PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 15-2236

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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.

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On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 2:12-cv-03824)

District Judge: Honorable Paul S. Diamond

Argued on July 14, 2016

Before: FUENTES,[*] SHWARTZ, and BARRY, *Circuit Judges*

(Opinion Filed: September 28, 2016)

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OPINION OF THE COURT

FUENTES, *Circuit Judge*.

Mylan Pharmaceuticals, Inc., a generic drug manufacturer, and several other Plaintiffs (hereinafter "Mylan") originally brought this action against Defendants, Warner Chilcott and Mayne Pharma, both name-brand drug manufacturers. Defendants manufacture and sell "Doryx," the name-brand version of delayed-release doxycycline hyclate, an oral antibiotic of the tetracycline class used to treat severe acne. Tetracyclines are a broad category of antibiotics, the most common being doxycycline monohydrate and minocycline, which vary in their use and

efficacy. Mylan alleges, among other things, that Defendants conspired to protect their position in the market through "product hopping," which involves making various insignificant modifications to a drug to keep generic competitors out of the market by forcing them to re-enter a cumbersome regulatory approval process.

After several Plaintiffs in this action settled their cases, Mylan was the only remaining Plaintiff. Mylan claims that Defendants are liable for: (1) creating an unlawful monopoly under § 2 of the Sherman Act; (2) attempted unlawful monopolization under § 2 of the Sherman Act; (3) entering into an agreement in restraint of trade under § 1 of the Sherman Act; and (4) tortiously interfering with prospective contractual relationships under Pennsylvania law. The Parties filed cross-motions for summary judgment, and the District Court granted Defendants' and denied Plaintiff's. In doing so, the District Court held that Defendants' conduct was not anticompetitive, and that, even if it was, Mylan's claims failed because it did not establish that Defendants had the requisite market power in the relevant product market. For the reasons that follow, we will affirm.

I. BACKGROUND[1]

We begin by describing the complex regulatory and industry-specific framework involved in most, if not all, pharmaceutical "product hopping" cases.[2]

[1] The District Court had jurisdiction under 28 U.S.C. §§ 1331, 1332(a), 1337(a), and 1367(a). We have jurisdiction under 28 U.S.C. § 1291.

A. Federal and State Law Governing Drug Approval

The pharmaceutical industry consists of both name-brand and generic drug manufacturers. In general, generic drugs are priced lower than, and compete with, their name-brand counterparts.[3] Both types of drugs are subject to certain approval requirements before they can be sold to the public. In particular, a company that wishes to market a new pharmaceutical product in the United States must first obtain approval from the Food and Drug Administration ("FDA").[4] This is called the New Drug Application ("NDA") process.[5]

Prior to 1984, both name-brand and generic drug manufacturers were required to go through the same NDA process. That year, Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act.[6] The Act loosened the approval rules for generics by creating an Abbreviated New Drug Application ("ANDA") process.[7] The ANDA process

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[2] Unless otherwise noted, the facts are drawn from the record before the District Court.

[3] *In re Barr Labs., Inc.*, 930 F.2d 72, 75 (D.C. Cir. 1991) (noting the price savings for low-income individuals between generic drugs and their name-brand equivalents).

[4] *See* 21 U.S.C. § 355.

[5] *Id.*

[6] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[7] *See id.* §§ 101-106, 98 Stat. 1585-97.

permits generic drug companies to rely on a name-brand drug company's original NDA approval for a particular drug in order to gain quicker, less costly FDA approval of a generic version of the drug.[8] By enabling generic manufacturers to "piggy-back on a brand drug's scientific studies" and the significant costs associated with their NDA, Hatch-Waxman "speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition."[9]

To rely on a name-brand's NDA, however, the generic drug manufacturer must demonstrate that the proposed generic product is both a "bioequivalent" and a "pharmaceutical" equivalent of the name-brand drug.[10] Put simply, these two equivalencies require a generic company filing an ANDA to show a certain level of design and formulaic similarity between its product and the approved drug. ANDA filers that successfully show that their drug is bioequivalent and pharmaceutically equivalent can then have their product deemed "AB-rated" to the name-brand drug by the FDA.

To be sure, once obtained, the AB rating carries a considerable corollary benefit for generics under state law. Every state in the United States has drug substitution laws.[11]

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[8] *See* 21 U.S.C. § 355(j)(2)(A)(iv).

[9] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013) (internal quotation marks, brackets, and citation omitted).

[10] *See* 21 U.S.C. § 355(j)(2)(A)(iv); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645 (2d Cir. 2015) (hereinafter "*Namenda*").

[11] *Namenda*, 787 F.3d at 644.

These state substitution laws "either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written."[12] Taken together, these laws oftentimes make obtaining a prescription cheaper for the consumer, and they can also prove to be highly profitable for generic drug companies.[13]

As the Court of Appeals for the Second Circuit recently noted in *New York ex rel. Schneiderman v. Actavis PLC* (hereafter "*Namenda*"),[14] Hatch-Waxman and state substitution laws also reflect the fact that the pharmaceutical market functions in a unique way.[15] As the *Namenda* Court put it, "[i]n a well-functioning market, a consumer selects and

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[12] *Id.* at 645.

[13] *See, e.g.*, *New York v. Actavis, PLC*, No. 14 Civ. 7473 (RWS), 2014 WL 7015198, at *8 (S.D.N.Y. Dec. 11, 2014); Stacey B. Lee, Pliva v. Mensing*: Generic Consumers' Unfortunate Hand*, 12 Yale J. Health Pol'y, L. & Ethics 209, 239 (2012) (noting role played by state substitution laws in "help[ing] generic manufacturers earn above-average profit margins"). Generic drugs are reported to have accounted for over 80% of the prescriptions dispensed in 2014, *see* Amicus Br. of FTC 6, and can save patients billions of dollars, *see* Amici Br. of AARP *et al.* 6 ("In 2013 alone, generic medications saved consumers $239 billion.").

[14] "Namenda" is the brand name for the prescription drug at issue in that case. As the parties have done, we will therefore refer to this case as "*Namenda*."

[15] 787 F.3d at 645-46.

pays for a product after evaluating the price and quality of the product."[16] In the prescription drug market, by contrast, the doctor selects the drug, which creates a certain separation between the buyer and the manufacturer.[17] Moreover, in most cases, a third-party, such as a health insurance company, pays for the drug.[18] As a result, consumer buying behavior may have less of an impact on manufacturer pricing than it otherwise would in a traditional open market.

With this regulatory and market framework in mind, we turn to the facts in this case.

B. The Parties and Product Development

The parties in this case are manufacturers and sellers of generic and name-brand pharmaceutical drugs worldwide. Defendant Mayne is a pharmaceutical company headquartered in Australia. Defendant Warner Chilcott acted as a United States distributor of Mayne's Doryx product, in both name-brand and generic form, for a number of years. Plaintiff Mylan, a generic drug manufacturer, began its effort to produce a generic version of Doryx in 2003.

A form of Doryx had been on the market for many years. In 1985, the FDA approved Mayne's Doryx capsules, an unpatented delayed-release version of doxycycline hyclate, for sale to the public. In the meantime, using Warner as a domestic sales channel, Mayne sold both branded and generic versions of Doryx for many years in the United States, but the

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[16] *Id.* at 645.

[17] *Id.* at 645-46.

[18] *Id.* at 646.

effort did not prove to be fruitful. Faced with shrinking profits in the early 1990s, Mayne contacted Warner to strategically bolster the Doryx brand instead of focusing on its generic version of the drug.

To sort out their strategy for growing the Doryx brand, Mayne and Warner entered into a licensing agreement in 1997. Under the contract, they agreed to take certain steps to bring a new Doryx product to the market. Mayne also agreed to pull its generic version of Doryx from the market, and Warner agreed to act as the exclusive distributor of Doryx in the United States. Warner further agreed to market and promote Doryx in return for the rights to all income from domestic sales and to use Mayne as its exclusive manufacturer and supplier. The parties also agreed to develop a delayed release Doryx tablet, as opposed to the capsule previously marketed, for Warner to sell in the United States.

The FDA approved Defendants' NDA for Doryx 75mg and 100mg tablets in May 2005. Defendants then introduced them to the market in September 2005 in an effort to transition the market for Doryx capsules over to Doryx tablets. As the District Court noted, it appears that Defendants took a number of steps regarding the capsules that, in conjunction, Mylan claims violated the Sherman Act. In particular, Defendants:

> (1) stopped selling the capsules to wholesalers; (2) removed Doryx capsules from the Warner Chilcott website; (3) worked with retailers to "auto-reference" the Doryx tablet whenever a doctor filed a Doryx prescription; (4) informed wholesalers, retailers, and doctors that "Doryx

> Capsules have been replaced by Doryx Tablets"; (5) destroyed some of their remaining capsule inventory; and (6) bought back some portion of the remaining capsule inventory.[19]

Mylan refers to these steps as a "hard switch" from capsules to tablets and claims that this was done in an effort to stifle generic competition.[20]

Beginning in 2007, Defendants made a number of other changes to the existing Doryx product and thereafter pulled older versions from the market. Each of these changes would have required generic manufacturers to file, and await approval of, a new ANDA demonstrating the similarities between their product and the reformulated Doryx product in order to continue selling generics that were AB-rated to the newest Doryx product.

First, Defendants worked to develop a 150mg strength Doryx tablet, in contrast to the previously available 75mg and 100mg tablets. The 150mg tablet would have a "score," which the District Court described as "a groove running across the tablet's surface."[21] The score would allow a patient to divide a 150mg Doryx tablet into two 75mg doses if the

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[19] *Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2015 WL 1736957, at *3 (E.D. Pa. Apr. 16, 2015) (record citations omitted).

[20] *See* Mylan Br. 11, 42 (referring to Defendants' conduct of pulling the Doryx capsule from the market, destroying existing supplies, and introducing the Doryx tablet as a "hard switch").

[21] *Mylan Pharm.*, 2015 WL 1736957, at *3.

patient, for instance, needed to self-adjust dosing based on sensitivity, doctor recommendation, or for any other reason. Defendants sought FDA approval for the 150mg single-scored tablet in December 2007, it was approved by the FDA in June 2008, and Defendants thereafter began marketing the tablet.

Soon after, Defendants turned their focus from marketing the unscored 75mg and 100mg tablets to marketing the 150mg single-scored tablet. Like the 150mg tablets, they then added a score to the 75mg and 100mg unscored Doryx tablets. The FDA approved the 75mg and 100mg scored tablets in early 2009.

Defendants then made another change to the Doryx 150mg tablet in 2010 by adding a second score line to the tablet. This dual-scored tablet could be split into two or three pieces, further enhancing a patient's ability to control self-dosing. After Defendants submitted their application for the dual-scored 150mg tablet to the FDA in February 2011, they then pulled the 75mg and 100mg single-scored Doryx tablets from the market. Then, after receiving approval in fall 2011 for the dual-scored 150mg tablet, Defendants stopped distributing single-scored 150mg tablets, just as they had done with the 75mg and 100mg single-scored tablets.

All told, it appears that Defendants made four critical changes to Doryx, all of which required generics to apply for AB-rating if they wanted to continue to benefit from state

substitution laws.[22] These modifications spurred this litigation.

C. Mylan's Efforts to Compete with Warner and Mayne Using Generic Doryx

It is also important to our discussion to note Mylan's parallel efforts to effectively compete with Defendants when they made each of the above-mentioned changes to name-brand Doryx. In particular, these efforts will be relevant to our discussion of whether Defendants' product changes had exclusionary effects on generic competition.

The capsule version of Doryx was unpatented for the first nineteen years after Mayne introduced Doryx to the market. During that period, another generic manufacturer, Sandoz, created its own generic version of the capsule. Mylan did not begin developing a generic Doryx capsule until April 2003. These efforts failed, however, and Mylan finally gave up on trying to create a capsule for marketing and sale around late 2005.

Instead of making a capsule, Mylan chose to develop generic versions of 75mg and 100mg doxycycline hyclate tablets. By September 2006, Mylan had created the formula for a generic tablet and, in March 2008, it filed an ANDA for approval. However, the FDA delayed its approval when Defendants' scored version of Doryx was released, because,

[22] In April 2013, Defendants introduced a 200mg Doryx tablet as a treatment for chlamydia, a sexually transmitted disease. The 200mg tablet was not approved by the FDA for acne treatment, unlike the previous versions of the drug.

among other complications, Mylan was then required, in accordance with FDA regulations, to alter its original tablet design to achieve an AB rating. The FDA finally approved Mylan's scored 75mg and 100mg generic tablets in December 2010, by which time Defendants were focused on marketing their single scored-version of the 150mg tablets. At that time, the FDA had, nonetheless, granted Mylan 180 days of exclusive selling rights for its generic version of the tablet, allowing Mylan to profit without any generic competition.

Finally, Mylan created a generic version of Defendants' 150mg single-scored tablet in late 2008, and the FDA granted approval of the drug in February 2012. By that point, however, Defendants had already received approval for their dual-scored 150mg tablet and were focused on marketing that version of the drug. This suit followed.

D. The Underlying Litigation

Mylan filed this lawsuit in July 2012, alleging violations of §§ 1 and 2 of the Sherman Act.[23] It also asserted a claim for tortious interference with contractual relations under Pennsylvania law. The crux of Mylan's complaint is that Defendants' product changes had "little or no therapeutic benefit,"[24] and that they served no purpose other than preventing generics from obtaining the benefit of automatic

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[23] This case was quickly consolidated with parallel lawsuits filed by other Plaintiffs. As noted, the other Plaintiffs settled their cases, leaving only Mylan to litigate its claims against Defendants.

[24] JA 154.

substitution under Hatch-Waxman and various state laws.[25] Mylan further claims that Defendants' anticompetitive "product hopping" strategy was designed to frustrate their efforts to release a generic version of Doryx to the market.[26] In support of its cross-motion for summary judgment before the District Court, Mylan specifically argued that the following four "hops" were anticompetitive:

(1) 2005 change from 75mg and 100mg capsules to 75mg and 100mg tablets;

(2) 2008 introduction of a single-scored 150mg tablet;

(3) 2009 addition of a single score to 75mg and 100mg tablets; and

(4) 2011 change from single to dual score on the 150mg tablet.[27]

In granting Defendants' motions for summary judgment and denying Mylan's cross-motion, the District Court found, viewing the facts in the light most favorable to Mylan, that Defendants had indeed made the Doryx "hops" primarily to "delay generic market entry."[28] Nonetheless, the court went on to conclude that Mylan's antitrust claims failed as a matter of law. With respect to the § 2 monopolization claim, the District Court held that Mylan failed to muster

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[25] JA 178-80.

[26] JA 154.

[27] *Mylan Pharm.*, 2015 WL 1736957, at *5.

[28] *Id.*

sufficient evidence of Defendants' monopoly power.[29] It rejected Mylan's narrow view of the market – comprising only branded and generic Doryx – and determined that the relevant product market was a broader one, consisting of name-brand Doryx and all oral tetracyclines prescribed to treat acne.[30] And, within this larger market, the District Court found that Defendants' market share was – at most – only about 18%, an amount insufficient to show that Defendants exercised monopoly power.[31] The District Court stated:

> In sum, Mylan has failed to produce economically plausible evidence to prove that Defendants hold monopoly power in the relevant market. Nor has Mylan shown that other factors might support finding that Defendants exercise monopoly power in the absence of predominant market share.[32]

As an alternative ground, the District Court also granted summary judgment to the Defendants on both Sherman Act claims because Mylan failed to put forth sufficient evidence of anticompetitive conduct.[33] The District Court held that Defendants did not exclude competition when they made product changes.[34] In particular, it found that

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[29] *Id.* at *7-11.

[30] *Id.*

[31] *Id.* at *8.

[32] *Id.* at *11.

[33] *Id.* at *12-16.

[34] *Id.*

Mylan was free to introduce a generic Doryx capsule any time after 1985, but it failed to do so, and that Mylan successfully introduced generic 75mg, 100mg, and 150mg Doryx tablets.[35] As the District Court observed:

> Throughout this period, doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug.[36]

The District Court also concluded that Mylan had failed to even attempt to market generic Doryx, "relying instead on the 'promotion' provided by state automatic substitution laws,"[37] and that "Defendants have no duty to facilitate Mylan's business plan by keeping older versions of branded Doryx on the market."[38] The District Court also distinguished a number of key cases dealing with alleged product hops, ultimately concluding that they were procedurally inapplicable.[39]

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[35] *Id.* at *12.

[36] *Id.* at *13.

[37] *Id.*

[38] *Id.* at *14.

[39] *Id.* at *15 (citing *Actavis*, 2014 WL 7015198; *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d

Finally, the Court addressed a concern about turning federal courts into innovation sufficiency tribunals, stating:

> Adoption of Mylan's theory of "anticompetitive product redesign" could well have adverse, unintended consequences. *Any* time a pharmaceutical manufacturer changes the formulation of a branded drug and so compels a manufacturer to reformulate (or, as in the instant case, formulate for the first time) its generic, this could trigger a . . . burden-shifting contest. Once 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. Mylan has failed to offer an intelligible test of innovation "sufficiency," and I doubt that courts could ever fashion one. Mylan's theory also risks slowing or even stopping pharmaceutical innovation. The 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.[40]

146, 151 (D.D.C. 2008); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006)).

[40] *Id.* at *15-16 (internal citations omitted).

After addressing Mylan's Sherman Act claims, the District Court also granted Defendants' motions for summary judgment on Mylan's claim of tortious interference with prospective contractual relations under Pennsylvania law, concluding that the only alleged "interference" with prospective customers was "privileged," in the sense that Pennsylvania law permits "competitors, in certain circumstances . . . to interfere with others' prospective contractual relationships."[41] Mylan's appeal followed.[42]

[41] *Id.* at *17 (quoting *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 215 (3d Cir. 2009) (citation omitted)).

[42] We review a grant of summary judgment de novo and apply the same standard as the District Court. *Cosmetic Gallery, Inc. v. Schoeneman Corp.*, 495 F.3d 46, 48 n.1 (3d Cir. 2007). Summary judgment is appropriate when there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Inferences drawn from the underlying facts must be viewed in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

II. DISCUSSION

A. Sherman Act Claims

1. Mylan's Section 2 Claims: Attempted and Actual Monopolization

Because both the District Court and the parties' arguments focus heavily on Mylan's monopolization and attempted monopolization claims under § 2, we will address those claims first.[43]

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[43] As an initial matter, Defendants assert that Mylan lacks antitrust standing, because Mylan suffered no antitrust injury. (Defs.' Br. 89-92.) Antitrust standing is a prudential limitation, and we assess several factors to determine its presence. *See Ethypharm S.A. Fr. v. Abbott Labs.*, 707 F.3d 223, 232-33 (3d Cir. 2013). Specifically, we consider: (1) the causal connection between an alleged antitrust violation and harm to the plaintiff as well as the defendant's intent to cause that harm; (2) whether the plaintiff has suffered an injury of the type the antitrust laws intend to redress; (3) the "directness of the injury," which seeks to preclude "speculative" claims; (4) the existence of more direct victims of the alleged violations; and (5) the potential for duplicative recovery or "complex apportionment of damages." *Id.* (citing *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1165-66 (3d Cir. 1993)). We reject Defendants' contention. Although we ultimately conclude that Mylan has failed to create fact issues for a jury on any of its claims, Mylan has offered at least some proof to satisfy each of these elements. We therefore conclude that Mylan has antitrust

Section 2 of the Sherman Act "makes it unlawful to monopolize, attempt to monopolize, or conspire to monopolize, interstate or international commerce."[44] To support a claim for actual monopolization, a party must prove: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[45] By contrast, to succeed on a claim of attempted monopolization under § 2, a plaintiff must prove "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power."[46]

We begin our analysis with the first element of Mylan's actual monopolization claim under § 2: Defendants' possession of monopoly power in the relevant market.

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standing. *See also W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 102 (3d Cir. 2010) (noting that "competitors in the restrained market" are among those capable of satisfying the antitrust-injury requirement).

[44] *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007) (citing 15 U.S.C. § 2).

[45] *Id.* at 307 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)).

[46] *Id.* at 317 (quoting *Crossroads Cogeneration Corp. v. Orange & Rockland Utils., Inc.*, 159 F.3d 129, 141 (3d Cir. 1998)).

Monopoly power can be demonstrated through direct or indirect evidence.[47] Mylan has provided neither.

a. Direct Evidence of Monopoly Power

We have previously stated in *Broadcom Corp. v. Qualcomm, Inc.* that monopoly power is "the ability to control prices and exclude competition in a given market."[48] We also stated there that, "[i]f a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly power,"[49] and therefore "[t]he existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output."[50] However, we have elsewhere emphasized that direct evidence of monopoly power to prove one's claims is only "rarely available."[51] And, to support a claim that a defendant set supracompetitive prices through direct evidence, a plaintiff must often provide an analysis of the defendant's costs, showing both that the defendant had an

[47] *Id.* at 307.

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 381 (3d Cir. 2005) (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (en banc)).

"abnormally high price-cost margin" and that the defendant "restricted output."[52]

To determine whether Mylan has offered the "rare" form of direct evidence of monopoly power, we must first examine whether the record includes any proof of Defendants' market power based on supracompetitive pricing or restricted output.[53] To support such a claim, Mylan relies heavily on its own expert testimony.

Here, in noting that Mylan failed to establish monopoly power, the District Court concluded:

> Mylan has not made a serious effort to present direct evidence of Defendants' monopoly power. To begin, Mylan offers no evidence of Defendants' "price-cost margins" for Doryx, nor does it explain whether those margins were abnormally high. Mylan's economic expert, Dr. Rubenfeld, elected to forego any analysis of

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[52] *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 500 (2d Cir. 2004).

[53] Mylan contends that we should look to its proffered expert testimony to conclude that Defendants exercised monopoly power even in the absence of clear evidence of supracompetitive prices or restricted output. We disagree. *See Broadcom Corp.*, 501 F.3d at 307; *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 464 (1992) (stating that "[m]arket power is the power 'to force a purchaser to do something that he would not do in a competitive market'" (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 14 (1984))).

> Defendants' margins because, as he opined, other available evidence of monopoly power was "more compelling," and margins are "difficult to measure" and "imperfect indicators of market power." Dr. Rubenfeld nonetheless states that at least some of Defendants' data suggested a margin of 83% in the second quarter of 2006–without explaining whether that figure is abnormally high. Regardless of whether or not evidence of Defendants' marginal and fixed costs was "compelling" or "difficult to measure," it is still required to prove monopoly power directly. Mylan has not made such a showing. Mylan also fails to show that Defendants restricted Doryx output to maintain monopoly profits, and fails to discuss the quantity of Doryx Defendants manufactured during the relevant period. In these circumstances, Mylan has not presented plausible direct evidence of market power.[54]

We agree with the District Court's analysis. We have held that expert testimony in support of summary judgment that contains only "general and theoretical observations and [which] is not tied to evidence in the record" can be "disregard[ed]."[55] As the District Court correctly observed, Mylan's expert reports are devoid of any substantiated quantitative analysis showing that Defendants maintained

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[54] *Mylan Pharm.*, 2015 WL 1736957, at *7 (internal citations and record citations omitted).

[55] *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 107 F.3d 1026, 1040 (3d Cir. 1997).

high price-cost margins or that Defendants markedly restricted output. And, to the extent that Mylan's experts offered any such conclusions, they were largely theoretical in nature. Accordingly, Mylan has failed to provide direct evidence of monopoly power.

b. Indirect Evidence of Monopoly Power

The second and more common way that a party may prove monopoly power is by providing indirect evidence, which includes "structural evidence of a monopolized market."[56] To support a claim of monopoly power through indirect evidence, Mylan must show that (1) Defendants had market power in the relevant market and (2) that there were barriers to entry into the market.[57]

"Proving the existence of monopoly power through indirect evidence requires a definition of the relevant

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[56] *Harrison Aire*, 423 F.3d at 381 (internal citations and quotations omitted); *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) (stating that direct proof is "only rarely available, [and] courts more typically examine market structure in search of circumstantial evidence of monopoly power" (internal quotation marks omitted)).

[57] *Broadcom Corp.*, 501 F.3d at 307 (citing *Microsoft Corp.*, 253 F.3d at 51). The relevant market determination typically has both product and geographic components. *See Borough of Lansdale v. Phila. Elec. Co.*, 692 F.2d 307, 311 (3d Cir. 1982). Defendants do not contest Mylan's expert's conclusion that the relevant geographic market is the United States. We therefore focus solely on the product component.

market,"[58] and "[t]he scope of the market is a question of fact as to which the plaintiff bears the burden of proof."[59] The question in this case, as in others, is whether the relevant market consists only of the defendants' product and the plaintiff's product, or whether the market comprises third-party products as well. To determine if two products are in the same market, we ask "if they are readily substitutable for one another," an inquiry that requires us to assess "the reasonable interchangeability of use between a product and its substitute."[60] We also look to their cross-elasticity of demand, which is defined as "[a] relationship between two products, usually substitutes for each other, in which a price change for one product affects the price of the other."[61]

Here, Mylan argues that the relevant market consists of generic Doryx and name-brand Doryx and that, within this market, Defendants allegedly maintained 100% of sales until generics entered.[62] We reject Mylan's position and agree with the District Court's conclusion that the market was much broader and consisted of all oral tetracyclines prescribed to

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[58] *Broadcom Corp.*, 501 F.3d at 307 (internal footnote omitted) (citing *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1062-63 (3d Cir. 1978)).

[59] *Id.* (citing *Queen City Pizza Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997)).

[60] *Id.* (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)).

[61] Black's Law Dictionary 458 (10th ed. 2014).

[62] *Mylan Pharm.*, 2015 WL 1736957, at *8.

treat acne, a market in which Defendants' market share never exceeded approximately 18%.

i. Interchangeability

To define the relevant market, we first consider the extent to which Defendants' product is interchangeable with alternative products in the field.[63] The term "'[i]nterchangeability' implies that one product is roughly equivalent to another for the use to which it is put."[64] It also means that "while there might be some degree of preference for . . . one [product] over the other, either would work effectively."[65]

As the District Court accurately observed:

> The record abounds with uncontradicted evidence . . . confirming and reconfirming the interchangeability of Doryx with other oral tetracyclines. There is a consensus among dermatologists that all oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purpose. The FDA has approved virtually identical labeling for most of these drugs, stating that in cases of "severe

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[63] *See Eastman Kodak Co.*, 504 U.S. at 482 (discussing how the interchangeability of products affects the definition of the relevant market).

[64] *Allen-Myland, Inc. v. Int'l Bus. Machs. Corp.*, 33 F.3d 194, 206 (3d Cir. 1994).

[65] *Id.*

> acne" the drugs "may be useful adjunctive therapy."[66]

To further undercut Mylan's position regarding interchangeability, and consistent with the underlying purpose of Hatch-Waxman and state substitution laws, health insurers and other managed care providers encouraged the widespread substitution of numerous other oral tetracyclines for Doryx. As the District Court stated:

> Managed care organizations have sought to constrain patients to substitute Doryx with other, less costly tetracyclines to treat acne. Some organizations have removed Doryx as a reimbursable medication; others have limited any reimbursement. A number of managed care organizations sent notices to healthcare providers urging them to substitute other oral tetracyclines for Doryx.[67]

Clearly, those in the managed care field acknowledged that other, more affordable tetracyclines were fully substitutable for Doryx. Moreover, products need not be perfectly fungible to be considered reasonably interchangeable for market-definition purposes.[68] With all of this in view, Mylan simply cannot escape the conclusion that

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[66] *Mylan Pharm.*, 2015 WL 1736957, at *9 (record citations omitted).

[67] *Id.* at *9 (record citations omitted).

[68] *DSM Desotech Inc. v. 3D Sys. Corp.*, 749 F.3d 1332, 1339-40 (Fed. Cir. 2014).

a high level of product interchangeability existed between Doryx and other oral tetracyclines prescribed to treat acne.

ii. Cross-elasticity of Demand

Interchangeability is only one aspect of establishing a relevant antitrust market through indirect evidence. In addition to evidence establishing Doryx's interchangeability, Defendants also point to their own unrebutted expert evidence showing cross-elasticity of demand between Doryx and other tetracyclines. This indirect evidence, they claim, further suggests that Defendants did not maintain monopoly power in the relevant market.

"Cross-elasticity of demand is a measure of the substitutability of products from the point of view of buyers. More technically, it measures the responsiveness of the demand for one product [X] to changes in the price of a different product [Y]."[69] So, for example, if we were to find that the Doryx market consisted, as Mylan proposes, only of name-brand Doryx and its generic counterpart, the cross-elasticity of demand between Doryx and other oral tetracyclines prescribed to treat acne would be very small, showing that Doryx's price changes had no effect on patient demand for those drugs. Here, as the District Court correctly noted, the opposite is true, as the undisputed evidence demonstrates that "when Defendants increased the price of

[69] *Queen City Pizza, Inc.*, 124 F.3d at 438 n.6 (quoting E. Thomas Sullivan and Jeffrey L. Harrison, *Understanding Antitrust and its Economic Implications* 217 (1994)).

Doryx, its sales decreased and the sales of other oral tetracyclines increased."[70]

More specifically, Defendants offered unrebutted expert testimony, including detailed statistical analyses, showing that demand for other generics rose in response to certain of Defendants' strategic marketing and sales decisions. Most convincingly, we view the customer response to the various changes in Doryx's prescription couponing scheme, which at times made Doryx more expensive than generics for consumers, as a strong indication of the existence of cross-elasticity.[71] In particular, this evidence demonstrated that Defendants responded to the market's reaction to their prices with sales promotions in an effort to increase their ability to compete with other tetracyclines. It also showed that when Defendants increased the price of Doryx, its sales decreased, and the sales of other tetracyclines increased. Moreover, Mylan offered no quantitative analyses to rebut these conclusions, but rather simply relied on its own expert's theoretical views on cross-elasticity. Given that Mylan carried the burden of proof in defining the market, its evidence was insufficient to create a jury question in light of Defendants' showing of cross-elasticity of demand.

In sum, given the high degree of interchangeability and cross-elasticity demonstrated in the record, we agree with the

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[70] *Mylan Pharm.*, 2015 WL 1736957, at *10.

[71] For instance, the reports measured the demand between Doryx and at least "Adoxa, generic immediate release doxycycline hyclate, and generic immediate-release doxycycline monohydrate." *Id.*

District Court that the relevant market consisted of Doryx and other oral tetracyclines prescribed to treat acne. And, within that market, we generally require a plaintiff alleging antitrust injury under Section 2 to show that Defendants maintained a market share "significantly larger than 55%" to establish antitrust liability.[72] However, Defendants' market share in the oral tetracycline market was relatively small. It never exceeded 18%.

c. Anticompetitive Conduct

Although the District Court acknowledged that its finding with respect to monopoly power resolved the § 2 monopolization claims, the Court went on to address anticompetitiveness because it was necessary to resolve the remaining claims. The District Court concluded that Defendants' "product hopping" strategy was not anticompetitive. Mylan contends that the District Court erred in its analysis, specifically with respect to whether Defendants' product changes barred Mylan from taking advantage of state substitution laws. Mylan further claims that this case is indistinguishable from the Second Circuit's decision in *Namenda* and that Defendants' conduct was

[72] *Dentsply*, 399 F.3d at 187. In the absence of sufficient market share, we have, nonetheless, held that other factors may indicate the presence of monopoly power, including "size and strength of competing firms, freedom of entry, pricing trends and practices in the industry, ability of consumers to substitute comparable goods, and consumer demand." *Id.* (citations omitted). Having reviewed the record, we conclude that none of those factors are present here.

undoubtedly anticompetitive. We discern no error in the District Court's conclusion and reject Mylan's contentions.

We have stated that "[a]nticompetitive conduct may take a variety of forms, but it is generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits."[73] Moreover, it is clear that the Sherman Act "directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself."[74]

In addressing allegations of anticompetitive conduct based on Defendants' product hops, the District Court properly applied the "rule of reason" burden-shifting framework set forth by the D.C. Circuit in *United States v. Microsoft Corp.*[75] Under that framework, the party seeking to impose liability must initially provide evidence of the anticompetitive nature of a defendant's conduct.[76] Once established, the defendant then has the burden of "proffer[ing] 'nonpretextual' procompetitive justifications for its conduct," and "[t]he plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit."[77] In conducting this analysis, we

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[73] *Broadcom Corp.*, 501 F.3d at 308 (citations omitted).

[74] *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993).

[75] 253 F.3d 34 (D.C. Cir. 2001) (en banc).

[76] *Namenda*, 787 F.3d at 652 (citing *Microsoft Corp.*, 253 F.3d at 58-60).

[77] *Id.* (quoting *Microsoft Corp.*, 253 F.3d at 58-59).

first consider whether Mylan produced evidence of Defendants' anticompetitive conduct. The District Court concluded that Mylan failed on this front, and we agree.[78] While product hopping under certain circumstances may be viewed as anticompetitive conduct, this is not one of those cases. As we explain, Mylan was not foreclosed from the market.

Doryx capsules were available for more than twenty years, and generic companies were free to engineer their own versions during that time. At least one did, but not Mylan.[79] Moreover, the record demonstrates that Mylan received 180 days of exclusive rights to market and sell its 75mg and 100mg tablets once approved, giving Mylan a significant leg up on generic competitors. And the undisputed evidence shows that Mylan set its tablet prices higher than the price of branded Doryx for at least some period of time. Finally, it is

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[78] *See Mylan Pharm.*, 2015 WL 1736957, at *12.

[79] The District Court was persuaded by the fact that Mylan chose to forego more aggressive research and development, marketing, and sales efforts. *See, e.g.*, *id.* at *13. We realize that it may not necessarily be cost-effective for generic manufacturers to promote their products with the same level of investment as their name-brand counterparts and that Hatch-Waxman seems to provide generics the means to participate in the market without necessarily promoting their products in their same way that name-brand manufacturers do. Nonetheless, as the District Court noted, Mylan is one of the largest generic pharmaceutical companies in the world, recording nearly $6.13 billion in revenue in 2011. *Id.* at *1. It is therefore difficult to perceive Mylan as a "David" and Defendants as "Goliath" in these circumstances.

clear that Mylan reaped generous profits from its sale of the generic tablet, in the amount of $146.9 million. Thus, far from being harmed by Defendants' product changes, Mylan was advantaged in the generic market by its 180-day exclusivity period and ability to profit generously while raising prices. In sum, we agree with the District Court that Mylan failed to satisfy its burden of demonstrating that Defendants engaged in anticompetitive conduct prohibited by the Sherman Act, thereby failing on the first prong of the *Microsoft Corp.* test.[80]

But even if we were to assume that the first prong of the test was met, Defendants have offered strong evidence of non-pretextual purposes for their various product changes. First, it is clear from the record that doxycycline capsules had been linked with esophageal problems. The capsule version of the drug was ultimately banned in France and Sweden, and Defendants faced a products liability lawsuit in Michigan regarding the same problems. Second, the record clearly demonstrates that Doryx experienced shelf-life stability problems, which in 2002 resulted in a largescale recall of Doryx capsules. Third, Defendants introduced different dosages for Doryx largely in response to the actions of their competitors. For instance, Defendants offered evidence that their decision to introduce the 150mg tablet was in response

[80] To be sure, we recognize that there are a number of documents that suggest that Defendants were, at least in part, focused on protecting their name-brand franchise. While these documents may imply that Defendants were motivated by an intent to compete with generics, the evidence nonetheless demonstrates that Defendants' product modifications had no anticompetitive effects on the market.

to the fact that both Adoxa and Solodyn, tetracyclines prescribed to treat acne, were offered in a variety of dosages. Defendants also offered evidence of a non-pretextual justification when they proposed the scoring modifications: an ability for consumers to more effectively self-dose at patient-specific levels.

We are also cognizant of the Second Circuit's reasoning in *Namenda*, which Mylan relies on heavily in its briefs. However, we find *Namenda* to be factually and procedurally distinguishable from this case.

In *Namenda*, which was decided a few weeks after the District Court's decision in this case, the Second Circuit affirmed a preliminary injunction in favor of the plaintiff, the State of New York, forcing the defendants, name-brand drug manufacturers, to keep an old version of Namenda IR, a prescription drug used to treat dementia, on the market for a period of time before introducing the new drug (Namenda XR).[81] *Namenda* involved the defendants' attempts to avoid a "patent cliff" – the end of patent exclusivity, corresponding to the brand drug's loss of market share – by stringing together new periods of patent exclusivity in order to completely bar generics from entering the market. It was alleged that the defendants did so by introducing changes to their product to delay the expiration of their patent.[82]

Here, there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral tetracycline market.

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[81] *Namenda*, 787 F.3d at 649-50, 663.

[82] *Id.* at 647-48.

Moreover, as Defendants correctly note in their brief, a lawyer for the State of New York in *Namenda* specifically stated that Mylan's case against the Defendants here, pending at the time, was distinguishable from New York's theory in *Namenda*.[83] Echoing this sentiment, the *Namenda* Court itself also persuasively distinguished this case, citing it as an example of a situation in which there was no evidence of consumer coercion, because generics "had already entered the market at the time of defendants' product reformulation."[84] Perhaps more importantly, the Second Circuit's decision in *Namenda* merely upheld a preliminary injunction, unlike this case, which proceeded through full discovery and resulted in a robust record void of any evidence of anticompetitive conduct.[85]

Mylan also cites a number of other procedurally inapposite cases in which courts have addressed product hopping claims at the motion-to-dismiss stage and allowed them to proceed against name-brand drug manufacturers.[86] Just as the courts did in those cases, here, the District Court allowed Mylan's claims to proceed against Defendants after

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[83] Defs.' Br. 4 (citing Dasgupta Letter 1-2, *Namenda*, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624), ECF No. 324).

[84] *Namenda*, 787 F.3d at 652 n.23 (citing *Mylan Pharm.*, 2015 WL 1736957, at *13).

[85] Indeed, the parties have provided the court with 21 appendices of discovery material, consisting of nearly 15,000 pages.

[86] *See Suboxone*, 64 F. Supp. 3d at 681-82; *TriCor*, 432 F. Supp. 2d at 422.

denying their motions to dismiss.[87] However, after a period of exhaustive discovery, the District Court thoroughly reviewed the record and concluded that Mylan failed to create triable issues of material fact to save any of its Sherman Act claims.

To be clear, we do not rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases. Thus, after applying the *Microsoft Corp.* framework, courts may need to consider a number of additional, non-exhaustive factors. For instance, courts might need to balance the important public interest in encouraging innovation in the pharmaceutical industry with our obligations to protect consumers and to ensure fair competition under the antitrust laws. At the same time, courts should also be wary both of second-guessing Congress's legislative judgment and of turning courts into tribunals over innovation sufficiency.[88] Moreover, courts

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[87] *See generally Mylan Pharm., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824, 2013 WL 5692880 (E.D. Pa. June 12, 2013).

[88] Indeed, Congress could have chosen to bar or significantly restrict name-brand drug manufacturers from making changes that would delay generic entry, but it did not do so. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) ("Because the balance struck between these competing goals is quintessentially a matter for legislative judgment, the court must attend closely to the terms in which the Congress expressed that judgment."); *Tri-Bio Labs. Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987) (Hatch-Waxman reflects a "statutory compromise of . . . competing concerns").

may need to be cognizant of the unique separation between consumers and drug manufacturers in the pharmaceutical market, especially in cases where there is evidence of extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer's version of a drug.[89] With all of this said, even in more difficult cases, the disposition of each claim will necessarily turn on the facts and circumstances surrounding a company's alleged anticompetitive conduct.

Of course, we need not reach these additional factors because we are not presented with such a close call. Here, Mylan's claims fail under a straightforward application of the *Microsoft Corp.* framework because Mylan has failed to produce evidence that Defendants' conduct was anticompetitive. Because Mylan's § 2 claims each require a showing of anticompetitive conduct in addition to monopoly power, we will therefore affirm the District Court's grant of summary judgment to Defendants on those claims.[90]

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[89] A court may also consider whether a so-called "patent cliff" is indicative of anticompetitive conduct, especially when a defendant's actions are paired with weak or inconsistent evidence of procompetitive justifications.

[90] Mylan also argues, alternatively, that Doryx is an antitrust "submarket" within the market for tetracyclines. We disagree. As noted, the evidence shows that Doryx is interchangeable with a wide variety of other tetracyclines. It therefore cannot be argued that the public recognizes Doryx as a distinct submarket within the class of tetracyclines. *Brown Shoe Co.*, 370 U.S. at 325 (a submarket's boundaries are determined by "such practical indicia as industry or public

2. Mylan's Section 1 Claim: Illegal Restraint of Trade

Mylan also argues that the District Court erred by granting Defendants' motions for summary judgment as to Mylan's §1 illegal restraint of trade claim based on the District Court's finding that Mylan produced insufficient evidence of Defendants' anticompetitive conduct. We reject Mylan's contention.

Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce."[91] "To establish a [S]ection 1 violation, a plaintiff must prove: (1) concerted action by the defendants; (2) that produced anticompetitive effects within the relevant product and geographic markets; (3) that the objects of the conduct pursuant to the concerted action were illegal; and (4) that it was injured as a proximate result of the concerted action."[92] As discussed above, Mylan has failed to prove that Defendants' product hops were anticompetitive, as required under the second element of this test.[93] Thus, the District

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recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors").

[91] 15 U.S.C. § 1.

[92] *Petruzzi's IGA Supermarkets, Inc. v. Darling-Del. Co.*, 998 F.2d 1224, 1229 (3d Cir. 1993).

[93] We have thoroughly reviewed the parties' remaining arguments, including Mylan's contentions relating to its

Court properly granted Defendants' motions for summary judgment on Mylan's Sherman Act Section 1 claim.

III. CONCLUSION

For substantially the same reasons set forth in the District Court's thorough and persuasive opinion, we will affirm the judgment of the District Court.

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tortious interference with prospective contractual relations claim under Pennsylvania law and its *Daubert* objections, and conclude that they are without merit.