IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., **Plaintiff,**	:	
v.	:	**Civ. No. 12-3824** **CONSOLIDATED**
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	
ROCHESTER DRUG CO-OPERATIVE, INC., **Plaintiff,**	:	
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	
MEIJER, INC., et al., **Plaintiffs,**	:	
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	
AMERICAN SALES COMPANY, LLC, **Plaintiff,**	:	
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al., **Defendants.**	:	

PLAINTIFF MYLAN PHARMACEUTICALS INC.'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") respectfully submits this Memorandum in Opposition to Defendant Warner Chilcott's Motion to Dismiss Plaintiff Mylan's Complaint and the Consolidated Amended Class Action Complaint (Dkt. No. 83) and Defendants Mayne Pharma Group Limited's and Mayne Pharma International Pty. Ltd.'s Motion to Dismiss (Dkt. No. 82).[1]

INTRODUCTION

This case concerns the intentional and effective exclusion of competitors to raise prices to consumers. Defendants' self-proclaimed "anti-generic strategy," which commenced as early as 2005, successfully prevented competition from lower-priced generic versions of Doryx. While lower-priced generic competition significantly benefits patients who take Doryx, Defendants understood that it would force their Doryx prices down. To combat this threat, Defendants engaged in a strategy to—in their own words—"preserve the franchise" and "eliminate generic competition" by (1) reformulating (but not improving) Doryx, (2) "swap[ping] out" the existing formulation for the reformulated product, and (3) discontinuing the existing formulation to impede generic substitution. *See, e.g.*, Compl. ¶ 49 ("[I]nternal Faulding (now Mayne) documents explain that '[t]he tablet is to be used as an anti-generic strategy' and that '[i]t is [Warner Chilcott's] intention to discontinue the Doryx capsule as soon as the tablet is available to eliminate generic competition.'"). Mylan alleges in its 119-paragraph Complaint that this strategy—which Defendants pulled off *three separate times*—harmed both consumers of Doryx

[1] Defendants are: Warner Chilcott Public Limited Company, Warner Chilcott Company, LLC, and Warner Chilcott (US), LLC (collectively, "Warner Chilcott") and Mayne Pharma Group Limited and Mayne Pharma International Pty. Ltd. (collectively, "Mayne" and with Warner Chilcott, "Defendants").

and Mylan by impeding competition from generic Doryx. Despite 80-pages of briefing, Defendants' motions to dismiss are entirely meritless and provide no grounds for preventing this case from moving forward.

Rule 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief" – and that requirement is met easily by the detailed factual allegations in Mylan's Complaint. The Complaint specifies the precise details of Defendants' "anti-generic" product-hopping scheme, a practice widely recognized as a serious violation of federal antitrust laws. Mylan has pled more than sufficient facts in support of its antitrust claims. Specifically it has alleged facts that, taken as true, establish 1) violations of Section 2 of the Sherman Act (monopolization and attempted monopolization), 2) violations of Section 1 of the Sherman Act, 3) causal antitrust injury attributable to the antitrust violations, and 4) tortious interference under Pennsylvania law. Mylan bears no further burden at this stage of the litigation. *See West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010), *cert. denied*, 132 S. Ct. 98 (2011).

As alleged in the Complaint, Defendants engaged in monopolization and attempted monopolization prohibited by Section 2 of the Sherman Act. Defendants illegally gamed the Hatch-Waxman regulatory structure to make changes to Doryx with little or no therapeutic significance and then removed the previous versions from the market, which in turn prevented generic substitution. This type of product switching is "precisely the sort of behavior the Sherman Act condemns." HERBERT HOVENKAMP, ET AL., IP & ANTITRUST § 15.3c1 (2d ed. 2011) (hereinafter, "IP & ANTITRUST"). Indeed, very similar allegations survived a motion to dismiss in a previous case (and later were tried to a jury), *see Abbott Labs. v. Teva Pharms. USA, Inc.*,

432 F. Supp. 2d 408, 423 (D. Del. 2006) (hereinafter, "*TriCor*"), and there is no contrary authority. Warner Chilcott itself entered a consent decree with the Federal Trade Commission (FTC) over similar conduct relating to a separate product called Ovcon 35 that enjoined Warner Chilcott from engaging in switching strategies for that product. *See FTC v. Warner Chilcott Holdings Co. III, Ltd.*, No. 1:05-cv-02179-CKK, Dkt. No. 90, at 8 (D.D.C. Oct. 23, 2006) (Final Order and Stipulated Permanent Injunction). Mylan's allegations thus more than adequately plead the exclusionary conduct element of a Sherman Act Section 2 claim.

Defendants' attack on Mylan's relevant market allegations fares no better. Definition of a relevant market is a subsidiary task to establishing the monopoly power element of a monopolization claim (as well as the market power element of an attempted monopolization or Sherman Act Section 1 claim). Defendants' own conduct demonstrates that they perceive generics to be their only significant pricing constraint and, thus, the only other products in the relevant market. Moreover, substantial authority holds that evidence of power to control prices and exclude competitors suffices to prove monopoly power directly, and Mylan pleads facts showing that Defendants were actually able to maintain supra-competitive prices and prevent generic entry. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). That alone suffices to meet Mylan's pleading burden.

Mylan's proposed market definition also comports with extensive precedent from pharmaceutical industry antitrust cases limiting the relevant antitrust markets to a particular drug and its AB-rated generic equivalents. *See, e.g.*, *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003). In fact, Defendants' own

efforts to prevent generic Doryx entry show that they are able to maintain supra-competitive prices in the absence of generic competition, for there would be no purpose to their actions if their product was already competitively priced. Defendants have at all relevant times held a 90-100% share of the market and technical and regulatory barriers prevent new entry. Mylan has, thus, amply alleged Defendants' power over the relevant market.

Mylan has also alleged facts sufficient to state a Sherman Act Section 1 claim. It has alleged that Warner Chilcott and Mayne, which are separate pharmaceutical companies, both agreed on the course of exclusionary conduct described in the Complaint, and that such conduct restrained trade and harmed competition in the market for Doryx and its AB-rated generic equivalents. Warner Chilcott could not have executed on its anti-generic strategy without the support of Mayne, the manufacturer of Doryx, and Mayne's public statements suffice to show that it agreed to, supported, and participated in that strategy. Nothing further is needed to plead an antitrust conspiracy. *See In re OSB Antitrust Litig.*, No. 06-826, 2007 WL 2253419, at *1 (E.D. Pa. Aug. 3, 2007) (Diamond, J.) ("Plaintiffs have made specific factual allegations of Defendants' wrongdoing. . . . *Twombly* requires no more."). Similarly, since either company could have brought an end to the anticompetitive scheme, Mayne and Warner Chilcott constitute "independent centers of decisionmaking" capable of engaging in a Section 1 conspiracy. *See Am. Needle, Inc. v. NFL*, 130 S. Ct. 2201, 2211-14 (2010). Mylan thus sufficiently alleges violations of Sherman Act Section 1.

Mylan plainly pleads causal antitrust injury, *i.e.*, "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). It has pled that

Defendants' product switching strategy blocked or delayed it from entering the market for Doryx and its AB-rated generic equivalents. "Such exclusion from the market is 'precisely the type of injury that the antitrust laws were intended to prevent,' because it reflects an injury to competition." *TriCor*, 432 F. Supp. 2d at 431 (quoting *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 772 (D.N.J. 1999)); *see also Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003) ("[T]he anticompetitive effects of exclusion [of generics] cannot be seriously debated."). Moreover, since the exclusion would not have happened in the absence of Defendants' tactic of making therapeutically insignificant modifications to Doryx and then withdrawing the prior versions from the market, that conduct was the obvious cause of Mylan's injuries. *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 356 (D.N.J. 2009) (causation established if "the violation was a material element of, and substantial factor in producing, the injury") (quoting *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 401 (7th Cir. 1993)). Mylan has thus sufficiently alleged its private antitrust claims.

Defendants' attempt to obtain dismissal on the pleadings based on their affirmative defenses fares no better. Their *Noerr-Pennington* argument fails as the misconduct challenged – 1) making product changes with little or no therapeutic benefit, 2) "swap[ping] out" the prior versions for the reformulated versions, and 3) withdrawing the prior versions from the market to prevent generic substitution – has nothing to do with any "petitioning" activity; and in any event an anticompetitive scheme is still actionable even if some of the conduct in furtherance of the scheme had been protected by *Noerr*. *See Rochester Drug Co-Op., Inc. v. Braintree Labs.*, 712 F. Supp. 2d 308, 320-21 (D. Del. 2010). Similarly, Defendants' statute of limitations argument

fails as Mylan has alleged an ongoing conspiracy and scheme in violation of the antitrust laws that has caused it harm within the applicable limitations period. *See West Penn*, 627 F.3d at 105-08. Defendants thus cannot obtain dismissal on the pleadings based on their affirmative defenses.

Mylan's claim for tortious interference with prospective economic relationships is likewise well-pleaded. The "competition privilege" Defendants assert does not apply where, as here, Defendants engaged in unlawful conduct, and no authority requires Mylan to plead its claims with the additional specificity Defendants demand. *See CBG Occupational Therapy, Inc. v. RHA Health Servs., Inc.*, 357 F.3d 375, 388-90 (3d Cir. 2004); *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 704 (E.D. Pa. 2004). Pennsylvania's continuing violation doctrine likewise precludes Defendants' statute of limitations argument. Mylan has thus fully met the pleading burden for its state-law claim.

Mylan's Complaint sets out factual support for each element of its causes of action against Defendants. It has fully met the requirements of Rule 8(a) and is entitled to proceed with litigating its claims on the merits. Defendants' motions to dismiss should accordingly be denied in their entirety.

FACTS

The following statement is derived from the facts as alleged in Mylan's Complaint rather than the hundreds of pages of material external to the Complaint submitted by Defendants, which should be disregarded. On a motion to dismiss, the court assumes the truth of the facts as pled in the complaint and may not rely on materials other than those attached to or specifically incorporated into the complaint. *West Penn*, 627 F.3d at 97 n.6 ("The general rule, of course, is

that a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings.") (citation omitted).

I. Relevant Regulatory Background

The backdrop for this suit is the Food, Drug, and Cosmetics Act's (FDCA), 21 U.S.C. § 301 *et seq*., regulatory structure for approval of pharmaceutical products, as modified by the Hatch-Waxman Act, 21 U.S.C. § 355(j) & 35 U.S.C. § 271(e). Mylan's Complaint offers a full discussion of the underlying statutory and regulatory regime. *See* Compl., Dkt. No. 1, ¶¶ 21-27 (July 6, 2012). This discussion notes three salient points for resolution of Defendants' motions.

First, the Hatch-Waxman Act balances the interests of branded pharmaceutical companies in recouping investments in new drugs with the public interest in availability of low-cost generics by facilitating generic entry after the branded firm's patent exclusivity period concludes. The statute enables the Food & Drug Administration ("FDA") to review and approve generic equivalents of branded drugs via an Abbreviated New Drug Application ("ANDA") rather than the longer New Drug Application ("NDA") which is typically required to be submitted for branded drugs. By meeting the ANDA requirements set out in 21 U.S.C. § 355(j)(2)(A) & (B), the generic can become AB-rated to the branded drug. Upon the generic's approval as an AB-rated equivalent drug, the FDA lists the generic in its "Orange Book," which lists drugs that have been approved through the NDA process and their AB-rated equivalents. *See* FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, iv-v (32nd ed. 2012), *available at* http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm071436.pdf. This facilitates generic entry and enables point-of-sale generic substitution, a process Defendants' derisively call "free-riding" but which Congress

deemed important to facilitating quicker public access to affordable medicines. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("A central purpose of the Hatch-Waxman Act . . . is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'") (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)). These purposes are defeated, however, by product-hopping strategies involving withdrawal of the branded product from the market. When a brand has been withdrawn, there can be no generic substitution because there is no product for which the generic can be substituted.

Second, state automatic substitution laws further facilitate generic entry by enabling, and in some cases mandating, substitution of less expensive generic products for more expensive branded products. As an example, Pennsylvania directs automatic substitution of generic equivalents for branded drugs by the dispensing pharmacist unless either the physician or the patient expressly directs the pharmacist to fill the prescription with the branded product. *See* 28 Pa. Code §§ 25.53(b) & (c) & 25.55(a) & (b). The governing regulations, however, require that any substitute product be listed in the Orange Book. *Id.* § 25.55(d). Thus, in addition to thwarting the policy goals of the antitrust laws and the Hatch-Waxman Act, pharmaceutical product hopping based on branded product withdrawal thwarts the policy goals of numerous state laws to promote generic substitution.

Third, despite all of this, the FDA has no authority to consider competition issues in its regulatory activities and does not review product changes for anything other than safety and efficacy. *See* 21 U.S.C. § 355(d) (enumerating factors agency may consider in product approval). *See generally* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709 (2009) ("[The FDA] has neither the mandate nor the power to take

competition concerns into account in approving particular pharmaceutical products.") (hereinafter, "Dogan & Lemley"). This stands in contrast to regulations like those applicable to telecommunications, which provide for competition concerns in the course of establishing industry regulation. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 405-06 (2004) (describing competition regulations in telecommunications). In particular, as relevant in this case, branded manufacturers can modify their products and withdraw the earlier products or obtain new labeling for their products, which forces the ANDA applicant to restart the application process in order to secure an AB rating. *See TriCor*, 432 F. Supp. 2d at 420-24; Dogan & Lemley at 709-17. Nothing in the FDA's mandate provides for FDA regulation of market competition or any other analogue to the function played by the antitrust laws, and indeed its regulations can be easily gamed by branded manufacturers to anticompetitive effect. *See In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 530-31 (D.N.J. 2004); *see also* Dogan & Lemley at 709 ("The pharmaceutical industry presents a perfect storm for regulatory gaming.").

II. Industry Background

Mylan competes with Defendants in the U.S. market for Doryx and its AB-rated generic equivalents (the "Doxycycline Hyclate Market").[2] Compl. ¶¶ 32-33 & 37-38. Doryx is the branded version of delayed-release doxycycline hyclate, a tetracycline-class antibiotic approved by the FDA for use in treating, *inter alia*, severe acne. *Id*. ¶ 30. Mayne (via its predecessor entity, Faulding) obtained FDA approval for 100 mg Doryx capsules in 1985. *Id*. ¶ 41. It

[2] As defined in Mylan's Complaint, the "Doxycycline Hyclate Market" consists of Doryx products and their AB-rated equivalents—*i.e.*, delayed-release doxycycline hyclate products. Compl. ¶¶ 30-40.

granted Warner Chilcott an exclusive license to market and sell Doryx in the United States in 1997. *Id.* Mayne obtained approval for a 75 mg capsule product in 2001, 75 mg and 100 mg tablet products in 2005, and 150 mg tablet products in 2008. *Id.* ¶¶ 42-44. Mylan obtained FDA approval for generic delayed-release doxycycline hyclate 75 mg and 100 mg tablets in 2010 and 150 mg tablets in 2012. *Id.* ¶¶ 63 & 70-71.

Delayed-release doxycycline hyclate is most widely prescribed as an adjunctive treatment to prescription topical medicines for severe acne. *Id.* ¶ 30. As severe acne cannot be treated with over-the-counter products and physicians must carefully consider which prescription products to order for a patient based on their particular medical history, there is low cross-elasticity of demand between delayed-release doxycycline hyclate and other prescription medicines. *Id.* ¶¶ 34 & 36. In particular, once a physician has prescribed a Doryx formulation, the patient cannot obtain anything other than the Doryx formulation or an AB-rated generic equivalent without a new prescription because the pharmacist cannot dispense anything else. *See id.* ¶¶ 22, 33, & 37.

Branded prescription medicines generally enjoy an extended period of exclusivity due to patent protections; that period of exclusivity can be extended well beyond the life of the patent if the branded manufacturer manipulates the regulatory process to prevent generic entry. *Id.* ¶¶ 23-27. Once generic versions enter the market, the price of the drug drops. *Id.* ¶¶ 28-29. Generic competition thus results in lower costs, saving consumers, private third-party payors, and the government billions of dollars each year. *Id.* ¶ 29.

III. Defendants' Anticompetitive Conduct

As alleged in the Complaint, Defendants engaged in at least three Doryx product "switches" to prevent generic competition. *Id*. ¶¶ 52-72. Their sole purpose was to block or delay generic entry, and the switches provided little to no benefit to patients. *Id*. ¶¶ 46-51.

The first switch involved changing the form of Doryx from capsules to tablets in 2005. Knowing that generic pharmaceutical companies would soon enter the Doxycycline Hyclate Market, and knowing that they had no lawful way to stop that, Defendants switched the form of their Doryx product from 75 and 100 mg capsules to 75 and 100 mg tablets. *Id*. ¶¶ 52-53. By thereafter ceasing production and distribution of the capsules, Defendants drove physicians to prescribe the tablets instead, switching 90% of the market within 6 months. *Id*. ¶ 53. The switch required generic manufacturers, including Mylan, to cease development of generic Doryx capsules (since such capsules would not be AB-rated to the Doryx tablets being prescribed), forcing them to write off the sunk costs of their prior development activities and to undertake development of tablets instead. *Id*. ¶ 54. The form change had no therapeutic benefits, as demonstrated by the fact that – among other things – Mayne markets Doryx in Australia as 75 and 100 mg capsules to this day. *Id*. ¶ 77. In fact, Mayne's own documents note that "[t]he tablet is to be used as an anti-generic strategy" and that the purpose of the switch from capsules to tablets was "to eliminate generic competition." *Id*. ¶ 49. Likewise, Warner-Chilcott described its "Swap-out Strategy" as intended "to preserve the [Doryx] franchise." *Id*.

The second switch moved the market from 75 and 100 mg tablets to 150 mg single-scored tablets beginning in 2008. *Id*. ¶ 61. Once again, by "swap[ping] out" the previous formulation for the reformulated product and withdrawing the previous formulation from the

market, Defendants drove 90% of the market to the 150 mg tablets before any AB-rated generic could enter the market with those products in late 2010. *Id.* ¶ 62. Patients derived little to no benefit from this product over the prior version, as the usual dose for an adult would be administered in 50 mg or 100 mg increments. *Id.* ¶¶ 64 & 66; *see also* FDA, *DORYX® (Doxycycline Hyclate Delayed-Release Tablets, USP) Prescribing Information*, at 4-5 (2011), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/050795s013lbl.pdf (describing usual dosage).

The third switch occurred just as Mylan received tentative approval for a single-scored 150 mg tablet product. Compl. ¶¶ 65-67. Defendants switched their Doryx product from a single-scored tablet to a dual-scored tablet. *Id.* ¶ 67. Warner Chilcott even attempted to get customers to return single-scored product, further reducing output in the market. Compl. ¶ 67. While the anticompetitive effects of Defendants' product change were mitigated by the FDA's refusal to require generic manufacturers to start over again with the ANDA process, it still required generic manufacturers to bear the cost of manufacturing dual-scored tablets going forward. *Id.* ¶¶ 68-70.

Defendants engaged in subsidiary acts that enhanced the anticompetitive effects of their product switching strategy. Despite having marketed their capsules product since 2003 with a label providing for administration of Doryx by sprinkling the product over applesauce, Defendants did not pursue a label for the tablets including applesauce delivery, instead delaying the initiation of the tablet applesauce study to pursue a labeling change in late 2006. *Id.* ¶¶ 57-58. This resulted in further delay of generic entry by requiring generic manufacturers to rework their product to comply with the new label. *Id.* ¶ 59. Defendants also introduced scoring for their 75

mg and 100 mg tablets in 2009, a modification designed to impose further switching costs and delays on generic manufacturers. *Id*. ¶ 60. Moreover, until Mylan finally overcame Defendant's numerous schemes and entered the market with its 150 mg tablet in 2012, Defendants had been planning yet another product switch to further delay generic entry. *Id*. ¶¶ 73-74. All of these efforts required substantial expenditures by Defendants for little or no patient benefit, demonstrating that the sole reason for the product changes was to preserve Defendants' monopoly position. *Id*. ¶¶ 55, 64, 72, & 75.

The negative impact on the generic manufacturers was not mere happenstance. To the contrary, this was a deliberate strategy undertaken by Defendants for the sole and express purpose of preventing generics from entering the market – what Defendants have described as their "anti-generic" swap-out strategy. *Id*. ¶¶ 46-49 & 67 (Defendants' statements describing their "relentless" campaign to implement "anti-generic strategy").

This conduct succeeded in harming competition by excluding effective generic competition, extending Defendants' market exclusivity well past any period that would have existed otherwise, and forcing consumers, third-party payors, and government programs to continue paying monopoly prices for Doryx. *Id*. ¶ 76. It harmed Mylan because Mylan was effectively excluded from the market. *Id*. ¶ 78. It had no offsetting benefits to consumers, but solely benefited Defendants by extending their monopoly and enhancing their profits. *Id*. ¶¶ 80-82.

Importantly, physicians had no choice but to prescribe the reformulated products, as Defendants' actions in withdrawing prior products from the market and refusing to supply those products prevented physicians from prescribing the earlier products. *See id*. ¶¶ 53 & 62.

Similarly, pharmacists faced with a prescription for the available version of Doryx could not substitute prior generics that worked just as effectively because Defendants' product switches deprived the pharmacists of the ability to substitute an AB-rated generic equivalent for Doryx. *See id*. ¶¶ 36-37. Defendants' conduct thus limited the choices of healthcare professionals, undermining their ability to make decisions based on patients' circumstances, as well as the choices of patients themselves.

ARGUMENT

I. Legal Standard

"Under Federal Rule of Civil Procedure 8, a complaint must contain a 'short and plain statement of the claim showing that the pleader is entitled to relief.'" *West Penn*, 627 F.3d at 98. To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The *Twombly* standard "'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556); *see also In re OSB*, 2007 WL 2253419, at *5 ("*Twombly* does not . . . require Plaintiffs to prove their allegations before taking discovery."). "[I]t is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *West Penn*, 627 F.3d at 98. Mylan need only provide Defendants "reasonable notice of [its] allegations" and "state[] a plausible claim for relief against" them. *See In re OSB*, 2007 WL 2253419, at *6. The Court should "accept as true the factual

allegations in the complaint and draw all reasonable inferences in the plaintiff's favor." *West Penn*, 627 F.3d at 91.

II. Mylan's Complaint States Plausible Federal Antitrust Claims

To state a private antitrust claim, Mylan must allege 1) a violation of the antitrust laws and 2) causal antitrust injury resulting in entitlement to damages under Section 4 of the Clayton Act, 15 U.S.C. § 15(a). *See Weiss v. York Hosp.*, 745 F.2d 786, 805 (3d Cir. 1984). As detailed below, Mylan has fully pleaded violations of Section 2 of the Sherman Act (monopolization and attempted monopolization) and Section 1 of the Sherman Act (conspiracy in restraint of trade) as well as causal antitrust injury.

A. Mylan Sufficiently Alleges Violations of Sherman Act § 2 (Monopolization & Attempted Monopolization)

Section 2 of the Sherman Act prohibits monopolization and attempted monopolization. 15 U.S.C. § 2. Monopolization requires proof of 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." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187-88 (3d Cir. 2005); *LePage's Inc. v. 3M*, 324 F.3d 141, 146 (3d Cir. 2003) (*en banc*). Attempted monopolization requires proof that Defendants 1) engaged in anticompetitive conduct, 2) with a specific intent to monopolize, and 3) with a "dangerous probability" of achieving monopoly power. *Broadcom*, 501 F.3d at 317-18. Mylan has pled all the necessary elements.

1. *Anticompetitive Conduct*[3]

Anticompetitive conduct is conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits. *LePage's*, 324 F.3d at 147; *see also Conwood Co. v. U.S. Tobacco Co.*, 290 F.3d 768, 784 (6th Cir. 2002) (citing *Caribbean Broad. Sys. Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998)). Here, Mylan alleges that Defendants' self-proclaimed "anti-generic strategy" with respect to Doryx was exclusionary. *See Broadcom*, 501 F.3d at 308. Anticipating lower-priced generic competition, Defendants 1) reformulated (but did not improve) Doryx, 2) "swap[ped] out" the existing formulation for the reformulated product, and then 3) withdrew the existing formulation from the market solely to impede generic substitution. Remarkably, Defendants switched the market *three* separate times—first, swapping out *capsules for tablets*; next, swapping out *75 and 100 mg tablets for 150 mg tablets*; and, finally, swapping out *150 mg single-scored tablets for 150 mg dual-scored tablets*. Compl. ¶¶ 52-72. Indeed, Defendants had plans to switch the market to a *fourth* formulation. *Id.* ¶¶ 73-75.[4] Moreover, they enhanced the anticompetitive effects of their switching conduct by strategically delaying the initiation of the applesauce study for the tablet

[3] Much of the section of Warner Chilcott's brief purportedly devoted to the issue of antitrust injury in fact concerns whether the conduct alleged is exclusionary. *See* Warner Chilcott Br. at 14-19. These arguments are thus responsive to that discussion as well.

[4] Defendants cite to an aside in Judge Martini's opinion holding that Mylan's products do not infringe a particular patent they asserted against Mylan. *See Warner Chilcott Labs. Ireland Ltd. v. Impax Labs., Inc.*, Nos. 2:08-cv-06304 WJM, 2:09-cv-01233 WJM, 2:09-cv-02073 WJM, 2012 WL 1551709, at *58 (D.N.J. Apr. 30, 2012), *aff'd*, 478 Fed. Appx. 672 (Fed. Cir. 2012) ("And while it is comforting to know that Warner Chilcott did not run afoul of any antitrust laws by implementing a 'pro-generic' strategy, that really has no relevance to any of the issues raised in this case."). Such an opaque statement that the court deems in the same breath "irrelevant" to the disposition of the case provides no support for Defendants' motions.

product and precisely timing the introduction of scoring on the tablets in order to keep up barriers to generic entry. *Id.* ¶¶ 57-60. These acts should not be viewed in isolation, for by Defendants' own admission they constitute an "anti-generic strategy" meant to prop up Defendants' profits at the expense of patients and third-party payors. *See id.* ¶¶ 47-49; *see also LePage's*, 324 F.3d at 162 ("The relevant inquiry is the anticompetitive effect of 3M's exclusionary practices considered together.") (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)); *West Penn*, 627 F.3d at 108.

Defendants' "anti-generic strategy" has been effective in suppressing generic competition by intentionally subverting the generic substitution process. Because a generic drug must be the same dosage form and strength as the branded drug to be AB-rated, a change in the dosage form or strength of the brand product prevents an AB rating, thereby defeating generic substitution. Compl. ¶¶ 47-49. Thus, when Defendants change the *form* of Doryx from a capsule to a tablet, "swap-out" capsules for tablets, and then remove capsules from the market, they effectively prevent generic substitution for Doryx, since generic capsules are not AB-rated to branded tablets, and branded capsules no longer exist. *Id.* ¶¶ 33, 52-60. Similarly, when Defendants change the *strength* of Doryx from 75 and 100 mg tablets to 150 mg tablets, "swap-out" 150 mg tablets for 75 and 100 mg tablets, and then remove 75 and 100 mg tablets from the market, they effectively prevent generic substitution for Doryx, since generic 75 and 100 mg tablets are not AB-rated to branded 150 mg tablets, and branded 75 and 100 mg tablets no longer exist. *Id.* ¶¶ 33, 61-64. Defendants' lather, rinse, repeat formula forces a generic manufacturer to re-start the

ANDA approval process and, in the meantime, denies consumers the benefit of lower-priced generic competition to Doryx.[5]

Legal Standards for Pharmaceutical Product Hopping. The anticompetitive impact of pharmaceutical product hopping is well established. As the leading treatise on the intersection of antitrust and intellectual property succinctly describes:

> The generic firm may, of course, continue to offer the first drug, for which it already gained approval. That means little, however, if the branded firm has pulled that drug from pharmacy shelves and convinced doctors to write prescriptions for its new product. Until the ANDA for that new product is approved (with its AB rating), state laws limit the ability of pharmacists to substitute the "old" generic for the "new" branded drug.

IP & ANTITRUST § 15.3c1.

Far from condoning Defendants' conduct, the IP & ANTITRUST treatise concludes that "product hopping to ward off generic competition is precisely the sort of behavior the Sherman Act condemns." *Id.* Likewise, the only court to have considered facts similar to those alleged here found that foreclosure of generic substitution through "allegedly manipulative and unjustifiable formulation changes" coupled with the removal of the old formulations from the market, if proven, would constitute anticompetitive conduct. *TriCor*, 432 F. Supp. 2d at 423 ("Competitors need not be barred 'from all means of distribution,' if they are barred 'from the

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[5] Notably, Warner Chilcott's argument that product hopping is not anticompetitive is contrary to its own experience. Indeed, the FTC investigated and filed a complaint against Warner Chilcott related to a similar strategy to "switch" the market from a non-chewable to a chewable form of one of its oral contraceptive products (Ovcon 35) in order to maintain its monopoly position and prevent generic entry. *See FTC v. Warner Chilcott Holdings Co. III, Ltd.*, No. 1:05-cv-02179-CKK, Dkt. No. 1, at ¶¶ 39-40 (D.D.C. Nov. 7, 2005) (Complaint for Injunctive and Other Equitable Relief). Warner Chilcott ultimately agreed to a stipulated permanent injunction prohibiting it from engaging in switching strategies with the subject product. *See id*. Dkt. No. 90, at 8.

cost-efficient ones.'") (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001) (*en banc*)). And, while monopolists have no general duty to aid competitors, "they do have an obligation to refrain from acts that have no purpose or effect except to exclude competition." IP & ANTITRUST § 15.3c1 (citing *Grinnell Corp.*, 384 U.S. at 571) (condemning behavior that "was done plainly and explicitly for a single purpose" of driving out competitors)). *See also LePage's*, 324 F.3d at 151-52 ("[A] monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior.").

Notwithstanding their conduct to defeat generic competition to Doryx through their multiple product "swap-outs," Defendants invoke "innovation" in defense of their exclusionary conduct. As an initial matter, Defendants' claim that their Doryx reformulations were product improvements directly—and impermissibly—contradicts Mylan's Complaint, for at this stage of the proceedings, Mylan's factual assertions must be accepted as true. Indeed, Mylan alleges the opposite: that each switch "provided little or no benefit other than to exclude generic competition from the market." Compl. ¶¶ 55, 64, 72.

Moreover, Defendants' after-the-fact arguments in support of their motions are at odds with their own contemporaneous business documents. For example, according to Defendants, "[t]hey [did] not expect to have any increase in sales as part of the switch [from capsules to tablets]," rather it was "merely [] an anti-generic strategy." Compl. ¶ 3; *see id.* ¶ 49 (that "[i]t is [Warner Chilcott's] intention to discontinue the Doryx capsule as soon as the tablet is available to eliminate generic competition.").

Finally, the determination of whether Defendants' multiple product "swap-outs" are exclusionary is properly evaluated by the finder of fact under the rule of reason. *See Microsoft*, 253 F.3d at 65; *TriCor*, 432 F. Supp. 2d at 422 ("Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.").

Even without the type of regulatory barriers to entry present here, courts have condemned predatory product changes under the rule of reason. The Federal Circuit engaged in a rule of reason analysis in *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340 (Fed. Cir. 1998), to affirm a "jury's conclusion that Bard maintained its monopoly position by exclusionary conduct, to wit, modifying its patented [Biopty] gun in order to exclude competing replacement needles." *Id*. at 1382. The court noted the "substantial evidence that Bard's real reasons for modifying the gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of 'copycat' needles." *Id*. It also found evidence that the product changes did not in fact improve product performance. *Id*. On this basis, it held that "the jury could reasonably conclude that Bard's modifications to its guns constituted 'restrictive or exclusionary conduct' in a market over which it had monopoly power." *Id*.

Similarly, the *en banc* D.C. Circuit in *United States v. Microsoft Corp*. noted that "[j]udicial deference to product innovation . . . does not mean that a monopolist's product design decisions are *per se* lawful," and undertook a rule of reason analysis of various design choices

made by Microsoft with respect to its Internet Explorer and Windows products. 253 F.3d at 65. Where the government identified anticompetitive effects and "Microsoft failed to meet its burden of showing that its conduct serves a purpose other than protecting its operating system monopoly," the court condemned the design changes as "exclusionary conduct, in violation of § 2." *Id*. at 67.

Mylan's Complaint clearly alleges anticompetitive effects from Defendants' product switching. Specifically, Mylan alleges that, as a result of Defendants' anticompetitive conduct, consumers and federal, state, and private payors have been forced to overspend on prescriptions for delayed-release doxycycline hyclate products and have been denied the substantial benefits of lower-priced generic competition to Doryx. Compl. ¶ 9. Moreover, by discontinuing its existing formulations of the drug as part of its "swap-out" scheme, Defendants' conduct has precluded and/or reduced, rather than expanded, consumer choice. *Id.* ¶ 82. Indeed, this reduction in consumer choice was critical to the court's analysis in *TriCor*:

> The per se standard proposed by Defendants presupposes an open market where the merits of any new product can be tested by unfettered consumer choice. But here, according to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations.

TriCor, 432 F. Supp. 2d at 422.

This rationale was also essential to the court's decision in *Walgreen*—a case in which AstraZeneca introduced Nexium, but *did not* remove Prilosec from the market or seek to prohibit generic substitution of Prilosec. *Walgreen Co. v. AstraZeneca Pharms. LP*, 534 F. Supp. 2d 146 (D.D.C. 2008). In granting defendant's motion to dismiss in that case, the court distinguished *TriCor* on the facts, explaining:

> The elimination of choice was a critical factor in the court's decision to deny Abbott's motion to dismiss the complaint. … Yet, here, there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca added choices. It introduced a new drug to compete with already-established drugs—both its own and others'—and with the generic substitutes for at least one of the established drugs.

Id. at 151.[6] Because Defendants here reduced, rather than enhanced, competitive alternatives to Doryx—both by removing prior formulations of the drug as well as suppressing lower-priced generic competition to Doryx by impeding generic substitution—Mylan alleges Defendants' conduct resulted in anticompetitive effects. *Accord* IP & ANTITRUST § 15.3c1 ("[U]nlike Abbott, AstraZeneca did not withdraw Prilosec from the market or seek to prohibit generic substitution of Prilosec. . . . *Walgreen* represents a case in which the patentee introduced a new product but did not take advantage of the regulatory scheme to interfere with the introduction of a generic drug by the patent challenger.").

Moreover, Mylan's allegations of anticompetitive effects from Defendants' "anti-generic strategy" meet its pleading burden. While Mylan also alleges that this scheme provided no offsetting procompetitive benefits (*see, e.g.*, Compl. ¶¶ 2, 9, 55, 64, 72, 82), it is Defendants' burden to prove any such benefits. *See Microsoft*, 253 F.3d at 67. Mylan's detailed allegations of Defendants' exclusionary conduct plainly raise a sufficient inference of a right to relief, and the Court should reject Defendants' premature attempt to litigate disputed facts on issues where they bear the burden. *See In re OSB*, 2007 WL 2253419, at *1 ("Plaintiffs have made specific factual allegations of Defendants' wrongdoing. . . . *Twombly* requires no more.").

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[6] *AstraZeneca AB v. Mylan Labs. Inc.* challenged the exact same conduct at issue in *Walgreen*, and is distinguishable on the same basis. Nos. 00 Civ. 6749, 03 Civ. 6057, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010), *aff'd sub nom. In re Omeprazole Patent Litig.*, 412 Fed. Appx. 297 (Fed. Cir. 2011).

Defendants attempt to distinguish *TriCor* on the grounds that the defendants in that case also changed the National Drug Data File ("NDDF") codes, but nothing in the *TriCor* opinion treats that issue as dispositive or essential to the claims. The IP & ANTITRUST treatise notes that the decisive anticompetitive act in *TriCor* was the same as here: the withdrawal of the older formulations after the introduction of reformulations with little or no patient benefit. *Id*. § 15.3c1. The *TriCor* district court's order summarily denying the defendants' motion for leave to file summary judgment on the product switching issue relies equally on the same point. *See Teva Pharms. USA, Inc. v. Abbott Labs.*, Nos. Civ. 02-1512-SLR, Civ. 05-360-SLR, Civ. 03-120-SLR, Civ. 08-155-SLR, Civ. 05-340-SLR, 2008 WL 4107684, at *1 (D. Del. Aug. 18, 2008).

Cases Approving Product Changes are Inapplicable Here. The cases Defendants cite to for the proposition that antitrust law promotes innovation (all of which were decided either post-trial or on summary judgment) in no way approve the sort of product switching scheme Defendants engaged in here. In *California Computer Products, Inc. v. IBM*, 613 F.2d 727 (9th Cir. 1979), the Ninth Circuit examined the competitive impact of IBM's integration of certain formerly separated computer components under the rule of reason. The Court observed that "the test is whether the defendant's acts, otherwise lawful, were *unreasonably* restrictive of competition." *Id*. at 735-36 (emphasis added). The court found that "[t]he evidence at trial was uncontroverted that integration was a cost-saving step, consistent with industry trends, which enabled IBM effectively to reduce prices for equivalent functions." *Id*. at 744. It thus approved the design change because the improved functionality and lower costs rendered the change reasonable under the rule of reason. *Id*. ("[E]quivalent function at lower cost certainly represents a superior product from the buyer's point of view."). Unlike in *IBM*, Mylan alleges here that

Defendants' product switches did not substantially improve functionality and raised costs to patients and third-party payors by preventing generic entry.

The Second Circuit likewise applied a rule of reason analysis for design changes in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979). Faced with a claim that Kodak's marketing of a new film along with its new camera harmed competition, the court reviewed the attributes of the new film and old film. *Id*. at 286. Finding that each film had benefits and downsides, the court concluded any choice between them was pure consumer preference, observing, "[i]n this context, therefore, the question of product quality has little meaning." *Id*. Since "[p]reference is a matter of individual taste," the court found a monopolist may enjoy the success from consumer preference for a new product "so long as that success was not based on any form of coercion." *Id*. at 287. Critically for the case, the court found that "[u]nless consumers desired to use the 110 camera for its own attractive qualities, they were not compelled to purchase Kodacolor II *especially since Kodak did not remove any other films from the market when it introduced the new one*." *Id*. (emphasis added). By contrast, Mylan alleges here that physicians and patients had no choice because Defendants withdrew prior formulations from the market, precluding generic substitution.

The *TriCor* court made exactly this distinction in allowing claims based on product switching to proceed. The court observed that "[a] major logical underpinning of the Second Circuit's reluctance [in *Berkey Photo*] to inquire into the alleged anticompetitive effect of Kodak's new products was the success of those products in an open market, and the related conclusion that the harm to Kodak's competitors was a matter of consumer choice." 432 F. Supp. 2d at 421. The court went on to find withdrawal of a prior product significant because "when the

introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate." *Id*. Concluding that "[i]n the absence of free consumer choice, the basis for judicial deference [to product changes] is removed," the court found the switching strategy subject to rule of reason analysis and permitted the antitrust claims to proceed. *Id*. at 421 & 424. Thus, for the same reasons laid out by the *TriCor* court, the reasoning of the *Berkey Photo* case actually supports allowing Mylan's claims to proceed.

Even the approach from *Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991 (9th Cir. 2010), an outlier case that rejected the *Microsoft* rule of reason approach, would still allow for liability on the facts alleged here. The court there only immunized "a design change that improves a product by providing a new benefit to consumers," and even there only "[a]bsent some form of coercive conduct by the monopolist . . . ." *Id*. at 998 & 1000; *see also id*. at 998 ("[C]hanges in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2."). Here, Mylan has alleged that the product changes did not "provid[e] new benefits to consumers" but served only to delay generic competition. Likewise, Mylan alleges coercive conduct by Defendants in manipulating the governing regulatory regime to preclude effective generic competition. For this reason, even under the *Allied Orthopedic* standard Mylan's Complaint states a claim.

Defendants also cannot claim the approval of Professor Hovenkamp's more general antitrust treatise. The treatise does not consider pharmaceutical product hopping, and thus offers no standard for the practice at issue here, but it expressly contemplates liability "where the defendant's position in the dominant product is so substantial that the market for the older

technology is eliminated not by consumer choice but by the defendant's withdrawal" and the innovation is "clearly not superior to the older technology." 3B PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 776a, at 286-87 (3d ed. 2008). It also contemplates liability for "the patent monopolist whose subsequent innovation eliminates or significantly limits a complementary market." *Id*. ¶ 777b, at 307. The proposed conditions for liability are 1) possession of "significant and substantial market power" before the innovation, 2) "the innovator knew before introducing the improvement to the market that it was absolutely no better than the prior version and that the only purpose of the innovation was to eliminate the complementary product of a rival," and 3) the innovation "eliminate[s] all or substantially all of the complementary products produced by rivals or raise the costs of all rivals significantly." *Id*. at 307-08.[7]

The arguably more demanding analysis in the portion of the ANTITRUST LAW treatise Defendants cite is also inapplicable here. The general discussion in that treatise assumes an open market governed by consumer choice. In this case, regulatory obstacles and market dynamics specific to pharmaceuticals require a different approach to product changes. Therefore, in this

[7] The statement elsewhere in the treatise that "all product innovation should be lawful in the absence of bundling, setting aside only the possible case where investment in innovation is used to facilitate predatory pricing — that is, where the innovation investment is reasonably expected to bring the defendant's prices below the appropriate cost measure" is taken out of context by Defendants and does not address the core product withdrawal conduct at issue here. *See* ANTITRUST LAW, ¶ 781, at 320. In this case, Defendants' manipulation of regulatory barriers specific to pharmaceutical products along with the limitations on consumer choice inherent in healthcare markets where physicians make product selections preclude recourse to general standards for pure product innovation with no other anticompetitive conduct. *See TriCor*, 432 F. Supp. 2d at 422 ("The nature of the pharmaceutical drug market, as described in Plaintiffs' allegations, persuades me that the rule of reason approach should be applied here . . . .").

context the appropriate standard is the full antitrust rule of reason, as the *TriCor* court held and the IP & ANTITRUST treatise counsels. Nevertheless, Mylan's Complaint meets these even more demanding criteria for which Defendants argue. It expressly alleges facts showing each product change offered little to no therapeutic benefit, so they were clearly not superior to earlier Doryx formulations, and Defendants' withdrawal of each prior formulation eliminated the market for a generic equivalent to the prior formulations entirely. Similarly, the Complaint identifies statements and evidence suggesting Defendants knew their revised formulations were no better than their prior formulations, and the product changes imposed huge costs on generic entrants and restricted consumer access to generic substitutes.

No Regulatory Displacement. Defendants' reliance on *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004) to argue that the presence of FDA regulations reduces the need for antitrust is seriously misplaced. The Court indeed found that the presence of "a regulatory structure designed to deter and remedy anticompetitive harm" meant "the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny." *Id*. at 412. But it was, of course, rendering its decision in an industry (telecommunications) governed by extensive competition regulation under the Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996).

Here, by contrast, the FDA has no antitrust-type function and exclusively concerns itself with the regulation of safety and efficacy claims regarding pharmaceutical products. *See* 21 U.S.C. § 355(d); Dogan & Lemley at 709. The FDA's regulatory mandate actually increases the need for antitrust scrutiny because it raises barriers to entry, as multiple courts have recognized.

See TriCor, 432 F. Supp. 2d at 422; *In re Remeron*, 335 F. Supp. 2d at 531 ("In the instant case, there exists no regulatory scheme so extensive as to supplant antitrust laws."); *accord In re Gabapentin*, 649 F. Supp. 2d at 367 ("The Hatch-Waxman regulatory scheme presents unique opportunities for gamesmanship . . . ."). *Trinko* itself anticipates this problem, noting, "Where, by contrast, '[t]here is nothing built into the regulatory scheme which performs the antitrust function,' *Silver v. New York Stock Exchange*, 373 U.S. 341, 358 (1963), the benefits of antitrust are worth its sometimes considerable disadvantages." 540 U.S. at 412.

Antitrust intervention is particularly appropriate in this context as Defendants' product hopping fundamentally disrupts the balance the Hatch-Waxman Act sought to achieve. The goal of Hatch-Waxman is to expedite generic entry into the market once the branded company's legitimate period of exclusivity has ended. *See Novartis Pharms.*, 482 F.3d at 1344 ("A central purpose of the Hatch-Waxman Act . . . is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'") (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)). Defendants' product hopping activities fundamentally disrupt this balance and should be condemned here. *See TriCor*, 432 F. Supp. 2d at 422 ("[I]nquiry as to product-switching conduct . . . is justified because that conduct 'seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect'") (quoting HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, IP & ANTITRUST § 12.5 (1st ed. 2006)).

Physician Choice. Defendants also make the easily rejected argument that physicians "chose" to prescribe the reformulated Doryx products after each switch. Warner Chilcott Br. at 29-31. Prescribing the only product offered does not constitute a "choice"; rather, such limited choice reflects the anticompetitive aspects of Defendants' conduct. *See Dentsply*, 399 F.3d at

194 ("An additional anti-competitive effect is seen in the exclusionary practice here that limits the choices of products open to dental laboratories . . . ."). Defendants' attempt to frame their shifting of 90% of the market as physician "choice" should thus be rejected.

Avoidance of Free-Riding. Defendants argue that their "anti-generic strategy" simply avoids free-riding and, therefore, cannot constitute exclusionary conduct. What Defendants' term as "free-riding," however, is precisely how generic competition is intended to operate under federal and state law. The Hatch-Waxman Act—passed by Congress in 1984 and designed to balance the public's interest in access to low-cost generic drugs with patentees' interest in maintaining their patent rights—expedites the FDA approval process for generic drugs. Compl. ¶¶ 21-22. Rather than conduct full clinical trials, a generic manufacturer may submit an Abbreviated New Drug Application (ANDA) demonstrating that its drug is bioequivalent to the reference listed drug. *Id.* ¶ 22. Once approved, the generic is deemed "AB-rated" to the reference listed drug, allowing (and sometimes mandating) pharmacists to substitute the generic when presented with a prescription for the brand under state law. *Id.* This allows for sale of generic pharmaceutical products at reduced costs that reflect, *inter alia*, the lack of promotion and detailing for specific generic products. *See TriCor*, 432 F. Supp. 2d at 423.

Describing this process as "free-riding" reflects "a misunderstanding of the role of free-riding analysis in antitrust law," for it ignores the ample compensation granted branded firms by years of freedom from generic competition. *See Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 368-69 (7th Cir. 1987) (Easterbrook, J.). Reducing prices to consumers after such a period of supra-competitive pricing is not "free-riding"; it is basic competition that both the Hatch-Waxman Act and the antitrust laws were meant to protect. *Id.* at

370 ("A group of firms trying to extract a supra-competitive price therefore hardly can turn around and try to squelch lower prices . . . by branding the lower prices 'free riding'!").

The entire point of having generic medicines available (and of facilitating automatic substitution by pharmacists) is to enable the type of efficient distribution that provides the foundation for the generic pharmaceuticals industry. If generic companies were required to detail their non-proprietary drugs, costs for the industry would increase substantially and consumer prices would go up as well. By engaging in product switching, Defendants blocked the entry of generic pharmaceutical products through the elimination of the most efficient distribution process (substitution of AB-rated generics at the pharmacy level), and thus wielded their monopoly power to exclude competition. *See Microsoft*, 253 F.3d at 64 ("[A]lthough Microsoft did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones.").

The But-For World. Defendants ask what the "but for" world would be if they had not engaged in exclusionary conduct. The answer is simple: the "but-for" market would feature competition on the merits among branded and generic versions of Doryx. Rather than Defendants withdrawing the prior branded formulation of Doryx through their anticompetitive "swap-out" scheme and obstructing physician and patient choice, physicians and patients could make an informed decision regarding whether a reformulation, if any is indeed introduced, actually represented an improvement, and the market would evolve organically toward the product that offered the best combination of price and quality. Defendants instead chose to utilize their monopoly power to short circuit market decision forces and impose reformulations with little or no therapeutic benefit on the market in order to impede generic competition. This

type of abuse of monopoly power is properly the subject of antitrust condemnation. *See generally TriCor*, 432 F. Supp. 2d at 423 ("[Generic manufacturers] cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case.").

2. *Monopoly Power in the Relevant Market*

Monopoly power 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). It can be proven through two methods: (1) direct evidence of power to control prices or exclude competition, or (2) indirect evidence such as the defendant's share of the relevant market and the existence of barriers to entry. *Broadcom*, 501 F.3d at 307. Defendants' motions to dismiss do not even address direct evidence of monopoly power. Thus, Defendants' claim that Mylan has failed to adequately allege a relevant market is not only incorrect; it is also insufficient to establish that the Complaint is deficient on the ultimate issue of adequately alleging monopoly power, since in this Circuit direct evidence of monopoly power does not require market definition. *Id.* at 307 n.3. Mylan has sufficiently set forth facts to demonstrate Defendants' monopoly power through 1) their own conduct and both 2) direct and 3) indirect evidence.

Defendants' Conduct. Defendants' own conduct confirms Mylan's market definition. A relevant market is based on cross-elasticity of demand and, thus, is comprised here only of those products that provide a significant constraint on Doryx prices. ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 577-80 (7th ed. 2012) (collecting cases); ABA SECTION

OF ANTITRUST LAW, MARKET DEFINITION IN ANTITRUST 8-10 (2012). As alleged in the Complaint, Defendants knew that products other than delayed-release doxycycline hyclate were not reasonable substitutes constraining Doryx pricing. Had they been constraints, Doryx prices would already have been at competitive levels and there would be no reason to engage in an anti-generic strategy because the entry of generics would not have added significantly to the constraint other products would already have been imposing. Instead, viewing generic competition as the closest competitive substitute to branded Doryx, Defendants engaged in an extensive "anti-generic strategy" spanning three separate product switches and other conduct designed to "buy time" to effectuate the switches. Defendants recognized that competing against a generic version of Doryx constrains the price of branded Doryx in a way that competition with other branded products simply does not. That is proof enough (or, here, a sufficient allegation) that the market consists of Doryx and its generic variants, not the various other products which offer little competitive constraint.

Direct Evidence. As the Supreme Court explained, "[s]ince 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.'" *Ind. Fed'n of Dentists*, 476 U.S. at 460-61 (quoting 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1511, at 429 (1986)). *See also Broadcom*, 501 F.3d at 307 ("The existence of monopoly power may be proven through direct evidence of supracompetitive prices and restricted output.").

Defendants' product hopping activities had the actual effect of excluding competition. These strategies prevented Mylan from bringing a competing generic version of Doryx to market through the most efficient channel of distribution. Compl. ¶ 78. Likewise, Defendants' conduct allowed them to control prices, maintaining Doryx's price levels without the price reductions (or lost sales) that Defendants knew would result if generics began to compete. *Id*. ¶ 81. These facts suffice to show Defendants' actual exercise of market power. *See Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (direct evidence of market power where the defendant "was remarkably successful in causing the 10 major toy manufacturers to reduce output of toys to the warehouse clubs, and that reduction in output protected [the defendant] from having to lower its prices to meet the clubs' price levels.").

Indirect Evidence. While Mylan's pleadings on direct evidence satisfy the pleading standard for monopoly power, the Complaint also sufficiently pleads facts to support an inference through indirect evidence. A plaintiff may demonstrate defendants' market power through indirect proof, *i.e.*, proof of a high share of the "relevant market," accompanied by significant barriers to entry into that market. *Broadcom*, 501 F.3d at 307. Here, Defendants have held a 90-100% share of the alleged market for several years, and regulatory and technological barriers undeniably make entry by new competitors extremely difficult. *See* Compl. ¶¶ 39-40. Defendants therefore limit their motion to the relevant markets Mylan alleges, "the Doxycycline Hyclate Market," and various submarkets. They claim Mylan has failed to define a relevant market, despite eleven full paragraphs devoted to the issue in the Complaint. *See id*. ¶¶ 30-40.

In the context of the pharmaceutical industry, courts have found the existence of well-defined markets consisting of the branded drug and its generic equivalents only.[8] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005) (finding that relevant market is limited to ciprofloxacin and does not include competing branded antibiotics), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008). *See also FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1238-41 (8th Cir. 2011) (two medicines for same condition in different product markets); *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343 (HB), 2008 WL 169362, at *7 (S.D.N.Y. Jan. 18, 2008); *In re Cardizem*, 105 F. Supp. 2d at 680; *Knoll Pharms. Co. v. Teva Pharms. USA, Inc.*, No. 01 C 1646, 2001 WL 1001117, at *3-4 (N.D. Ill. Aug. 24, 2001); *Mut. Pharm. Co. v. Hoechst Marion Roussel, Inc.*, No. Civ. A. 96-1409, 1997 WL 805261, at *3 (E.D. Pa. Dec. 17, 1997).

Mylan has here alleged facts showing that the relevant product market is limited to the various formulations of Doryx and their AB-rated generic equivalents, which comprise the overall delayed-release doxycycline hyclate market. Compl. ¶¶ 36-37. The unique dynamics of prescription medication markets make it entirely plausible for a single medication to constitute an independent antitrust market, even when other medications treat similar conditions, and a final resolution of the issue requires a fact-intensive inquiry that cannot be done on a motion to dismiss. *See Todd v. Exxon Corp.*, 275 F.3d 191, 199-200 (2d Cir. 2001) ("Because market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure

[8] Some courts have defined the market even more narrowly in the context of pharmaceuticals, concluding that the branded and generic versions of the *very same* drug constituted separate product markets for antitrust purposes. *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496-99 (2d Cir. 2004) (concluding that generic warfarin sodium constituted its own relevant market, and branded warfarin sodium should not be included).

to plead a relevant product market."). Delayed-release doxycycline hyclate is labeled for use in the treatment of severe acne, which by definition is acne that is non-responsive to over-the-counter treatments or less drastic prescription treatments. The sort of severe, cystic acne for which systemic treatments are indicated cannot be treated by "wipes" or other routine interventions, so excluding them from the market makes perfect sense. Likewise, in light of the lack of head-to-head studies comparing delayed-release doxycycline hyclate to other possible oral antibiotics, physicians will presumably prescribe the medication they are most comfortable using without regard to price.

Definition of the relevant market is thus a highly factual inquiry more appropriate to the summary judgment or trial stage. *See Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199 (3d Cir. 1992) ("[T]he determination of a relevant product market or submarket ('market') is a highly factual one best allocated to the trier of fact.") (citing *Weiss*, 745 F.2d at 825); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 547 (D.N.J. 2000) ("The relevant market element of an antitrust claim 'can be determined only after a factual inquiry into the commercial realities' of the market.") (quoting *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 482 (1992)); *Newcal Indus., Inc. v. IKON Office Solution*, 513 F.3d 1038, 1045 (9th Cir. 2008).

Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 436 (3d Cir. 1997) is not at all contrary. It recognizes that "in most cases, proper market definition can be determined only after a factual inquiry." The allegations there were of a market that was preposterous on its face, limited to supplies for Domino's pizza—wholly unlike the widely acknowledged market definition Mylan alleges here. *Id.* at 434. For the forgoing reasons, Mylan has not only

adequately pled a valid relevant market, but more importantly has adequately pled facts supporting monopoly power—through both direct evidence and indirect evidence.

3. *Mylan Sufficiently Alleges Attempted Monopolization*

As discussed above, Mylan alleges that Defendants engaged in anticompetitive conduct in furtherance of their self-proclaimed "anti-generic strategy" intended solely to foreclose competition from lower-priced generic alternatives. As a result, Defendants have maintained and extended their monopoly power and/or have had a dangerous probability of doing so. Compl. ¶¶ 55, 64, 72, 101-08. Mylan's attempted monopolization allegations are thus also sufficient to state a Section 2 claim.

B. Mylan Sufficiently Alleges a Violation of Sherman Act § 1 (Conspiracy in Restraint of Trade)

A claim under Sherman Act § 1 requires 1) the existence of an agreement 2) that the agreement is an unreasonable restraint on trade. *West Penn*, 627 F.3d at 99; *see also Ind. Fed'n of Dentists*, 476 U.S. at 457-58. "An agreement exists when there is a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme." *West Penn*, 627 F.3d at 99. "A plaintiff may plead an agreement by alleging direct or circumstantial evidence, or a combination of the two." *Id*.

Defendants make no argument that Mylan has insufficiently pled the requisite harm to competition needed to satisfy the "unreasonable restraint of trade," the second element under Section 1. They argue only the first element, asserting that Mylan fails to allege an agreement or conspiracy. However, Mylan has alleged direct evidence of an agreement—Defendants' internal documents and public statements—and that Mayne and Warner Chilcott engaged in acts in furtherance of a conspiracy to suppress generic competition. *See* Compl. ¶¶ 46-51. In fact,

Mylan's allegations go far beyond what the case law requires. *See West Penn*, 627 F.3d at 98.[9] The Complaint notes Mayne's public admission that it works with Warner Chilcott to implement "life cycle strategies" to block generic competition, "remain[ing] relentless in defending [its] proprietary position and market share with [its] marketing partners . . . ." Compl. ¶ 48. In fact, Mayne's public releases indicate that it was the driving force behind, at a minimum, the third market switch. *Id*. ¶ 67. Internal documents from Mayne (and its predecessor entity) confirm its knowledge of and participation in Defendants' scheme to "eliminate generic competition." *Id*. ¶ 49. And, of course, there is no way Warner Chilcott as Mayne's distributor could have implemented its product hopping strategy without the active assistance of its supplier. *See id*. ¶ 41 (noting supplier-distributor relationship).

Defendants' position that a patent-holder and licensee are legally incapable of conspiring under the *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984) "single entity" doctrine is simply incorrect. Contrary to Defendants' reading of *Levi Case Co. v. ATS Products, Inc.*, 788 F. Supp. 428 (N.D. Cal. 1992) (Walker, J.), the case makes clear that a patent holder and its licensee can conspire if the relationship "deprives the marketplace of independent actors." *Id*. at 431. Unlike the alleged conspiracy between Mayne and Warner Chilcott, *Levi* did not involve an agreement between two independent sources of economic power who were plausibly independent actors in the marketplace. In *Levi*, the court held that an individual was incapable of conspiring with the company he formed, and conveyed his patents to, in order to exploit his

[9] Notably, the "detailed facts" standard advocated by Mayne is contrary to the plain language of the *Twombly* decision. *Compare* Mayne Br. at 4 (demanding "detailed facts") *with Twombly*, 550 U.S. at 545 ("[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations . . . .").

patent. Subsequent decisions, including a decision by Judge Walker (who authored *Levi*), have limited *Levi's* holding to its facts. *See, e.g.*, *Pecover v. Elecs. Arts Inc.*, 633 F. Supp. 2d 976, 983-85 (N.D. Cal. 2009) (Walker, J.) (declining to extend Levi's application of *Copperweld* because a "series of agreements between EA and [the NFL, AFTL and NCAA] could plausibly deprive the marketplace of independent sources of economic power."); *see also Townshend v. Rockwell Int'l Corp.*, No. C 99-0400 SBA, 2000 WL 433505, at *6 (N.D. Cal. Mar. 28, 2000). *See generally Am. Needle*, 130 S. Ct. at 2212 ("The question is whether the agreement joins together 'independent centers of decisionmaking.' . . . If it does, the entities are capable of conspiring under § 1, and the court must decide whether the restraint of trade is an unreasonable and therefore illegal one.") (quoting *Copperweld*, 467 U.S. at 769).

Defendants also cite *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. CIV. A. 10-1077, 2011 WL 2174499 (D. Del. May 26, 2011), in which the court dismissed Mylan's Section 1 counterclaims (with leave to amend). Unlike *Shionogi*, Mylan's Complaint in this action states detailed non-conclusory facts and sufficiently pleads a Section 1 conspiracy between Mayne and Warner Chilcott. Moreover, the court in *Shionogi* did not engage in the analysis articulated by *American Needle*, which both limited and clarified the applicability of *Copperweld*. *American Needle* reinforced that "substance, not form" determines whether an entity is capable of conspiring, and that the fact of a licensing arrangement is not enough to justify single-entity treatment. 130 S. Ct. at 2211. Thus, Defendants cannot be entitled to immunity from Section 1 scrutiny under *Copperweld* merely on the basis of a patent-licensing agreement. The key factual inquiry is whether there is a "contract, combination, or conspiracy amongst separate economic actors pursuing separate economic interests such that the agreement deprives the marketplace of

independent centers of decisionmaking and therefore of diversity of entrepreneurial interests, and thus of actual or potential competition." *Id.* at 2212 (internal marks and citations omitted).

The functional analysis required by *American Needle* makes clear that Defendants are independent decision makers for Section 1 purposes: Warner Chilcott could have refrained from executing the switch strategy in the United States, and Mayne could have continued providing the prior versions, refused to reallocate its production capacity to the changed versions of Doryx, or otherwise prevented the fulfillment of the product hopping strategy. Indeed, Defendants' own filings acknowledge that they are separate and independent specialty pharmaceutical companies. Warner Chilcott Br. at 4-5. In any event, to the extent Defendants are now claiming they are no longer independent, whether the companies are capable of conspiring is a factual issue subject to discovery and not appropriate for consideration at the pleading stage of litigation. *See, e.g.*, *Townshend*, 2000 WL 433505, at *6 (declining to dismiss complaint under *Levi* holding because the question of capability to enter a conspiracy is a question of fact). Their motions to dismiss should thus be denied as to Mylan's Section 1 claims.

C. Mylan Sufficiently Alleges Causal Antitrust Injury

"[C]ausal antitrust injury, is an element of all antitrust suits brought by private parties seeking damages under Section 4 of the Clayton Act." *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1433 (9th Cir. 1995). Antitrust injury is defined as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Brunswick*, 429 U.S. at 489. A plaintiff that seeks to compete in a market but is excluded by antitrust defendants' conduct incurs antitrust injury. *Hammes v. AAMCO Transmissions, Inc.*, 33 F.3d 774, 783 (7th Cir. 1994) (Posner, J.) (excluding plaintiff who

"wanted to compete by underselling" defendants incurs antitrust injury); *accord Palmyra Park Hosp. Inc. v. Phoebe Putney Mem'l Hosp.*, 604 F.3d 1291, 1303 (11th Cir. 2010); *Valley Drug*, 344 F.3d at 1311 n.27 ("[T]he anticompetitive effects of exclusion [of generics] cannot be seriously debated."); *Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 317 (4th Cir. 2007). As it is a highly factual inquiry, "the existence of antitrust injury is not typically resolved through motions to dismiss." *Schuylkill Energy Resources, Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (citing *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995)).

Mylan alleges that Defendants' conduct obstructed and delayed its efforts to bring to market an AB-rated generic that could be substituted by pharmacists for Doryx at a lower cost to the ultimate payor. *See* Compl. ¶¶ 76-86. Defendants' conduct excluded Mylan from competing and deprived Doryx consumers of the benefits associated with lower-cost generics. *Id.* "Such exclusion from the market is 'precisely the type of injury that the antitrust laws were intended to prevent,' because it reflects an injury to competition." *TriCor*, 432 F. Supp. 2d at 431 (quoting *Biovail*, 49 F. Supp. 2d at 772). *See also TriCor*, 432 F. Supp. 2d at 423-24 (antitrust injury sufficiently pled where product changes "suppressed competition by blocking the introduction of generic" substitutes, which is "alleged to be their cost-efficient means of competing in the pharmaceutical drug market"); *In re Remeron*, 335 F. Supp. 2d at 532 (noting that a patent-holder's actions to unlawfully maintain monopoly power or to use a lawful patent to manipulate the ANDA process could lead to anticompetitive effects). Defendants' arguments that Mylan has not alleged antitrust injury are thus baseless.

Defendants' causation argument similarly runs contrary to decades of established antitrust jurisprudence and should be rejected here. Warner Chilcott Br. at 38-44. Mylan alleges

that its injury flows directly from Defendants' anticompetitive conduct. *See, e.g.*, Compl. ¶¶ 78-86. That other aspects of the legal and regulatory structure facilitated Defendants' anticompetitive scheme does not undermine causation, for Defendants' conduct need only be a "material cause" of Mylan's injuries. *In re Gabapentin*, 649 F. Supp. 2d at 356 (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969)). Mylan "need not allege that [Defendants'] anticompetitive actions were the sole cause of its injury," but need only allege "the violation[s] w[ere] a material element of, and substantial factor in producing, the injury." *Id.* (quoting *Greater Rockford*, 998 F.2d at 401). "[R]equiring otherwise 'would effectively deny private remedies, because multiple causes always affect everyone.'" *Id.* (quoting 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 338a, at 317 (2d ed. 2000)). That aspects of the FDA approval process may also have hindered Mylan's entry in no way precludes a finding of causation at this stage in the proceedings. *See id.* ("Nor must Purepac completely discredit in its initial pleadings all possible intervening causes of its delayed launch . . . .").

Defendants also make the easily dismissed argument that because Mylan is a larger company than them overall, it cannot sustain antitrust injuries from their actions. As but one example of why this argument utterly fails, retail giant Wal-Mart successfully sued Visa and MasterCard over their anticompetitive activities, obtaining substantial relief for itself and members of a retailer class even though it generates more revenue than either credit card company. *See Wal-Mart Stores, Inc. v. Visa USA, Inc.*, 396 F.3d 96 (2d Cir. 2005). Defendants' monopoly power *with respect to Doryx* enables them to exclude generic competition and maintain high prices irrespective of whether they are larger than, smaller than, or the same size

as their potential competitors, and there is no rule preventing large companies from pursuing the treble damages remedy.

D. Defendants' Affirmative Defenses Provide No Grounds for Dismissing Mylan's Antitrust Claims

1. *Noerr-Pennington*

The Supreme Court's decision in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) ("*Noerr*"), serves to protect the rights of private parties to influence government, and when they do so, to be free from antitrust attack. The Court grounded *Noerr* in two objectives, neither of which is implicated in the present case: to protect (1) the Constitutional rights of individuals to petition the government, and (2) the decision making process of the government. *Id.* at 137-38. The *Noerr* safe harbor, therefore, protects parties whose conduct may have anticompetitive effects but are "the *result* of valid governmental action, as opposed to private action" and further explains that no antitrust violation "can be predicated upon *mere* attempts to influence the passage or enforcement of laws." *Id.* at 135-36 (emphasis added).

The present case simply does not fall into the category of activity the Supreme Court sought to protect in *Noerr*. The anticompetitive effects of Defendants' "anti-generic strategy" were not the *result* of valid governmental action or a *mere* attempt to influence government. Rather, Defendants' purely *private actions*, prior and subsequent to FDA approval of their products—product reformulation (without improvement), "swap-out" of the existing formulation for the reformulated product, and discontinuation of the existing formulation solely to impede generic substitution—caused the anticompetitive result. These actions involved no petitioning activity whatsoever and, therefore, are far outside the scope of *Noerr*. *Accord Organon Inc. v.*

Mylan Pharms., Inc., 293 F. Supp. 2d 453, 458-59 (D.N.J. 2003) (*Noerr* inapplicable when acts in question were "not petitioning activity"); *In re Gabapentin*, 649 F. Supp. 2d at 360 n.23 (collecting cases). Similarly, the fact that Defendants had to file with the FDA to bring their products to market does not suffice to provide their anticompetitive activities with *Noerr-Pennington* immunity. *See Litton Sys., Inc. v. AT&T*, 700 F.2d 785, 807 (2d Cir. 1983) ("AT&T cannot cloak its actions in *Noerr-Pennington* immunity simply because it is required, as a regulated monopoly, to disclose publicly its rates and operating procedures.").

Defendants' briefs cite nothing to support their attempt to expand *Noerr* to stand for the proposition that government approval of a product—here FDA's approval of the multiple versions of Defendants' products as "safe and effective," a review that does not involve any determination of whether a product is better or improved from its prior version—can insulate other, independent private acts *devoid of any government assent or review* that cause anticompetitive results. Just as a government issued driver's license does not authorize the holder to run over his neighbor's mailbox, the FDA's approval of a product for marketing does not authorize and immunize every other act the Defendants take with respect to that product line.

Moreover, Defendants cite no law for an interpretation of *Noerr* that would extend immunity from one potentially protected action to other *entirely private* actions. Precedent is to the contrary. None of the challenged activity here involves any petitioning activity. But even if some did, it remains true that, when an "overall scheme" of anticompetitive behavior includes both *Noerr* protected and unprotected behavior, courts have refused to dismiss plaintiffs' claims. In *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240 (9th Cir. 1982), the Ninth Circuit reversed the lower court holding that an anticompetitive scheme will not be

insulated from antitrust scrutiny just because it includes some *Noerr* protected acts—if the protected acts of petitioning "were part of a larger antitrust conspiracy, the conspiracy is subject to the antitrust laws." *Id.* at 1264 ("'It is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute.'") (quoting *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513-14 (1972)). In rejecting the defendants' arguments, the court noted: "The defendants' actions do not enjoy immunity, even though a part of the actions may have involved protected first amendment petitioning. The reach of the *Noerr-Pennington* doctrine is not that extensive, and the antitrust laws are not that impotent." *Id.* at 1265. *See also Rochester Drug Co-Op.*, 712 F. Supp. 2d at 320-21 (denying a motion to dismiss based on *Noerr* refusing to parse out the component parts of the plaintiff's theory which included both protected and unprotected activity).

The *TriCor* decision further supports this conclusion. While not expressly referencing *Noerr*, the court addressed defendants' attempt in that case to immunize their conduct under the First Amendment relying upon *Trucking Unlimited*. Specifically, the court rejected defendants' assertion that their conduct was commercial speech, finding the defendants' conduct not immunized from antitrust scrutiny when it was "used as an integral part of conduct which violates a valid statute." 432 F. Supp. 2d at 424 (quoting *Trucking Unlimited*, 404 U.S. at 514). The court concluded that "the changes in the NDDF code are alleged to be part of the Defendants' anticompetitive scheme, and those changes are an appropriate part of the circumstances to be considered in this case when evaluating Defendants' allegedly unlawful actions." *Id.* Likewise here, Defendants' reformulation/swap-out/discontinuance recipe for eliminating generic

competition to Doryx—and other conduct designed to effectuate these successive product cannibalizations—is not immunized under *Noerr*.

2. *Statute of Limitations*

Defendants' statute of limitations argument simply misstates and misapplies the law. It ignores entirely the continuing violation doctrine in the context of antitrust law and applicable Third Circuit authority. *See West Penn*, 627 F.3d at 106. The only case Defendants cite in support of their argument is a case that addressed the narrow issue of when the statute of limitations applies under the Racketeer Influenced and Corrupt Organizations Act. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 182 (1997). In the context of a continuing violation under Sections 1 and 2 of the Sherman Act, as Mylan has alleged, each time a plaintiff is injured by an act of the defendants, a cause of action accrues. *See West Penn*, 627 F.3d at 105-08 (applying continuing violation doctrine to Section 1 claim); *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481, 502 n.15 (1968) (applying the same doctrine to Section 2 claim). Mylan has properly alleged a continuing violation in which Defendants committed a series of acts in furtherance of their anticompetitive scheme within the statute of limitations period. Compl. ¶¶ 52-72. Therefore, Mylan's Sherman Act claims are not barred by the statute of limitations.

III. Mylan States a Claim for Tortious Interference Under Pennsylvania Law

Mylan has sufficiently alleged facts supporting all elements of a claim for tortious interference with prospective economic advantage under Pennsylvania law. Compl. ¶¶ 109-19. Mylan has alleged: (1) prospective contractual relationships existed between Mylan and its prospective customers; (2) Defendants took purposeful action in order to interfere with Mylan's relationships with prospective customers, through their continued efforts to convert the Relevant

Markets to new versions of Doryx on the eve of generic entry and manipulate the FDA regulatory process; (3) no privilege applies; and (4) damages resulted from the Defendants' scheme to prevent, delay, or inhibit generic competition. *See Remick v. Manfredy*, 238 F.3d 248, 263 (3d Cir. 2001) (stating elements of the tort).

Defendants' argument that the competition privilege precludes Mylan's tortious interference claim has no merit. The competition privilege only applies where "the actor does not employ wrongful means" and "does not create or continue an unlawful restraint of trade." *See CBG Occupational Therapy*, 357 F.3d at 388 (quoting RESTATEMENT (SECOND) OF TORTS § 768 (1979)).[10] Because the very essence of Mylan's allegations are that Defendants' wrongful conduct created an unlawful restraint on trade, Defendants' claim of the competition privilege is unjustified. *See Yeager's Fuel, Inc. v. Pa. Power & Light Co.*, 953 F. Supp. 617, 667 (E.D. Pa. 1997) (recognizing that the same conduct that gives rise to an antitrust violation may give rise to a tortious interference claim); *see also Babyage.com, Inc. v. Toys "R" Us, Inc.*, 558 F. Supp. 2d 575, 589 (E.D. Pa. 2008) (denying dismissal of antitrust and tortious interference claims).

Defendants' argument that the law requires that Mylan identify each specific customer or contract also fails. In *TriCor*, the court expressly rejected the argument that Plaintiff's complaint must identify the specific relationships that have been disrupted. *TriCor*, 432 F. Supp. 2d at 433. *See also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 704 (E.D. Pa. 2004) (allegation that SmithKline brought a sham patent infringement suit against Torpharm for the purpose of keeping it out of the generic Paxil market is sufficient to state a tortious interference

[10] Pennsylvania courts follow the RESTATEMENT (SECOND) OF TORTS approach for tortious interference law. *CGB Occupational Therapy*, 357 F.3d at 389.

claim); *Cornell Cos., Inc. v. Borough of New Morgan*, 512 F. Supp. 2d 238, 270-71 (E.D. Pa. 2007) (general allegations of prospective relationships suffice). In the context of claims of tortious acts that prevent, delay, or inhibit generic entry, the interference is with *all* prospective customers of the generic drug. Mylan has alleged such interference. Nothing more is required at this stage.

Finally, the continuing violation doctrine defeats Defendants' state statute of limitations argument. Pennsylvania courts have recognized the continuing tort theory and applied it to intentional tort claims, including intentional interference. *Brillhart v. Sharp*, No. 4:CV-07-1121, 2008 WL 2857713, at *5 (M.D. Pa. July 21, 2008) (citing, *inter alia*, *CBG Occupational Therapy, Inc. v. Bala Nursing and Ret. Ctr.*, 2005 WL 280838, at *3 (Pa. Ct. Comm. Pl. Jan. 27, 2005) and *Dellape v. Murray*, 651 A.2d 638, 640 (Pa. Commw. Ct. 1994)). A claim falls within the continuing violations theory if (1) at least one act occurred within the filing period and (2) the claim is more than an occurrence of isolated or sporadic acts. *Brillhart*, 2008 WL 2857713, at *5. Mylan has alleged multiple acts which were part of Defendants' broader scheme to interfere with the sale of generic Doryx products to Mylan's prospective customers, which continued through the first quarter of 2012. Because Mylan has alleged a continuing violation, its tortious interference claims relating to capsules are not barred.

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss should be denied in their entirety.

Respectfully Submitted,

Dated: November 15, 2012

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

By: /s/ Jonathan M. Jacobson

Jonathan M. Jacobson (*pro hac vice*)
Michael S. Sommer (*pro hac vice*)
Daniel P. Weick (*pro hac vice* pending)
1301 Avenue of the Americas, 40th Floor
New York, NY 10019
Tel: (212) 497-7758
Fax: (212) 999-5899

Seth C. Silber (*pro hac vice*)
Jonathan R. Lutinski (*pro hac vice*)
Christopher A. Williams (*pro hac vice*)
1700 K Street, NW, Fifth Floor
Washington, DC 20006
Tel: (202) 973-8824
Fax: (202) 973-8899

Joseph M. Donley
Jonathan W. Hugg
Nolan G. Shenai
THORP REED & ARMSTRONG, LLP
2005 Market Street, Suite 1000
One Commerce Square
Philadelphia, PA 19103-7041
Tel: (215) 640-8500
Fax: (215) 640-8501

Counsel for Mylan Pharmaceuticals Inc.

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the foregoing to be served this day upon all counsel of record in this proceeding via CM/ECF and electronic mail.

Dated: November 15, 2012

/s/ Jonathan M. Jacobson
Jonathan M. Jacobson