C. Cir. 2001) (*en banc*), or indirect evidence, such as a large share of a relevant market subject to entry barriers. *See Broadcom*, 501 F.3d at 307 (citing *Microsoft* and *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1062-63 (3d Cir. 1978)); *see also Actavis*, 133 S. Ct. at 2236 (direct evidence of anticompetitive effects can be sufficient to show market power); *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 458-61 (1986) (same).

Antitrust inquiries "must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns Inc. v. Law Office of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). That "admonition is particularly relevant in an industry, like the pharmaceutical industry, that is subject to extensive regulation in which Congress has balanced the protection of intellectual property and the need for competition." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 216-17 (3d Cir. 2012), *cert. granted, vacated and remanded sub nom. Upsher-Smith Labs., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013). Here, the "particular structure and circumstances" of the pharmaceutical industry cast serious doubt on the district court's rationale for granting summary judgment.

In general, generic prescription drugs are uniquely effective sources of competition for their brand-name counterparts. *See* pp. 6-7, *supra*. For example, generic drugs end up priced 85 percent lower on average than the corresponding brand-name drugs and capture on average about 90 percent of the market (by unit

sales). *See Pay-for-Delay Report* at 8. Generic entry has such radical competitive effects precisely because the generic is a uniquely close competitor to its brand-name counterpart, and many brand-name prescription drugs face only weak competition from other drugs. Generic entry would not have such an enormous average impact on price and market share if competition from other drugs had already driven down prices for typical brand-name drugs.

In short, price competition from other drugs is often so attenuated in the absence of automatic substitution that brand-name manufacturers can maintain "prices substantially above the competitive level," the key criterion for monopoly power. *Microsoft*, 253 F.3d at 51. That market power arises from the unique disconnect in the pharmaceutical industry between prescribers and payors—the fact that "the consumer who pays does not choose, and the physician who chooses does not pay." *Drug Product Selection* at 2-3. The most important agents of price competition are often pharmacies, empowered by state automatic-substitution laws to fill prescriptions for brand-name drugs with therapeutically equivalent generic drugs at much lower prices. But that particular source of price competition is by definition confined to a branded drug and its generic equivalents.[13]

[13] *See, e.g., In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 388-89 (D. Mass. 2013) (properly constituted market may be comprised of single product; lower courts have ruled that both brand-name drug and its generic analogs can constitute a relevant antitrust market) (internal citation omitted); *see also In re Brand Name*

The district court was thus mistaken when, on summary judgment, it found a broader market here on the basis of ostensible evidence that many dermatologists view other oral tetracyclines as therapeutically "interchangeable" with Doryx for some patients. JA.32. Functional interchangeability between products is the beginning, not the end, of the analysis.[14] At bottom, the monopoly-power analysis asks whether the prospect of substitution is strong enough to keep *prices* at competitive levels. *See, e.g.*, *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc*, 386 F.3d 485, 496 (2d Cir. 2004) ("The goal in defining the relevant market is to identify the market participants and competitive pressures that restrain an individual firm's ability to raise prices above the competitive level"). In pharmaceutical markets, the prescriber-payor disconnect often limits such price-motivated substitution, even among therapeutically similar drugs.[15]

Prescription Drugs Antitrust Litig., 186 F.3d 781, 787 (7th Cir. 1999) ("It would not be surprising, therefore, if every manufacturer of brand name prescription drugs had some market power.").

[14] *See, e.g.*, *Nexium*, 968 F. Supp. 2d at 387-88 ("[t]he reasonable interchangeability of a set of products is not dependent on the similarity of their forms or functions'") (quoting *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc.*, 508 F.2d 547, 552 (1st Cir. 1974)); *Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 58 (D.D.C. 2009) (functional interchangeability probative but "certainly not dispositive").

[15] *See, e.g.*, *Geneva Pharm.*, 386 F.3d at 496-96 (relevant market limited to generic version of brand-name drug); *SmithKline Corp.*, 575 F.2d at 1064-65 (despite some functional interchangeability among antibiotics, specific class of antibiotics represented separate product market based on a lack of cross-elasticity); *see also*

The district court further erred when it relied on evidence that Doryx sales declined in response to effective increases in its price. *See* JA.32-34. Even if there were no material issue of fact on the extent of this phenomenon, the district court was wrong to assume that competition from other drugs kept Doryx prices below monopoly levels or demonstrated that the other products fall within a relevant antitrust market for assessing the effects of the conduct at issue.[16] Price-motivated substitution is found in monopolistic markets as well as competitive ones, and here Doryx might well have been priced at monopoly levels even though further increases *above* that level triggered some substitution. Under established economic theory, buyers are sensitive to price increases in monopoly markets, as in other markets, and they therefore defect to other, increasingly distant products when price is increased.[17] As the Supreme Court has explained, therefore, "[t]he

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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]").

[16] Antitrust speaks of the "relevant" market because market definition is merely a tool to assess the competitive effects of particular conduct. *See, e.g.*, *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993); *Gen. Indus. Corp. v. Hartz Mtn. Corp.*, 810 F.2d 795, 805 (8th Cir. 1987).

[17] "[I]n seeking out a profit-maximizing price the monopolist … finds a price so high that a still further price increase would be unprofitable because too many sales would be lost. As a result, cross-elasticity of demand is high when prices are already monopolistic." *See* 2B Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 539, at 317 (4th ed. 2014). A failure to appreciate this point, and to infer a

existence of significant substitution in the event of *further* price increases or even at the *current* price does not tell us whether the defendant *already* exercises significant market power." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 471 (2002) (internal quotation marks omitted). Here, price-motivated substitution to other antibiotics is entirely consistent with the claim that Doryx was *already* priced at monopoly levels. And Warner Chilcott's profit margins—apparently as high as 83 percent at times (*see* JA.29)—provide further reason to hesitate before inferring a lack of monopoly power from such substitution, although the significance of such margins varies with the facts of each case.

Finally, the very fact that a brand-name company has executed a product-hopping strategy may itself be evidence of monopoly power. "Market power can sometimes be inferred from an exclusionary practice that would not be a rational act for a firm lacking significant power." 2B Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 520b2, at 214 (4th ed. 2014). Here, when a brand-name company makes minor changes to a drug formulation "primarily to defeat generic competition," as the district court found Warner Chilcott did, *see* JA.25, the most natural explanation is that the company wishes to maintain substantial profits that (1) generic versions of the same drug would undermine and (2) no

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competitive market from the mere fact of price-related substitution, is known as the "*Cellophane* fallacy." *See id.*

alternative drug, competing in the same market, has yet disciplined. *See Actavis*, 133 S. Ct. at 2236 (observing that expensive efforts to block generic competition can demonstrate market power); *accord King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1797, 2015 WL 356913, at *10 (E.D. Pa. Jan. 28, 2015). Otherwise, the brand-name company would likely perceive little value in executing the product hop.

Again, the FTC takes no position on whether Mylan should ultimately prevail on the monopoly-power issue; that depends on the facts. But the district court's grant of summary judgment rested on economically unsound rationales that ignore defining features of the pharmaceutical marketplace.

II. PHARMACEUTICAL PRODUCT REDESIGN CAN VIOLATE SECTION 2 OF THE SHERMAN ACT

The district court also erred in granting summary judgment on the alternative ground that, even if Warner Chilcott had monopoly power, its product hops could not have constituted "the willful … maintenance of that power" through anticompetitive means. *Broadcom*, 501 F.3d at 307 (quoting *Grinnell*, 384 U.S. at 570-71). The district court's rationale for that conclusion, too, reflects an erroneous understanding of how competition works in the pharmaceutical industry and effectively embraces a rule of nearly per se legality for product-hopping conduct. That approach contradicts the decisions of this and several other courts.

A. Product-Hopping Schemes Designed To Destroy Efficient Generic Distribution Mechanisms Can Constitute Exclusionary Conduct

A monopolist's conduct is anticompetitive if, "through something other than competition on the merits, [it] has the effect of significantly reducing usage of rivals' products and hence protecting [the] ... monopoly." *Microsoft*, 253 F.3d at 65; *see also Broadcom*, 501 F.3d at 308; *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187, 191 (3d Cir. 2005). Such conduct violates Section 2 of the Sherman Act when its anticompetitive effects outweigh its procompetitive benefits. *See Microsoft*, 253 F.3d at 58-59; 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651b5, at 107 (3d ed. 2008) (addressing "raising rivals' costs" doctrine of antitrust liability).

Unlawful exclusive-dealing arrangements—in which a monopolist ties up distribution channels to keep its rivals less efficient and protect its monopoly prices—are perhaps the best-known application of this general principle. As this Court and others have held, a monopolist supplier violates Section 2 if, without a countervailing efficiency justification, it uses exclusive dealing to force rival suppliers 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)).

Applying this same basic principle, the Second Circuit recently held in *Namenda* that a pharmaceutical manufacturer can violate Section 2 if it uses a product-hopping scheme to foreclose rival generic manufacturers from *their* most efficient distribution channel: automatic substitution at the pharmacy for AB-rated drugs. In that case, a brand-name manufacturer altered the formula for an anti-Alzheimer's drug to avoid automatic generic substitution, and it took various steps, including sharply limiting supply of the legacy version, to ensure that most physicians would prescribe only the reformulated version before the expected date of generic entry. The Second Circuit concluded that "[b]ecause Defendants' forced switch 'through something other than competition on the merits[] has the effect of significantly reducing usage of rivals' products and hence protecting its own … monopoly, it is anticompetitive.'" *Namenda*, 787 F.3d at 655 (quoting *Microsoft*, 253 F.3d at 65).

The district court's decision here, which would foreclose liability for product-hopping under virtually any circumstances, contradicts both *Namenda* and this Court's own Section 2 precedent. The district court accepted Mylan's argument that, like the brand-name manufacturer in *Namenda*, Warner Chilcott

undertook the Doryx product hops "primarily to defeat generic competition." JA.25. But the court found that "there was no exclusionary conduct" because generics could "reach consumers though, *inter alia*, advertising [or] promotion." JA.41. In other words, the district court held that a brand company may with impunity destroy what is often the only means of generic distribution—automatic substitution—so long as generics remain hypothetically free to pursue new and more costly distribution alternatives, such as direct advertising to physicians.

The Second Circuit correctly rejected a virtually identical argument in *Namenda*. "For there to be an antitrust violation," it held, "generics need not be barred 'from all means of distribution' if they are 'bar[red] ... from the cost-efficient ones.'" *Namenda*, 787 F.3d at 656 (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.

Indeed, as the *Namenda* court concluded, "competition through state drug substitution laws" is often "the *only* cost-efficient means of competing available to generic manufacturers." 787 F.3d at 655-56 (emphasis added). Because different generic companies' AB-rated products are by design mutually substitutable at the pharmacy, "a generic manufacturer promoting a product would have no way to

ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors," and thus "additional expenditures by generics on marketing would be impractical and ineffective." *Id.* at 656. And even if a generic manufacturer could expect that its marketing redounds only to its own benefit, "marketing costs [would] severely impact generic manufacturers' ability to offer the lower prices upon which they compete." *Id.* at 656 n.30.[18] In the context of therapeutically equivalent generic drugs, that outcome would thwart the efforts of Congress and the states to make such generics available to consumers by means of automatic substitution and thus without the extra costs imposed by marketing.

The district court also suggested that Warner Chilcott's efforts to shut down automatic substitution "were hardly predatory" because, in the court's view, automatic substitution is a mere "regulatory windfall." JA.47. There is no basis for either the "windfall" characterization or the court's legal conclusion. Congress and the states created automatic substitution mechanisms to correct a market failure arising from prescription drug regulation: the disconnect between the physicians who choose among drugs and the patients and insurers who pay for

[18] "Generic manufacturers are able to sell their products for lower prices because," *inter alia*, they "generally do not pay for costly advertising, marketing, and promotion." FDA, *Facts about Generic Drugs* (June 19, 2015), http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm.

them. *See* pp. 3-5, *supra*. "The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, speed[s] the introduction of low-cost generic drugs to market, thereby furthering drug competition." *Actavis*, 133 S. Ct. at 2228 (citations and internal quotation marks omitted). This legislatively sanctioned and procompetitive mechanism is now an integral component of the "particular structure and circumstances of the industry at issue," *Trinko*, 540 U.S. at 411, which antitrust law takes as given. A monopolist may not avoid antitrust liability for destroying its rivals' only efficient distribution mechanism simply because that mechanism was created in part by legislation designed precisely to enhance competition.

The Second Circuit is hardly alone in so ruling. A number of courts and leading commentators have concluded that, in various circumstances, product-hopping can violate Section 2 of the Sherman Act. *See, e.g.*, *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa.. Dec. 2014); *Abbott Labs. v. Teva Pharm.*, 432 F. Supp. 2d 408 (D. Del. 2006); Herbert Hovenkamp et al., *IP and Antitrust* § 15.3 at 15-75, 15-78.3 to 15-79 (2d ed. 2010 & Supp. 2014); Stacy Dogan & Mark Lemley, *Antitrust Law and Regulatory Gaming*, 87 Texas L. Rev. 685 (2009); *but cf. Walgreen Co. v. Astrazeneca Pharms., L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) (ruling that alleged conduct did not cause antitrust injury or harm to competition). The district court here departed from that growing

consensus by adopting broad rationales that would bar product-hopping liability in almost all circumstances.

B. Innovation Concerns, While Relevant and Important, Should Not Categorically Preclude Product-Hopping Liability

Once a plaintiff demonstrates harm to competition, the burden shifts to the defendant to show a "nonpretextual" and offsetting procompetitive justification. *Microsoft*, 253 F.3d at 59; *see, e.g.*, *Namenda*, 787 F.3d at 652. A defendant typically defends a product hop on the grounds that the revised formulation is superior to the original one and that the specter of liability would deter future pharmaceutical innovation. The district court appeared to accept that innovation concern as a basis for rejecting product-hopping liability in *any* context, no matter how trivial the proffered innovation might be in any given case and no matter how aggressively the monopolist shifts the market to a revised formulation before it can face generic substitution for the original formulation. JA.43-44. That position contradicts established antitrust doctrine. Innovation concerns are important and relevant to the antitrust analysis, but they should not categorically bar product-hopping liability.

"As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." *Microsoft*, 253 F.3d at 65; *see also Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d, 263, 281 (2d Cir. 1979). "Judicial deference to product innovation, however,

does not mean that a monopolist's product design decisions are per se lawful." *Microsoft*, 253 F.3d at 65. For example, the *en banc* D.C. Circuit unanimously held that two of Microsoft's software changes violated the Sherman Act because they had no "procompetitive justification" and served no purpose "other than protecting [Microsoft's] operating system monopoly" against nascent competition. *Id.* at 59, 67. In another case, the Federal Circuit likewise upheld a finding of antitrust liability where the evidence on product improvement was mixed but the defendant's "real reasons for modifying [its product] were to raise the cost of entry." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382 (Fed. Cir. 1998).[19]

The potential for anticompetitive product redesign is particularly acute in the pharmaceutical industry. In well-functioning markets, consumers choose the products they pay for, and the success of a product modification is thus presumed to reflect increased consumer welfare. As discussed, however, the physicians who

[19] *See also Xerox Corp. v. Media Scis., Int'l, Inc.*, 511 F. Supp. 2d 372, 387 (S.D.N.Y. 2007) (several courts have found competition-suppressing, unjustified product redesign can violate antitrust laws); Herbert Hovenkamp et al., *IP and Antitrust*, § 15.3 at 15-75 (2d ed. 2010). The Ninth Circuit appears to attach somewhat greater weight than other courts to innovation defenses in Section 2 cases. *See Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991 (9th Cir. 2010). But even the Ninth Circuit recognizes such a defense only if the "design change is an improvement," and even then, a "monopolist's discontinuation of its old technology may violate Section 2 if it effectively forces consumers to adopt its new technology." *Id.* at 1000, 1002 (internal quotation marks omitted).

choose prescription drugs do not pay for them and thus do not account for the economic costs of anticompetitive product modifications. *See Abbott Labs.*, 432 F. Supp. 2d at 422 ("[t]he nature of the pharmaceutical drug market" does not always permit "the merits of any new product [to] be tested by unfettered consumer choice"). There is thus no reason to conclude that the "success" of such modifications necessarily reflects either genuine innovation or increased consumer welfare.

Genuine pharmaceutical innovation is also unlikely to be chilled simply because antitrust law may hold brand-name manufacturers liable for minor product tweaks that have little or no therapeutic value and serve only to avoid generic competition. First, a manufacturer that incorporates a genuine innovation in its reformulated product can offer that fact as a procompetitive justification. Second, as the *Namenda* court observed, actionable product-hopping conduct typically consists not only of a product reformulation, but also calculated efforts to damage or destroy the market for the original formulation. *See Namenda*, 787 F.3d at 659 ("While *introducing* Namenda XR may be procompetitive, that argument provides no procompetitive justification for *withdrawing* Namenda IR."). A company is unlikely to face potential antitrust liability if it does not take targeted steps to damage the market for the original formulation and instead allows the marketplace itself to choose between that formulation and the modified version.

But when a brand-name company conducts an anticompetitive product hop with no countervailing justification, the benefits of antitrust enforcement—the promotion of competition and efficient pricing—outweigh any residual risk of chilling actual pharmaceutical innovation. Indeed, if anything, *foreclosing* antitrust liability in those circumstances might itself sometimes chill genuine innovation. As the Second Circuit explained, "immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant, innovations." *Id.* at 659.

In this case, Mylan argues that Warner Chilcott's product hop had no redeeming therapeutic value and was designed solely to thwart generic competition. The district court did not examine that claim on the merits; instead, it expressed broad-brush opposition to product-hopping liability in any circumstances. This Court should thus remand the case with instructions to apply the antitrust principles set forth above.

CONCLUSION

The Court should reverse and remand for further proceedings.

Respectfully submitted,

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September 30, 2015

COMBINED CERTIFICATES – CASE 15-2236
BRIEF OF AMICUS CURAIE FEDERAL TRADE COMMMISSION AS SUPPORTING OF PLAINTIFFS-APPELLANTS

I hereby certify that:

1. This brief complies with the type-volume limitation of Fed. R. Civ. P. 32(a)(7)(B) and L.A.R. 29.1(b). It has 6,767 words as counted by Microsoft Word 2010.
2. The electronic version of this brief is identical to the version sent in hard copy to this Court.
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