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

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| **MYLAN PHARMACEUTICALS, INC., ROCHESTER DRUG CO-OPERATIVE, INC., MEIJER, INC., MEIJER DISTRIBUTION, INC., and AMERICAN SALES COMPANY, LLC,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,**<br><br>**Defendants.** | **Civ. No. 12-3824**<br>**CONSOLIDATED** |

**MEMORANDUM OF LAW IN SUPPORT OF**
**DEFENDANT WARNER CHILCOTT'S MOTION TO DISMISS**

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## INTRODUCTION

This is a monopolization case turned upside down. Plaintiff Mylan is one of the world's largest pharmaceutical companies, with a wide array of its own branded and generic anti-acne treatments. Mylan is more than twice the size of Warner Chilcott, and 100 times the size of Mayne.[1] Yet Mylan asks this Court to adjudicate (and limit) which FDA-approved anti-acne products Warner Chilcott may market, and when. Mylan is asking this Court to use the antitrust laws to impose an unmanageable — and anticompetitive — duty on Warner Chilcott to affirmatively help Mylan more successfully compete.

The Complaints allege nothing more than innovation by Defendants, and the marketing of those innovations once government approvals were obtained. Innovation is certainly not illegal under the Sherman Act. And the Sherman Act certainly does not impose a duty on Defendants to assist a larger rival, Mylan, with its innovations.

Nor is any such duty created by the "automatic substitution" laws of certain states, on which Plaintiffs base their entire theory of competitive loss and damage. Recognizing this void, Plaintiffs base their claims entirely on the timing and speed of Warner Chilcott's innovation, basically conceding that the alleged injury in this case was caused by Mylan's inability to "keep pace with" Warner Chilcott. Mylan Compl. ¶ 71. Instead of alleging anti-competitive behavior, which they cannot, Plaintiffs allege that Defendants improved their anti-acne products too quickly. But rapid innovation is the lifeblood of competition, and Defendants' outpacing of Mylan cannot provide grounds for an antitrust action, either by Mylan or the Direct Purchasers.

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[1] "Plaintiffs" are Mylan Pharmaceuticals, Inc. ("Mylan"), Rochester Drug Co-Operative, Inc. ("Rochester Drug"), Meijer, Inc., Meijer Distribution, Inc. (collectively, "Meijer"), and American Sales Company LLC. "Defendants" are Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, Warner Chilcott Holdings Company III, Ltd., and Warner Chilcott Public Limited Company (collectively, "Warner Chilcott"), Mayne Pharma Group Limited, and Mayne Pharma International Pty. Ltd. (collectively, "Mayne").

Tellingly, at no point in either complaint do Plaintiffs ever allege:

- any act that *actually blocked* Mylan from launching a generic Doryx product — as Plaintiffs allege, Mylan either launched after FDA approval, and sells today, or chose to abandon the product;

- any act to *improperly obtain FDA approval* for Defendants' Doryx products — as Plaintiffs allege, the FDA approved each product at issue, and Plaintiffs do not allege Defendants broke any rules in obtaining those approvals; or

- any act that was "*exclusionary*" under the Sherman Act — Plaintiffs allege only new product launches or new uses but do not allege any "coercive" behavior that would justify punishing innovation.

In fact, the Complaints acknowledge that Mylan developed and brought to market at least six new generic Doryx products. For these reasons, Plaintiffs fail to allege facts to justify any of the relief they seek, and the Complaints should be dismissed with prejudice.

*First*, the Complaints should be dismissed on antitrust injury grounds, because alleged losses from "product switching" by innovator companies are not cognizable antitrust harms. *Second*, Plaintiffs fail to allege any exclusionary conduct under the Sherman Act. *Third*, Defendants' FDA submissions are protected *Noerr-Pennington* activity, and Plaintiffs never allege "sham petitioning." *Fourth*, Plaintiffs cannot allege causation, as any alleged injuries were caused by lawful FDA approvals or other intervening factors Plaintiffs do not dispute. *Fifth*, Plaintiffs' attempt to cast the vertical Warner Chilcott/Mayne patent license as antitrust conspiracy is contrary to black letter antitrust law. *Sixth*, Plaintiffs propose unprecedented product markets of individual Doryx dosage strengths, and a partial molecule Doryx market. *Seventh*, most of the alleged conduct occurred outside of the applicable four-year statutes of limitations, and is time-barred. *Eighth*, Mylan's tortious interference claim fails to plead several required elements and ignores the competitor's privilege.

## STATEMENT OF FACTS

Although on a motion to dismiss the Court assumes the accuracy of the well-pled facts, the Court is not limited to the four corners of the Complaints. It is well-established in this Circuit that in deciding a motion to dismiss, the Court may consider facts contained in the documents that Plaintiffs quote, cite, or rely on in the Complaints.[2] Additionally, the Court may take judicial notice of SEC filings and publicly available documents on the FDA's website.[3]

### A. The Parties

#### 1. Plaintiff Mylan

Plaintiff Mylan has "a global commercial footprint that spans approximately 150 countries and territories."[4] Mylan is "the third largest generic and specialty pharmaceuticals company in the world, in terms of revenue," reporting $6.13 billion in total revenues in 2011.[5] Currently, "Mylan markets a global portfolio of approximately 1,100 different products[.]"[6] According to Mylan, "[o]ne in every 11 prescriptions dispensed in the U.S. is a Mylan

[2] *See Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) ("In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based on these documents."); *In re Burlington Coat Factory Securities Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (court may rely on documents which the complaint was based upon, even if not explicitly cited); *Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004) (documents referenced in complaint may be considered for motion to dismiss).

[3] *See In re NAHC, Inc. Securities Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (judicial notice proper on motion to dismiss for documents "integral to or explicitly relied on in complaint," documents filed with SEC, and data compiled by Dow Jones news service); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003) (on motion to dismiss, taking judicial notice of report published on FDA website).

[4] Mylan 2011 Form 10-K at 51 (Ex. 1). This Court may take judicial notice of the parties' SEC filings. *See First State Orthopedics v. Concentra, Inc.*, 534 F. Supp. 2d 500, 520 (E.D. Pa. 2007) (taking judicial notice of defendant's annual report contained in 10-K filing).

[5] Mylan 2011 Form 10-K at 3, 52 (Ex. 1).

[6] Mylan 2011 Form 10-K at 4 (Ex. 1).

product." *Id.* Although Mylan began as a generic drug company, Mylan will sell $700 million of branded drug products in 2012.[7]

**2. The Purported "Direct" Purchaser Plaintiffs**

The Direct Purchaser Plaintiffs seek to assert claims on behalf of "[a]ll persons or entities in the United States who purchased Doryx tablets directly from any of the Defendants at any time during the period July 2008 through the present (the 'Direct Purchaser Class')." Class Compl. ¶ 22. The class excludes only the Defendants and federal government agencies. *Id*.

Meijer, Inc. and Meijer Distribution, Inc. are related to the Meijer chain of retail pharmacies. They do not allege that they purchased Doryx directly from Defendants, but instead were assigned the claim of wholesaler Frank W. Kerr Co. *Id.* at ¶ 10. American Sales Company, LLC ("ASC") also does not allege that it purchased Doryx directly from Defendants but instead is an assignee of wholesaler McKesson Corp. ("McKesson"). *Id.* at ¶ 11. Yet ASC and Meijer seek to bring this action "on behalf of themselves" and their assignors. Class Compl. ¶¶ 11, 22.[8] Rochester Drug Co-Operative, Inc. ("RDC") is a wholesaler serving "community retail pharmacies, long-term care pharmacies, and home health care stores."[9]

**3. Defendants Warner Chilcott and Mayne**

Warner Chilcott is a specialty pharmaceuticals company with less than half of Mylan's 2011 revenues.[10] Compared to Mylan's 1,100 products, just eight products made up more than

[7] Mylan 2011 Form 10-K at 118 (Mylan's "Specialty [Segment] engages mainly in the manufacture and sale of branded specialty nebulized and injectable products.") (Ex. 1); Mylan February 2012 Investor Day Presentation at 114 (predicting revenue of $710 million from Mylan's specialty segment in 2012) *available at* Mylan's Investor website (Ex. 2).

[8] Because the Meijer and ASC plaintiffs are "indirect purchasers," they lack standing to sue on their own behalf under the antitrust laws. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 745-46 (1977) (limiting antitrust standing to "direct purchasers").

[9] RDC Website, About RDC, *available at* http://www.rdcdrug.com/about/ (Ex. 3).

[10] *See* Warner Chilcott 2011 Form 10-K at 52 (Ex. 4).

93 percent of Warner Chilcott's revenue in the most recent quarter.[11] While Mylan boasts a full range of anti-acne treatments, Doryx is Warner Chilcott's only anti-acne treatment.

Mayne is an Australian specialty pharmaceuticals company, with six products.[12] Lacking a U.S.-based sales force, Mayne licensed Warner Chilcott to sell Doryx in the United States. Mylan Compl. ¶ 41 ("Mayne granted Warner Chilcott an exclusive license."). Mayne had less than 1/100$^{th}$ the revenues of Mylan.[13]

### B. Pharmaceutical Regulatory Scheme and Petitioning the FDA

The marketing and sale of pharmaceuticals in the United States is highly regulated.

#### 1. New Drugs (NDAs)

The FDA has exclusive jurisdiction to determine whether to approve a new drug application ("NDA") to market and sell a drug in the U.S. 21 U.S.C. §§ 355(a), (b). Prior to receiving FDA approval, an NDA applicant must submit clinical studies demonstrating that the drug is both "safe" and "effective" for its proposed uses. *Id.*; *see also* Class Compl. ¶ 38. The NDA applicant also must submit the proposed labeling, including the drug's pharmacology, indications, recommended dosage, adverse events, and contraindications. *See* 21 U.S.C. § 355(b); 21 C.F.R. §§ 314.50(c)(2)(i), 314.125(b)(2)-(5), 314.126. The FDA will approve an NDA only "after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c).

#### 2. Generic Drugs (ANDAs)

The FDA also exclusively regulates generic drugs. Under the Hatch-Waxman Act, generic drug manufacturers may file an Abbreviated New Drug Application ("ANDA"), relying

[11] *See* Warner Chilcott Form 10-Q filed Aug. 3, 2012 at 23 (Ex. 5).

[12] Mayne 2011 Annual Report at 4, 5 (cited in Mylan's Complaint at ¶ 8) (Ex. 6).

[13] Mayne had $50.1 million in sales in 2011. Mayne 2011 Annual Report at 9 (Ex. 6).

on the FDA's previous findings of safety and effectiveness made for the innovator's relevant "reference listed drug," *i.e.*, the subject of the original NDA. *See* 21 U.S.C. § 355(j); Mylan Compl. ¶ 21; Class Compl. ¶¶ 40-41. To receive FDA approval, an ANDA applicant must submit data demonstrating that its proposed generic drug is, among other things, both bioequivalent and pharmaceutically equivalent to the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A); Class Compl. ¶ 41; Mylan Compl. ¶ 22. Since the Hatch-Waxman Act was adopted, the use of generics has risen dramatically, from 19 percent of all drug prescriptions filled in 1984 to 80 percent of all prescriptions filled in 2011.[14]

**C. State Substitution Laws**

State laws regulating the substitution of branded drugs with generic drugs at the pharmacy level vary considerably by state. As the Complaints acknowledge, some states have "automatic substitution" laws that "require pharmacists to substitute AB-Rated generic versions for prescriptions written for reference listed branded drugs." Mylan Compl. ¶ 22; Class Compl. ¶ 36 ("in some cases require[]"). Only fourteen states have automatic substitution laws.[15] Even in such "automatic" substitution states, state law typically creates an exception for the

[14] *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* ix (JULY 1998) (referenced in Mylan's Complaint at ¶ 29) (Ex. 7); U.S. Food and Drug Administration, *Facts About Generic Drugs* (Sept. 19, 2012), *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understanding genericdrugs/ucm167991.htm ("Today, nearly 8 in 10 prescriptions filled in the United States are for generic drugs.") (Ex. 8).

[15] Only Florida, Hawaii, Kentucky, Maine, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont, and West Virginia automatically require substitution. *See* Fla. Stat. Ann. § 465.025(2) (2012) (Florida); Haw. Rev. Stat. § 328-92(a) (2012) (Hawaii); Ky. Rev. Stat. Ann. § 217.822(1) (2012) (Kentucky); Me. Rev. Stat. Ann. tit. 32, § 13781 (2012) (Maine); Mass. Gen. Laws Ann. Ch. 112, § 12D (2012) (Massachusetts); Minn. Stat. Ann. § 151.21 (2012) (Minnesota); Nev. Rev. Stat. § 639.2583.1 (2012) (Nevada); N.J. Stat. Ann. § 24:6E-7, 6E-8 (2012) (New Jersey); N.Y. Educ. L. § 6816-a (McKinney 2012) (New York); 35 Pa. Cons. Stat. § 960.3(a) (2012), 72 Cons. Pa. Stat. § 3761-510(a) (2012) (Pennsylvania); R.I. Gen. Laws §§ 5-19.1-19, 5-37-18.1, 21-31-16.1 (2012) (Rhode Island); Tenn. Code Ann. §§ 53-10-204(a), 53-10-205(a) (2012) (Tennessee); Vt. Stat. Ann. tit. 18, § 4605(a) (2012) (Vermont); W. Va. Code § 30-5-12b(b) (2012) (West Virginia).

prescribing physician to request the branded drug product. Mylan Compl. ¶ 22. Other states merely "permit[]" pharmacists to substitute generics for branded drugs. Class Compl. ¶ 36.

### D. The Anti-Acne Treatments at Issue

#### 1. Defendants Develop, and the FDA Approves, Doryx 75 mg and 100 mg Capsules (1985-2001)

Doryx is a "tetracycline-class oral antibiotic that is widely prescribed for the adjunctive treatment of severe acne" as well as certain other bacterial infections. Mylan Compl. ¶ 30; *see also* Class Compl. ¶ 1. The active ingredient in Doryx is doxycycline hyclate. Mylan Compl. ¶ 27. In 1985, F.H. Faulding & Company Limited ("Faulding"), a predecessor to Mayne, obtained FDA approval to market Doryx 100 mg strength capsules. Mylan Compl. ¶ 41; Class Compl. ¶ 53. In 2001, Faulding obtained FDA approval to market for 75 mg capsules. Mylan Compl. ¶ 42; Class Compl. ¶ 54.

#### 2. FDA Approves Doryx 75 mg and 100 mg Tablet Form (2005)

On May 6, 2005, the FDA approved Faulding's NDA for new 75 mg and 100 mg Doryx tablets. *See* Mylan Compl. ¶ 43; Class Compl. ¶ 57. But, as U.S. District Judge William J. Martini found in the 2012 Doryx tablet patent litigation, years earlier Faulding scientists had discovered an issue with the previous capsule form of Doryx. *See Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharma Inc.*, No. 08-cv-06304, 2012 WL 1551709, at *3 (D.N.J. Apr. 30, 2012) ("*Mylan*"). The company's scientists found that the delayed-release properties of the capsule actually diminished over time — "dissolution storage stability." *See id.* Eventually, they solved that problem by adding a "stabilizing coat" between the drug core and the delayed release coating of the pellets, thus prolonging the stability of the drug and allowing the Doryx active ingredient to be "contained in a tablet instead of a capsule." *See id.* at *4. Faulding applied for

and received a patent (Patent No. 6,958,161, the "Doryx Tablet Patent") embodying its invention for "improving dissolution stability." *Id.* at *4, 58.

**3. FDA Approves Labeling for Applesauce Administration (2006)**

The Complaints allege that in February 2006, Defendants sought FDA approval for a labeling change for Defendants' 75 mg and 100 mg Doryx tablets, indicating that a Doryx tablet could be administered by breaking up the tablet and sprinkling the tablet contents over applesauce. Mylan Compl. ¶ 57; Class Compl. ¶ 62. This helps those patients who are unable to swallow the tablet whole. The Complaints acknowledge the FDA approved such labeling on December 19, 2006. Mylan Compl. ¶ 58; Class Compl. ¶ 62.

**4. FDA Approves Scored Doryx 150 mg Tablet (2008)**

On June 20, 2008, the FDA approved Defendants' 150 mg strength tablet. *See* Mylan Compl. ¶ 44; Class Compl. ¶ 5. Defendants' 150 mg strength tablet was initially introduced with a single score, allowing a patient to break the tablet into two 75 mg portions. Sept. 23, 2011 Citizen Petition at 2.[16] Although Mylan contends that Defendants "soon . . . stopped promoting" the 75 and 100 mg tablets after receiving approval for the 150 mg tablet in 2008, Mylan Compl. ¶ 44, elsewhere Mylan concedes that Defendants continued marketing the two doses — including in 2009 introducing changes to their 75 and 100 mg tablets — a year after receiving approval for the 150 mg tablet. *Id.* at ¶¶ 60, 62.

**5. FDA Approves Scoring of 75, 100, and 150 mg Doryx (2009-2011)**

After the FDA approved the single-scored 150 mg Doryx tablet, Defendants subsequently introduced single-scoring for both their Doryx 75 mg and 100 mg tablets.[17] The FDA approved

[16] Defendants' Sept. 23, 2011 Citizen Petition is cited in Mylan's Complaint ¶ 67 (Ex. 9).

[17] Although Mylan's Complaint obscures the sequence of events by not presenting the various FDA approvals in chronological order (*compare* Mylan Compl. ¶ 60, *with* ¶ 62), Mylan's Complaint admits

the scored version of Defendants' 100 mg tablet in February 2009, and the 75 mg tablet in March 2009. Mylan Compl. ¶ 60. Defendants subsequently filed a supplemental NDA for the Doryx 150 mg tablet supporting a manufacturing change from single-scored to dual-scored tablets and received FDA approval in September 2011. Mylan Compl. ¶ 67; Class Compl. ¶ 77. By changing from single to dual-scoring, a 150 mg tablet could be used as a 50 mg, 100 mg, or 150 mg dose. *See* Sept. 23, 2011 Citizen Petition at 2; Mylan Compl. ¶¶ 65-66.

**E. Mylan's Generic Doryx Anti-Acne Treatment**

According to the FDA website, seven AB-rated generic drugs are approved by the FDA as therapeutic equivalents to Doryx products.[18] Actavis, Impax, and Mylan each have AB-rated therapeutic equivalent generics for Doryx 75 mg and 100 mg tablets, and Mylan has an AB-rated therapeutic equivalent generic for Doryx 150 mg tablets. *Id*. According to Mylan's complaint, Mylan currently manufacturers and markets three generic Doryx tablets — the 75, 100, and 150 mg dosage strengths. Mylan Compl. ¶ 32.

Impax, the first company to have filed an ANDA for generic Doryx, did so on March 18, 2008 for the 75 and 100 mg tablets. Class Compl. ¶ 66. Mylan subsequently filed its ANDA for those dosage strengths on March 31, 2008 for the 150 mg tablets. Mylan Compl. ¶ 59; Class Compl. ¶ 66. Both Mylan and Impax received final approval from the FDA on December 28, 2010. Mylan Compl. ¶ 62; Class Compl. ¶ 66. Mylan also filed an ANDA (No. 91-052) in December 2008, seeking approval for a 150 mg generic Doryx tablet product. Mylan Compl. ¶ 65. Mylan received tentative FDA approval for its 150 mg generic Doryx tablet on June 10,

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that the scored 150 mg tablet was approved and marketed before the scored 75 and 100 mg tablet. *Id.* ¶ 62 (Doryx 150 mg tablet approved in June 2008); *id.* ¶ 60 (Doryx single-scored 75 mg and 100 mg tablets approved in February and March 2009).

[18] The FDA website provides therapeutic equivalents data to the public, *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Generics. A copy of the Doryx therapeutic equivalents is attached as Ex. 10.

2011. *Mylan*, 2012 WL 1551709, at *5. Mylan received final FDA approval to market its 150 mg generic Doryx tablet on February 8, 2012. Mylan Compl. ¶¶ 70-71.

**F. The Doryx Tablet Patent Litigation Against Mylan (2008–April 30, 2012)**

Patent litigation between the Defendants and Mylan concerning the innovation of the Doryx tablet is referenced in both Complaints (Mylan Compl. ¶ 2 & n.2; Class Compl. ¶ 60) and was conducted before Judge Martini in the U.S. District Court for the District of New Jersey, with a final trial court decision in April 2012. *See generally Mylan*, 2012 WL 1551709. Judge Martini entered a preliminary injunction against Mylan barring the sale of Mylan's 150 mg Doryx generic on September 22, 2012. *Id.* at *5. As discussed below, after the Federal Circuit vacated the injunction, Mylan agreed to a TRO pending the outcome of the February 2012 bench trial on validity and infringement. *Id.* at *5-6.

Neither complaint acknowledges that Judge Martini in his April 30, 2012 opinion found the Doryx Tablet Patent ('161) to be a valid invention, and an advance over the prior art — that is, the Doryx "Tablet ***improved the dissolution stability of the Capsule*** (among other things)." *Id.* at *58 (emphasis added). In fact, the Class Complaint appears to have brought its claims under the mis-impression that Judge Martini had *invalidated* the '161 patent. Class Compl. ¶ 60 (the '161 patent "that covered Doryx (later held to be invalid)").

**STANDARD OF REVIEW**

Antitrust complaints that fail to plausibly state a claim must be dismissed at the outset. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (explaining that courts should expose deficiencies "at the point of minimum expenditure of time and money by the parties and the court"). It is not enough to allege that a defendant *may* have violated the law; the complaint must "nudge[] . . . [the] claims . . . across the line from conceivable to plausible." *Ashcroft v.*

*Iqbal*, 556 U.S. 662, 680 (2009). "Naked assertion[s] devoid of further factual enhancement" or "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are insufficient to survive dismissal. *Id.* at 678. "[M]erely saying so does not make it so for pleading-sufficiency purposes." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 258 (3d Cir. 2010). In evaluating plausibility, the court must consider "context" and "draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

The Supreme Court has stressed that the "costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint." *Twombly*, 550 U.S. at 558 (citations omitted).

## ARGUMENT

### I. Plaintiffs Cannot Allege Antitrust Injury

The only conduct challenged in the Complaints is innovation that was approved by the government and then marketed. The only injury claimed is based on the failure of a competitor to "keep pace with" that innovation. Mylan Compl. ¶ 71. As discussed below, such claims are directly contrary to the purposes of the antitrust laws and should be dismissed.

#### A. Antitrust Injury Is an Essential Element of Every Antitrust Claim

An antitrust plaintiff does not state a claim simply by claiming injury from the defendant's conduct. To be granted standing to seek treble damages under the antitrust laws, the plaintiff must allege "antitrust injury." Mylan and the Direct Purchaser Class Plaintiffs fail to do this, and all of their antitrust claims should be dismissed for this reason alone.

Antitrust injury is "injury of the type the antitrust laws were intended to prevent." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 484, 488-89 (1977) (rejecting plaintiffs' claim that competition prevented them from increasing their market share and holding

that it would be "inimical to the purposes of [the antitrust] laws to award damages for the type of injury claimed here"); *see also City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (quoting *Brunswick*, 429 U.S. at 489); *Mathews v. Lancaster Gen. Hosp.*, 87 F.3d 624, 641 (3d Cir. 1996) (same). The Third Circuit has warned that "were the 'heavy power [of antitrust law] brought into play too readily it would not safeguard competition, but destroy it.'" *City of Pittsburgh*, 147 F.3d at 264 (quoting *Capital Imaging Assoc. v. Mohawk Valley Med. Assoc.*, 996 F.2d 537, 539 (2d Cir. 1993)).

The antitrust laws protect competition, *not competitors*. *See Brunswick*, 429 U.S. at 488 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). "The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). Antitrust law does not impose a duty on anyone to slow down innovation, roll out new products at a certain pace, keep older versions on the market, or do anything else to help competitors compete. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) ("[T]here is no duty to aid competitors."); Seth C. Silber & Kara Kuritz, *Product Switching in Pharmaceutical Industry: Ripe for Antitrust Scrutiny?*, J. OF GENERIC MEDS. (2010) (concluding that "it would still be unchartered territory for a court to create an exception to the general rule that there is no duty to aid competitors in product hopping cases").

**B. Competitive Loss from Alleged "Product Switching" Is Not Antitrust Injury**

Three courts have considered claims that new pharmaceutical products constituted illegal "product switching" in violation of the antitrust laws. Every court but one has rejected such claims at the outset.

In *Walgreen Co. v. AstraZeneca Pharm. L.P.*, the District Court for the District of Columbia dismissed the plaintiffs' complaint on the pleadings for failure to allege antitrust

injury. 534 F. Supp. 2d 146, 148 (D.D.C. 2008). The plaintiffs in *Walgreen* (including Meijer) alleged that defendant "switched the market" from its heartburn drug Prilosec to an over-the-counter version and a separate, nearly identical treatment (Nexium) before the generic version of Prilosec launched. *Id*. at 147, 150. Specifically, the plaintiffs alleged, as here, that had defendant kept its older version of the drug on the market longer, the generic manufacturer would have had something to compete directly against and would have been more successful in the marketplace. *Id*. at 149. As here, the plaintiffs also alleged that AstraZeneca "ceased promoting and detailing Prilosec" after launching its new versions. *Id*. The plaintiffs also claimed, as here, that because there was "almost no difference between Nexium and Prilosec, and that there is no pharmacodynamic reason why" one version would interact with the body differently than the other, defendant's conduct was exclusionary under Section 2. *Id.*

The *Walgreen* court, however, rejected plaintiffs' theory and dismissed the complaint on the pleadings. The alleged injury — "product switching" — was not the "injury of the type the antitrust laws were intended to prevent." *Id.* at 149, 152–53. The court made clear,

> Plaintiffs have also not identified any antitrust law that requires a product new to the market — with or without a patent — to be superior to existing products. Antitrust law holds, and has long held, to the contrary. ***Courts and juries are not tasked with determining which product among several is superior***. Those determinations are left to the marketplace.

*Id.* at 151 (emphasis added).

Notably, the plaintiffs in *Walgreen* alleged additional conduct that Plaintiffs here do not allege, yet the court still dismissed the antitrust claims. For example, with respect to the launch of (and alleged "switch" to) an over-the-counter version of Prilosec, the plaintiffs alleged that defendants made the "switch" in part because it would cause managed care organizations to cease covering the prior version, thus raising the cost of generic substitutes for that version. *See* Pls.' Opp'n to Defs.' Mot. to Dismiss at 3-4, *Walgreen*, No. 06-cv-02084 (D.D.C. May 21,

2007), ECF No. 35 (Ex. 11). The plaintiffs alleged that this created a major pricing impediment for the generic to market its copy of prescription Prilosec. *See id.* at 8; Compl. ¶ 40, *Walgreen*, No. 06-cv-02084 (D.D.C. Dec. 7, 2006), ECF No. 1. Despite their claimed impediment, the court dismissed for failure to plead antitrust injury. Here, Plaintiffs allege no such impediment to competition by Mylan. Nothing Warner Chilcott did prevented Mylan from selling its competing versions of Doryx, including deploying Mylan's significant sales force to do so.

In the most recent case to consider this issue, the Southern District of New York granted a motion to dismiss Mylan's antitrust counterclaim that AstraZeneca's launch of new omeprazole products was illegal "product switching." *AstraZeneca AB v. Mylan Labs. Inc.*, Nos. 00 Civ. 6749, 03 Civ. 6057, 2010 WL 2079722 (S.D.N.Y. May 19, 2010). In a separate action, in a different court, involving the same AstraZeneca products involved in the *Walgreen* case discussed above, Mylan alleged, as here, that the innovator defendant violated Sections 1 and 2 of the Sherman Act by attempting to "convert sales of" Prilosec to Nexium and an OTC version, "thereby replacing revenue that would otherwise have gone to suppliers of generic omeprazole products" and "before substantial or additional generic competition to Prilosec® could occur." *Id.* at *2. The court rejected Mylan's theory, citing the above decision in *Walgreen* and holding,

> [T]he Court finds that ***Mylan has failed to plausibly allege "predatory or exclusionary acts or practices*** that have the effect of preventing or excluding competition within the relevant market," . . . as required to state a claim under § 2 of the Sherman Act, because ***the alleged conduct introducing new products — is generally considered pro-competitive***.

*Id.* at *6 (emphasis added) (citations omitted).

The sole decision to allow a claim of "product switching" to survive early dismissal — the District of Delaware's decision in *Abbott Labs. v. Teva Pharm. USA, Inc.* — is not to the contrary. 432 F. Supp. 2d 408 (D. Del. 2006). *Abbott* involved conduct (not present here) which, if true, arguably could have blocked competition and formed the basis of a claim. In

*Abbott*, a generic pharmaceutical manufacturer alleged that a maker of brand name TriCor (used to treat high cholesterol and triglyceride levels) violated various state and federal antitrust laws by: (i) illegally obtaining patents by defrauding the U.S. Patent and Trademark Office, (ii) improperly listing the patents in the Orange Book, (iii) enforcing the patents through sham litigation, and (iv) blocking generic manufacturers from selling their generic forms of TriCor after Defendants launched new versions. *Id.* at 414-19.

As to the last allegation, the plaintiffs claimed that Abbott began marketing new forms of TriCor over old forms (*i.e.*, a 145 mg tablet instead of a 160 mg, and a 48 mg tablet instead of a 54 mg) and completely blocked generic manufacturers from selling their versions by manipulating the coding of their products to prevent sales. *Id.* at 417-18. Specifically, Abbott allegedly changed the coding of its products in the National Drug Data File ("NDDF") to "obsolete" when generic versions of those products were approved.[19] *Id.* at 416. By changing the NDDF codes to "obsolete" and taking the "reference listed drug" (the prior versions of TriCor) out of the system, Abbott prevented doctors from prescribing, and pharmacies and others from substituting, generic versions of TriCor. *Id.* The NDDF coding change for TriCor also meant that the plaintiffs' generic forms no longer could be called "generic," such that, even if the plaintiffs tried to market them, they allegedly would be treated as brands and subject to the higher patient co-pay obligations of branded drugs. The NDDF change was alleged to have been a major impediment to generic sales. *Id.*

Plaintiffs do not, and cannot, allege TriCor-style conduct here. Plaintiffs allege neither fraud on the PTO, nor improper Orange Book listing, nor sham litigation. Importantly, plaintiffs

[19] The NDDF is a database, relied on by physicians and other healthcare providers, which assigns a unique code to each FDA-approved drug and any approved generic version. *See* Academy of Managed Care Pharmacy, *available at* http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=12549.

also do not allege Warner Chilcott or Mayne changed the NDDF codes for Doryx or took any action that *actually blocked* generic entry in a similar way. With Doryx, Mylan was able to launch, and did launch, its generic copies of Doryx once the FDA approved them. Mylan Compl. ¶¶ 3, 32-33, 59, 63, 67-68, 70, 85; Class Compl. ¶¶ 48, 50, 66.

### C. Antitrust Law Does Not Impose a Duty to Market Doryx in a Manner that Benefits Mylan, and Plaintiffs' Alleged Losses Are Not Antitrust Injury

Plaintiffs' claims boil down to the following:

(1) Warner Chilcott offered a new product or a new use.

(2) Doctors embraced each new product or new use, allowing Warner Chilcott to get sales that Mylan, selling the old version, would have liked to have won.

(3) Mylan — in order to "keep pace with" Warner Chilcott — had to spend money to catch up, while earning revenue from the older versions. Mylan Compl. ¶ 71.

(4) Direct purchasers bought the new versions but contend that, had Warner Chilcott kept older versions on the market, the market prices would have been lower.

This is not antitrust injury.

*First*, Plaintiffs' claims depend entirely on the existence of a duty to help competitors that does not exist. Plaintiffs argue that Defendants owed Mylan a duty to continue marketing older versions of Doryx, so that Mylan's generic Doryx could be automatically substituted for Doryx prescriptions and Mylan would take the sale. No such duty exists under the antitrust laws.

Plaintiffs assert that certain state laws (i.e., the automatic substitution laws of 14 states) that afford Mylan the right to automatically capture a generic sale without any marketing effort ***also*** impose a duty on Defendants to market certain versions of their branded drugs solely for Mylan's benefit. Out of the more than 120 years of cases interpreting the Sherman Act, we are not aware of a single case imposing such a duty.

Indeed, an amorphous duty to compete at a certain pace or refrain from innovating would be at war with the competitive rivalry that Section 1 of the Sherman Act expects. As strong as

Apple is, the Sherman Act does not compel Apple to continue marketing the iPhone 4S after it introduces the iPhone 5. Nor does Apple owe any duty to Nokia, Samsung, or RIM/Blackberry to delay the launch of the iPhone 5 so that those competitors can "keep pace with" Apple. The Sherman Act does not compel any company to market its older products when newer versions become available or delay the launch of the newer version. Over time, all manufacturers engage in "product hopping" through product upgrades or improvements. "New and improved" is the way of the world.

*Second*, Plaintiffs concede each alleged "product switch" involved the launch of a new product or new use of a product. Mylan Compl. ¶¶ 2-5, 41-44, 48-49, 53-54, 60-62, 67, 77; Class Compl. ¶¶ 4-6, 53-54, 57, 59, 62, 67. And the only injuries alleged here derive from this new competition. But the antitrust laws are not designed to protect Mylan or anyone else from competition. *See, e.g., City of Pittsburgh*, 147 F.3d at 266 (citing *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990)); *Alpern v. Cavarocchi*, No. 98-3105, 1999 WL 257695, at *5 (E.D. Pa. Apr. 28, 1999); *see also Pool Water Prods. v. Olin Corp.*, 258 F.3d 1024, 1034 (9th Cir. 2001).

*Third*, what is the "but-for" world that Plaintiffs propose? What would competition look like if Plaintiffs were right? 150 mg Doryx comes out in 2016? Doryx is never scored? Under Plaintiffs' interpretation of the antitrust laws, the Sherman Act would impose the following choices on Warner Chilcott and Mayne (and for that matter any innovator):

- When Defendants have a new product (*e.g.*, a scored pill to allow splitting), must they refrain from launching it?
- After obtaining FDA approval for an improvement, must they seek a court ruling confirming that it is a "sufficient" improvement under the Sherman Act?
- Alternatively, should they notify their competitors in advance and delay the launch until competitors catch up?

- Must Defendants wait for one or for all ANDA filers?
- Must Defendants devote the resources necessary to keep both the old and new versions on the market? And for how long must they continue?

This is not and cannot be what the antitrust laws require. Mylan's alleged competitive losses — and purchasers' alleged payment of "overcharges" as a result of Mylan's competitive losses — are not cognizable antitrust injury.

Plaintiffs may argue that, because they allege that the new Doryx products were launched as part of an "anti-generic strategy," they have stated an antitrust claim. Mylan Compl. ¶¶ 1-3, 8, 47-49, 74, 76; Class Compl. ¶¶ 37, 57-58, 71, 75-81, 99-100. But it is the *exact opposite* that would be anticompetitive. Mylan made a similar argument about "anti-generic strategy" to the court presiding over the patent litigation regarding Doryx, and the District of New Jersey rightly rejected it, holding:

> [T]he fact that a company developed a [Doryx tablet] as part of a business strategy is thoroughly unsurprising. . . . [I]t is comforting to know that Warner Chilcott did not run afoul of any antitrust laws by implementing a "***pro-generic strategy***" . . . .

*Mylan*, 2012 WL 1551709, at *58 (emphasis added).

Finally, it is no antitrust violation to have "stopped marketing" or "discontinued" an earlier version. Mylan Compl. ¶¶ 43-44, 49, 53, 62; Class Compl. ¶¶ 4-5, 57-58, 62-63, 67, 72, 74, 80. Even assuming Defendants stopped marketing an old version when a new version was launched, such conduct is either competition-enhancing (if the new version represented an improvement), or *at worst* competition-neutral because one version was replaced by another. Courts have made clear that harm from competition-neutral behavior cannot satisfy the antitrust injury requirement. *See City of Pittsburgh*, 147 F.3d at 266 (affirming the dismissal of a complaint where "'utilities' purported antitrust violation can only be said to have been competition-neutral and as such, is not actionable" (citing *Atl. Richfield*, 495 U.S. at 344 ("The

antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-reducing aspect or effect of the defendant's behavior."))); *Alpern*, 1999 WL 257695, at *5 (same); *Pool Water Prods.*, 258 F.3d at 1034 ("If the injury flows from aspects of the defendant's conduct that are beneficial or neutral to competition, there is no antitrust injury, even if the defendant's conduct is illegal *per se*." (citations omitted)).

## II. Plaintiffs Fail to Allege Exclusionary Conduct

The crux of Plaintiffs' Complaints is that Defendants illegally maintained a monopoly. But none of the alleged conduct, even if Plaintiffs' allegations were true, is exclusionary under the law.

### A. Section 2 Claims Require Plausible Allegations of Exclusionary Conduct

Monopolization is not a status offense. A plaintiff plausibly must allege not only monopoly power, but also anticompetitive conduct to *exclude* competitors to state a claim. Particularly in the context of the huge, fragmented anti-acne market, Plaintiffs do not come close to alleging plausibly that Warner Chilcott has monopoly power in a relevant product market. *See infra* Section VI. But even assuming — against economic reality and common sense — that Warner Chilcott has monopoly power in a relevant antitrust market, Plaintiffs' Sherman Act Section 2 claims should be dismissed because Plaintiffs fail to allege any exclusionary conduct.

Section 2 of the Sherman Act requires "the willful acquisition or maintenance of [monopoly] 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). As the Supreme Court explained in *Trinko*,

> The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices — at least for a short period — is what attracts "business acumen" in the first place; it induces risk taking that produces innovation and economic growth. ***To safeguard the***

> ***incentive to innovate***, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive ***conduct***.

540 U.S. at 407; *see also Handicomp, Inc. v. U.S. Golf Ass'n*, No. 99-5372, 2000 WL 426245, at *3 (3d Cir. Mar. 22, 2000) (control of 72% of market insufficient to state Section 2 claim because defendant did not use market share to exclude competition); *Behrend v. Comcast Corp.*, No. 03-6604, 2012 WL 1231794, at *19 (E.D. Pa. Apr. 12, 2012).

As discussed above, the antitrust laws do not impose a duty to help competitors. *See supra* Section I.A; *see also Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 379 (7th Cir. 1986) ("[I]f conduct is not objectively anticompetitive the fact that it was motivated by hostility to competitors . . . is irrelevant."); *Ball Mem'l Hosp. v. Mut. Hosp. Ins.*, 784 F.2d 1325, 1338 (7th Cir. 1986) ("'[I]ntent to harm rivals' is not a useful standard in antitrust."); *Cal. Computer Prods. v. IBM*, 613 F.2d 727, 744 (9th Cir. 1979) ("[IBM] was under no duty to help CalComp or other peripheral equipment manufacturers survive or expand. IBM need not have provided its rivals with disk products to examine and copy . . . nor have constricted its product development so as to facilitate sales of rival products.").

In *Trinko*, the Supreme Court evaluated a claim of monopolization in a regulated market, providing guidance for courts considering claims of exclusionary conduct in regulated industries (there, telecommunications). In rejecting the claim that Verizon's failure to share access with competitive local exchange carriers was exclusionary under Section 2, the Court held:

> Compelling such firms [even with market power] to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities. ***Enforced sharing*** also requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing — a role for which they are ill suited.

540 U.S. at 407 (emphasis added).

The *Trinko* Court also emphasized a factor that is particularly relevant to this litigation: "an awareness of the significance of regulation." *Id.* at 411 (citing *United States v. Citizens & S. Nat'l Bank*, 422 U.S. 86, 91 (1975); *Concord v. Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.); IA PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 240c3 (2d ed. 2000)). The Court held that the presence of the regulatory regime (like the FDA drug approval process in this case) was one of the factors counseling against using the antitrust laws to compel sharing by competitors. *Id.* at 412-13.

**B. Antitrust Law Encourages Innovation**

Innovation is expensive, often fails, but is vital to competition. Antitrust law protects innovation, both because it is important and because second-guessing innovation is bound to discourage it. The Sherman Act does not regulate or inhibit innovation.

Courts rightly have been reluctant to hold that a new product or design is "exclusionary," even in the face of a claim that the defendants' innovation was "not innovative enough." As the Second Circuit explained in *Berkey Photo, Inc. v. Eastman Kodak Co.*:

> [T]he question of product quality has little meaning. A product that commends itself to many users because superior in certain respects may be rendered unsatisfactory to others by flaws they considered fatal . . . . If a monopolist's products gain acceptance in the market, therefore, it is of no importance that a judge or jury may later regard them as inferior, ***so long as that success was not based on any form of coercion***.

603 F.2d 263, 286-87 (2d Cir. 1979) (emphasis added); *see also Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010) ("Absent some form of coercive conduct by the monopolist, the ultimate worth of a genuine product improvement can be adequately judged only by the market itself."); *Walgreen*, 534 F. Supp. 2d at 151-52; IIIB PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 781e (3d ed. 2008) ("We

therefore conclude that all product innovation should be lawful in the absence of bundling . . . .").

Similarly, in *Allied Orthopedic*, the Ninth Circuit rejected the claim that Tyco's launch of a new pulse oximeter, and simultaneous halt of sales of the older version, violated Section 2 of the Sherman Act. As the court explained,

> To weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the "right" amount of innovation, which would maximize social gains and minimize competitive injury. A seemingly minor technological improvement today can lead to much greater advances in the future. The balancing test proposed by plaintiffs would therefore require courts to weigh as-yet-unknown benefits against current competitive injuries.

592 F.3d at 1000; *see also ILC Peripherals Leasing Corp. v. IBM, Corp.*, 458 F. Supp. 423, 439 (N.D. Cal. 1978) ("Where there is a difference of opinion as to the advantages of two alternatives which can both be defended from an engineering standpoint, the court will not allow itself to be enmeshed 'in a technical inquiry into the justifiability of product innovations.'") (quoting *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F.2d 1307, 1330 (5th Cir. 1976)).

Refraining from second-guessing the market for the new product is all the more appropriate in this case. Here, prescribing decisions are initially made by learned physicians entrusted with judging the benefits of drugs for individual patients. *See, e.g., Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 851 (10th Cir. 2003) ("[P]hysicians based upon knowledge of their own patients, bear the final responsibility for the decision to prescribe medications and to warn the patient of possible side effects."); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 382 (D.N.J. 2004) ("It is for the prescribing physician to use his own independent medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug"). Post hoc weighing of the merits of an

innovation punishes the product and chills future innovation. *See Trinko*, 540 U.S. at 414 ("Mistaken inferences and the resulting false condemnations 'are especially costly, because they chill the very conduct the antitrust laws are designed to protect.'") (quoting *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)).

**C. Avoiding Free Riding Is Not Exclusionary Conduct**

The U.S. Supreme Court last year recognized the expense (and value) of pharmaceutical detailing — that is, a manufacturer's sales force calling on physicians. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659-60 (2011). The *Sorrell* majority observed that when a patent expires and generics enter, this expensive pharmaceutical marketing ends. *Id.* at 2660 ("Detailing is an expensive undertaking, so pharmaceutical companies most often use it to promote high-profit brand-name drugs protected by patent. Once a brand-name drug's patent expires, less expensive bioequivalent generic alternatives are manufactured and sold."). Plaintiffs admit here that the promotion of Doryx involved detailing and was expensive: "Defendants launched an expensive promotional campaign, unleashed a tide of sales force 'detailers' to convince doctors to prescribe each successive reformulation . . . ." Pls.' Statement of the Case in Joint Rule 16 Conf. Report, Dkt No. 80 (Sept. 25, 2012); *see also* Mylan Compl. ¶¶ 55, 62; Class Compl. ¶¶ 33, 58.

*Sorrell*'s recognition of the potential end of this marketing upon generic entry is natural, because innovators have no economic incentive to market for the benefit of generic manufacturers. The Supreme Court's antitrust case law has recognized the legitimate concerns of manufacturers in avoiding the "free rider" effect. *See Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 890 (2007) (discounters "can free ride on manufacturers who furnish services and then capture some of the increased demand those services generate"); *Cont'l T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 55 (1977) (overturning *Schwinn* based in part on legitimate concern of retailers to avoid "free rider" effect by inducing dealers to provide service

and repair). Automatic substitution laws, touted by Plaintiffs here, create the incentive for the termination of marketing by any pharmaceutical manufacturer.

Mylan would like the antitrust laws to create a duty for pharmaceutical manufacturers to promote the drugs Mylan would sell via automatic substitution. But antitrust law recognizes the peril of free riders and the legitimate business concern of avoiding the free rider problem. *See Sorrell*, 131 S. Ct. at 2659-60; *Leegin*, 551 U.S. at 890-91; *Sylvania*, 433 U.S. at 55. Accordingly, as Judge Posner wrote in *Olympia Equip. Leasing*, avoiding one competitor's free-riding on its competitor's sales force is not exclusionary under Section 2:

> So if a firm went to a monopolist and said, "Please — for the sake of competition — give me a loan so I can compete with you and make this a competitive market," and it was turned down, it could not invoke the Sherman Act. A monopolist has no duty to . . . extend a helping hand to new entrants . . . .
>
> But Olympia had no right under antitrust law to take a ***free ride on its competitor's sales force***. You cannot conscript your competitor's salesmen to sell your product even if the competitor has monopoly power and you are a struggling new entrant. Advertising a competitor's products free of charge is not a form of cooperation commonly found in competitive markets; ***it is the antithesis of competition***.

797 F.2d at 376-79 (emphasis added) (citations omitted). Mylan, with its three-quarters of a billion dollar business and own detailing sales force, is perfectly free to promote generic Doryx. But Defendants' decision not to provide free marketing services to Mylan — interesting doctors in their drugs only to lose the sale automatically to Mylan in certain states — cannot be the basis for a monopolization claim.

### D. Plaintiffs Do Not and Cannot Allege Any Exclusionary Conduct Here

Plaintiffs allege none of the "coercion" required to justify second-guessing Defendants' improvements to their Doryx treatment. Plaintiffs allege no bundling, tying, or predatory pricing. Nor do Plaintiffs allege any exclusive agreements with customers or distributors requiring the purchase of Warner Chilcott products and preventing the purchase of Mylan's

products. Plaintiffs do not allege that Mylan ever *tried and was prevented* from marketing any products. Plaintiffs do not allege that Mylan ever tried to market capsules after the launch of tablets; in fact they concede Mylan *chose to abandon* capsules. Mylan Compl. ¶ 54. Mylan has a sales force. But Plaintiffs do not allege Mylan ever used that sales force to convince doctors to prescribe their products, or that they were blocked from doing so.

Instead, Plaintiffs concede that, ever since the FDA approved Mylan's generic versions, *Mylan has been free to sell — and has sold* — its generic Doryx products. *Id.* ¶¶ 3, 32-33, 59, 63, 67-68, 70, 85; Class Compl. ¶¶ 48, 50, 66. In fact, during the period of alleged "exclusionary conduct," Mylan successfully developed and launched at least six different versions of generic Doryx (*e.g.*, 75 mg tablets; 100 mg tablets; scored 150; scored 75; scored 100; double-scored 150). Mylan Compl. ¶¶ 56, 60, 63, 65, 68, 71.

With respect to the specific alleged "switches" mentioned in the Complaints, none can be treated as exclusionary under Section 2, even accepting all of Plaintiffs' allegations as true.

**1. Plaintiffs Fail to Allege the Launch of Tablets Was Exclusionary**

Plaintiffs claim injury (competitive loss and overcharges) from Defendants' launch of a tablet form. Mylan Compl. ¶¶ 3, 54-56; Class Compl. ¶¶ 2, 56-59. Plaintiffs' claim is based on their allegation that 75 mg and 100 mg Doryx tablets offer "little or no benefit" over their capsule counterparts. Mylan Compl. ¶ 55; Class Compl. ¶ 56.

**a. The Doryx Tablet Is Protected by a Valid Patent**

But Doryx tablets are covered by a patent ('161 Patent), and in the patent litigation between Mylan and Defendants, the patent court confirmed that the tablets represent a novel, patentable advance over the prior art. Specifically, Judge Martini found that: "To the extent that Defendants are arguing that the Capsule and the Tablet have identical properties, ***that is plainly incorrect***. The **Tablet *improved the dissolution stability*** of the **Capsule** (among other things)."

*Mylan*, 2012 WL 1551709, at *58 (emphasis added). Judge Martini expressly upheld the validity of the '161 Patent in the face of Mylan's challenge. *Id.* at *2 ("However, this does not change the Court's overall finding that the '161 Patent is not invalid as anticipated."); *id.* at *59 ("[T]he Court concludes that Defendants failed to prove by clear and convincing evidence, that the '161 Patent is obvious in light of prior art.").

In its appeal to the Federal Circuit, Mylan did not challenge Judge Martini's ruling that the Doryx Tablet Patent (the '161 Patent) was valid. The Doryx Tablet ('161) Patent is an invention — that it was found by the court to represent an advance over the prior art.[20] *Id.* at *2 ("The Court finds that the dissolution storage stability limitations of the '161 Patent are not rendered obvious by the prior art."); *id.* at *53 ("Given the complexity of dissolution storage stability problems, and the lack of information about the cause of the problem in the Doryx Capsule, the Court finds that a person of ordinary skill in the art in April 2002 would be faced with a litany of possible paths and dead-ends, none of which would have any greater likelihood of success than the others."). The patent court found that the "Doryx Capsule [which] was marketed with a two year shelf life" had "a problem with the drug's dissolution storage stability" beyond that two years. *Id.* at *3. The Doryx Tablet ('161) Patent solved that problem. *See, e.g.*, *id.* at *4. Consequently, it is already settled that there is an invention — the Doryx Tablet Patent — which solved the stability problem of the earlier capsule formulation of Doryx. Defendants' launch of an innovative tablet product cannot be characterized as exclusionary.

[20] Courts may take judicial notice of any public record. *See Kramer v. City of Jersey City*, No. 10-2963, 2011 WL 6367806, at *206-07 (3d Cir. Dec. 20, 2011) (district court did not err in taking judicial notice of relationship between steroids and aggressive behavior, as established in study by National Institute of Health); *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 705 n.5 (3d Cir. 2004) (in noting "[w]e may take judicial notice of . . . public records," took judicial notice of a Notice of Allowance for a trademark listed on PTO website).

**b. Direct Purchasers Brought This Suit Apparently Unaware that the Doryx Tablet Patent Has Been Held to be Valid**

Despite Judge Martini's ruling that the Doryx Tablet Patent was valid, the putative Direct Purchasers appear not to be aware of this fact. In their Class Complaint, the Direct Purchasers allege that "defendants had obtained a patent (U.S. Patent No. 6,958,161) that covered Doryx ***(later held to be invalid)***." Class Compl. ¶ 60 (emphasis added). But the '161 patent has never been held invalid, and after a trial in February 2012, Judge Martini upheld the validity of the '161 patent. *Mylan*, 2012 WL 1551709, at *2, 59. Direct Purchasers appear to have brought this lawsuit misreading or unaware of Judge Martini's opinion.

**2. Plaintiffs Fail to Allege the Addition of Scoring Was Exclusionary**

Plaintiffs claim injury from Defendants' addition of scoring to the Doryx tablets, first in adding scoring to the 75 and 100 mg tablets and later in adding dual-scoring to the single-scored 150 mg tablets. Mylan Compl. ¶ 60; Class Compl. ¶¶ 4, 61-66. But the Complaints recognize the benefits for patients of a scored tablet. Specifically, Plaintiffs admit that scoring makes it easier for a patient to break a tablet in half for dosing:

> A "score" on the 75 and 100 mg Doryx tablet meant that the tablet was debossed across the tablet's center ***to facilitate a patient's breaking it in half for half-tablet dosing,*** a change which the FDA approved in early 2009.

Class Compl. ¶ 62 (emphasis added); *see also id.* ¶ 63 ("formulation[s] of generic Doryx tablets . . . capable of being 'sprinkled over applesauce' and taken in halves using a 'score'"). The Mylan Complaint is to the same effect. Mylan Compl. ¶ 60 (describing scores as "allow[ing] patients to break the tablets into halves"). As such, scoring tablets is not exclusionary, even according to Plaintiffs.

### 3. Plaintiffs Fail to Allege the Launch of a 150 mg Tablet Was Exclusionary

Plaintiffs also claim injury from Defendants' launch of a 150 mg tablet. *Id.* ¶¶ 61-64; Class Compl. ¶¶ 5, 67-73. Plaintiffs allege there was "little to no benefit" of Defendants' releasing a higher dose tablet. Mylan Compl. ¶¶ 2, 7, 9, 64, 75; Class Compl. ¶¶ 68-69. But as the cases discussed above make clear, such a speculative claim cannot be the basis for Section 2 liability. *See supra* Section III.B.

In addition, even assuming for this Motion that Plaintiffs' claim regarding the benefit of a 150 mg dose is true, Plaintiffs admit that Mylan was not excluded from selling any product as a result of the 150 mg tablet launch. Plaintiffs allege Mylan began selling its 75 and 100 mg doses (the doses Mylan alleges it was trying to sell when the 150 mg was launched) once Mylan received FDA approval, and Plaintiffs do not allege the 150 mg launch delayed FDA approval by even a minute. Mylan Compl. ¶¶ 3-4, 59; Class Compl. ¶¶ 50, 66, 73. Plaintiffs therefore fail to allege that the launch of the Doryx 150 mg tablet was exclusionary.

### 4. Plaintiffs Fail to Allege that Obtaining Approval for Use with Applesauce Was Exclusionary

Plaintiffs' claim injury from Warner Chilcott's obtaining approval for new labeling describing the administration of Doryx with applesauce and Mylan asserts Warner Chilcott strategically timed or delayed this labeling change. Mylan Compl. ¶¶ 3, 57-58; Class Compl. ¶¶ 3, 62-66. But Mylan does not (and cannot) contend that the ability to sprinkle the contents of a medication on applesauce is not a tangible benefit for those patients who have trouble swallowing medicine whole. *See* Mylan Compl. ¶¶ 3, 57-59 ("Defendants' Applesauce Study"). This is not surprising, as the FDA has provided industry-wide guidance on the benefits of

administration with applesauce for delayed release products.[21] The FDA, exercising its judgment, reviewed the study provided by Defendants on applesauce administration for tablets and specifically approved the label change. Class Compl. ¶ 62. Like the others, this FDA-approved improvement of Doryx cannot be deemed to be exclusionary.

Moreover, Mylan's contention that Defendants waited "over three years" to release the 2006 "Tablet Applesauce Study" obscures that the cited Tablet Applesauce study was done contemporaneous to the tablets' approval in mid-2005 and was necessary for the labeling change for *tablets.*[22] *Id.* ¶ 58. To suggest a delay, Mylan instead refers to a study done in 2002 with Doryx capsules (not tablets). *Id.* Review of the Tablet Applesauce Study cited in the Complaint shows the study started in late 2004, utilized Doryx tablets (which were not finally approved until May 2005), and was completed in late 2005.[23] Thus, Plaintiffs admit there was no timing issue by conceding the Tablet Applesauce Study was "released" or used shortly thereafter in February 2006. *Id.* ¶ 57; *see also* Class Compl. ¶ 62.

**5. With Each Improvement, Doctors Exercised Their Independent Clinical Judgment and Chose Improved Versions of Doryx by a Nine to One Margin over Older Doryx Products**

FDA-approved, prescription pharmaceuticals are available only with a doctor's prescription. Class Compl. ¶ 32 (pharmacists prohibited from "dispensing many pharmaceutical products, including delayed-release doxycycline hyclate, to patients without a prescription written by the patient's physician"); *see also* Mylan Compl. ¶ 22 (describing AB substitution for

[21] *See* FDA, CDER, "Guidance for Industry Size of Beads in Drug Products Labeled for Sprinkle," at 1 (May 2012), *available at* http://www. fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/UCM240243.pdf (alternative administration technique that "is particularly common with drug products designed to have extended-or delayed-release characteristics.").

[22] A copy of the Applesauce Tablet Study cited in Mylan's Complaint is attached hereto as Ex. 12.

[23] Tablet Applesauce Study at 4 ("2.1.2 Study Period: November 28, 2004 to December 23, 2004"); *id.* at 7 ("2.2.2 Study Period: August 14, 2005 to September 01, 2005") (Ex. 12).

prescription drugs); Class Compl. ¶ 52 (same). Plaintiffs admit as they must that the prescribing physician determines what drug gets prescribed: "the patient's ***physician*** chooses which product the patient will buy." Class Compl. ¶ 32 (emphasis added); *see also* Pls.' Statement of the Case ("doctors, not consumers, select which products will be bought").

After receiving information on the new Doryx products, in each instance, doctors nationwide overwhelmingly exercised their professional training and judgment, deeming the newer Doryx products superior by a 9 to 1 margin. *See* Mylan Compl. ¶ 62 (converted the market "by shifting approximately 90 percent of the ***prescriptions*** to the Doryx 150 mg Tablet Product") (emphasis added); *id.* ¶ 63 (defendants' marketing to doctors and thus "shifting approximately 90 percent of ***prescriptions*** to the Doxycycline Hyclate 150 mg Tablet Product Market") (emphasis added). As set forth above, doctors are entrusted with weighing the benefits of various drugs for their individual patients, and here Plaintiffs fail to allege exclusionary conduct by Defendants where these learned intermediaries repeatedly chose the new forms of Doryx. *See supra* Section II.B.

In none of these instances of "switching" do Plaintiffs allege that competition was excluded or prevented in any way. Plaintiffs do not allege that Defendants changed any NDDF codes (as in *Abbott*) or did anything else that blocked Mylan from launching. There is no dispute that Mylan has launched and makes generic 75 mg, 100 mg, and 150 mg tablets.

Nor do Plaintiffs allege that Warner Chilcott ever violated any part of the Hatch-Waxman Act or any of the complex rules governing pharmaceuticals. As in *Trinko*, that regulatory structure should be considered when a court decides whether to impose an obligation on a regulated company to help competitors. 540 U.S. at 411; *see also In re Indep. Serv. Orgs.*

*Antitrust Litig.*, 203 F.3d 1322, 1327-28 (Fed. Cir. 2000) (intent to monopolize irrelevant when conduct authorized by statute); ABA, ANTITRUST LAW DEVELOPMENTS 243-44 (7th ed. 2012).

### E. Plaintiffs Fail to State a Claim of Attempted Monopolization

Plaintiffs' attempted monopolization claims also fail for the reasons discussed above. To plead attempted monopolization, the plaintiff must allege, among other things, anticompetitive or exclusionary conduct. 15 U.S.C.A. § 2; *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 214 (3d Cir. 2005). As discussed above, Plaintiffs fail to allege any exclusionary conduct under Section 2 of the Sherman Act. Accordingly, Plaintiffs' attempt claim should be dismissed as well.

## III. The *Noerr-Pennington* Doctrine Bars Plaintiffs' Claims

The product innovations at the center of Plaintiffs' allegations were in each instance submitted to the FDA for regulatory approval. That petitioning of the FDA, and the FDA's subsequent actions, are fully immunized under the *Noerr-Pennington* doctrine.

### A. *Noerr-Pennington* Immunity Protects Anticompetitive Petitioning Aimed at Influencing Government Action Against a Competitor

The *Noerr-Pennington* doctrine provides complete antitrust immunity (absent sham, not alleged here) to those who petition the government, even when those petitioners have anticompetitive intentions. In *E. R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961), the Supreme Court ruled that government petitioning is protected by the First Amendment, and thus parties who engage in petitioning activity are immunized from antitrust liability, even when that petitioning has an anticompetitive effect. *Id.* at 138; *accord United Mine Workers of Am. v. Pennington*, 381 U.S. 647, 670 (1965). This doctrine extends to the petitioning of courts and government agencies. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972).

Congress did not intend in the Sherman Act to reach petitioning efforts, including those aimed at harming a competitor. *Columbia v. Omni Outdoor Adver.*, 499 U.S. 365, 382 (1991) ("Any lobbyist or applicant, in addition to getting himself heard, seeks by procedural and other means to get his opponent ignored. Policing the legitimate boundaries of such defensive strategies, when they are conducted in the context of a genuine attempt to influence governmental action, is not the role of the Sherman Act."). The First Amendment prevents the Sherman Act from impeding petitioning of Congress, regulatory agencies, or the courts. Speech is protected, regardless of whether the motivations behind such speech are self-interested or harmful to competitors. *See Sorrell*, 131 S. Ct. at 2671 (holding Vermont law prohibiting pharmaceutical detailing unconstitutional because "[u]nder the Constitution, resolution of th[e] debate [regarding the benefits of new drugs] must result from free and uninhibited speech").

Apart from immunity for anticompetitive petitioning, it is also settled law that the *Noerr-Pennington* doctrine precludes any recovery based on the resulting government action. "'[W]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action,' those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) (quoting *Noerr*, 365 U.S. at 136); *accord Omni Outdoor*, 499 U.S. at 379-80 (city and competitor immune from antitrust laws for activities relating to enactment of ordinances because "[t]he federal antitrust laws . . . do not regulate the conduct of private individuals in seeking anticompetitive action from the government"). *Noerr-Pennington* protects companies engaging in political activity that has anticompetitive results, even when the pursuit of such results would be a violation of the antitrust laws if caused through other means:

> ***Monopolists or collaborators are privileged to pursue their private selfish objectives through legislation, adjudication, or executive and administrative***

> ***machinery***. This right is founded in our Constitution but can also be independently derived from statutory interpretation of the antitrust laws. . . . [W]hen anticompetitive harm results from the government actions — such as when a private petitioner requests and receives anticompetitive legislation — then the government itself becomes the 'cause' of the restraint, and the private petitioner is relieved from liability.

I PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 201a (3d ed. 2008) (emphasis added); *see, e.g.*, *TEC Cogeneration Inc. v. Fla. Power & Light Co.*, 76 F.3d 1560, 1570 (11th Cir. 1996) ("[C]oncerted efforts to restrain or monopolize trade by petitioning government officials are protected from antitrust liability under the Sherman Act.").

Neither of the two exceptions to the *Noerr-Pennington* doctrine (sham exception or fraud on the Patent Office) are at issue here.[24] Plaintiffs cannot allege any facts for either exception.

### B. Any Allegedly Anticompetitive Conduct of Defendants Is Petitioning Protected by *Noerr-Pennington*

#### 1. Obtaining FDA Approval to Market Doryx in Tablet Form

The conduct alleged by Plaintiffs with regards to the "switch" to 75 mg and 100 mg Doryx tablets is protected by the *Noerr-Pennington* doctrine. The Complaints expressly recognize that Defendants sought government approval at the FDA of their new tablet products:

- "Given the threat posed by impending generic competition, Defendants acted to prevent competition to their Doryx franchise. Specifically, Defendants (1) ***sought and obtained FDA approval*** to market the Doryx 75 mg and 100 mg Tablet Products . . . ." Mylan Compl. ¶ 53 (emphasis added).

- "Fearing the onset of generic competition to their 75 and 100 mg Doryx capsules, and knowing that they had no patent protection for Doryx, on April 5, 2004, the ***defendants applied to the U.S. Food and Drug Administration ('FDA') for approval to market*** a 75 and 100 mg tablet version of Doryx . . . ." Class Compl. ¶ 56 (emphasis added).

Any such alleged anti-competitive motive on Defendants' part is fully within the *Noerr-Pennington* doctrine. *Noerr*, 365 U.S. at 139-40 ("We reject such a construction of the

[24] *See, e.g., Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993); *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965).

[Sherman] Act and hold that, at least insofar as the railroads' campaign was directed toward obtaining governmental action, its legality was not at all affected by any anticompetitive purpose it may have had."). It does not matter if Defendants' motives were anticompetitive — "seeking further FDA approval in order to take advantage of the drug substitution laws." Class Compl. ¶ 2. And *Noerr-Pennington* also protects Defendants from a "restraint upon trade or monopolization [that] is the result of valid government action." *Allied Tube*, 486 U.S. at 499.

**2. Obtaining FDA Approval for the Applesauce Label Change**

Similarly, Defendants' success in obtaining FDA approval to add an applesauce instruction to its label is fully protected by the *Noerr-Pennington* doctrine. Plaintiffs allege that they were harmed because Defendants released a study about the efficacy of Doryx when crushed and sprinkled over applesauce and obtained a subsequent labeling change from the FDA:

- "In 2006, Defendants released studies and sought a labeling change regarding the use of their Doryx 75 mg and 100 mg Tablet Products when broken into pieces and sprinkled over applesauce for patient consumption (the 'Tablet Applesauce Study'). Again, ***because a generic product needs to be the same as its reference listed branded drug equivalent*** — including any changes in labeling — Defendants' conduct required Mylan to undertake studies similar to the Tablet Applesauce Study." Mylan Compl. ¶ 57 (emphasis added).

- "Specifically, on February 17, 2006, the defendants ***proposed a labeling change*** to explain how to administer Doryx by breaking up the Doryx tablet and sprinkling the contents over applesauce. ***FDA approved this label change on December 19, 2006***." Class Compl. ¶ 62 (emphasis added).

Each allegation admits that FDA regulatory approvals were the anticompetitive conduct sought. This is nothing more than seeking and obtaining government action, fully immunized under *Noerr-Pennington.* A motivation such as "tim[ing] FDA label changes to be imposed on would-be generic makers," *id.* ¶ 3, is simply irrelevant under *Noerr-Pennington*. *Noerr*, 365 U.S. at 138-39 (rejecting district court's finding that the "sole purpose in seeking to influence the

passage and enforcement of laws" was to destroy the market for competitors "could transform conduct otherwise lawful into a violation of the Sherman Act").

### 3. Obtaining FDA Approval of 150 mg Doryx Tablets

Plaintiffs also allege they were injured when Defendants obtained FDA approval to market 150 mg Doryx tablets:

- "***After seeking and obtaining FDA approval for [a] 150 mg single-scored delayed-release tablet version of Doryx ('Doryx 150 mg Tablet Product') in June 2008***, Defendants again converted the Doxycycline Hyclate Market — this time from the Doryx 75 mg and 100 mg Tablet Products to the Doryx 150 mg Tablet Product — by shifting approximately 90 percent of the prescriptions to the Doryx 150 mg Tablet Product ***before Mylan was able to receive FDA approval for its ANDA*** covering the 75 mg and 100 mg tablet strengths in December 2010." Mylan Compl. ¶ 62 (emphasis added).

- "[D]efendants, for no legitimate medical or clinical reason, ***filed an application with FDA*** to market a 150 mg dosage strength of Doryx tablets. Six months later, on June 20, 2008, ***FDA approved the application, and the defendants began to market 150 mg branded Doryx tablets***." Class Compl. ¶ 67 (emphasis added).

When changing dosage, pharmaceutical companies are required to seek FDA approval before marketing a dosage that varies from one already approved. *See* 21 C.F.R. § 314.54. The fact that Defendants obtained that regulatory change through petitioning the FDA is fully immune under *Noerr-Pennington.*

### 4. Obtaining FDA Approval for Scoring the 75 mg and 100 mg Tablets

Similarly, Plaintiffs allege injury because Defendants obtained FDA approval for a score placed on the Doryx tablet.

- "For example, in February 2009, ***Defendants obtained approval*** for a 'scored' version of the Doryx 100 mg Tablet Product and, in March 2009, obtained approval for a 'scored' version of the Doryx 75 mg Tablet Product." Mylan Compl. ¶ 60 (emphasis added).

- "A 'score' on the 75 and 100 mg Doryx tablet meant that the tablet was debossed across the tablet's center to facilitate a patient's breaking it in half for half-tablet dosing, a change ***which the FDA approved in early 2009***." Class Compl. ¶ 62 (emphasis added).

- "[S]cored versions . . . ***were designed to force Mylan to modify*** its product . . . ***in order to obtain FDA approval***." Mylan Compl. ¶ 60 (emphasis added).

- "The defendants knew that these changes to branded Doryx tablets ***would likely require any would-be generic competitor's formulation of generic Doryx*** tablets to be capable of being 'sprinkled over applesauce' and taken in halves using a 'score' ***while maintaining a similar drug release profile to that of a whole tablet***." Class Compl. ¶ 63 (emphasis added).

Again, the Complaints simply allege regulatory petitioning. Mylan recognizes that the FDA process requires solid experimentation and concrete results. Mylan Compl. ¶ 57 (alleging that Mylan was injured when it was forced "to go back to the drawing board and reformulate a product that could achieve the necessary delayed-release properties when broken into pieces and sprinkled over applesauce").

**5. Petitioning the FDA through a Citizen Petition (Mylan Complaint)**

Mylan (but not the Direct Purchasers) alleges it suffered injury when Defendants filed a so-called "citizen petition" with the FDA, attempting to dissuade the agency from approving Mylan's ANDA. *Id.* ¶ 5 ("Soon after approval of the dual-scored Doryx 150 mg tablets, Defendants discontinued sale of the single-scored 150 mg tablet and filed a citizen petition with the FDA requesting that the agency not approve Mylan's (or any other ANDA applicant's) 150 mg generic Doryx tablet until the generic product is modified from single-scoring to dual-scoring.").

*Petitioning* the FDA through a *citizen petition* is simply, as the name implies, protected speech. Lobbying for or against a government action, no matter how self-interested, is the quintessential activity protected by the *Noerr-Pennington* doctrine and by the First Amendment right to petition. *Noerr* at 139-40 (petitioning government to influence its action does not violate the Sherman Act, regardless of party's anticompetitive intent); I PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 201a (3d ed. 2008) ("Monopolists or collaborators are

privileged to pursue their private selfish objectives through legislation, adjudication, or executive and administrative machinery.").

On double-scoring, the FDA sided with the merits of Defendants' position, and as the Mylan complaint admits, going forward the FDA required Mylan to double-score its tablets. Mylan Compl. ¶ 68 ("However, the ***FDA*** informed Mylan that — going forward — [Mylan] ***could no longer manufacture single-scored 150 mg tablets*** and needed to make changes to its manufacturing process to be consistent with the new dual-scored configuration") (emphasis added); *id.* ¶ 71 (Mylan was required by the FDA "to comply with the new dual scoring configuration" for its generic of Doryx 150 mg).

Two of the purported Direct Purchasers in their original complaints set forth allegations about this citizen petition. Am. Sales Co. Compl. ¶ 61 ("Defendants then sought to tie-up the ANDAs for Generic Doryx 75 mg and 100 mg Tablets in the FDA review and approval process by filing citizen petitions before the FDA . . . ."); Meijer Compl. ¶ 84 ("[A]s soon as Defendants learned that their change in scoring would not hold up Mylan's expected FDA approval, they quickly sought to achieve the same anticompetitive effect through the citizen petition process."). The Class Complaint of the Direct Purchasers conspicuously dropped these allegations.

The citizen petition is not alleged to have been a sham. Moreover, the petition was during the six-month period when Mylan was enjoined from launching by Judge Martini's Preliminary Injunction and then by the agreed TRO.

### C. *Noerr-Pennington* Likewise Bars Plaintiffs from Recovering on State Tort Claims

It is settled law in this Circuit that *Noerr-Pennington* immunity extends to the state law claims with equal force. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 128 (3d Cir. 1999) ("the same First Amendment principles on which *Noerr-Pennington* immunity is based

apply to the [state] tort claims" and dismissing New Jersey tort claims) (citing *Brownsville Golden Age Nursing Home, Inc. v. Wells*, 839 F.2d 155, 160 (3d Cir. 1988) (dismissing claims for civil conspiracy and interference with a business relationship under Pennsylvania law because "[t]he rule that liability cannot be imposed for damage caused by inducing legislative, administrative, or judicial action [articulated in *Noerr*] is applicable here")).

## IV. Plaintiffs Fail to Allege that Defendants' Conduct Caused Their Alleged Injuries

To have standing to pursue any of Plaintiffs' antitrust claims, Plaintiffs must allege facts sufficient to show that their injuries were directly caused by Defendants' conduct and *not*, for example, by intervening governmental action. Because Plaintiffs have not alleged such facts here, their antitrust claims must be dismissed.

### A. Causation Is an Essential Element of Every Antitrust Claim

A private plaintiff suing under the antitrust laws must prove that it was injured "by reason of" the defendant's anticompetitive conduct. 15 U.S.C. § 15(a); *see, e.g.*, *Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc.*, 63 F.3d 1267, 1273 (3d Cir. 1995) (antitrust claim requires proof of "causal connection" between alleged antitrust violation and plaintiff's alleged injury); *City of Pittsburgh*, 147 F.3d at 265 (holding that city suffered no antitrust injury because "any injury suffered by the City did not flow from the defendants' conduct, but, rather, from the realities of the regulated environment in which all three were actors"); *Sound Ship Bldg. Corp. v. Bethlehem Steel Co.*, 533 F.2d 96, 98 (3d Cir. 1976) (granting summary judgment against plaintiff who "failed to develop a theory or set out any facts . . . which would show a causal link between [defendant's] acts and [plaintiff's] losses.").

Dismissal is required when an independent cause — such as FDA approval and a binding court order in this case — fully accounts for the plaintiff's alleged injury and breaks the causal connection between the alleged antitrust violation and the plaintiff's alleged harm. *See, e.g.*, *City*

*of Pittsburgh*, 147 F.3d at 265. This is true even where a defendant has committed a *per se* antitrust violation, which is not the case here. *See Atl. Richfield*, 495 U.S. at 341-45 (even *per se* violation require antitrust injury as an element).

Courts routinely dismiss antitrust claims where the claimed injury is not caused by the alleged antitrust violation, particularly where the alleged injury results from lawful government action. *See City of Pittsburgh*, 147 F.3d at 265 (affirming dismissal where injury caused by regulatory aspects of industry and not by defendants' conduct); *Midland Export, Ltd. v. Elkem Holding, Inc.*, 947 F. Supp. 163, 166 (E.D. Pa. 1996) (holding "ITC's action was still the direct cause of the harm alleged here. Defendants' conspiracy, even if a significant influence on the ITC's determination, was nonetheless an indirect cause of Midland's harm."); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006) (affirming dismissal where injury caused by FDA's import restrictions, not defendants' conduct); *RSA Media, Inc. v. AK Media Group*, 260 F.3d 10, 15 (1st Cir. 2001) (affirming summary judgment because alleged injury was caused by regulatory scheme that prevented plaintiff's construction of new billboards, not defendant's threats). In a case brought by Mylan accusing competitors of making illegal payments to the FDA to speed its regulatory approvals and delay Mylan's, the court held the alleged injury "basically resulted from the uncompetitive aspects of the regulatory system mandated by Congress rather than any uncompetitive actions by defendants. Although defendants are alleged to have abused this system, their taking advantage does not necessarily lead to the conclusion that Mylan suffered an antitrust injury." *Mylan Labs., Inc. v. Akzo, N.V.*, 770 F. Supp. 1053, 1062-63 (D. Md. 1991).

### B. Plaintiffs Do Not and Cannot Allege that Defendants' Conduct Caused Their Alleged Injuries

Plaintiffs have failed to allege the causal link required for their antitrust claims. For each of the alleged "switches," Plaintiffs' Complaints make clear that government approval of the Doryx formulations caused whatever losses Plaintiffs claim as injury. In addition, with respect to Mylan's challenge to Warner Chilcott's FDA citizen petition regarding dual-scored tablets, any delay in Mylan's entry was caused by the independent, intervening event of a court-ordered preliminary injunction and TRO, not the citizen petition.

#### 1. Any Competitive Losses (or Overcharges) Following Any Alleged "Switch" Were Caused by FDA Governmental Action

All of the alleged losses result from Warner Chilcott seeking FDA approval, the FDA granting approval, and Mylan deciding to try to "catch up" to the newly-approved version of Doryx. Plaintiffs' own allegations demonstrate that any alleged harm flowed from government action, rather than Defendants' private conduct.

Plaintiffs admit that Defendants sought and obtained government approval of their new tablet formulation. *See supra* Section III; *see also* Mylan Compl. ¶ 53 (FDA approval to market Doryx 75 mg and 100 mg Tablets); Class Compl. ¶ 56 (same); Mylan Compl. ¶ 57 (FDA approval for the applesauce label); Class Compl. ¶ 62 (same); Mylan Compl. ¶ 62 (FDA approval to market 150 mg Doryx tablets); Class Compl. ¶ 67 (same); Mylan Compl. ¶ 60 (FDA approval to market scored 75 mg and 100 mg Doryx Tablets); Class Compl. ¶ 62 (same). Plaintiffs further admit that any alleged "delay" in the entry of generic tablets resulted from government (FDA) action and regulatory restrictions. *See, e.g.*, Mylan Compl. ¶ 2 ("***Because of regulatory requirements*** that generic drugs generally be the 'same' as the reference listed drug, these switches forced generic manufacturers such as Mylan to change their products in development . . . ." (emphasis added)).

Plaintiffs' admissions that government agency action caused any delays in approvals of generic Doryx are fatal to their antitrust claims. *See City of Pittsburgh*, 147 F.3d at 265; *Armstrong Surgical Ctr., Inc. v. Armstrong Cnty. Mem'l Hosp.*, 185 F.3d 154, 160 (3d Cir. 1999) (dismissing complaint where "plaintiff's alleged injuries result[ed] from state action"; "antitrust liability cannot be imposed on a private party who induced the state action by means of concerted anticompetitive activity"); *Mass. Sch. of Law at Andover, Inc. v. Am. Bar. Ass'n*, 937 F. Supp. 435, 440, 442 (E.D. Pa. 1996) (plaintiff's alleged harm was "the proximate result of governmental action"), *aff'd*, 107 F.3d 1026 (3d Cir. 1997).

**2. Mylan Cannot Allege the September 2011 Citizen Petition Caused Any Delay in Generic Entry**

With respect to the 150 mg tablets, Mylan cannot plausibly allege that Defendants' filing of a citizen petition with the FDA, requesting that the FDA not approve Mylan's ANDA, caused any "delay" in the launch of generic 150 mg Doryx tablets. *See* Mylan Compl. ¶ 50 (alleging that September 23, 2011 citizen petition was "designed to further delay Mylan's ability to enter" the market). Setting aside the fact that Mylan never alleges (as they must) that the citizen petition was a sham, and that the filing of such a petition is protected speech under *Noerr-Pennington* and the First Amendment, *see supra* Section III, Mylan's causation theory fails for additional, independent reasons. Specifically, for the entire period the citizen petition was pending, Mylan was barred from launching its 150 mg generic tablet due to: (i) regulatory barriers, *i.e.*, lack of FDA approval, (ii) a court-ordered preliminary injunction, and (iii) a court-ordered restraining order, to which Mylan voluntary consented.

*First*, when Defendants' filed the citizen petition at issue, Mylan could not have launched its generic 150 mg Doryx tablet because it did not have the required FDA approval to do so. As Mylan admits, an "ANDA applicant can sell the generic product in the United States ***only upon***

***receipt of final approval from the FDA***." Mylan Compl. ¶ 26 (emphasis added). Defendants filed their citizen petition on September 23, 2011. *Id.* ¶ 5. Yet Mylan did not have FDA approval to market its generic version of the Doryx 150 mg tablet until February 8, 2012. *Id.* ¶¶ 70-71. Thus, Mylan cannot plausibly allege that Defendants' filing of a citizen petition delayed Mylan's generic entry.

*Second*, under the Food and Drug Administration Amendments Act of 2007, which was in effect when Defendants' filed their 2011 citizen petition, Congress amended the citizen petition process so the FDA could approve an ANDA during the pendency of a citizen petition. *See In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 303 & n.6 (E.D. Pa. June 2, 2011) (explaining that "[u]ntil 2007, the FDA refrained from approving any ANDA while a citizen petition relating to the ANDA was pending" but "[i]n 2007, Congress amended § 355 and explicitly allowed the FDA to approve an ANDA despite a pending citizen petition" (citing 21 U.S.C. § 355(q)(1)(A)(ii) (as amended)).

*Third*, during the five months in which Mylan alleges it was delayed, Mylan separately and independently was barred by patent court order from selling its 150 mg generic tablet:

- On September 22, 2011, one day *before* Defendants filed their citizen petition, the district court in the related patent infringement litigation granted a preliminary injunction "to enjoin Mylan from selling its 150 mg ANDA product." *Mylan*, 2012 WL 1551709, at *5.

- Following the Federal Circuit's ruling, Mylan consented to a TRO blocking its entry until the district court ruled. The TRO was entered on February 8, 2012, the same day the FDA responded to Defendants' citizen petition. TRO, *Mylan*, No. 09-cv-2073 (D.N.J. Feb. 8, 2012), ECF No. 133 ("By agreement of the parties, in order to permit this Court time to complete the pending trial of this matter, consider the evidence and render a decision, Mylan and those acting in concert with Mylan are hereby temporarily restrained from launching a generic version of Doryx . . . ."). The TRO was in place until the court announced its ruling on April 30, 2012.

Thus, there can be no allegation that Defendants' citizen petition caused any delay. Where, as here, "anticompetitive harm is caused by the decisions of a court, even though granted

at the request of a private party, no private restraint of trade occurs because the intervening government action breaks the causal chain." *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 818 (D.C. Cir. 2001); *Egervary v. Young*, 366 F.3d 238, 246-47 (3d Cir. 2004) (observing that "the actions of a judicial officer may sever the chain of causation. . . . *In the usual case, the order of the court would be the proximate cause and the various preliminary steps would be remote causes of any injury from imprisonment or restraint under the court order*.") (citation omitted).

### C. There Is No Delay in Generic Entry Because Mylan Launched Its Generic Doryx Tablets as Soon as the Law Allowed

Plaintiffs' theory of causation also fails as to the 75, 100, and 150 mg tablets because, as Plaintiffs admit, Mylan ***was not blocked*** from entry. As Plaintiffs admit, an "ANDA applicant can sell the generic product in the United States only upon receipt of final approval from the FDA . . . ." Mylan Compl. ¶ 26. With respect to the 75 mg and 100 mg tablets, "Mylan received final FDA approval of its 75 mg and 100 mg ANDA products in December 2010, and thereafter began selling its 75 mg and 100 mg ANDA products in the United States." *Mylan*, 2012 WL 1551709, at *5; *see also* Mylan Compl. ¶ 63 (alleging that "Mylan received FDA approval for its generic versions of the Doryx 75 mg and 100 mg Tablet Products on December 28, 2010 — and subsequently launched and sought to commercialize these products."); Class Compl. ¶ 50 ("Consequently, when Impax and Mylan received final approval for their generic 75 and 100 mg Doryx tablets on December 8, 2010, they launched them immediately, 'at risk,' despite the pendency of the defendants litigation against them over the '161 Patent."). Mylan continues to sell generic 75 mg and 100 mg tablets today. *See* Mylan Compl. ¶ 32 ("Mylan manufactures and sells a generic 75 mg delayed-release doxycycline hyclate tablet product that is an AB-rated

equivalent to the Doryx 75 mg Tablet Product . . . and a 100 mg delayed-release doxycycline hyclate tablet product that is an AB-rated equivalent to the Doryx 100 mg Tablet Product . . . .").

As for the 150 mg tablets, Mylan also "gained final approval for and launched a generic 150 mg delayed-release doxycycline hyclate tablet product that is an AB-rated equivalent to the Doryx 150 mg Tablet Product." *Id.* ¶ 32. On February 8, 2012, when Mylan received FDA approval to launch the 150 mg tablet, Mylan also agreed to a temporary restraining order precluding launch of the 150 mg tablet until the patent litigation was resolved on its merits. TRO, *Mylan*, No. 09-cv-2073 (D.N.J. Feb. 8, 2012), ECF No. 133. Mylan launched its product immediately following the April 30, 2012 resolution of the patent litigation.[25]

## V. Plaintiffs Fail to Allege an Illegal Conspiracy in Violation of the Sherman Act

Plaintiffs' contention that Warner Chilcott's IP license somehow constitutes an illegal agreement under Section 1 of the Sherman Act fails to state a claim. Warner Chilcott incorporates the arguments set forth in Mayne's Motion to Dismiss Plaintiffs' Complaints.

### A. Under *Copperweld*, for Antitrust Law Purposes, Exclusive Licensees and Licensors Are a Single Entity

As a result of their relationship as patent holder and exclusive licensee (Mylan Compl. ¶ 41; Class Compl. ¶ 53), Defendants are a single entity under the antitrust laws and thus incapable as a matter of law of conspiring to violate Section 1. *See Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984) (parent and wholly owned subsidiary "always have a 'unity of purpose or a common design'") (citations omitted); *see also Am. Needle, Inc. v. Nat'l Football League*, 130 S. Ct. 2201, 2206-07, 2213 (2010) (emphasizing that single entity status depends on degree of alignment of economic interests); *Siegel Transfer, Inc. v. Carrier Express,*

[25] *See* Mylan Press Release, *Mylan Launches First Generic Version of Doryx 150 mg*, April 30, 2012, *available at* http://investor.mylan.com/releasedetail.cfm?ReleaseID=668717 (Ex. 13).

*Inc.*, 54 F.3d 1125, 1133 (3d Cir. 1995) (extending *Copperweld* to other corporate relationships where the entities "were, in substance, one economic unit").

Courts treat patent holders and their exclusive licensees as a single entity incapable of conspiring under Section 1. *See Shionogi Pharma., Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499, at *5 (D. Del. May 26, 2011) (dismissing Mylan's Section 1 claim and holding patent holder and licensee defendants were a single entity incapable of conspiring with one another under *Copperweld*) (Baylson, J., sitting in transferred case); *Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428, 432 (N.D. Cal. 1992) (patent holder and exclusive licensee do not have "independent sources of economic power" and are not independent actors in marketplace); *see also Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. 99-6299, 2000 WL 987865, at *6 (E.D. Pa. July 18, 2000) (where "alleged illegal behavior is purely derivative of the legal patent monopoly and legal exclusive distributorship, . . . there can be no claim against [the exclusive licensee] under Section 1 resulting from this agreement").

### B. Plaintiffs Fail to Allege Plausibly that Defendants Illegally Agreed to Restrain Trade

The Complaints are fatally vague as to any restraint of trade. If the Plaintiffs are claiming that Defendants' IP license agreement itself violates Section 1, such a claim fails because Plaintiffs have not alleged any facts about any aspect of the agreement that could be illegal. If Plaintiffs are claiming Defendants entered into some form of separate, unlawful side agreement, then Plaintiffs' failure is stark. Plaintiffs rely on selected public statements by Defendants which Plaintiffs claim reflect an "anti-generic" strategy. Mylan Compl. ¶¶ 8, 46, 49; Class Compl. ¶¶ 75-77. But such conclusory language says nothing about what Defendants purportedly agreed to do and how that could be illegal under the Sherman Act. *See Iqbal*, 556 U.S. at 680 (complaint must "nudge[] . . . [the] claims . . . across the line from conceivable to

plausible"); *Dentsply*, 602 F.3d at 253 ("[A] plaintiff must allege facts plausibly suggesting 'a unity of purpose or a common design and understanding, or a meeting of the minds in an unlawful agreement.'" (quoting *Copperweld*, 467 U.S. at 771)).[26] In *Shionogi Pharma., Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499 (D. Del. May 26, 2011), Judge Baylson dismissed on the pleadings Mylan's Section 1 claims in part because "Mylan has not pled any factual allegations concerning an agreement" between licensor-licensee. *Id.* at *5. The mere allegation that the defendants "were motivated 'to delay and prevent generic competition'" were "purely conclusory." *Id.*

### C. The Direct Purchaser Plaintiffs Fail to Allege an Illegal Conspiracy to Monopolize Under Section 2 of the Sherman Act

The purported Direct Purchasers additionally allege that Defendants conspired to monopolize in violation of Section 2 of the Sherman Act. Class Compl. ¶¶ 122-30. But this claim fails for the same reasons that Plaintiffs' Section 1 claims fail. Warner Chilcott also incorporates the arguments set forth in Mayne's motion to dismiss regarding this claim. Namely: (1) that the Defendants' must be treated as a single entity for purposes of Section 2;[27] (2) Plaintiffs fail to allege any facts that plausibly suggest an illegal agreement;[28] and (3) Plaintiffs have failed to plead a relevant product market.[29]

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[26] *See also TruePosition, Inc. v. LM Ericsson Telephone Co.*, 844 F. Supp. 2d 571, 593 (E.D. Pa. 2012) (plaintiffs must allege defendants "had a conscious commitment to a common scheme designed to achieve an unlawful objective" (citation omitted)).

[27] *See Carpenter Tech. Corp. v. Allegheny Tech., Inc.*, 646 F. Supp. 2d 726, 734 (E.D. Pa. 2009) (dismissing complaint on *Copperweld* grounds, holding doctrine "equally applicable to Section 2 conspiracy to monopolize claims").

[28] *See Dentsply*, 602 F.3d at 254 (dismissing complaint where plaintiffs failed to adequately allege agreement between defendants).

[29] *See Carpenter Tech.*, 646 F. Supp. 2d at 734 ("The failure to plead a relevant product market is fatal to [a conspiracy to monopolize] claim.").

## VI. Plaintiffs' Allegations of the Relevant Product Market Are Implausible and Contrary to Settled Law

"Plaintiffs have the burden of defining the relevant market." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). Product definition is "critical" in this Circuit for attempted monopolization. *Sweeney & Sons, Inc. v. Texaco, Inc.*, 637 F.2d 105, 117 (3d Cir. 1980) (citing *Coleman Motor Co. v. Chrysler Corp.*, 525 F.2d 1338 (3d Cir. 1975)).

### A. Mylan's Five Separate Individual-Dosage-Strength Product Markets Are Without Any Basis in Law and Contrary to Its Product-Hopping Theory

Mylan's Complaint asserts that "each separate version of Doryx . . . constitutes a separate relevant market . . . ." Mylan Compl. ¶ 37. Mylan goes on to assert that Doryx 75 mg capsules are a distinct product market unto itself. *Id.* Then, Doryx 100 mg capsules are a second distinct product market; Doryx 75 mg tablets a third distinct product market; Doryx 100 mg tablets the fourth distinct product market; and Doryx 150 mg tablets a fifth separate product market. *Id.* Thus, the tautology goes, Defendants are monopolists — the only sellers of each FDA-approved dosage strength, with 100% market share of each dose. *Id.* ¶ 40. By the same token, Ford is a monopolist with 100% market share in the sale of blue 2012 Mustangs, in the sale of 2012 Mustangs with a 305-hp V6, and again in the sale of 2012 Mustangs with a 412-hp V8 engine.

Our research has uncovered no case in which a court has accepted an individual dosage strength as a stand-alone relevant market. In the pharmaceutical world, it would mean that every dosage strength of every FDA-approved branded drug is monopolized, an untenable conclusion. *See Sweeney*, 637 F.2d at 118 ("Accepting these arguments would lead to the conclusion that every manufacturer of a trademarked product has monopoly power over that product. No legal precept stands for this proposition . . ."); *see also Brown* Shoe, 370 U.S. at 325; *Queen City*, 124 F.3d at 436-37 (reasonably interchangeable products must be considered in product market). The only reported decision to address such a proposal rejects individual-dosage-strength product

markets. *See Akzo*, 770 F. Supp. at 1061-62 & n.6 (holding that Mylan's failure to allege a relevant product market, alleged to include specific drug dosages, "would be sufficient to dispose of Mylan's antitrust claims").

Fundamentally, the "product-hopping" allegations defeat these product markets on their face. The Mylan Complaint alleges that each new dosage strength had "little or no benefit" over the older versions, so by definition each was reasonably interchangeable with the other under the Complaint's theory of "product hopping." *E.g.*, Mylan Compl. ¶ 2 (Defendants made "relatively minor changes to branded Doryx – a dosage form, strength, or tablet scoring modification with little or no therapeutic benefit"); *see also* Class Compl. ¶ 56 ("The new tablet formulation offered no medical or clinical benefits over the existing capsules. They are therapeutically identical."). Mylan's Complaint alleges "little or no benefit" between the 75 and 100 mg capsules and the same dosage tablets, Mylan Compl. ¶ 55, so those are interchangeable, according to Plaintiffs. Mylan's admissions also mean that the single-scored and double-scored 150 mg tablets are part of all four of those allegedly separate product markets because, for example, the dual-scored 150 mg tablet could be broken into 100 mg doses, and the single-scored into 75 mg. *See id.* ¶ 66. The Complaint is at war with itself.

### B. Plaintiffs' Alternative "Delayed Release" Subset of a Single-Molecule Product Market Is Contrary to Law and Fails to Exclude Obvious Alternatives for Use

According to the Class — and Mylan apparently in the alternative — the relevant product market is comprised exclusively of "delayed-release doxycycline hyclate" products that are AB-rated or "automatically substitutable" under some state laws:

> Mylan's approved generic delayed-release doxycycline hyclate products are AB-rated to their Doryx branded equivalents only, which means, under most state substitution laws, they are automatically substitutable for their Doryx branded equivalents only. . . . Generic delayed-release doxycycline hyclate products are priced substantially below the price Defendants charge for their branded Doryx

> products. Upon entry of AB-rated generic delayed-release doxycycline hyclate products, these lower-priced but interchangeable products divert substantial sales from branded Doryx products . . . . Because of this . . . such products comprise a distinct relevant product market for antitrust purposes.

*Id.* ¶¶ 33, 35-36; *see also* Class Compl. ¶ 96 (relevant market: "all delayed-release doxycycline hyclate products — *i.e.*, Doryx (in all its forms and dosage strengths) and AB-rated bioequivalent doxycycline hyclate products"). Plaintiffs' asserted product market is a subset of the doxycycline molecule, as it excludes immediate release doxycycline hyclate and is limited to "delayed release" doxycycline hyclate. Plaintiffs' market and their Complaints also exclude doxycycline monohydrate, another form of doxycycline, which is striking since Mylan obtained FDA approval for a 150 mg capsule of immediate release doxycycline (monohydrate) just one month before filing this Complaint.[30]

First, "automatically substitutable" by pharmacists in some states is not the product market test. Rather, "the outer boundaries of a relevant market are determined by reasonable interchangeability of use." *Queen City*, 124 F.3d at 437; *see also Brown Shoe*, 370 U.S. at 325 ("The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it."). In *Queen City*, plaintiffs relied on a franchise agreement, rather than interchangeability, to define the product market. The Third Circuit affirmed dismissal of the antitrust claims on the pleadings:

[30] Mylan's website lists as one of its "New Products" 150 mg Doxycycline capsules, *available at* http://www.mylanpharms.com/product/new_products.aspx (Ex. 14). Mylan obtained FDA approval for these doxycycline capsules on June 8, 2012. *See* Application A202778, "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," June 8, 2012, *available at* http://www.accessdata.fda.gov/scripts/ob/docs/obdetail.cfm?Appl_No=202778&TABLE1=OB_Rx (Ex. 15). This is the seventh doxycycline product Mylan has brought out.

> Here, the dough, tomato sauce, and paper cups that meet Domino's Pizza, Inc. standards and are used by Domino's stores are interchangeable with dough, sauce and cups available from other suppliers and used by other pizza companies. . . . Thus, the relevant market, which is defined to include all reasonably interchangeable products, cannot be restricted solely to those products currently approved by Domino's Pizza, Inc. for use by Domino's franchisees.

124 F.3d at 438. Similarly, Plaintiffs' reliance on state substitution laws, *see* Mylan Compl. ¶¶ 33, 35-36, provides an untenable theory for defining the relevant product market. For one thing, most states — 36 states — do not have automatic substitution laws. State substitution laws fail to address the ultimate questions of interchangeability and cross-elasticity of demand. *Brown Shoe*, 370 U.S. at 325; *United States v. E.I. duPont de Nemours & Co.*, 351 U.S. 377, 393-95 (1956); *see also Sweeney*, 637 F.2d at 117 (collecting authorities).

Nowhere in their Complaints do Plaintiffs explain their rationale for limiting the relevant product market to this subset of a single molecule: "delayed-release doxycycline hyclate." Plaintiffs admit that Doryx is "prescribed for the treatment of severe acne and other bacterial infections," Mylan Compl. ¶ 1, yet fail to allege why a consumer (patient) would not view any other anti-acne or antibacterial products as adequate substitutes for Doryx. *See, e.g.*, *Am. Sales Co., Inc. v. AstraZeneca AB*, No. 10 Civ. 6062, 2011 WL 1465786, at *3 (S.D.N.Y. Apr. 14, 2011) (dismissing monopolization claim where complaint did not allege "why a consumer would not view any other number of products as adequate substitutes for treatment of frequent heartburn" or "why Prilosec OTC constitutes its own market among purchasers of proton pump inhibitor products"). It is common experience that there are a vast number of over-the-counter acne treatments, and there is no "industry or public recognition" of a single-molecule doxycycline hyclate product market. *See Brown Shoe*, 370 U.S. at 325. In fact, the medical

literature is to the contrary.[31] The failure to discuss other acne treatments is even more indefensible here, where Mylan's website touts several best-selling acne treatments, such as BenzaClin (topical antibiotic)[32] and Amnesteem (topical isoretinoin).[33]

But the Complaints do not address, let alone plausibly address, why these acne treatments (including those sold by Mylan) are not in the hypothesized product market. Single molecule markets have been dismissed on the pleadings (and here Plaintiffs proposed a subset). *See Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 578 (S.D.N.Y. 2011) (dismissing monopolization counterclaim based on single-molecule market and noting that dismissal is appropriate where "the proposed market makes no rational or economic sense and is far too narrow"); *Fresh Made, Inc. v. Lifeway Foods, Inc.*, No. 01-4254, 2002 WL 31246922 (E.D. Pa. Aug. 9, 2002) (dismissing antitrust claims because complaint "d[id] not allege facts establishing that the market for specialty Russian dairy products, such as kefir, is distinct from the market for yogurt, other drinkable yogurt products, or from other dairy products in general"); *B.V. Optische Indus. de Oude Delft v. Hologic, Inc.*, 909 F. Supp. 162, 171-72 (S.D.N.Y. 1995) (dismissing antitrust claim based because there were no allegations that the "chest equalization radiography" market was independent from the "overall X-ray market," and complaint failed to "refer to any

[31] *See, e.g.*, D. GOLDBERG & A. BERLIN, ACNE AND ROSACEA – EPIDEMIOLOGY, DIAGNOSIS & TREATMENT 15 (2012) ("Numerous therapeutic agents have been developed over the years for the treatment of acne vulgaris (Table I). . . . Topical agents are the mainstay of acne therapy. . . . Benzoyl peroxide has been available both by prescription and over-the-counter for over 50 years, making it one of the most commonly used medications in acne."); *id.* at Table I (listing also *e.g.*, topical antibiotics, retinoids, oral antibiotics, isoretinoin) (Ex. 16).

[32] *See* Mylan Press Release, *Mylan Begins Marketing First Generic Version of BenzaClin Acne Treatment*, Aug. 27, 2009 (generic BenzaClin is "a prescription-strength topical antibiotic used to treat acne"), *available at* http://investor.mylan.com/releasedetail.cfm?releaseid=405704 (Ex. 17).

[33] *See* Mylan Press Release, *Mylan Laboratories Inc. Announces First ANDA Approval for Isoretinoin; Bertek Pharmaceuticals Inc. to Market Amnesteem*, Nov. 11, 2002, *available at* http://investor.mylan.com/releasedetail.cfm?releaseid=408179 (Ex. 18). This was to be a branded generic marketed under the trade name "Amnesteem."

reasonably interchangeable alternatives" or to "offer an explanation" as to why the product market was defined "in such narrow terms"); *United States v. Ciba Geigy Corp.*, 508 F. Supp. 1118, 1153-55 & n.29 (D.N.J. 1976) (rejecting narrow single-molecule hydrochlorothiazide market and instead finding relevant market of all products indicated for the treatment of hypertension, where patients were typically given various dosages and combinations of drugs to obtain optimum control of disease).

In *Shionogi*, Judge Baylson dismissed on the pleadings Mylan's Section 2 monopolization claim based on the single-molecule product market of "orally disintegrating prednisolone tablets." 2011 WL 2174499, at *6. Mylan's "wholly conclusory allegations" failed to show "facts showing of product market of reasonably interchangeable commodities from the perspective of the consumer, as required by *Queen City Pizza*." *Id.*

Plaintiffs include only conclusory allegations to support their partial-molecule market: "[d]elayed-release doxycycline hyclate products are not reasonably interchangeable with other products due to, for example, price, use, qualities, characteristics, and/or distinct customers or end uses." Mylan Compl. ¶ 34; *see also* Class Compl. ¶ 90 ("Doryx does not exhibit significant, positive cross-elasticity of demand with respect to price, with any doxycycline, antibiotic, or other product other than AB-rated generic versions of Doryx."). Every branded manufacturer has some pricing power over its goods, and this is insufficient under Supreme Court authority. *Sweeney*, 637 F.2d at 118 (quoting *DuPont*, 351 U.S. at 393, "this power that, let us say, automobile or soft-drink manufacturers have over their trademarked products is not the power that makes an illegal monopoly. Illegal power must be appraised in terms of the competitive market for the product."); *Mogul v. Gen. Motors Corp.*, 391 F. Supp. 1305, 1313 (E.D. Pa. 1975)

("I may, and do, take judicial notice that the relevant product market cannot be limited to Cadillac.").

Accordingly, the Court should dismiss Plaintiffs' antitrust claims for failure to allege a plausible relevant product market. *See Fresh Made*, 2002 WL 31246922, at *5 ("[W]here a 'complaint fails to allege facts regarding substitute products, to distinguish among apparently comparable products, or to allege other pertinent facts relating to cross-elasticity of demand,' a motion to dismiss may be properly granted."); *Syncsort, Inc. v. Sequential Software, Inc.*, 50 F. Supp. 2d 318, 332-33 (D.N.J. 1999) (dismissing monopolization claim because plaintiff failed to allege that defendant's product was unique, "inexplicably ignored the broader . . . market," and "did not explain its rationale for ignoring other existing or potential sources of supply").

## VII. The Federal Statute of Limitations Bars Plaintiffs from Almost All of the Recovery They Seek

The applicable statute of limitations for antitrust causes of action is four years. 15 U.S.C. § 15b; *see Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971); *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997) (analogizing civil RICO statute of limitations to antitrust cases). The first of these actions was filed in July 2012. "Generally, a cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business." *Zenith*, 401 U.S. at 338. "[T]he commission of a separate new overt act generally does not permit the plaintiff to recover for the injury caused by old overt acts outside the limitations period." *Klehr*, 521 U.S. at 189-90 ("[A]s in antitrust cases, the plaintiff cannot use an independent, new predicate act as a bootstrap to recover for injuries caused by other earlier predicate acts that took place outside the limitations period.").

### A. Plaintiffs' Claims for Damages Resulting from the Launch of Doryx Tablets Are Time-Barred

Plaintiffs' own allegations establish that they may not recover damages from the introduction of the 75 mg and 100 mg tablets. Plaintiffs admit that Defendants received FDA approval for the 75 mg and 100 mg tablet products on May 6, 2005 — over *three* years outside the four-year statute of limitations period. Mylan Compl. ¶ 53; Class Compl. ¶ 57. According to the complaints, Defendants discontinued marketing the capsules by the end of June 2006. Mylan Compl. ¶ 53; Class Compl. ¶ 58. Thus, the four-year statute of limitations precludes any recovery by Plaintiffs based on the sale of 75 and 100 mg tablets over capsules.

### B. Plaintiffs' Claims for Damages Allegedly Caused by the Applesauce Labeling Change or the Launch of the 150 mg Tablet Are Time-Barred

Similarly, the applesauce labeling change is time-barred. Plaintiffs allege that on February 17, 2006 — more than *two* years outside the four-year statute of limitations — Defendants proposed to the FDA a label change regarding breaking up a tablet and sprinkling it over applesauce. *See* Mylan Compl. ¶¶ 57-58; Class Compl. ¶ 62.

The 150 mg tablet introduction is also time-barred. The 150 mg dosage strength allegations fall outside the limitations period, which began to run at the earliest on July 6, 2008 (for Mylan, still later for the Class). Plaintiffs concede that Defendants obtained FDA approval and launched the 150 mg tablet in "June 2008." Mylan Compl. ¶ 62; Class Compl. ¶¶ 67, 69. And Plaintiffs allege Defendants petitioned for FDA approval of the 150 mg tablet in an application filed even earlier, on December 18, 2007. *E.g.*, Class Compl. ¶ 67.

### C. Plaintiffs' Attempt to Characterize Defendants' Product Innovations as a "Strategy" or "Scheme" Does Not Entitle Plaintiffs to Avoid the Statute of Limitations

Labeling Defendants' product developments as an "overarching strategy," Mylan Compl. ¶ 8, or "overall scheme," Class Compl. ¶ 1, does not save Plaintiffs' claims. *See Klehr*, 521 U.S.

at 190. Plaintiffs cannot aggregate Defendants' individual product innovations into an ongoing conspiracy and recover damages for acts occurring outside the limitations period. *See id.* As discussed above, Plaintiffs allege that Defendants received FDA approval for tablets in 2005 and "converted" the market from capsules to tablets by June 2006. *See* Mylan Compl. ¶¶ 52-53; Class Compl. ¶¶ 57-58. Plaintiffs also allege that in September 2011 Defendants launched the dual-scored 150 mg tablet, which Plaintiffs also challenge. *See* Mylan Compl. ¶ 67; Class Compl. ¶¶ 69-70. These events are over six years apart; that one event is within the limitations period does not justify recovering damages for conduct that is indisputably time-barred.

### D. The Only Alleged Conduct Occurring within the Four-Year Statute Caused No Cognizable Injury

The statute of limitations bars recovery based on all but one alleged act by Defendants. The Complaint's allegation of Defendants' introduction of the dual-scored version of the 150 mg tablet on September 21, 2011 occurred within the four-year statute of limitations. Mylan Compl. ¶ 67. But even though the statute of limitations, standing alone, would not require the dismissal of claims regarding that launch, dismissing the other claims as time-barred is nonetheless important and would serve judicial economy. That is because that last standing allegation — the launch of the dual-scored 150 mg tablet — fails for its own independent reasons. As discussed above, Mylan cannot recover damage based on that product launch because, for the entire period of alleged delay in launching a competing product, Mylan was barred by government orders from selling a generic 150 mg tablet at all. *See supra* Section IV.B.2.

## VIII. Mylan's Tortious Interference Claim Must Be Dismissed as a Matter of Law

Mylan's state law claim for tortious interference with prospective economic relationships against the Defendants — Mylan's competitors — must be dismissed as a matter of law.

### A. The Competition Privilege Precludes Mylan's Claim

Pennsylvania law disfavors tortious inference claims between competitors, and Mylan has not pleaded, and cannot plead, facts sufficient to negate the competition privilege. Pennsylvania requires a party complaining about competitor conduct to affirmatively plead and overcome the competition privilege, ***on the face of the complaint***.[34] *See Acumed, LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 214 (3d Cir. 2009) (describing competition privilege: "Pennsylvania courts require the plaintiff, as a part of his *prima facie* case, to show that the defendant's conduct was not justified." (citations omitted)); *Glenn v. Point Park Coll.*, 272 A.2d 895, 900 (Pa. 1971) (dismissal for failure to overcome defendant's competition privilege).

"[C]ompetitors, in certain circumstances, are privileged in the course of competition to interfere with other's prospective relationships." *Acumed*, 561 F.3d at 215 (citing RESTATEMENT (SECOND) OF TORTS § 768 (1979)). The competition privilege exists because "if more than one party seeks to sell similar products to prospective purchasers, ***both necessarily are interfering with the other's attempt to do the same thing***." *Id.* (emphasis added). In short, Pennsylvania law follows the well-established view that outpacing one's competitors is not a tort, and "it is no tort to beat a business rival to prospective customers." W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 130 (5th ed. 1984). Under Pennsylvania law, which follows Section 768 of the Restatement (Second) of Torts, the competition privilege means that a competitor, acting at least in part to benefit his own competitive self-interest, is privileged to interfere with the

[34] The Pennsylvania Supreme Court has repeatedly held that the "elements ***must appear in a complaint*** in order for the plaintiff to state a cause of action for intentional interference with prospective contractual relations." *Thompson Coal Co. v. Pike Coal Co.*, 412 A.2d 466, 471 (Pa. 1979) (emphasis added) (citing *Glenn v. Point Park Coll.*, 272 A.2d 895, 898 (Pa. 1971)). The plaintiff "has the burden of pleading and proving" all elements. *Int'l Diamond Imps., Ltd. v. Singularity Clark, L.P.*, 40 A.3d 1261, 1275 (Super. Ct. Pa. 2012). Those *prima facie* elements include both "the absence of privilege or justification on the part of the defendant" and "a prospective contractual relation." *See Thompson Coal Co.*, 412 A.2d at 471.

business relationships of another competitor, ***unless*** his conduct constitutes an unlawful restraint of trade or he uses "wrongful means" to interfere.[35]

Mylan's claim must be dismissed because the Complaint's only treatment of the competition privilege is the bald recitation — far below the requirements of *Twombly* or *Iqbal* — that "Defendants' conduct was wrongful, improper and without privilege or justification." Mylan Compl. ¶ 115. Further, Mylan's claim should be ***dismissed with prejudice***, because Mylan has conceded elements of the competition privilege and cannot plead facts to overcome it.

*First*, Mylan's Complaint asserts that the motive for Defendants' conduct was to gain "marketplace advantage over Mylan," *id.* ¶ 116; in other words, the Complaint asserts that Defendants' "purpose is at least in part to advance [their] interest" in competing with Mylan. RESTATEMENT (SECOND) OF TORTS § 768(1) (1979). Moreover, Mylan repeatedly asserts that Defendants "converted" sales from one form or dose of Doryx to another ***to keep those sales from Mylan***. Mylan Compl. ¶¶ 6, 53, 62, 75, 88, 96, 103. Mylan's theory is that Defendants were, in the words of the Restatement, directing their conduct "at least in part, to the improvement of [their] position in the competition," RESTATEMENT (SECOND) OF TORTS § 768 cmt. g (1979) — which they were privileged to do.[36] *Second*, as set forth above, Mylan has failed to adequately allege a restraint of trade required to overcome the competition privilege — the conduct alleged is in fact pro-competitive innovation. *Third*, the alleged conduct is not

[35] *See Acumed*, 561 F.3d at 215 (A competitor "does not interfere improperly with the other's relation" if: "(a) the relation concerns a matter involved in the competition between the actor and the other; (b) the actor does not employ wrongful means; (c) his action does not create or continue an unlawful restraint of trade; and (d) his purpose is at least in part to advance his interest in competing with the other" (quoting RESTATEMENT (SECOND) OF TORTS § 768(1) (1979)).

[36] Based on the allegations of the Complaint, it is irrelevant if Defendants had any other motives. Where a competitor is acting to improve its position versus another as Mylan has admitted here, under the Restatement, if a competitor's "conduct is directed, at least in part, to that end, the fact that he is also motivated by other impulses as, for example, hatred or a desire for revenge is not alone sufficient to make his interference improper." RESTATEMENT (SECOND) OF TORTS § 768 cmt. g (1979).

"wrongful." Under Pennsylvania law, "for conduct to be wrongful it must be actionable for a reason independent from the claim of tortious interference itself." *Acumed*, 561 F.3d at 215. Mylan's antitrust claims are focused on so-called "product hopping" — conduct that is in fact lawful innovation. Where Mylan has failed to identify other conduct that is independently actionable, Mylan's tortious interference claim should be dismissed as a matter of law.[37]

**B. Mylan Failed to Plead Required Facts Concerning Customers and Contracts**

Under Pennsylvania law, a plaintiff must identify the specific customers or contracts with which the defendant allegedly interfered. *See Cnty. of Lackawanna v. Verrastro*, 9 Pa. D. & C. 5th 35 (Pa. Com. Pl. 2009) ("As no prospective contractual relationship has been identified by defendant [] their claim for tortious interference . . . is legally insufficient"). Mylan does not identify any specific prospective customers, but instead vaguely refers only to anonymous "consumers and federal, state, and private payors." Mylan Compl. ¶ 9. Applying Pennsylvania law, courts have readily dismissed complaints where the plaintiff has failed to allege such specifics. *See Brunson Commc'ns, Inc. v. Arbitron, Inc.*, 239 F. Supp. 2d 550, 578 (E.D. Pa. 2002) (dismissing complaint where "[p]laintiff has not identified a single past, present, or prospective customer of WGTW with whom it had a prospective contract which did not finalize because of [d]efendant's actions"); *Verrastro*, 9 Pa. D. & C. 5th 35 (granting preliminary objection and noting "the case law indicates more than generalities [are] need[ed] to plead in order to succeed on a claim for tortious interference with prospective contractual relations"). This court should do the same here.

[37] *See Acumed*, 561 F.3d at 216-18 (dismissing plaintiff's tortious interference claim where jury rejected underlying tort claim); *Assembly Tech. Inc. v. Samsung Techwin Co.*, 695 F. Supp. 2d 168, 181 (E.D. Pa. 2010) (dismissing complaint where manufacturer's conduct was not sufficiently wrongful to bar competitor's privilege).

### C. Mylan's Claim Is Barred by the Two-Year Pennsylvania Statute of Limitations

Pennsylvania's two-year statute of limitations bars claims by Mylan for tortious interference for the period prior to July 6, 2010. *See Bednar v. Marino*, 646 A.2d 573, 577 (Pa. Super. Ct. 1994) (citing 42 PA. CONS. STAT. § 5524(3)) (tortious interference claim barred by two-year limitations period). Any claims regarding Mylan's capsules are fully time-barred, as Mylan's Complaint alleges that prior to 2006 Mylan abandoned its capsule efforts, six years before filing its Complaint, and well outside the two-year statute of limitations. Mylan Compl. ¶¶ 3, 53 (following 2005 FDA approval of Defendants' tablets Mylan decided to "forego efforts to develop the capsules"). Mylan makes only a single specific allegation regarding conduct within the two years preceding Mylan's Complaint (*i.e.*, after July 6, 2010), concerning the change of Defendants' 150 mg tablet from single- to dual-scored. *Id.* at ¶¶ 5, 65, 67. But this allegation fails as a matter of law, as discussed above.

## CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court dismiss all of Plaintiffs' claims with prejudice.

Respectfully submitted this 1st day of October, 2012.

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**CERTIFICATE OF SERVICE**

I, Peter J. Carney, certify that on October 1, 2012, I caused true and correct copies of the foregoing Memorandum of Law in Support of Defendant Warner Chilcott's Motion to Dismiss, and accompanying exhibits to be served through the CM/ECF system and by e-mail upon all counsel of record.

Dated: October 1, 2012

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