No. 15-2236

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

MYLAN PHARMACEUTICALS INC.,

Appellant,

—v.—

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

Appellees.

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

BRIEF FOR THE AMERICAN ANTITRUST INSTITUTE AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF–APPELLANT

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

INTEREST OF AMICUS CURIAE

The American Antitrust Institute ("AAI") is an independent and non-profit education, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. The AAI is managed by its Board of Directors with the guidance of an Advisory Board consisting of more than 130 prominent antitrust lawyers, law professors, economists, and business leaders. *See* http:/www.antitrustinstitute.org.[1]

The questions raised in this appeal are important to the AAI's mission, which includes the preservation of competition in prescription drug markets. The AAI has filed successful amicus briefs in cases involving "reverse payments," *see FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013); *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015), as well as "product hopping," *see New York* ex rel. *Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (*Namenda*).

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

AAI submits this brief to urge the Court to reject efforts to immunize brand-drug manufacturers from antitrust scrutiny when they engage in product hopping to game state drug substitution laws to thwart generic entry, just as the Supreme Court in *Actavis* rejected arguments that drug manufacturers should be immune from antitrust scrutiny when they use pay-for-delay agreements to game the Hatch-Waxman Act to delay generic entry.

INTRODUCTION AND SUMMARY OF ARGUMENT

The district court essentially adopted a rule of *per se* legality for product hopping. The court held that defendants' introduction of minor reformulations of the branded drug Doryx and withdrawal of older versions of the drug—for the purpose of defeating generic competition via generic substitution laws—is not "exclusionary conduct" where generic firms "remain[] able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development." Op. 25. This holding is at odds with sound antitrust policy, good economics, leading academic commentary, and the case law. Notably, the Second Circuit's recent *Namenda* decision rejected a hands-off approach towards product hopping and many of the rationales offered by the court below. The trial court also committed errors in granting summary judgment for defendants on the monopoly-power issue by failing to analyze the question in light of plaintiff's theory and evidence of competitive harm.

Courts are properly skeptical of claims that a monopolist's redesign of its product is exclusionary conduct actionable under Section 2 of the Sherman Act. *See United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc) (per curiam). After all, consumers benefit not only from low prices, but also from innovation. But "[j]udicial deference to product innovation . . . does not mean that a monopolist's product design decisions are per se lawful." *Id.* "Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). Some markets have characteristics that increase the opportunity and incentive for a monopolist to redesign its product not to benefit consumers, but to exclude rivals. The prescription drug market is one of those markets.

In *Actavis*, the Supreme Court rejected immunity for "reverse payment" settlements in prescription drug markets, in part based on "Hatch-Waxman's unique regulatory framework," which "unintentionally . . . created special incentives for collusion" to prevent the risk of generic entry. 133 S. Ct. at 2235. Likewise, state generic substitution laws create a special incentive for brand drug manufacturers to engage in anticompetitive product redesigns to thwart generic entry.

A critical characteristic of prescription drug markets is the "price disconnect," that is, the doctor chooses the product the consumer will buy, but the consumer (and/or her insurer), not the doctor, pays for the product. This leads to outcomes

that do not reflect quality/price tradeoffs that are normally expected from well-functioning markets. State generic substitution laws seek to mitigate this market failure by allowing or requiring the pharmacist (with the consumer's consent) to substitute a cheaper generic drug in lieu of the more expensive brand drug. These laws enable generic competition that leads to significant increases in consumer welfare. Product hopping can be used to impair the very mechanism (generic substitution) that the regulatory scheme has adopted to ameliorate the market failure.

Where the product-hopping scheme involves a "hard switch"—*i.e.*, the old product is removed from the market—liability is clear. *See Namenda*, 787 F.3d at 652 ("Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition."). But anticompetitive product hopping is not limited to hard switches. It can also include softer switches designed to preempt generic competition when the product reformulation is shown to have no clinical benefits, or when a product reformulation may have benefits for some consumers, but would not be introduced in a well-functioning market. In each of these circumstances one cannot rely on the market to protect consumer welfare.

The district court erroneously believed its ruling was justified because defendants' product hops did not entirely exclude generic competition. But the law is clear in this circuit and others that complete foreclosure of rivals is not required to

establish anticompetitive harm in a Section 2 case. Moreover, the court ignored Mylan's theory and evidence of anticompetitive effects, namely that by delaying meaningful generic entry, defendants' product-hopping scheme substantially increased prices for consumers and third-party payors. Fundamentally, the district court misapprehended the nature of generic substitution laws and the consequences of allowing brand manufacturers freely to thwart them with minor product reformulations. Far from a "regulatory 'bonus,'" Op. 25, these laws are "the only cost-efficient means of competing available to generic manufacturers." *Namenda*, 787 F.3d at 655–56. Market realities preclude generics or managed care companies from relying on promotional efforts to defeat product-hopping schemes.

The court also erred in suggesting that any judicial review of product hopping was problematic because courts are not well-equipped to determine whether a product reformulation's benefits outweigh its anticompetitive harms, and judicial review would harm pharmaceutical innovation. In this case, the point is irrelevant because the court assumed, for purposes of summary judgment, that the product changes and withdrawals had no procompetitive justification. As a leading treatise cogently explains, "It makes no sense to immunize patently anticompetitive behavior because of the risk that some cases might prove tough to decide. The proper standard requires deference to innovation, but not complete abdication." Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to*

Intellectual Property Law ¶15.3c1 (2d ed. 2014) (*IP and Antitrust*). In any event, the rule of reason provides an intelligible test for assessing product hopping, and provides sufficient certainty to avoid chilling innovation, whereas immunizing product hopping from antitrust scrutiny is likely to harm innovation, as *Namenda* recognizes.

The district court also erred in its analysis of monopoly power and market definition. It failed to consider these issues in light of plaintiff's theory of anticompetitive harm and the direct evidence of anticompetitive effects, i.e., that market prices fell when meaningful generic entry eventually occurred. Such direct evidence of anticompetitive effects is also powerful direct evidence of defendants' monopoly power. Contrary to the district court's conclusion, demonstrating monopoly power through direct evidence does not necessarily require proof of a defendant's fixed and marginal costs or restricted output. Finally, the district court erred by finding that evidence of cross-price elasticity between Doryx and other oral tetracyclines at *supracompetitive* prices showed that the relevant market was broader than just delayed release doxycycline hyclate (Doryx).

ARGUMENT

I. THE "PRICE DISCONNECT" PREVENTS THE MARKET FROM DETERRING ANTICOMPETITIVE PRODUCT HOPPING

Empirical research suggests the annual consumer-welfare losses from anticompetitive pharmaceutical redesigns are on the order of some tens of billions of dollars a year. *See* Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 49 Rutgers L.J. 1, 3 (2009). That is, as a result of these "product hops," which extend the life of a brand monopoly, consumers annually are paying billions more for redesigned products that bring little or no additional clinical benefit as compared to the original products they replaced.

The skeptic asks: If the high-priced redesigned product is not substantially better than the generic version of the original product, why would consumers buy the redesigned product? Won't the redesigned product fail in the market if it is not substantially better than the original product?

Understanding the economics that underlie the answer to these questions is the key to understanding why product hops are an effective way for brand manufacturers to thwart competition from generics. Understand why drug purchasers pay $2 per pill for a branded tablet when a generic capsule is available for 20¢, and one understands why product hops can be anticompetitive.

A. A "Price Disconnect" Plagues Prescription Drug Markets

The relevant economics are straightforward and well documented in the literature. In well-functioning markets, manufacturers' product design changes ordinarily lead to increased consumer welfare. When a consumer both selects and pays for the new product, she will weigh its qualities against its price and decide whether any additional cost is worth the benefit. With the price/quality trade-off in consumers' hands, manufacturers will be incentivized to make design changes that consumers are likely to value enough to pay for. New products that do not meet the "market test" will simply fail. However, these market forces break down in the prescription drug market, for reasons articulated by the Second Circuit in *Namenda*:

> Hatch–Waxman and state substitution laws were enacted, in part, because the pharmaceutical market is not a well-functioning market. . . . In the prescription drug market . . . the party who selects the drug (the doctor) does not fully bear its costs, which creates *a price disconnect*. Moreover, a patient can only obtain a prescription drug if the doctor writes a prescription for that particular drug. The doctor selects the drug, but the patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. As a result, the doctor may not know or even care about the price and generally has no incentive to take the price into account.[2] . . . As the Federal Trade Commission has explained:
>
> > The basic problem is that 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

[2] The extensive literature on doctors' insensitivity to drug prices is gathered in Shadowen, *supra*, at 10–11 & n.33.

> pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescription.

Namenda, 787 F.3d at 645–46 (quoting FTC, Bureau of Consumer Prot., *Drug Product Selection* 2–3 (1979), *available at* http://bitly/1JqKd4G) (emphasis added); *see also* Alison Masson & Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* at 5 (1985) (*FTC Generic Substitution Report*) ("The institutions of the prescription drug market are markedly different from those in most other product markets."), *available at* https://www.ftc.gov/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection.

Brand manufacturers exploit this market defect by promoting their brand products to doctors on bases other than price through armies of sales force "detailers." *See* Shadowen, *supra*, at 11 & n.36; Mark A. Hurwitz & Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 J.L. & Econ. 299, 300 (1988) ("Prescribers' weak incentives for selecting the lowest-priced brand enhance the payout to such policies.").

B. Generic-Substitution Laws Were Intended to Restore Market Forces

The Hatch-Waxman Act seeks to ensure that generics can enter the market as soon as the brand drug goes off patent, and encourages generics to challenge

such patents. *See Actavis*, 133 S. Ct. at 2228–29. But generic entry would be largely ineffective in a world without state generic-substitution laws. As the Second Circuit explained, "State substitution laws are designed to correct for th[e] price disconnect by shifting drug selection, between brand drugs and their corresponding generics from doctors, to pharmacists and patients, who have greater financial incentives to make price comparisons." *Namenda*, 787 F.3d at 646. These laws permit or require the pharmacist to dispense a cheaper generic drug in lieu of a brand drug whenever the consumer consents.

The economic insight underlying those laws is straightforward:

> Since physicians are an unlikely force behind a switch to lower-cost brands after the patent period has expired, an erosion of the patent-conferred monopoly must depend on others who have both the power and the incentive to respond to lower prices. That is the role envisioned for the drug product selection laws: to transfer some of this power to pharmacists. Consumers are the ones most interested in a lower price, and pharmacists must respond to consumer demand because of direct competition from other pharmacies on prescription prices.

FTC Generic Substitution Report, *supra*, at 7. In short, generic substitution laws "foster price competition by allowing the only principals who have financial incentives to make price comparisons—the pharmacist and the patient—to select drug products on the basis of price." FTC, *Drug Product Selection*, *supra*, at 7.

When the generic substitution system works as intended, the availability of a generic alternative effectively puts the price/quality choice back in consumers'

hands. The doctor, price insensitive and conditioned by years of brand marketing, may continue to write prescriptions for the brand product. But pursuant to the generic substitution laws, the pharmacist (with the consumer's consent) can substitute the less expensive generic. Consumers benefit from lower drug costs and lower health-insurance premiums.

C. Product Hopping Can Thwart the Generic Substitution that Would Restore Market Forces

Other aspects of the regulatory regime provide an opportunity for brand manufacturers to prevent generic substitution. As a health and safety measure, the generic substitution laws permit generic substitution only if the FDA finds that the generic product is bioequivalent (is absorbed in the body at approximately the same rate) and therapeutically equivalent (has the same active ingredient, form, dosage, strength, and safety and efficacy profile) to the brand drug. The FDA awards an "AB-rating" to a generic drug that meets these substitution criteria, meaning that the pharmacist can substitute it when presented with a prescription for the branded product. This puts a premium on the generic obtaining an "AB-rating." *See* Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 Fla. L. Rev. 1009, 1018 (2010).

Brand manufacturers like defendants can prevent generic substitution—they can game the system—by changing the dosage form of the brand product before

the generic enters the market. Then the generic product will not be AB-rated to the reformulated brand drug and will not be substitutable for it. Tweaking the dosage form prevents generic substitutability and thereby substantially impairs the generic's only viable means of competing. That tweaking also simultaneously erects a new set of regulatory barriers to entry—a years-long process of getting FDA approval for the new formulation[3] and, if the reformulation is patented, patent litigation and a 30-month stay against generic entry. *Id.* at 1018.

D. The Ability of Third-Party Payors to Induce Generic Substitution is Limited

Various market realities prevent most third-party payors from defeating product-hopping schemes. *See* Shadowen, *supra*, at 18–22. For example, competition among third-party payors to provide generous prescription drug coverage may make it difficult for a single payor to cover only the generic product and deny or restrict coverage for the reformulated product, particularly if it requires doctors to switch patients for a second time. *See Namenda*, 787 F.3d at 656 (noting that "third-party payors are reluctant to require patients to switch from a drug they are currently taking to a new drug, so health plans would be unlikely to require patients to switch to [the] less-expensive generic"). Compounding this impediment,

[3] In 2014 the median time to get FDA approval of an Abbreviated New Drug Application under Hatch-Waxman was 42 months. *See* Dept. of Health & Human Serv., Food & Drug Admin., *Justification of Estimates for Appropriations Committees for Fiscal Year 2016*, at 65, *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf.

third-party payors face their own free-rider problem in convincing doctors to change their prescription habits, since all payors would benefit. Consequently, despite the billions of dollars in lost consumer welfare, payor action to defeat anticompetitive product reformulations is very much the exception rather than the rule. *See* Shadowen, *supra*, at 19 ("Despite MCOs' theoretical ability to use disadvantaged formulary placement and other tactics to defeat anticompetitive product reformulations, they have not done so.").

II. THE DISTRICT COURT'S REASONS FOR FINDING NO EXCLUSIONARY CONDUCT ARE MISPLACED

A. Complete Foreclosure Is Not Required

The district court concluded that defendants' product hops were not anticompetitive because Mylan and other generic firms were able to enter the market, and "Mylan remains able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development." Op. 25. While recognizing that "'[t]he test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit,'" *id.* at 21 (quoting *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005), the court concluded that defendants' product hops did not "severely restrict the market's ambit." *Id.* at 24 (internal quote marks omitted).

As an initial matter, the court's reasoning is faulty because the court apparently failed to consider Mylan's theory of anticompetitive effects, which is that the

delayed entry of brand-compatible generics allowed defendants to maintain supra-competitive prices and volume. And the court likewise apparently failed to consider the best evidence in support of this theory, which is that market prices fell significantly when Mylan's AB-rated generic eventually did enter in competition with branded Doryx before defendants were able to switch the market again. Whatever the degree of foreclosure, evidence that prices would have been lower absent defendants' conduct is direct evidence that the conduct had anticompetitive effects.

Moreover, even without considering this direct evidence, the fact that Mylan and other generic firms entered and could compete in various ways is simply not dispositive. As this court explained in *Dentsply*, "[t]he proper inquiry is not whether [another distribution method] enable[s] a competitor to 'survive' but rather whether [it] 'poses a real threat' to defendant's monopoly." 399 F.3d at 193 (quoting *Microsoft*, 253 F.3d at 71); *see also McWane, Inc. v. FTC*, 783 F.3d 814, 838 (11th Cir. 2015) (fact that targeted rival entered the market and increased its market share did not prove the absence of substantial foreclosure; "monopolists [may be] liable for anticompetitive conduct where, as here, the targeted rival gained market share—but less than it likely would absent the conduct").

"For there to be an antitrust violation, generics need not be barred 'from all means of distribution' if they are 'bar[red] . . . from the cost-efficient ones.'" *Na-*

menda, 787 F.3d at 656 (quoting *Microsoft*, 253 F.3d at 64) (alteration and ellipsis in original). And "competition through state drug substitution laws is the *only* cost-efficient means of competing available to generic manufacturers." *Id.* at 655–56 (emphasis added).

Generic marketing. Generic manufacturers cannot be expected to defeat an anticompetitive product switch by spending more on marketing because they cannot profitably use detailers or other doctor-oriented marketing to get doctors to switch their prescribing from the reformulated product back to the original product. As the Second Circuit explained, "additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors." *Namenda*, 787 F.3d at 656; *see also* Shadowen, *supra*, at 15 & n.48 (explaining that "post-generic entry free-riding makes active promotion of the product by anyone—brand and generic manufacturers alike—economically infeasible").[4]

Managed care organizations' efforts to promote substitution. The district court also suggested that competition was not harmed because the "unidis-

[4] The district court also thought Mylan's substantial size advantage over the defendants militated against finding exclusionary conduct. *See* Op. 24; *id.* at 1–2 (noting that Mylan had more than twice the revenues of Warner Chilcott). While the size of the victim can certainly be relevant to the plausibility and effectiveness of a predatory strategy, it is not here because even a large victim cannot be expected to engage in unprofitable counterstrategies (such as promoting a generic drug).

puted evidence shows that managed care organizations [MCOs] promoted the substitution of lower-cost generics for branded Doryx even though they are not AB-rated." Op. 22. While it is conceivable that the structural impediments to MCOs defeating an anticompetitive product reformulation, discussed above, could be overcome in a particular case, the relevant question is whether the MCOs' promotional efforts here *were effective* in blunting the impact of the extension of defendants' monopoly through its anti-generic product reformulation strategy. If Mylan's evidence is credited, they were not. And attributing Warner Chilcott's success in maintaining its market share to its substantial promotional expenditures aimed at health care professionals, *see id.*, entirely misses the point about the price disconnect, and *confirms* that Warner Chilcott was able to exploit the market failure that the generic substitution laws seek to correct.

"Regulatory bonus." According to the district court, Mylan, instead of using "advertising, promotion, cost competition, or superior product development," "seeks to take advantage of generic substitution laws and thus increase its profits. Defendants have no duty to facilitate Mylan's business plan by keeping older versions of branded Doryx on the market. *See Verizon Commc'ns Inc.*, 540 U.S. at 415 (no general duty to aid competitors). Defendants certainly did not exclude competition by denying Mylan the opportunity to take advantage of a regulatory 'bonus.'" Op. 25.

However, as explained above, "price competition at the pharmacy, facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States." *Namenda*, 787 F.3d at 655 (internal quotations and brackets omitted). Drug substitution laws are not a "regulatory windfall" that allows generics such as Mylan to avoid promotion costs in the face of brand manufacturers' "considerable efforts to promote" their branded drugs. Op. 22, 31. Rather, as the Second Circuit explained,

> [W]hat Defendants call "free riding"—generic substitution by pharmacists following the end of [the brand drug's] exclusivity period—is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch–Waxman Act by promoting drug competition, and by preventing the practical extension of brand drug manufacturers' monopoly . . . .

Id. at 657–58 (citation, internal quotation marks, and brackets omitted). Again, the district court's argument ignores the price disconnect. Drug substitution laws are not some supra-competitive regulatory bonus. They *restore* competition that otherwise would not exist due to the price disconnect. Anticompetitive product hopping undermines the generic substitution that those laws foster, and thus prevents the restoration of competition to *normal* levels.

B. The Rule of Reason Provides an Intelligible Test for Assessing Product Hopping

Other circuits have recognized the need for skepticism "'about claims that competition has been harmed by a dominant firm's product design changes,'" *Na-*

menda, 787 F.3d at 652 (quoting *Microsoft*, 253 F.3d at 65), and the challenges of evaluating the technical merits of such changes, but have nonetheless considered the rule of reason up to the task. *Id.* (noting that in *Microsoft*, "the D.C. Circuit, sitting en banc, established a helpful framework for determining when a product change violates § 2 based on the rule-of-reason test"); *see also C.R. Bard, Inc. v M3 Sys*., *Inc.,* 157 F.3d 1340, 1382 (Fed. Cir. 1998) (upholding liability for design change where procompetitive justification was pretextual).

One important limiting factor is the nature of the market at issue. Microsoft redesigned its operating system so that Netscape's rival Internet browser would not be compatible with the system. The strong "network effects" and installed base of existing Microsoft customers impaired free consumer choice and thereby increased the importance of compatibility between Microsoft's operating system and rivals' internet browsers. Professor Hovenkamp explains that in *Microsoft* this "premium on compatibility" allowed "a dominant firm . . . [to] exclude rivals anticompetitively by engineering incompatibilities between the dominant product and the product offered by rivals." IIIB Phillip Areeda & Herbert Hovenkamp, *Antitrust Law* ¶776c, at 297 (3d ed. 2008). In markets with significant network externalities, compatibility may be "a key to market success." *Id.* Consequently, the premium on compatibility "increas[ed] both the incentive and the opportunities" for an-

ticompetitive product redesigns. *Id.* These economic realities supported antitrust scrutiny of Microsoft's product redesigns under the rule of reason.

Like the network effects in *Microsoft*, the price disconnect in the pharmaceutical market prevents consumers from making the relevant price/quality choice and thus heightens the importance of compatibility—AB substitutability—of generic drugs. Just as in *Microsoft*, the brand-drug monopolist has the ability and incentive to redesign the product with anticompetitive effect, and its redesign therefore must be subject to antitrust scrutiny.[5] *See Actavis*, 133 S. Ct. at 2235 (regulatory framework for pharmaceuticals "unintentionally . . . created special incentives" for anticompetitive conduct); *Namenda*, 787 F.3d at 658 & n.34 ("Leading antitrust authorities have encouraged courts to acknowledge market defects, such as a price disconnect and the exclusivity of patents, in their antitrust analysis."); *Abbott Labs. v. Teva Pharm. USA, Inc.,* 432 F. Supp. 2d 408, 422 (D. Del. 2006) ("The nature of the pharmaceutical drug market . . . persuades me that the rule of reason approach should be applied here . . . .").

The district court nonetheless believed that the rule of reason is overbroad because "[*a*]*ny* time a pharmaceutical manufacturer changes the formulation of a

[5] The district court thought that *Microsoft* was inapposite because Mylan competes with defendants in the same relevant market, not a complementary one. *See* Op. 25–26. But that is irrelevant. The products are complementary in the important sense that the generic cannot meaningfully compete without being AB-compatible with the brand.

branded drug . . ., this could trigger a *Microsoft* burden-shifting contest," and "[o]nce the branded drug manufacturer offered a procompetitive justification for the product change that the generic manufacturer could not rebut, courts and juries would have to determine which product changes were 'sufficiently innovative' to justify their anticompetitive effects." Op. 27. But the district court's concerns about fashioning an intelligible test for "innovation 'sufficiency'" are misplaced for several reasons.

First, the court's fears make no sense in this case, in which the court assumed for purposes of summary judgment that the "product changes were intended to delay generic market entry" and defendants had no procompetitive justification for the product hops. *Id.* at 9. In the absence of a procompetitive justification, of course, there is no need to balance harms and benefits. Second, where, as here, the brand manufacturer withdraws its old product, despite consumer demand for it, and thus coerces consumers and doctors to switch to the reformulated version, there is no need for a court to consider the extent of the advantages of the new product, for any semblance of a "market test" has been pre-empted. *See Namenda*, 787 F.3d at 654–55, 659 ("While *introducing Namenda* XR may be procompetitive, that argument provides no procompetitive justification for *withdrawing* Namenda IR.").[6]

[6] A "soft switch" before the generic comes onto the market may also involve an element of coercion or deception when the brand manufacturer seeks to switch the market by making the original product less attractive or available. *See* FTC's Brief

Third, when a product reformulation has some, non-pretextual, procompetitive justification, courts and juries are no less capable of balancing the procompetitive benefits against anticompetitive harms than in many other technical contexts where the rule of reason applies. *See, e.g., Leegin Creative Leather Prods., Inc. v. PSKS, Inc.,* 551 U.S. 877 (2007) (resale price maintenance); *United States v. Oracle Corp.*, 331 F.Supp.2d 1098, 1173–75 (N.D. Cal. 2004) (mergers, including impact on new products); *see also* Hilary Greene, *Muzzling Antitrust: Information Products, Innovation and Free Speech,* 95 B.U. L. Rev. 35, 87–88 (2015) ("Internal documents as well as expert assessments can guide the court" in assessing product redesigns).[7]

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as Amicus Curiae at 13, *Mylan Pharm., Inc. v. Warner Chilcott PLC*, No. 12-3824 (E.D. Pa. Nov. 21, 2012) (FTC Dist. Ct. Amicus Br.) (brand company can achieve same result as hard switch "through indirect means"). In any event, it is hard to see a soft switch as a "market test" between the old and new products when doctors receive an entirely one-sided presentation of the benefits of the new drug versus the old. *See* Carrier, *supra*, at 1019.

[7] A reformulated product may have some benefits and also fail the more defendant-friendly "no economic sense" test, which requires no balancing. *See IP and Antitrust*, *supra*, § 12.3e3 ("If a design change makes no economic sense unless the exclusion of rivals is taken into account, it is reasonable to infer both that the purpose behind the design change was anticompetitive and, more importantly, that the anticompetitive effects of the design change predominated over any technological benefits. . . . But this test may be underinclusive; a design change may constitute a rational business decision in its own right and still impose competitive harms disproportionate to any social benefit."); *cf. Namenda*, 787 F.3d at 659 (defendants failed to explain how withdrawal of profitable old drug "makes economic sense in the absence of the benefit derived from eliminating generic competition").

C. Immunizing Product Hopping Threatens Innovation

The district court believed that antitrust scrutiny of product hopping would "strongly discourage pharmaceutical development and innovation." Op. 31. The Second Circuit rejected a similar claim as being without foundation. "To the contrary," the court 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." *Namenda*, 787 F.3d at 659.

"Brand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug." C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 615 (2011). Preventing brand manufacturers from maintaining their monopolies through product hopping schemes promotes innovation rather than deters it, because "immunity from competition is a narcotic, and rivalry is a stimulant, to industrial progress; . . . the spur of constant stress is necessary to counteract an inevitable disposition to let well enough alone." *United States v. Aluminum Co. of America*, 148 F.2d 416, 427 (2d Cir. 1945) (L. Hand, J.); *see also* FTC Dist. Ct. Amicus Br. at 8 (threat posed by generic competition "can incentivize the brand company facing dramatic loss of

sales to develop new and innovative drugs that benefit consumers" or to engage in product hopping "to impede generic substitution and thus meaningful generic competition").

The district court feared that "[t]he prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs." Op. 28. This argument proves too much. It suggests that Section 2 of the Sherman Act should be abolished because, of course, "[w]hether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern." *Microsoft*, 253 F.3d at 58. In any event, brand manufacturers can avoid potential liability for product reformulations if their principal goal and reasonable expectation is to improve the product rather than thwart generic entry though drug substitution laws.[8] And empirical evidence indicates the vast majority of product reformulations are not temporally linked to the manufacturer's concern about imminent generic competition. *See* Shadowen, *supra*, at 27.

[8] Notably, under the consumer-welfare balancing test, like the no-economic sense test, product innovations are "evaluated from an ex ante perspective, based on information reasonably available at the time that the innovator made its investment decision." Steven C. Salop, *Exclusionary Conduct*, *Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 Antitrust L.J. 311, 339, 341–42 (2006).

III. ANALYSIS OF MARKET DEFINITION AND MONOPOLY POWER SHOULD BE INFORMED BY THE PLAINTIFF'S THEORY OF ANTICOMPETITIVE EFFECTS

A. Anticompetitive Effects Can Demonstrate Monopoly Power

Courts, legal commentators, and economists agree that while a violation of Section 2 requires both monopoly power and exclusionary conduct, proof that a defendant has engaged in exclusionary conduct *that raises prices above the level that would have prevailed absent the conduct* is sufficient to establish a violation of Section 2. That is because proof of such conduct and its effect not only establishes the conduct element of Section 2, but it directly establishes defendant's monopoly power, which is "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). Such proof also implicitly establishes a relevant market, for it means that substitute products failed to constrain the defendant's ability to maintain supracompetitive prices.

The essential inquiry for any Sherman Act offense is whether the challenged conduct resulted in an anticompetitive effect. Under the rule of reason in Section 1 cases, it is well settled that direct evidence of anticompetitive effects obviates the need for circumstantial proof of market power from a high market share. *See FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460–61 (1986) ("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.'") (quoting 7 Phillip E. Areeda, *Antitrust Law* ¶ 1511, at 429 (1986)); *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 109–10 (1984).

These principles have also been extended to Section 2 of the Sherman Act. This Court has recognized that, "[b]ecause market share and barriers to entry are merely surrogates for determining the existence of monopoly power, direct proof of monopoly power does not require a definition of the relevant market." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 n.3 (3d Cir. 2007) (internal citation omitted); *see also Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 381 (3d Cir. 2005) ("Monopoly power can be demonstrated with either direct evidence of supracompetitive pricing and high barriers to entry, or with structural evidence of a monopolized market.") (internal citations omitted).[9]

As the Supreme Court noted in *Kodak*, "[i]t is clearly reasonable to infer that Kodak has market power to raise prices and drive out competition in the aftermarkets, since respondents offer direct evidence that Kodak did so." *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 477 (1992); *see also United*

[9] Numerous other circuits also follow this direct-evidence rule in Section 2 cases. *See* Andrew I. Gavil et al., *Antitrust Law in Perspective* 918-21 (2d ed. 2008) (citing cases).

States v. Addyston Pipe & Steel Co., 85 F. 271, 292 (6th Cir. 1898) ("The most cogent evidence that [defendants] had [market] power is the fact . . . that they exercised it."). Indeed, the ultimate issue in a monopolization claim is not whether the defendant has monopoly power in the abstract. Rather, "[t]he pertinent inquiry . . . is whether the defendant has engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition, thus creating or maintaining market power." *PepsiCo, Inc. v. Coca-Cola Co.,* 315 F.3d 101, 108 (2d Cir. 2002).

Leading commentators agree that direct evidence of anticompetitive effects is not only an appropriate method of proving monopoly power, it is *superior* to the indirect method of establishing a high market share in a relevant market. *See, e.g.,* Gavil et al., *supra*, at 919 ("[E]vidence of the actual ability to restrict output, raise prices, or otherwise determine product characteristics normally shaped by competition, establishes market power . . . and it may do so more reliably than market share evidence."); Lawrence A. Sullivan & Warren S. Grimes, *The Law of Antitrust* 74 (2d ed. 2006) ("Disputes about market definition . . . are of little consequence in the face of actual evidence of anticompetitive effects."); Phillip Areeda, *Market Definition and Horizontal Restraints*, 52 Antitrust L.J. 553, 565 (1983) ("Once we know that significant price enhancement has occurred . . . we know that the defendant has substantial market power. At that point market definition would

be superfluous and irrelevant. . . . [M]arket definition and market shares are second best to direct measurement.").

As Professor Salop has cogently explained,

> Although market power and market definition have a role in antitrust analysis, their proper roles are as parts of and in reference to the primary evaluation of the alleged anticompetitive conduct and its likely market effects. They are not valued for their own sake, but rather for the roles they play in an evaluation of market effects.
>
> Market power and market definition, therefore, should not be analyzed in a vacuum or in a threshold test divorced from the conduct and allegations about its effects. Instead, market power should be measured as the power profitably to raise or maintain price above the competitive benchmark price, which is the price that would prevail in the absence of the alleged anticompetitive restraint.

Steven C. Salop, *The First Principles Approach to Antitrust,* Kodak*, and Antitrust at the Millennium*, 68 Antitrust L.J. 187, 188 (2000).

Accordingly, "[i]f there is direct evidence of anticompetitive effect, then a separate test of market power, let alone a *threshold* test of market power, is redundant. In essence, the evidence of anticompetitive effect also proves market power in the affected market." *Id.* at 200; *see also* Lawrence J. White, *Market Power and Market Definition in Monopolization Cases*, in II ABA Section on Antitrust Law, *Issues in Competition Law and Policy* 913, 923 (2008) ("[F]or cases where the plaintiff alleges that the defendant's actions were exclusionary, the question of

market definition can be largely shunted aside and the focus instead should be on the price effects of the alleged exclusion, i.e., if the [competitor] had not been foreclosed by the defendant's actions, would the consequence have been a small but significant nontransitory *decrease* in the price (SSN*D*P) charged by the defendant?") (emphasis in original).

B. The District Court's Analysis of Monopoly Power Is Erroneous

The district court ignored these important principles and erred in several respects. First, rather than starting with the direct evidence of anticompetitive effects offered by Mylan that the entry of AB-rated generic Doryx substantially drove down average prices in the market, or considering such evidence in evaluating the relevant market, the court considered the relevant product market as a threshold issue, without regard to the plaintiff's theory of harm.

Second, the district court erroneously suggested that "direct evidence" of monopoly power had to include a showing of the defendants' marginal and fixed costs, citing two district court cases that relied on *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485 (2d Cir. 2004). But *Geneva* imposes no such requirement,[10] nor would such a requirement make sense. By definition, "supracompetitive pricing" must be measured against a competitive benchmark, and a good,

[10] *Geneva* suggests that a post-entry price decline may not be conclusive of pre-entry monopoly power, 386 F.3d at 500, but that is a far cry from holding, as the district court did here, that such a price decline is not *probative* of market power in the absence of information about defendants' fixed and marginal costs.

if not the best, approximation of that benchmark is the pricing that occurs when there is competition. Indeed, the Supreme Court in *Actavis* assumed that the low prices that typically result from generic entry indicate "the presence of higher-than-competitive profits—a strong indication of market power." *Actavis*, 133 S. Ct. at 2236.[11]

Third, the district court erred by requiring that direct evidence of monopoly power include not only evidence of supracompetitive pricing but also a showing of restricted output. This makes no sense, particularly in markets like prescription drugs in which generic entry tends to lower prices significantly, but not necessarily expand the market. *See* Gautier Duflos & Frank R. Lichtenberg, *Does Competition Stimulate Drug Utilization? The Impact of Changes in Market Structure on US Drug Prices, Marketing and Utilization*, 32 Int. Rev. L. & Econ. 95 (2012). As a "consumer welfare prescription," *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (internal quotation marks omitted), the Sherman Act is concerned when

[11] The Court noted studies referred to in the FTC's brief, which show that reverse-payment agreements cost consumers billions of dollars per year because delayed generic entry prevents prices from falling, on average, 85% in a mature generic market. *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (Jan. 2010) (cited in Brief for the Petitioner at 45, *Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416)). To be sure, supracompetitive pricing may be insufficiently extensive in duration or amount to reflect "monopoly" power.

monopolistic conduct raises prices even if it has no effect on allocational efficiency (output).[12]

Finally, the district court erred by suggesting that evidence of cross-price elasticity between Doryx and other tetracyclines undercut a market definition limited to delayed release doxycycline hyclate. The court fell into the notorious *Cellephone* trap. If, as plaintiffs' evidence suggested, the prices at which switching occurred were monopoly prices, price elasticity would be expected. *See Kodak*, 504 U.S. at 471 ("'[T]he 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.'" (quoting Phillip Areeda & Louis Kaplow, *Antitrust Analysis* ¶ 340(b) (4th ed. 1988))) (alteration and emphasis in original); Salop, *First Principles*, *supra*, at 197 (describing *Cellophane* fallacy).

[12] In *Broadcom* this Court did say, "The existence of monopoly power may be proven through direct evidence of supracompetitive prices *and* restricted output." 501 F.3d at 307 (emphasis added). However, "and" should be read disjunctively. While supracompetitive prices are normally associated with restricted output, that is not always the case, and nothing in *Broadcom* suggests that a showing of supracompetitive pricing alone is insufficient. *See* U.S. Dep't of Justice & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (1995) ("Market power is the ability profitably to maintain prices above, *or* output below, competitive levels for a significant period of time.") (emphasis added); *Gordon v. Lewistown Hospital*, 423 F.3d 184, 210 (3d Cir. 2004) ("detrimental effects," for which market power is a surrogate, include "reduced output, raised prices or reduced quality").

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF COUNSEL

I, Richard M. Brunell, hereby certify that:

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

2. This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)((7)(B) because it contains 6942 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Local Appellate Rule 29.1(b).

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s/ Richard M. Brunell

September 25, 2015

CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2015, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. To the best of my knowledge, all parties to this appeal are represented by counsel who are registered CM/ECF users and will be served electronically by the appellate CM/ECF system.

s/ Richard M. Brunell