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.

TABLE OF CONTENTS

United States v. Grinnell Corp.
384 U.S. 563 (1966)

Rebecca S. Yoshitani & Ellen S. Cooper, Pharmaceutical Reformulation: The

gather marketwide information directly from businesses and other market participants to prepare "systematic, institutional studies 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 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

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 encourage (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 auto-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

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 singlemindedly 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

---

[7] See CBO, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 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. 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 the

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 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 a 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. The court further characterized automatic substitution as a "regulatory windfall" for 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.

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

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 p3(y)]TJ Td [( )Tjo>2 0 Tc p-]TJ /TT1 i7 Tw

The district court was thus mistaken when, on summary judgment, it found a broader market thereon 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

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.”s(h)(.if)6(h)1()-8(e)4(i)-8()-t5 Tw -260210.900.32 0 T4 ( )Tj 0.

alternative drug, competing in the same market, has yet disciplined it. *See Actavis*, 133 S. Ct. at 2236 (observing that expensive efforts to block generic competition can demonstrate market power); *cf. 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

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

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 through, 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

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/

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 ground 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 innovation concerns as a basis for rejecting product-

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.

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,

STEPHEN WEISSMAN
Deputy Director

JONATHAN E. NUECHTERLEIN
General Counsel

MARKUS H. MEIER
Assistant Director

JOEL MARCUS
Director of Litigation

BRADLEY S. ALBERT
Deputy Assistant Director

DOMINIC E. VOTE
HEATHER M. JOHNSON
Attorneys
Bureau of Competition

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.
3. The electronic version of this brief is in PDF and was scanned using Symantec Endpoint Protection Version 12.1.2.4156 with virus definitions updated September 29, 2015. No viruses were detected.
4. 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.
5. I have caused to be sent to the Court seven hard copies of this brief via