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

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

DIRECT PURCHASER PLAINTIFFS' SUMMARY SUBMISSION
IN RESPONSE TO DEFENDANTS' 12(b)(6) MOTIONS

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I. INTRODUCTION

Pursuant to this Court's order of October 5, 2012, the direct purchaser plaintiffs Rochester Drug Co-Operative, Inc., Meijer, Inc., et al., and American Sales Company, LLC submit this summary argument in response to the defendants' Rule 12(b)(6) motions.[1] We do not respond to arguments directed at Mylan only.

The facts were previously summarized in the parties' Joint Rule 16 Report filed on September 25, 2012 [dkt. no. 80] and are not repeated here. The operative complaint is the Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint filed on August 13, 2012 [dkt. no. 63] (the "complaint"), a copy of which is attached for the Court's convenience.

We respond *seriatim* to each of the defendants' seven arguments applicable to the direct purchasers.

[1] This submission is, in effect, a highly condensed preview of plaintiffs' upcoming response to defendants' 77 pages of briefing filed in support of their motions to dismiss. Since defendants are seeking to dismiss our case at the pleading stage, we felt constrained to respond to defendants' many arguments, though we recognize that our submission is longer than the Court indicated. We respectfully beg the Court's understanding.

II. ARGUMENT

1. The Antitrust Injury Issue.

Brand name drug product hopping schemes involving manipulative and unjustifiable product changes can cause antitrust injury by preventing the most efficient means of competition by generic companies. The complaint alleges Warner Chilcott and Mayne made useless product changes to Doryx (e.g., tablet to capsule, unscored to single-scored) and that these changes were combined with the defendants' removal of the previous Doryx formulations from the market thereby preventing generic substitution substitution. Can the complaint be dismissed for failure to allege antitrust injury?

a. Brand name drug product hopping impedes generic competition and causes antitrust injury.

When a brand pharmaceutical company seeks to extend its statutory monopoly by repeatedly tweaking its product and replacing it with a "new" version, while destroying the market for the prior version of the drug and thereby removing generic competition through substitution – an exclusionary tactic known as "product hopping" – it causes antitrust injury.[2] Product hopping impedes generic competition that the Hatch –Waxman Act[3] was designed to foster. Impeding generic competition is unarguable antitrust injury.[4]

In *TriCor*, the brand maker employed a very similar product hopping scheme that switched the market first from a capsule formulation to a tablet formulation, and then from one pair of dosage strengths to another. With each hop to a new formulation, the defendants stopped selling the prior formulations.[5] In ruling on the defendants' motion to dismiss, Judge Jordan held that defendants' conduct, "if true, arguably could have blocked competition and formed the

[2] *Abbott Labs. v. Teva Pharms.USA, Inc. (In re TriCor Direct Purchaser Antitrust Litig.)*, 432 F. Supp. 2d 408 (D. Del. 2006) (Jordan, J.) ("*TriCor*").

[3] 21 U.S.C. §§ 301-392. Hatch-Waxman was enacted in 1984 as an amendment to the Federal Food, Drug, and Cosmetic Act.

[4] *In re Warfarin Antitrust Litig.*, 214 F.3d 394, 397, 401 (3d Cir. 2000) (allegation that brand company "disabled [generic's] market penetration" constitutes a "formidable demonstration of antitrust injury").

[5] As the defendants have done here, the defendants in *TriCor* ignored the plaintiffs' allegations that the changes to the products were not actual improvements. Judge Jordan made a specific point of stating that plaintiffs' allegations describing the steps defendants took to obtain FDA approval were not "concessions . . . that would support dismissal of their claims." *Id.* at 423.

basis of a claim."[6] It caused cognizable antitrust injury.

The *TriCor* defendants argued that because the generics "had not been prevented from marketing the formulations that were the subject of their ANDAs, i.e., the old TriCor formulations, they were not completely foreclosed, and were free to compete."[7] In rejecting the argument, Judge Jordan explained that to show that conduct has an anticompetitive effect, "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."[8] Thus, "while a monopolist may compete and is not required to aid its competitors . . . a monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior."[9] Once the original formulation had been removed from the market, the court explained, "generic substitution was no longer possible."[10]

b. Antitrust scrutiny is required for brand name product hopping because the regulatory scheme is designed to promote generic competition.

Why does the law impose antitrust scrutiny on brand name drug product hopping schemes?

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[6] Warner Chilcott Br. at 14.

[7] *TriCor*, 432 F. Supp. at 423 ("Defendants are correct that, according to Plaintiffs' allegations, Teva and Impax have not been prevented from marketing the formulations that were the subject of their ANDAs, i.e., the old TriCor formulations").

[8] *Id.* at 422-23 (citing *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) and *U.S. v. Microsoft Corp.*, 253 F.3d 34, 65-67 (D.C. Cir. 2001) ("[j]udicial deference to product innovation, however, does not mean that a monopolist's product design decisions are per se lawful")).

[9] *Id.* at 424 (citing *LePage's Inc. v. 3M*, 324 F.3d 141, 151-52 (3d Cir. 2003)) (internal citations and quotations omitted).

[10] *Id.* at 416; *see also id*. at 424 (quoting *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 & n. 39 (2d Cir. 1979) (finding no liability but stating that "the situation might be completely different" if the defendant stopped producing old products or removed them from the market)).

The Supreme Court observed in *Trinko* that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry in question."[11] The background regulatory regime may counsel for greater, or less, or neutral antitrust scrutiny. Where regulation already deters antitrust harm, less may be warranted. But "[w]here, by contrast, there is nothing built into the regulatory scheme which performs the antitrust function . . . the benefits of antitrust are worth its sometimes considerable disadvantages."[12]

Here, the regulatory scheme involves the myriad laws that establish branded drug exclusivities and, with the sunset of those exclusivities, generic entry under Hatch-Waxman. On the one hand, federal patent and drug laws create opportunities for branded drug exclusivity; statutorily created monopolies provide brand name makers with a time limited opportunity to charge monopoly prices.

On the other hand, the law expects the statutorily created monopoly to end. Hatch-Waxman addressed the rising cost of prescription drugs by encouraging the safe and fast development and approval of generic versions of brand drugs.[13] Hatch-Waxman lowered the regulatory hurdles for generic companies by permitting them to file Abbreviated New Drug Applications ("ANDAs") with the FDA, relying on the safety and efficacy data submitted by the proposed generic's brand-name counterpart in its New Drug Application ("NDA").[14] And Congress enacted Hatch-Waxman shortly after every state enacted generic substitution laws (also known as Drug Product Selection or DPS laws) permitting or requiring pharmacists to automatically dispense lower cost generics, even when the physician's prescription listed the

[11] *Verizon Commc'ns, Inc. v. Trinko*, 540 U.S. 398, 411 (2004).

[12] *Id.* at 412 (citation and internal quotes omitted).

[13] *See* Complaint ¶ 39 (dkt. no. 62); *In re Barr Labs, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices — fast.").

[14] Complaint ¶ 40.

brand. Under this regulatory regime, after multiple generics for a given brand enter the market, the prices for the molecule (that is, the brand and corresponding generic together) can reach discounts of up to 90% off the pre-generic brand price, and generics capture as much as 90% of the brand's pre-generic sales.[15]

Regulatory barriers to generic entry, however, provide opportunities for brand companies to game the system and wrongfully extend their monopoly by tweaking their products and interfering with consumer choice. Under Hatch-Waxman and state regulatory regimes, only generic drugs that have been AB-rated by the FDA may be automatically substituted for the brand drug. In order to receive an AB-rating, a generic drug must be: (1) pharmaceutically equivalent to the brand, meaning that it has the same active ingredient, dosage form (tablet, capsule, etc.), and dosage strength, and (2) bioequivalent to the brand, meaning that it is absorbed in the body at approximately the same rate and to the same extent as is the brand drug.[16] Because a generic drug exists only by reference to its brand counterpart, if doctors are not prescribing it because it is no longer being marketed, there simply is no AB-rated generic.

Product hopping frustrates Hatch-Waxman's effort to encourage generic competiton and inject price into the pharmaceutical product marketplace. Where a brand drug's new formulations replace therapeutically identical formulations – that is, where the therapeutically identical formulation is no longer marketed – any comparion between the original and allegedly "innovative" new product is denied, and purchasers are coerced into adopting the new formulation.[17] Competition is destroyed.

Brand name product hopping requires particular antitrust scrutiny because a generic

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[15] *See* Cong. Budget Off., *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, 28-31 (July 1998) ("CBO Study"); Complaint ¶ 52.

[16] Complaint ¶¶ 51-52.

[17] *TriCor*, 432 F. Supp. 2d at 422.

substitute can only, as a practical matter, compete on price. In efficient markets, price plays an important role in product selection because the person selecting the product also pays for the product. In the pharmaceutical marketplace, however, the person selecting the product − the doctor − does not pay for the product.[18] Thus, there is a "price disconnect" that prevents the marketplace from functioning efficiently.[19]

Brand-name companies such as Warner Chilcott exploit this market defect by promoting their brand products to doctors, without reference to price.[20] Generic companies return price to the equation by offering low prices to wholesalers and pharmacies, and distributing their products, without promotion, through automatic substitution.[21] That is how generic prices stay low, as Hatch-Waxman envisions. DPS laws thus "shift the choice of [drug product] for most prescriptions from the physician to the pharmacist."[22] As the FTC noted, "the laws foster price competition by allowing the only principals who have financial incentives to make price comparisons – the pharmacist and the patient – to select drug products on the basis of price."[23]

A generic company cannot reasonably promote a generic product to doctors because the generic maker could not insure the pharmacist would dispense its generic product rather than

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[18] Complaint ¶¶ 32-33.

[19] Complaint ¶¶ 32-33. *See also* Drug Product Selection, Staff Report to the FTC (Jan. 1979) ["FTC Staff Report"] at 2-3 ("the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescriptions") (available at http://catalog.hathitrust.org/Record/000258518); *see also* A. Masson and R. Steiner, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS ["Generic Substitution"] at 5 (FTC 1985) ("the institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among brands; it has been the physician") (available at http://catalog.hathitrust.org/Record/002589428).

[20] Complaint ¶ 33; *see also* FTC Staff Report at 35-36 (heavy detailing reinforces "doctors' brand-name prescribing habits," extends brand dominance "long after patents have expired," and "reduces the degree of substitutability between products," allowing higher prices).

[21] Complaint ¶¶ 34, 36, 52.

[22] Generic Substitution at 7.

[23] FTC Staff Report at 7.

another's. It is a generic product, after all. Upon AB-rated generic entry, Hatch-Waxman treats generic products as commodities that cannot be differentiated through drug marketing efforts to physicians or others except on the issue of price.

c. *Tricor* and other product hopping cases support the imposition of liability here.

The defendants' seek to distinguish *TriCor* by arguing that product hopping was accompanied by claims of other anticompetitive conduct, *i.e., Walker Process* fraud, sham litigation and sham Orange Book listing.[24] But this argument mischaracterizes *TriCor*. First, the party asserting the Orange Book listing claim in *TriCor* had already agreed to drop that claim before the motion to dismiss was decided.[25] Second, the case that went to trial in *TriCor* was solely based upon the product hopping allegations, without the sham litigation or *Walker Process* claims. As *TriCor* demonstrates, a product hopping claim is sufficient to proceed to trial as an independent claim.[26]

Walgreen v. AstraZeneca is consistent with sustaining the plaintiffs' allegations here. The court in *Walgreen* distinguished *TriCor* on the ground that AstraZeneca did not remove the older drug from the market, and instead added the new product which gave doctors and patients a choice between the products. As the *Walgreen* court noted, "there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca added choices. It introduced a new drug to compete with already-established drugs – both its own and others' –

[24] Warner Chilcott Br. at 14-15 (dkt. no. 84).

[25] *Id*. at 424 (noting Teva had agreed to dismiss the Orange Book listing claim).

[26] *See also C.R. Bard v. M3 Sys*., 157 F.3d 1340, 1382 (Fed. Cir. 1998) (where Bard contended that its product modification was an improvement, but there was substantial evidence "that Bard's real reasons for modifying the gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of 'copycat' needles," "the jury could reasonably conclude that Bard's modifications to its guns constituted 'restrictive or exclusionary conduct' in a market over which it had monopoly power"); *Xerox Corp. v. Media Scis. Int'l, Inc.*, 511 F. Supp. 2d 372, 388-89 (S.D.N.Y. 2007) (denying motion to dismiss antitrust claim challenging Xerox's patented redesign of ink sticks for printers; Xerox may present evidence that modifications improved product and outweigh anticompetitive effect).

and with the generic substitutes for at least one of the established drugs."[27] The direct purchasers here allege the defendants reduced consumer choice, including by no longer marketing prior versions of Doryx.[28]

Finally, the defendants' argument ignores the realities of the pharmaceutical marketplace where generic drugs, by regulatory design, compete on the basis of price via automatic substitution, not via detailing. Once the stopped marketing the prior version, when a doctor prescribed Doryx, the pharmacist could only fill it with the new version. Doctors did not "embrace[]" each new version of Doryx, as defendants contend.[29] They had no choice.

This case is on all fours with *TriCor* and all other cases that support the simple proposition that deprivation of the ability to purchase lower cost generic products constitutes antitrust injury.[30]

[27] *Walgreen v. AstraZeneca*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

[28] Complaint ¶¶ 58, 62, 69, 72, 74.

[29] Warner Chilcott Br. at 16.

[30] Defendants' attempt to suggest that the court hearing the Doryx patent litigation decided antitrust issues is misleading. The court there found only that evidence that Mylan presented of defendants' "anti-generic" strategy, which the court accepted as true, was not relevant to the question of patent validity. *Warner Chilcott Labs. v. Impax Labs., Inc.*, No. 08-cv-6304, 2012 WL 1551709, *58 (D.N.J. Apr. 30, 2012).

2. The Exclusionary Conduct Issue.

Pharmaceutical product reformulations that offer little to no benefits to consumers, or that are accompanied by the destruction of the sales base of the older formulations, are exclusionary and subject to rule of reason antitrust scrutiny. The complaint alleges would-be generic makers of Doryx were foreclosed from providing generic substitutes for the then current Doryx formulations due to manipulative product reformulations and destruction of the sales base. Should the complaint suffer Rule 12(b)(6) dismissal for failure to allege exclusionary conduct?

a. Product hopping that constricts consumer choice is exclusionary.

As Judge Jordan held in *TriCor*, when a monopolist switches from one formulation to another and constricts consumer choice, a claim for actionable exclusionary conduct lies.[31] This is particularly true when "[d]efendants allegedly prevented such a choice by removing the prior formulations from the market while introducing new formulations."[32] The introduction of the new formulation itself can be actionable in that context when the anti-competitive harm outweighs any procompetitive benefits from the product change.[33] To be actionable, exclusionary conduct need not completely foreclose generic competitors from the market; it is sufficient to demonstrate the generics were blocked from generic substitution (which is the "cost-

[31] 432 F. Supp. 2d at 421 ("when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate") (citing *Berkey Photo*, 603 F.2d at 287 (noting consumers there were "not compelled" to purchase the new product because "Kodak did not remove any other films from the market when it introduced the new one")). *See also Microsoft*, 253 F.3d at 65-66 (integration of Internet Explorer browser into Windows was exclusionary); *Xerox Corp.*, 511 F. Supp. 2d at 388-89 (patented redesign of ink stick was cognizably exclusionary).

[32] *Id.* at 422. Defendants argue that a critical anticompetitive act in *TriCor* was the added step of obsoleting the older formulation of TriCor from the National Drug Data File ("NDDF") (which is a private commercial database commonly used in the pharmaceutical market). Warner Chilcott Br. at 16. While that did occur in *TriCor*, Judge Jordan focused on both the NDDF obsolescence and the discontinuation of the older formulation. *See id*. at 423 ("[b]y removing the old products from the market and changing the NDDF code, Defendants allegedly suppressed competition by blocking the introduction of generic fenofibrate . . . the allegations of product removal and NDDF code changes, like the allegations related to the product changes themselves, support Plaintiffs' antitrust claims"). Ultimately, the NDDF code changes were simply another part of the scheme, which included the discontinuation of the old product; at no point in the *TriCor* opinion did Judge Jordan single out the code changes as the only (or necessary) exclusionary conduct.

[33] *Id.* (plaintiffs need not show the new formulation was no better than the prior formulation or that the only purpose was to eliminate the rival; plaintiff need only show anticompetitive harm from the change that is to be weighed against any benefits presented by defendants) (*citing Microsoft*, 253 F.3d at 59, 66-67).

efficient" means of distribution) as a result of manipulative and unjustifiable formulation changes.[34]

b. The complaint alleges that Doryx formulation switches were exclusionary because they were achieved through coercion of consumer choice.

Each time that Warner Chilcott introduced its new Doryx product, its sales force aggressively detailed doctors to switch to the new formulation.[35] There was no generic yet available for the prior version, and therefore no price-based reason for the market to remain with the prior formulation. With no generic competition, and with Warner Chilcott's detailers promoting only the "new" formulation, doctors had no reasonable alternative but to switch to the new formulation. By no longer marketing its prior formulations,[36] defendants forced doctors to prescribe the "new" formulation if they wished to prescribe delayed release doxycycline hyclate.

Remember that the system designed by Congress and the states permits and encourages generic companies to obtain sales through automatic substitution, and a generic that is AB rated and substitutable for one branded formulation is *not* AB rated and substitutable for another. Thus, for example, by no longer marketing branded Doryx *capsules* and replacing them with *tablets*, defendants could (and did) block generic capsules from competing effectively because pharmacists cannot substitute a capsule product for a tablet product (different dosage forms are not AB-rated pharmaceutical equivalents automatically substitutable under the well-known DPS laws). This eliminated the most efficient means of competition for generic companies that had or were seeking approval for generic Doryx capsules. Those companies had no viable alternative

[34] *Id.* at 423 (citing *Dentsply*, 399 F.3d at 191 and *Microsoft*, 253 F.3d at 64).

[35] Complaint ¶ 80.

[36] Complaint ¶¶ 58, 62, 69, 72, 74.

except either to abandon any effort to market a generic Doryx product, or to go back to the drawing board to formulate a generic Doryx tablet.[37]

This is exactly the situation that occurred in *TriCor*, which survived a motion to dismiss, and ultimately went to trial solely on the product hop claims. Warner Chilcott executed a product hop several times over a short period, each time making very slight modifications to Doryx, which offered no benefits to patients, but which allowed Warner Chilcott to sell essentially the same product without the generic competition that the Hatch Waxman Act and state substitution laws were enacted to foster and encourage.

The defendants focus only on the allegations about the launch of the new formulations of Doryx. They ignore the allegations that the switch to each new formulation was not based upon consumer choice, but was coerced through the destruction of the sales base of the prior formulation. The combination of the introduction of new formulations with actions to coerce consumer choice, including through no longer marketing the older formulation, is cognizably exclusionary and causes anticompetitive harm.

The complaint alleges an overall scheme, or "anti-generic strategy." Courts consider all of the allegations in the context of the whole scheme, instead of separating out each part of the scheme and subjecting it to individual scrutiny.[38] Nonetheless, plaintiffs describe the exclusionary nature of each aspect of the scheme below. The alleged harm to consumers is not

[37] In *TriCor*, the generic company attempted to market its generic product as a brand drug, and garnered only "modest" sales, 432 F. Supp. 2d at 416, which is a far cry from the 90% or more generic substitution in a competitive market. And, detailing a normal generic to doctors is not efficient or feasible. Revenues from generic sales cannot justify detailing doctors, because the investment, which must be paid for with higher pricing for the product, can never be recouped as non-detailing generic competitors could offer lower prices to wholesalers and pharmacies and take all of the sales away from the detailing generic company.

[38] When determining antitrust liability based on a collection of factual allegations, "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *TriCor*, 432 F. Supp. 2d at 428 (*quoting LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) (*citing Cont'l Ore Co. v. Union Carbide & Carbon Corp*., 370 U.S. 690 (1962))).

offset by any alleged benefits from the new formulations, which offered no clinical or medical benefits to consumers.

(1) The switch from Doryx capsules to Doryx tablets was exclusionary.

In 2005, the defendants began the first switch from Doryx capsules to tablets. The defendants took steps to "destroy the pre-existing demand for Doryx capsules" and "[b]y June 2006, the defendants had withdrawn Doryx capsules from the market altogether.[39] This was exclusionary and anticompetitive because, by no longer marketing Doryx capsules, the defendants deprived consumers of the opportunity to determine whether Doryx tablets were an improvement, and it foreclosed the cost-efficient means of competition for generic (capsule) competitors – AB-rated generic substitution. Additionally, Doryx tablets offered no medical or clinical benefit over capsules, meaning the anticompetitive harm outweighs any potential procompetitive benefit from the switch.[40] And reformulating Doryx from a capsule to a tablet was predatory.[41]

The defendants contend that the tablet formulation was an improvement because it was protected by a patent, and, as a result of the patented process, it offered improved dissolution stability.[42] The defendants are free to offer that as a procompetitive justification to be weighed against the anticompetitive effect. Notably, however, the implication that a tablet formulation of Doryx was required to achieve whatever benefit derives from Patent No. 6,958,161 is belied by

[39] Complaint ¶ 58.

[40] Complaint ¶ 56.

[41] Complaint ¶¶ 57, 80. "A 'predatory' practice is one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor." *Covad Comm'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005). *See also Neumann v. Reinforced Earth Co.*, 786 F.2d 424, 427 (D.C. Cir. 1977) (Bork, J.) ("predation involves aggression against business rivals through the use of business practices that would not be considered profit maximizing except for the expectation that . . . actual rivals will be driven from the market, or the entry of potential rivals blocked or delayed, so that the predator will gain or retain a market share sufficient to command monopoly profits").

[42] Warner Chilcott Br. at 25.

the fact that Claim 15 of the patent says the formulation can be employed in a capsule, and the summary of the invention states that "[i]n one form, a plurality of such coated core elements may be provided in a capsule."[43] And, similarly, the defendants in *TriCor* argued that they had patent protected improvements on their new formulations, but the product hop allegations there were still sufficient to overcome the motion to dismiss and to go to trial. That a product redesign is protected by a patent does not deprive the redesign of its exclusionary character.[44]

(2) The defendants' switch to a scored tablet was exclusionary.

As with the switch to the first tablet, when the defendants introduced the scored formulation of the 75 and 100 mg tablets in 2008 and 2009, they stopped marketing the prior formulation of the tablets and forced consumers to switch to the new formulation.[45] The switch to the scored tablet formulation similarly falls within the *TriCor* paradigm.

The defendants contend the addition of scoring was not exclusionary because, they say, being able to break the tablets in half benefits consumers.[46] But the controlling allegation is that this was not a medical or clinical benefit for consumers.[47] This switch, particularly when combined with the applesauce study for the tablets described below, specifically disrupted the efforts of generic competitors to react to the first exclusionary switch, and gave the defendants time to fully switch consumers over to the 150 mg product before generics were able to enter

[43] Defendants correctly note an error in Plaintiffs' Consolidated Amended Complaint at paragraph 60 that stated that the patent was later held invalid. Plaintiffs apologize for the error. What plaintiffs should have alleged was that the patent was later held not to be infringed. Nonetheless, plaintiffs' claims do not in any way depend on that mistaken language.

[44] *C.R. Bard*, 157 F.3d at 1382 (product redesign was exclusionary despite patent on redesigned gun and biopsy needles); *Xerox Corp.*, 511 F. Supp. 2d at 389 (product redesign was cognizably exclusionary despite patent on redesigned solid ink sticks).

[45] Complaint ¶ 63.

[46] Warner Chilcott Br. at 27.

[47] Complaint ¶ 65.

with generic 75 and 100 mg tablets.[48] Once again, the product redesign is alleged to be predatory.[49] And as with the prior versions, this formulation switch requires scrutiny under the rule of reason because consumer choice was coerced.

(3) The applesauce study was strategically timed to exclude competition.

The defendants also conducted studies on sprinkling the Doryx tablet over applesauce in order to obtain a labeling change to instruct patients how to take Doryx in this manner. The defendants mischaracterize the plaintiffs' allegations as some kind of admission that defendants did not delay seeking a labeling change related to the applesauce study. On the contrary, the plaintiffs specifically alleged that defendants strategically held back these studies until such time as they would "maximally disrupt" efforts of their generic competitors formulating generic versions of the tablets.[50] This conduct is different from the tablet formulation switches in that introduction of this labeling did not require destruction of the sales for an existing formulation. However, this conduct is anticompetitive when viewed in the context of the entire anti-generic strategy employed by defendants. Indeed, the defendants admit in their memorandum that they had conducted applesauce studies on the older capsule product.[51] Tablets, scored or not, were not required for taking Doryx with applesauce; that was a feature available with the subsequently discontinued Doryx capsules. Indeed, requiring consumers to break apart the compressed tablet formulation in order to sprinkle it over applesauce likely made it *harder* for consumers to take Doryx tablets in that fashion compared with Doryx capsules. The only benefit was the disruptive

[48] Complaint ¶ 64.

[49] Complaint ¶¶ 65, 80.

[50] Complaint ¶ 64.

[51] Warner Chilcott Br. at 29.

effect on generic competition from strategically delaying the addition of that information to the tablet label.[52]

(4) The switch to the 150 mg tablet was exclusionary.

As with the switch to the tablets from the capsule, and to scored tablets from unscored tablets, the switch to the 150 mg tablet and the double scored 150 mg tablet was exclusionary because the 150 mg formulation offered no improvement for consumers, and defendants repeated their efforts to destroy demand for 75 and 100 mg tablets, to shift demand to the 150 mg tablet, and to stop marketing the 75 and 100 mg tablets in order to delay and preclude generic competition.[53] The plaintiffs allege that the introduction of the 150 mg tablet was predatory.[54] The defendants argue that their switch to the 150 mg tablets did not delay launch of the 75 and 100 mg tablets, so it could not have been exclusionary. In addition to contradicting the plaintiffs' averments to the contrary,[55] this argument reflects a complete misunderstanding of the *TriCor* decision. The destruction of the sales base for the prior formulation facing imminent generic competition (in this context the 75 and 100 mg tablet product) results in the benefit to the defendants in the shift of the sales to the new formulation not facing imminent generic competition (here the 150 mg tablet). Had the defendants not introduced the 150 mg tablet and not coerced consumers to switch to that formulation, sales of the 75 and 100 mg tablets would not have been affected, and automatic generic substitution of generic 75 and 100 mg delayed-release doxycycline hyclate tablets for branded 75 and 100 mg Doryx tablets would have proceeded apace, without the suppression of pharmacy substitution brought about by defendants' predatory introduction of a new dosage strength that was not substitutable with generic 75 and

[52] Complaint ¶¶ 65-66, 80.

[53] Complaint ¶¶ 68-69, 71-72.

[54] Complaint ¶¶ 71-72, 80.

[55] Complaint ¶¶ 61, 65-67.

100 mg delayed-release doxycycline hyclate. Although the generic companies were able to get approval for generic equivalents to the prior formulations despite the formulation changes, they were nevertheless foreclosed from the cost-efficient means of distribution, and generic substitution could not occur.

The defendants argue that the existence of the FDA's drug approval process itself counsels against enforcing antitrust laws here – implying that FDA's regulations provide a safe haven for anticompetitive behavior.[56] They do not.[57] FDA regulations are not concerned with anticompetitive behavior. The defendants selectively quote *Trinko* for the proposition that the existence of regulation in an industry militates against antitrust enforcement.[58] But *Trinko* teaches that a regulatory environment may require greater antitrust scrutiny.[59]

c. Even innovation, used coercively by a monopolist, is actionable.

"[A] monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior."[60] Defendants suppressed competition by delaying the introduction of a generic product through each of their "innovations," the conversion of the market to the "new" product through extensive detailing efforts, and the discontinuance of the previous formulations.

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[56] Warner Chilcott Br. at 21.

[57] FDA approval of new versions of Doryx does not indicate the new formulations represent an improvement over pervious versions. Before marketing a new drug in the United States a manufacturer must obtain the approval of the FDA contingent upon clinical (i.e., human) testing showing that the drug is (1) safe and (2) effective. *See* 21 U.S.C. §355(a),(d). Demonstrating improvement over a prior formulation is *not required*. Thus, FDA approval demonstrates *only* that the drug, in the proposed version under consideration, is more effective than a placebo, not more effective than other drugs.

[58] Warner Chilcott Br. at 21.

[59] *Trinko*, 540 U.S. at 412.

[60] *Dentsply*, 399 F.3d at 187 (quoting *LePage's*, 324 F.3d at 151-52).

Such conduct, which results in consumer coercion, is anticompetitive.[61] The defendants cite *Berkey Photo* for the proposition that courts are reluctant to weigh in on the question of whether a new product design is exclusionary.[62] But the reluctance of the court in *Berkey Photo* was based on the conclusion that the anticompetitive effects resulted from consumers' free choice. "Consumers who are free to choose among various products enjoy the presence of competition rather than its absence."[63] But the court noted that "the situation might be completely different if, upon introduction of the [new] system, Kodak had ceased producing film in the [old] size, thereby compelling camera purchasers to buy [the new] camera. . . In such a case the technological desirability of the product change might bear on the question of monopolistic intent."[64] "In the absence of free consumer choice, the basis for judicial deference is removed"[65] and innovation used as coercive means of extending market power is actionable.[66]

[61] *Berkey Photo*, 603 F.2d at 274-75 (noting that a monopolist does not violate antitrust law simply by the existence of a monopoly, but by actions it takes which tend to destroy competition: "to avoid the proscriptions of § 2, the firm must refrain at all times from conduct directed at smothering competition. . . a firm with a legitimately achieved monopoly may not wield the resulting power to tighten its hold on the market"); *Dentsply*, 399 F.3d at 187 ("[u]nlawful maintenance of a monopoly is demonstrated by proof that a defendant has engaged in anti-competitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power").

[62] Warner Chilcott Br. at 21.

[63] *Tricor*, 432 F. Supp. 2d. at 423.

[64] *Berkey Photo*, 603 F.2d at 287 n.39.

[65] *Tricor* 432 F. Supp. 2d. at 423.

[66] *Xerox Corp.*, 511 F. Supp. 2d 372, 387 ("several courts have found that product redesign, when it suppresses competition and is without other justification, can be violative of the antitrust laws") (citing *Microsoft*, 253 F.3d at 65-67); *In re IBM Peripheral EDP Device Antitrust Litigation*, 481 F. Supp. 965, 1003 (N.D. Cal. 1997) ("[i]t is not difficult to imagine situations where a monopolist could utilize the design of its own product to maintain market control or to gain competitive advantage . . .if those [] changes had no purpose and effect other than the preclusion of [competitors], this Court would not hesitate to find that such conduct was predatory [and] . . .that use of monopoly power would be condemned").

d. "Free-riding" is at the heart of the Hatch-Waxman regulatory scheme.

The defendants bemoan "free-riding" and argue that innovators should not be forced to aid generic competition.[67] But "[t]his understanding of free-riding has no support in our case law" and is not a cognizable defense.[68] Drug companies are not free to cripple the automatic substitution system set up by Congress and the states through a series of meaningless product changes and the use of their detailing force. The statutory framework constructed by Hatch-Waxman explicitly contemplates the ability of generics to create bioequivalent copies of branded drugs. As the Supreme Court itself has noted, there is sometimes considerable debate in many circumstances whether "free-riding" is harmful or beneficial.[69] There is no such debate here. By enacting the Hatch-Waxman framework, Congress explicitly favored the "piggybacking" ability of generics in order to facilitate savings for consumers. "I am not persuaded that . . . the prevention of 'free riding' is a legitimate business justification. Indeed, the Hatch-Waxman Act establishes and condones the opposition proposition, the 'piggybacking' of generics."[70]

[67] Warner Chilcott Br. at 23.

[68] *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 485 (1992).

[69] *Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 915-16 (2007).

[70] *Tricor*, 2008 U.S. Dist. LEXIS 89777, *11-12 (D. Del. Nov. 5, 2008) (citing *Teva Pharms. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("[a] central purpose of the Hatch-Waxman Act … is to enable competitors to bring cheaper, generic … drugs to market as quickly as possible.")). *See also SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003) ("SmithKline points out that Apotex wants to take a free ride ('usurping,' SmithKline calls it) on the considerable investment made by SmithKline in obtaining FDA approval for Paxil. It is indeed much easier to establish bioequivalence than it is to convince the FDA that an original drug is safe and effective. But that kind of free riding the law permits, and indeed the Hatch-Waxman Act encourages")).

3. The Noerr-Pennington Issue.

Under the *Noerr-Pennington* doctrine, efforts to petition the government are protected by the First Amendment from antitrust liability. Private commercial conduct, however, is not petitioning activity protected under *Noerr-Pennington*. The conduct challenged in this case concerns defendants' private commercial activity in switching Doryx formulations and destroying the market for older Doryx formulations to impede generic competition to the older Doryx formulations. Should the complaint be dismissed under the *Noerr-Pennington* doctrine when it challenges private commercial activity?

a. *Noerr-Pennington* provides immunity only for petitioning activity, not market behavior.

The *Noerr-Pennington* doctrine provides protection for genuine (i.e., not sham and not fraudulent) acts of lobbying or petitioning governmental agencies.[71] However, the scope of the doctrine only extends to *petitioning* activity; it does not license anticompetitive actions that followed petitioning activity that is arguably subject to *Noerr-Pennington*.[72] Merely because the defendants had to submit a supplemental NDA to the FDA for approval of their successive versions of Doryx does not immunize their product changes or the destruction of the market for the prior formulations of Doryx that defendants undertook after FDA approval. In fact, there is not a single reported decision characterizing a drug company's submission of an NDA as petitioning activity under *Noerr-Pennington*, and defendants cite none in their briefs. If filing an NDA were protected petitioning activity under *Noerr-Pennington*, then *TriCor* — where defendants filed NDAs to change the formulation of TriCor from a capsule to a tablet, and then

[71] *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

[72] *See, e.g.*, *Cont'l Ore*, 370 U.S. at 708 ("[r]espondents were engaged in private commercial activity, no element of which involved seeking to procure the passage or enforcement of laws. To subject them to liability under the Sherman Act for eliminating a competitor from the Canadian market by exercise of the discretionary power conferred upon Electro Met of Canada by the Canadian Government would effectuate the purposes of the Sherman Act and would not remotely infringe upon any of the constitutionally protected freedoms spoken of in *Noerr*"); *see also Litton Sys., Inc. v. Am. Tel. & Tel. Co.*, 700 F.2d 785, 807 (2d Cir. 1983) (*Noerr Pennington* did not apply to private commercial activity of imposing and maintaining interface tariff, even though filed with FCC; FCC's failure to strike down tariff does not make the conduct lawful).

from a tablet of one dosage strength to a tablet of another dosage strength — would have been subject to *Noerr-Pennington* and dismissed.[73] Instead, *TriCor* went to trial.

b. The direct purchasers do not challenge petitioning activity; theychallenge defendants' market behavior.

The defendants misunderstand the plaintiffs' claims. The direct purchasers do not complain that the defendants filed NDAs with the FDA. Instead the challenge is to the *market conduct* of the defendants in connection with products that were the subject of NDAs and supplemental NDA filings. While the defendants would have been unable to market their new formulations of Doryx without first having obtained FDA approval, the plaintiffs are not claiming the defendants should not have been able to file applications with the FDA for their "new" formulations of Doryx. The plaintiffs challenge the defendants' marketing of reformulated Doryx products that offered no medical or clinical benefits over the prior formulations of Doryx and the defendants' actions to destroy the market for the prior versions of Doryx in order to delay, stifle, and avoid generic competition. None of those activities is petitioning activity protected under *Noerr-Pennington*.

[73] Even in *Nexium*, the court dismissed product hopping claims because, unlike *Tricor* (and unlike this case), defendants did not withdraw the prior versions of omeprazole (Prilosec) from the market. *Walgreen v. AstraZeneca*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008). The fact that the FDA approved the new versions of omeprazole (Nexium) was irrelevant.

4. The Causation Issue.

An anticompetitive scheme can be a proximate cause of a plaintiff's injury even where elements of the scheme standing alone would not be unlawful. Plaintiffs allege that defendants implemented an overarching scheme to suppress generic competition by marketing "new" versions of Doryx that provided no clinical improvement over the earlier versions while at the same time removing their earlier versions from the market before generic equivalents could be approved. Should the complaint be dismissed where plaintiffs allege that the overall scheme caused their injury, even if some elements of the scheme standing alone would not be unlawful?

a. To state a violation of the antitrust laws, the defendants' conduct need only be a material cause, not the sole cause, of the plaintiffs' harm.

Allegations that a defendant's conduct is a material cause of the suppression of generic competition states a claim for a violation of the antitrust laws.[74] A scheme to manipulate Hatch-Waxman to suppress generic competition can result in significant overcharges that are recoverable under the antitrust laws, whether or not each element of the scheme standing alone violates the antitrust laws.[75] Whether particular elements of an overarching scheme were the proximate cause of an antitrust injury is a fact-intensive inquiry that will not support dismissal in the Rule 12 context.[76]

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[74] *E.g.*, *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 649 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003) (defendants' conduct need only be a material cause, not the sole cause, of plaintiffs' harm); *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) ("[a]n antitrust violation can be a proximate cause of a plaintiff's injury even if there are additional independent causes of the injury").

[75] *E.g.*, *Cardizem*, 105 F. Supp. 2d at 663.

[76] *See, e.g.*, *In re Metoprolol Succinate*, 2010 U.S. Dist. Lexis 36303 at * 28 (D. Del. Apr. 13, 2010) ("As it is not clear at this stage whether Sandoz diverted resources in this case, or whether the FDA's grant of tentative approval was slowed as a result of diverted resources, the court cannot resolve this issue on a Rule 12(b)(6) motion."); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 355 (D. N.J. 2009) ("'the existence of antitrust injury is not typically resolved through motions to dismiss.'"); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) ("Defendants' ability to pose a plausible and legally permissible version of events that explains why generic manufacturers of Wellbutrin SR have not yet entered the market does not compel this Court to grant their Motion. Rather, because this is a motion to dismiss, the Court must draw all reasonable inferences in favor of Plaintiffs.").

b. The direct purchasers allege an overarching scheme that violated the antitrust laws and imposed antitrust injury.

Direct purchasers of Doryx incurred massive overcharges because the defendants' product hopping scheme destroyed the market for therapeutically equivalent generic versions of Doryx, forcing direct purchasers to buy the much more expensive branded version in order to meet their customers' demand. The defendants' overarching, multi-faceted product hopping scheme suppressed generic competition for Doryx.[77] The alleged scheme included the defendants' efforts to (a) develop "new" versions of Doryx that provided no clinical benefits, and (b) destroy the market for the prior brand versions before Mylan could get approval and launch (of those prior brand versions) its generic.[78] "It is difficult to imagine a more formidable demonstration of antitrust injury" than allegations of overcharges caused by conduct which impeded generic competition.[79]

c. The defendants' claim that the absence of generic competition resulted from their lawful applications to the FDA to market serially tweaked versions of Doryx does not support dismissal.

The defendants argue it was the regulatory system that they "gamed" – rather than defendants' successful scheme to manipulate or "game" that system – that caused the plaintiffs' harm.[80]

Filing applications for the new formulations, by itself, would not have successfully suppressed generic competition, especially where, as plaintiffs allege here, the "new" formulations provide no meaningful therapeutic benefits. The defendants' product hopping scheme involved more than filing of applications to market "new" formulations. It included

[77] Complaint ¶¶ 55-84.

[78] *Id*.

[79] *In re Warfarin.*, 214 F.3d at 401

[80] Warner Chilcott Br. at 38.

coercing consumer choice by destroying the market for the prior versions that forced plaintiffs to pay higher brand prices rather than lower generic prices for most of their customers' Doryx requirements. Neither the FDA nor Hatch-Waxman required or encouraged defendants to engage in this conduct. The FDA simply reviewed applications submitted to it, and determined whether each product was safe and effective. FDA never determined – and was never asked to determine – whether defendants' new versions of Doryx were "improvements" over the prior versions. Nor did the FDA ever determine whether defendants' efforts to convert doctors to the "new" versions while destroying the market for the old versions were anticompetitive. FDA has neither the authority nor expertise to make such determinations.[81] The anticompetitive product hopping scheme was devised and implemented entirely by the defendants, and the competitive harm caused by this scheme was clearly caused by defendants' private actions, rather than government action.[82]

The defendants cite cases where plaintiffs' injuries were, as a factual matter, caused "fully" by government action, rather than the private defendants' conduct.[83] Such cases are inapposite where, as here, the private defendants' conduct is a "material cause" of the suppression of generic competition.[84] This principle applies in product hopping cases where, by

[81] 21 U.S.C. § 355(d).

[82] Defendants' citation to *Massachusetts School of Law at Andover, Inc. v. American Bar Association* is not to the contrary. There, the plaintiff law school alleged that it was harmed by the ABA because it recommended accreditation requirements that the plaintiff could not meet, thereby diminishing the school's reputation and causing the school to lose business. The court held that it was the decision by various states to adopt the requirements that was the direct cause of plaintiffs' harm. 937 F. Supp. 435, 440-41 (E.D. Pa. 1996). It also noted, however, that plaintiff could have adequately stated a claim if it had alleged that the ABA had directly caused the school's reputation to be diminished. *Id.* at 442. Plaintiffs here have clearly alleged that defendants' private conduct was a direct and material cause of the suppression of generic competition and the overcharges resulting from that diminished competition.

[83] Warner Chilcott Br. at 39 (citing *inter alia City of Pittsburgh v. West Penn Power Co.,* 147 F.3d 256, 265 (3d Cir. 1998)).

[84] *Cardizem*, 105 F. Supp. 2d at 649.

definition, defendants hop from one FDA-approved product to another to thwart effective generic competition.

The defendants conclusorily claim that "all of the alleged losses" resulted "fully" from Warner Chilcott lawfully seeking and obtaining FDA approvals for its new versions of Doryx.[85] They are wrong. While urging the Court to consider the "realities of the regulated environment," the defendants ignore the fact that one of the primary purposes of the Hatch-Waxman regulatory system is to ensure that consumers get the price benefits of effective generic competition as soon as possible, after the expiry of any legitimate exclusivity periods.[86] Congress did not enact the system to be gamed.[87]

[85] Warner Chilcott Br. at 40.

[86] *In re Barr Labs, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices — fast.").

[87] *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (E.D. Pa. 2004) ("Congress intended the HWA to simplify, not inhibit, the process of bringing generic drugs to the market"), ***aff'd***, 686 F.3d 197 (3d Cir. 2012).

5. The Conspiracy Issue.

The direct purchasers allege an unlawful conspiracy between Mayne and Warner Chilcott to prolong the Doryx monopoly through the overaching product hopping scheme, and that they jointly committed acts in furtherance of the conspiracy. To avoid conspiracy liability, defendants ask the court to make the factually-intense finding that they should be treated as a single entity incapable of conspiracy in violation of the Sherman Act. Should the Court ignore the Supreme Court's directive not to place form over function and instead create antitrust conspiracy immunity for all licensors/licensees?

a. Whether the defendants have capacity to conspire is a question of fact involving functional, not formalistic, consideration.

Whether the defendants are capable of conspiring is a question of fact not capable of resolution on a Rule 12(b)(6) motion.[88] The Supreme Court recently observed in *American Needle*[89] that the focus regarding the single entity issue is not upon "formalistic distinctions," but instead on "functional consideration of how the parties involved in the alleged anticompetitive conduct actually operate."[90] In short, it is not "determinative that two legally distinct entities have organized themselves under a single umbrella or into a structured joint venture. The question is whether the agreement joins together independent centers of decision making."[91] "[T]he fact that joint ventures pursue the common interest of the whole is generally not enough by itself to render them a single entity" because "a commonality of interest exists in every cartel."[92] Neither the necessity of cooperation nor that fact that the actors "operate jointly in some sense" mean that they are automatically immune from liability.[93]

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[88] *Los Angeles Mem. Coliseum Comm'n v. Nat'l Football League*, 726 F.2d 1381, 1387 (9th Cir. 1984) (holding that "the nature of an entity and its ability to combine or conspire in violation of § 1 is a fact question").

[89] *Am. Needle, Inc. v. Nat'l Football League*, 130 S. Ct. 2201 (2010).

[90] *Id.* at 2209.

[91] *Id.* at 2212 (quotations omitted).

[92] *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 836 (3d Cir. 2010) (quotations and citation omitted).

[93] *Id.* at 2214.

Because of the factually intense record needed to determine whether two parties are a single entity, most of the cases relied on by defendants to support their single entity argument are summary judgment opinions, issued on a full factual record.[94] The Court does not yet have the factual record necessary to decide whether defendants were capable of conspiring in violation of Sections 1 and 2 of the Sherman Act.

b. The complaint alleges Warner Chilcott and Mayne worked together to prolong the Doryx monopoly through the product hopping scheme.

To state a cognizable claim, "a complaint must contain factual allegations that, taken as a whole, render the plaintiff's entitlement to relief plausible."[95] This "does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element."[96]

The complaint alleges a conspiracy by Mayne and Warner Chilcott to restrain trade. It sets out the actual agreement between Mayne and Warner Chilcott. It sets forth the existence, object and accomplishment of the joint scheme. And it specifies overt conduct in furtherance of the conspiracy by both Mayne and Warner Chilcott. The result of the scheme was higher prices paid by direct purchasers of Doryx.

The complaint explains that *both* defendants learned that various companies were planning to seek FDA approval to manufacture generic Doryx capsules which would destroy their Doryx monopoly and that such threat triggered their unlawful product hopping scheme.[97]

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[94] *See, e.g., Eichorn v. AT&T Corp.*, 248 F.23d 131 (3d Cir. 2001); *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125 (3d Cir. 1995); *City of Mt. Pleasant v. Assoc. Elec. Coop., Inc.*, 838 F.2d 268 (8th Cir. 1988); *Wahl v. Rexnord, Inc.*, 481 F. Supp. 573 (D.N.J. 1979), *rev'd on other grounds*, 624 F.2d 1169 (3d Cir. 1980); *Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428 (N.D. Cal. 1992).

[95] *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d. 85, 98 (3d Cir. 2010) (citations omitted).

[96] *West Penn*, 627 F.3d at 98 (internal quotations omitted) (citing *In re Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

[97] Complaint ¶¶ 54-55.

Both defendants admit to working together to prolong the Doryx monopoly, including through the anticompetitive product hopping scheme, causing direct purchasers of Doryx to pay supracompetitive prices.[98]

Mayne, for its part, has publicly admitted that it has "relentlessly" worked with Warner Chilcott, its marketing partner, on "life cycle strategies" for Doryx to prevent generic competition and boasted that those efforts included "successfully reformulat[ing] Doryx from capsules into tablets in 2005 and subsequently releas[ing] a new Doryx 150mg tablet in 2008."[99] Warner Chilcott also has publicly admitted to employing multiple strategies to forestall generic competition and has boasted of its ability to move the Doryx market in advance of generic competition,[100] something that would be impossible without the complete agreement of Mayne, Warner Chilcott's Doryx supplier.

The complaint alleges that Mayne, the manufacturer of Doryx, and Warner Chilcott, the marketer of Doryx in the United States,[101] conspired to forestall generic competition using an overarching anticompetitive product hopping scheme.[102] Each switch made as part of the scheme required coordinated efforts and overt acts by each of the defendants. For instance, the switch from capsules to tablets required Mayne, as the manufacturer of Doryx, to expend significant resources (a) developing and seeking FDA approval of the tablet formulation and (b) changing the manufacturing process to effectuate the market switch.[103] Likewise, Warner

[98] Complaint ¶¶ 75-77.

[99] Complaint ¶ 75.

[100] Complaint ¶ 75.

[101] Complaint ¶ 53.

[102] Complaint ¶ 1.

[103] Complaint ¶¶ 56-57; *see also id.* ¶¶ 61-62, 67-74.

Chilcott, as the marketer of Doryx, was responsible for, among other things, destroying the market for Doryx capsules and shifting the demand to Doryx tablets.[104]

c. There is no bright-line rule that a licensor and licensee are incapable of conspiring.

The defendants ask the Court to reject the Supreme Court's instructions in *American Needle* to not put form over substance, and instead adopt a bright-line rule that licensees and licensors cannot conspire with each other.[105]

The defendants pretend that the license at issue here is for a formulation patent that grants defendants a legal monopoly on Doryx, that precludes generic competition. In reality, the defendants' agreements and anticompetitive activities relate simply to their desire to maintain a monopoly over the Doryx market despite the existence of non-infringing generic competition. The cases the defendants cite for the establishment of the licensee/licensor exception to antitrust conspiracy liability have no application here.

The defendants rely on dicta in *Shionogi Pharma, Inc. v. Mylan, Inc.* (involving a patent license),[106] where the court cited the summary judgment decision in *Levi Case Co. v. ATS Prods., Inc.* [107] (involving a patent license and heavily relied upon by defendants) for the proposition that patent licensors and licensees cannot conspire.[108] However, *Levi Case* does not create such a bright-line rule for patent licensee/licensors, let alone the licensing relationship before the Court here. That argument has already been rejected by the Northern District of California in

[104] Complaint ¶¶ 57-58; *see also id.* ¶¶ 72-74.

[105] Such an argument is belied by the numerous cases in which courts have allowed conspiracy claims against licensees/licensors to proceed. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F.Supp.2d 408 (D. Del. 2006) (Abbott was Fournier's licensee); *In re Wellbutrin XL Antitrust Litig.*, 2009 U.S. Dist. LEXIS 21286 (E.D. Pa. Mar. 13, 2009) (SmithKline was Biovail's licensee).

[106] 2011 WL 2174499, *5 (D. Del. May 26, 2011).

[107] 788 F. Supp. 428 (N.D. Cal. 1992).

[108] *Shionogi*, 2011 WL 2174499, at *5.

Townshend v. Rockwell Intern. Corp., [109] which held that "[w]hile the facts in *Levi Case* resulted in a finding by that court that a patent holder and its exclusive licensee were incapable of entering into a conspiracy with respect to their conduct and sublicensees, the court did not set forth a bright-line rule that patent holders and their licensees could never conspire."[110]

Not only does *Levi Case* not create a bright-line test,[111] the facts of the summary judgment decision are starkly different from the allegations that control here. In *Levi Case*, the holder of a patent relating to ductwork, Shea, granted an exclusive patent license to Sterling Imperial and only retained the right to royalties and to approve sublicenses, one of which was granted to ATS.[112] Shea and ATS were accused of conspiring to monopolize a submarket for ductwork produced using Shea's patent.[113] As the Northern District of California recently explained, "[t]he patent holder [Shea], by virtue of the exclusive license, could not compete in the market covered by the patent and neither could anyone else because a patent is a legally-sanctioned restraint on trade,"[114] thus justifying the *Levi Case* court's single entity finding based on the facts before it. Here, of course, there is no legally-sanctioned restraint on trade. The plaintiffs do not allege that the market generics are kept out of is for the '161 patent (akin to the ductwork in *Levi Case*); instead, the complaint alleges the market is for Doryx, which is subject

[109] No. C99-0400, 2000 WL 433505 (N.D. Cal. Mar. 28, 2000).

[110] *Id.* at *6.

[111] *See* Nathaniel Grow, *American Needle and the Future of the Single Entity Defense Under Section One of the Sherman Act*, 48 Am. Bus. L.J. 449, 495 (2011) (explaining that because the patent licensor (Shea) and licensee (ATS) "remained competitors despite their exclusive license" the "court's single entity characterization [in *Levi Case* is] questionable in light of *American Needle*").

[112] *Levi Case*, 788 F.Supp. at 431.

[113] *Id.* at 430.

[114] *Pecover v. Electronic Arts, Inc.*, 633 F. Supp. 2d 976, 984 (N.D. Cal. 2009).

to non-infringing generic competition.[115] The alleged conduct is product hopping, not a refusal to license a patent that grants a legal monopoly. As such, *Levi Case* has no application here.[116]

[115] *Warner Chilcott Labs. Ireland Ltd. v. Mylan Phamra Inc.*, No. 08-06304, 2012 WL 1551709 (D.N.J. Apr. 30, 2012) (finding that Mylan's generic Doryx did not infringe the '161 patent).

[116] We also point out that most of the cases relied on by defendants to support their single entity argument are summary judgment opinions, aided by a factual record that does not exist here. *See, e.g., Eichorn v. AT&T Corp.*, 248 F.23d 131 (3d Cir. 2001); *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125 (3d Cir. 1995); *City of Mt. Pleasant v. Assoc. Elec. Coop., Inc.*, 838 F.2d 268 (8th Cir. 1988); *Wahl v. Rexnord, Inc.*, 481 F. Supp. 573 (D.N.J. 1979), *rev'd on other grounds*, 624 F.2d 1169 (3d Cir. 1980); *Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428 (N.D. Cal. 1992).

6. The Relevant Market Issue.

A properly defined relevant product market (assuming such a definition is required) includes only products that exhibit significant positive cross-price elasticity of demand with one another and is a highly fact-intensive inquiry. Here, only AB-rated generic versions of Doryx are alleged to exhibit significant positive cross-price elasticity with Doryx – despite the existence of other acne medications. Should the complaint be dismissed for failure to allege a relevant product market that includes drugs that might treat some of the same conditions Doryx does but that do not exhibit significant cross elasticity of demand with Doryx?

a. Definition of the relevant product market is a question of fact not susceptible to resolution at the pleading stage.

The definition of the relevant product market is a fact-intensive analysis and dismissal for failure to plead an adequate relevant product market is disfavored. "The proper market definition in this case can be determined only after a factual inquiry into the 'commercial realities' faced by consumers."[117] "Because market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure to plead a relevant product market."[118] "[T]he type of challenges made by Defendants to Plaintiffs' definition of the relevant market are best resolved on a motion for summary judgment or at trial."[119]

b. Only products that exhibit significant positive cross-elasticity of demand with respect to price belong in the same antitrust product market as Doryx.

The standard for deciding what products belong in a relevant product market in an

[117] *Eastman Kodak Co.*, 504 U.S. at 482; *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199 (3d Cir. 1992) ("the determination of a relevant product market or submarket . . . is a highly factual one best allocated to the trier of fact"). Of course, if the direct purchasers can demonstrate through direct evidence that defendants enjoyed monopoly power with respect to Doryx, they need not define a relevant antitrust product market at all. *See Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 307 n.3 (3d Cir. 2007) ("*direct proof of monopoly power does not require a definition of the relevant market*")(emphasis added); *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 107-08 (2d Cir. 2002) ("[w]e agree with PepsiCo that there is authority to support its claim that a relevant market definition is not a necessary component of a monopolization claim").

[118] *Todd v. Exxon Corp.*, 275 F.3d 191, 199-200 (2d Cir. 2001) (citation omitted); *Weiss v. York Hosp.*, 745 F.2d 786, 825 (3d Cir. 1984) ("[m]arket definition is a question of fact").

[119] *Peerless Heater Co. v. Mestek, Inc.*, No. Civ. A. 98-6532, 1999 WL 624481, *1 (E.D. Pa. Aug. 6, 1999).

antitrust case is their "reasonable interchangeability."[120] But products are not "reasonably interchangeable" simply because they have similar uses. Reasonable interchangeability depends on whether the products are economic substitutes for one another – whether relative changes in the price of one product cause substantial shifts in the quantities demanded for another – commonly referred to as "cross-elasticity of demand."[121] Included in the relevant product market with a particular product under consideration (such as Doryx) are only those products that exhibit significant, positive cross-elasticity of demand with it.[122]

Thus, in *SmithKline Corp. v. Eli Lilly & Co.*, the district court held that the relevant market was limited to "cephalosporins," and did not include other antibiotics or anti-infectives.[123] Like the defendants here, Lilly argued that the relevant market should include all other anti-infective drugs in the therapeutic class.[124] The district court rejected Lilly's argument. The mere fact that other drugs were used for similar purposes was insufficient to compel their inclusion in the relevant market.[125] After a full trial, the district court found that "[c]ross elasticity of demand and price sensitivity do not exist, to any significant degree, between the

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

[121] *Id.* at 437-38 ("products in a relevant market are characterized by a cross-elasticity of demand, in other words, the rise in price of a good within a relevant product market would tend to create a greater demand for other like goods in that market").

[122] *Id.* at 438 n.6 ("[c]ross elasticity is a measure of interchangeability" and is "the economic tool most commonly referred to in determining what should be included in the market"); *Babyage.com, Inc. v. Toys "R" Us, Inc.*, 2008 U.S. Dist. LEXIS 40476, *4-6 (E.D. Pa. May 19, 2008); *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1096, 1100, 1118-19 (E.D. Pa. 1976), *aff'd*, 575 F.2d 1056, 1063 (3d Cir. 1978) (market definition is drawn with reference to cross-price elasticity of demand); *Coca-Cola Bottling Co. of Shreveport, Inc. v. Coca-Cola Co.*, 696 F. Supp. 97, 131 (D. Del. 1988) (equating reasonable interchangeability with cross-elasticity of demand). *See also Auburn News Co. v. Providence Journal Co.*, 504 F. Supp. 292, 302 (D.R.I. 1980) ("When one gets down to brass tacks, or any other specific product, almost all products have substitutes: even buses, skywriters and road signs compete with newspapers for advertising. Antitrust law, however, is only concerned with products reasonably interchangeable with one another, in other words, products for which there is some cross elasticity of demand") (citing *Brown Shoe, Inc. v. U.S.*, 370 U.S. 294 (1962)).

[123] *SmithKline Corp.*, 575 F.2d at 1064.

[124] 427 F. Supp. at 1116.

[125] *Id.* at 1096.

cephalosporins and other antibiotic or anti-infective drugs."[126] The court also noted the lack of price sensitivity due to unique characteristics of the pharmaceutical industry. Due to the laws of generic substitution, "[a] prescription for a cephalosporin cannot be filled with a non-cephalosporin, such as penicillin, ampicillin or tetracycline. Thus, the hospital physician population, in practice, does not view other antibiotics as reasonably interchangeable with the cephalosporins."[127] The district court limited the market definition to the branded and generic cephalosporins *despite* the existence of obvious functional and therapeutic similarities between cephalosporins and, for instance, penicillin,[128] and *despite* finding that "[t]here is a certain degree of interchangeability among *all* antibiotic drugs."[129] The Third Circuit affirmed. Many other courts have ruled in favor of a relevant antitrust product market limited to branded and generic versions of a single formulation of a single drug (and sometimes even narrower definitions) in the Rule 12, Rule 56, and other postures.[130]

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[126] *Id.* at 1096*; see also id.* at 1100 ("[c]hanges in the relative amounts of cephalosporins and non-cephalosporins purchased by hospitals are not directly related to the relative costs thereof"); *id.* at 1118-19 (noting absence of price sensitivity).

[127] *Id*. at 1097.

[128] *Id*. at 1097-98

[129] *Id*. (emphasis added)

[130] *Andrx Pharms. Inc. v. Elan Corp*., 421 F.3d 1227, 1235-36 (11th Cir. 2005) (relevant market limited to controlled release naproxen); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc*., 386 F.3d 485, 496-99 (2d Cir. 2004) (relevant market limited to generic versions of warfarin sodium, excluding other blood thinners and even chemically-identical branded version of warfarin sodium); *La. Wholesale Drug Co., Inc. v. Sanofi-Aventis*, 2008 WL 169362, *7 (S.D.N.Y. Jan. 18, 2008) (product market limited to branded and generic versions of rheumatoid arthritis drug Arava, and excluding all other rheumatoid arthritis drugs, was cognizable); *In re Lorazepam & Clorazepate Antitrust Litigation*, 467 F.Supp. 2d 74, 81-82 (D.D.C. 2006) (relevant markets limited to generic versions of lorazepam and clorazepate, respectively and excluding other anti-anxiety agents); *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 363 F. Supp. 2d 514, 522-23 (E.D.N.Y. 2005) (relevant market limited to drug product ciprofloxacin, excluding other antibiotics, including other flouroquinolone antibiotics); *In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla.2005) (relevant market limited to branded and generic terazosin hydrochloride and excluding other drugs in the therapeutic class); *FTC v. Schering-Plough Corp*., 2003 FTC LEXIS 187, *58-59 (F.T.C. 2003) (branded and generic versions of potassium supplement K-Dur 20 "define[] the area of trade we need to focus on" in a suppressed generic competition case), rev'd on other grounds, 402 F.3d 1056 (11th Cir. 2005); *Knoll Pharmaceuticals Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 01-C-1646, 2001 WL 1001117, *3-4 (N.D. Ill. Aug. 24, 2001) (product market limited to hydrocodone bitartrate/ibuprofen was cognizable); *In re Cardizem CD Antitrust Litig*., 105 F. Supp.2d 618, 680-81 (E.D. Mich.

c. Only AB rated versions of Doryx exhibit significant positive cross-price elasticity of demand and should be included in the same antitrust product market.

The direct purchasers define the relevant product market (assuming such a definition is ultimately required) to include Doryx and all AB-rated generic versions of Doryx.[131] The exclusion of other (non-AB rated) doxycycline products and other antibiotics from the relevant market is a function of the unique characteristics of the pharmaceutical marketplace,[132] and the simple fact thatbranded Doryx does not exhibit substantial cross-price elasticity of demand with any drug other than generic delayed-release doxycycline hyclate.[133]

In most other industries, faced with the availability of products that function similarly to their product, manufacturers have a strong incentive to lower their product's price to maintain profitability. Branded pharmaceutical manufacturers do not face the same incentives[134] because (in large part and in contrast with most products) those mandated by law to select pharmaceutical products (i.e., physicians) do not pay for the product. Physicians are price insensitive.[135] The

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2000) (product market limited to branded and generic versions of Cardizem CD was cognizable); *Mutual Pharm. Co., Inc. v. Hoechst Marion Roussel, Inc*., 1997 WL 805261 (E.D. Pa. Dec. 17, 1997) (reasonable jury could find that relevant market was limited to non-sedating antihistamine Seldane, and excluded non-sedating antihistamine Claritin, because of unique formulations and differences in suitability for particular patients).

[131] Complaint ¶ 96 ("all delayed-released doxycycline hyclate products – i.e. Doryx (in all its forms and dosage strengths) and AB-rated bioequivalent doxycycline hyclate products").

[132] *Id*. ¶¶ 31-37, 52, 88-98.

[133] *Id.* ¶¶ 88-90.

[134] *Id*. ¶¶ 31-32 ("[w]hen the same person has both the payment obligation and the choice of products… manufacturers have a strong incentive to lower the price of their products to maintain profitability. The pharmaceutical marketplace, by contrast, is characterized by a 'disconnect' between the payment obligation and the product selection").

[135] *Id*. ¶ 33 ("[s]tudies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, including because they do not themselves have the obligation to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection").

Third Circuit has ruled that "[m]arket definition must take into account the fact that physicians, who regulate use of drugs are not cost-conscious."[136]

As a result of this "disconnect" between product choice and the payment obligation, and as a result of the large forces of sales representatives employed by branded manufacturers to persuade physicians to prescribe their product irrespective of price, products that serve a similar medical function often exhibit little or no downward price competition with one another.[137]

With the introduction of a generic equivalent, normal competitive pressures are restored to the pharmaceutical marketplace. Generics compete on price. Only the introduction of a competing AB-rated generic version of Doryx has rendered the defendants unable to profitably maintain their prices for Doryx without losing substantial sales. Only AB-rated generic versions of Doryx exhibit significant, positive cross-price elasticity of demand with branded Doryx, and *a fortiori* only AB-rated generic version of Doryx belong in the same product market with branded Doryx.

d. The defendants' emphasis on the existence of other acne medications ignores cross-elasticity of demand.

The defendants agree that the ultimate question of which products belong in the relevant market is a function of cross-elasticity of demand.[138] Yet they ignore this and advocate the inclusion of products in the relevant market simply because they serve a similar therapeutic

[136] *Columbia Metal Culvert Co., Inc. v. Kaiser Alum. & Chem. Corp.*, 579 F.2d 20, 28 n.22 (3d Cir. 1978).

[137] *Id.* ¶ 35 ("[w]hen the relative importance of the price between two branded pharmaceuticals . . . is low, the price elasticity of demand – the extent to which sales go down when price goes up – is by definition also low, which in turn gives branded manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales").

[138] Warner Chilcott Br. at 50 ("[s]tate substitution laws fail to address the ultimate questions of interchangeability and cross-elasticity of demand') (citations omitted).

purpose.[139] It is error to include in a relevant product market products that might function similarly but which are not shown to have exhibited sufficient cross-elasticity of demand to constrain prices to competitive levels.[140]

[139] *Id.* ("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 docycycline hyclate product market") (citation omitted).

[140] *See, e.g.*, *Telecor Communications, Inc. v. Southwestern Bell Telephone Co.*, 305 F.3d 1124, 1132 (10th Cir. 2002) ("[r]easonable interchangeability does not depend on product similarity"); *Brookins v. Int'l Motor Contest Ass'n*, 219 F.3d 849, 854 (8th Cir. 2000) (absence of cross-elasticity of demand between two products compels conclusion that products do not inhabit same antitrust product market); *U.S. Anchor Mfg., Inc. v. Rule Industries, Inc.*, 7 F.3d 986, 995-99 (11th Cir. 1993) (despite functional interchangeability, absence of price-related demand and supply elasticities prevents products from residing in same market); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 & n.1 (8th Cir. 1989) (sugar and high fructose corn syrup, though functionally interchangeable, do not reside in same antitrust product market because "a small change in the price of HFCS would have little or no effect on the demand for sugar" such that cross-elasticity of demand is low, despite evidence of actual substitution of corn syrup for sugar by consumers); *Hayden Pub. Co. v. Cox Broadcasting Corp.*, 730 F.2d 64, 70 (2d Cir. 1984) (district court committed reversible error in "neglect[ing] the factor of cross-elasticity of demand," which directs that the court determine not just ability of products to be substitutes for one another from a functional standpoint, but primarily "how *far* buyers will go to substitute one commodity for another") (emphasis supplied); *FTC v. Staples*, 970 F. Supp. 1066, 1074 (D.D.C. 1997) (finding, on basis of absence of cross-elasticity of demand, that products reside in separate product markets despite functional interchangeability of products); *id.* at 1075 ("the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes").

7. The Statute of Limitations Issue.

An inherently fact-intensive inquiry, the four-year statute of limitations for federal antitrust claims does not bar a purchaser's suit against a monopolist for overcharges paid within the previous four years even if the underlying anticompetitive actions occurred before the limitations period. This July 2012 case seeks overcharges paid since July of 2008. Should the complaint be dismissed at the pleading stage as barred by the limitations statute?

a. The statute of limitations involves a fact-laden inquiry as to when the cause of action accrued.

The statute of limitations is a fact-intensive affirmative defense disfavored in the Rule 12 context. A defendant "bears a heavy burden in seeking to establish that the challenged claims are barred as a matter of law."[141] "In antitrust actions in particular, Rule 12 Motions should be scrutinized carefully and granted rarely[.] Ordinarily, the statute of limitations is an affirmative defense which cannot be asserted on a motion to dismiss."[142]

b. A federal antitrust cause of action does not accrue until all elements of the claim, including overcharge damages, have occurred.

When a monopolist engages in a scheme of continuing misconduct designed to maintain monopoly power and exclude competition unlawfully, each act in furtherance of the scheme is part of a continuing violation of the Sherman Act, is treated as accumulating harm to competition, and resets the limitations period.[143] *Hanover Shoe* itself found the limitations period did not bar forty year-old "conduct which constituted a continuing violation of the Sherman Act and which inflicted continuing and accumulating harm."[144] Further, the Third Circuit explicitly rejected an understanding of the statute of limitations that would convert it from a doctrine barring claims for past acts completed long ago into a license to engage in

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[141] *Meijer, Inc. v. 3M*, 2005 WL 1660188, *2 (E.D. Pa. July 13, 2005).

[142] *In re Linerboard Antitrust Litig.*, 2000 WL 1475559, *4 (E.D. Pa. Oct. 3, 2000).

[143] *West Penn*, 627 F.3d at 106-07.

[144] *See Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 502 n.15 (1968).

ongoing illegal conduct or, as *West Penn* put it, that "would . . . improperly transform the limitations statute from one of repose to one of continued immunity."[145] So long as overcharges continue to be incurred within the limitations period, the challenged unlawful acts can occur much earlier.[146] Thus, an antitrust plaintiff may recover overcharge damages resulting from defendants' anti-competitive conduct – regardless of whether some or all of that conduct occurred outside the limitations period – at least for the four years immediately preceding the complaint.[147]

c. The complaint alleges overcharges within the limitations period.

The complaints were filed in July 2012 and seek certification of a class of purchasers of "Doryx tablets directly from any of the Defendants at any time during the period July 2008 through the present."[148] The overcharge damages sought here exist entirely within the four-year limitations period. And the allegations charge the defendants with repeated misconduct as part of a continuing scheme designed to maintain monopoly power and exclude competition for Doryx. This misconduct, some of which occurred outside the limitations period, caused overcharges for Doryx purchases made within the limitations period. The allegations also charge

[145] *West Penn*, 627 F.3d at 105 (quotations omitted).

[146] *West Penn*, 627 F.3d at 108 ("Under *Zenith*, West Penn's conspiracy claims are not time-barred because the complaint adequately alleges that the defendants performed injurious acts in furtherance of the conspiracy within the limitations period"); *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d Cir. 1993) (holding limitations period did not bar continuing refusal to deal conspiracy claims where, *inter alia*, overcharge damages occurred within the limitations period); *Meijer*, 2005 WL 1660188, at *4 ("in purchaser antitrust actions, the requisite injurious act within the limitations period can include being overcharged as a result of an unlawful act which took place outside the limitations period").

[147] *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338-42 (1971) (holding no limitations bar where complained-of antitrust violation occurred outside the limitations period but caused calculable damages inside the limitations period); *Continental-Wirt Electronics Corp. v. Lancaster Glass Corp.*, 459 F.2d 768, 770 (3d Cir. 1972) (holding limitations period did not start until damages were actually suffered notwithstanding that the antitrust violation occurred outside the limitations period).

[148] Complaint ¶ 22.

misconduct as part of the ongoing scheme within the limitations period, *i.e.*, when, in 2011, the defendants again reformulated Doryx through introduction of the dual-scored tablet.[149]

d. Neither *Zenith* nor *Klehr* support dismissal on limitations grounds.

Warner Chilcott seeks dismissal arguing that all but one part of plaintiffs' alleged anticompetitive scheme occurred outside the limitations period.[150] However, Warner Chilcott's own cited case, *Zenith*, makes clear this is not the law. An antitrust plaintiff can recover damages incurred within the limitations period in connection with anticompetitive conduct that occurred outside the limitations period.[151] And in this case the episodes of challenged misconduct cannot fairly be considered in isolation. It is the cumulative effect of all the misconduct that forecloses or delays competition for Doryx generics. This is precisely the kind of "continuing violation" discussed in *Hanover Shoe*, *Lower Lake Erie*, *West Penn*, and *Meijer* that is not barred by the statute of limitations.

Finally, Warner Chilcott cites the RICO case *Klehr*[152] for the proposition that plaintiffs "cannot use an independent, new predicate act as a bootstrap to recover for injuries caused by other earlier predicate that took place outside the limitations period."[153] The reliance is misplaced. In *Klehr*, plaintiffs sought damages in connection with an allegedly defective product purchased outside the limitations period, and were completely unable to identify any harm that did not already exist when the limitations period expired. In contrast, Plaintiffs here seek overcharge damages in connection with purchases made entirely within the limitations period,

[149] Complaint ¶ 70.

[150] Warner Chilcott Br. at 53-55.

[151] *Zenith*, 401 U.S. at 338-42 (holding no limitations bar where complained-of antitrust violation occurred outside the limitations period but caused calculable damages inside the limitations period).

[152] *Klehr v. A.O. Smith Corp.*, 521 U.S. 189, 190 (1997).

[153] Warner Chilcott Br. at 54-55.

and each of these overcharges represents a new, distinct harm that occurred within the limitations period.

III. CONCLUSION

The answer to each of the seven questions is:

1. No, the complaint should not be dismissed for failure to allege antitrust injury. Branded drug product hopping, when coupled with destruction of the prior product versions, can violate antitrust laws, delay generic substitution and cause higher prices to be paid for drug products.

2. No, the complaint should not be dismissed for failure to allege exclusionary conduct. The repeated useless product changes of Doryx coupled with the destruction of the market for the prior product versions foreclosed generic substitution, the cost-efficient method of competition in this area.

3. No, the complaint should not be dismissed under *Noerr-Pennington*. This case involves private market misconduct, not governmental petitioning.

4. No, the complaint should not be dismissed for lack of adequate causation pleading. The defendants' private market misconduct caused foreclosure of cost-efficient generic substitution.

5. No, the complaint should not be dismissed for lack of conspiracy simply because the defendants also happen to be in a licensor/licensee relationship. Functional, not formalistic, considerations apply and the allegations allege concerted action.

6. No, the complaint should not be dismissed for failure to allege relevant product market. Only AB-rated generic versions of Doryx are alleged to exhibit significant, positive cross-price elasticity with Doryx.

7. No, the complaint should not be dismissed due to the statute of limitations. The cause of action did not accrue until the period within the four year statute applicable to antitrust claims.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this date I caused a true and accurate copy of Direct Purchaser Plaintffs' Summary Submission in Response to Defendants' 12(b)(6) Motions to be filed via CM/ECF in this action and served upon all counsel of record therein.

October 9, 2012

/s/ David S. Nalven
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