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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'
OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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I. INTRODUCTION

The health and welfare of millions of Americans depends on access to safe, effective, and affordable medications. The high cost of drugs can mean no treatment, or inadequate treatment, for many. Affordable drugs lead to better treatment and prevention. At root, then, in the American system of access to prescription drugs is a basic principle: once the statutory period for branded exclusivity expires, generic manufacturers can compete with less expensive, automatically substitutable generic products that the FDA has approved as being "the same as" the brand. Put differently, brand name drug manufacturers have a statutory period of time, *but only that period of time*, to charge high prices for medications that, in fact, cost little to manufacture. Once the lawful periods of exclusivity expire, generic companies may get FDA approval as being the "same as" the brand, and the generic companies are free to compete against brand manufacturers with generic products that are just as safe, just as effective, but far less expensive than the brand. The medication then becomes affordable for all, and the health and welfare of consumers is no longer burdened by the high price of the drug.

This antitrust case involves an overarching scheme by defendants to manipulate and abuse the statutory scheme in order to impede generic competition and extend their monopoly profits for longer than the law allows. The prescription drug is Doryx, a brand name delayed-release antibiotic generically known as delayed-release doxycycline hyclate. Plaintiffs are pharmaceutical manufacturer Mylan Pharmaceuticals, Inc. ("Mylan") and pharmaceutical purchasers Rochester Drug Co-Operative, Inc., Meijer, Inc. and Meijer Distribution, Inc., and American Sales Company, LLC ("direct purchaser plaintiffs") (collectively, "plaintiffs"). Defendants are the manufacturers and distributors of Doryx: Warner Chilcott Public Limited Company, Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Laboratories Ireland Limited (collectively,

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"Warner Chilcott"), and Mayne Pharma Group Limited and Mayne Pharma International Pty. Ltd. ("Mayne") (collectively, "defendants"). Warner Chilcott markets branded Doryx under an exclusive license from Mayne.

Defendants unlawfully suppressed generic competition to Doryx. From 1985 until recently, Doryx was completely free from competition from a generic delayed-release doxycycline hyclate. Defendants prolonged their delayed-release doxycycline hyclate monopoly — and the nearly $300 million in annual sales it generated — from less-expensive generic competition beyond the term of legal entitlement by using (as their own internal documents tell) a deliberate "product hopping" or "swap-out" scheme." [1]

Product hopping schemes (like the one alleged here) involve (1) introducing new products with trivial or no substantive improvements, but to which generic versions of the prior formulation are not AB-rated, and (2) destroying the prescription base for the prior formulation and converting the vast majority of demand to the new (non-AB rated) formulation, so that, by the time generic versions of the prior formulation get to market, there are very few prescriptions that can be substituted with that generic by a pharmacist. According to defendants' own documents, their scheme was not aimed at innovation or expanded output. According to defendants' own documents, "[t]hey did not expect to have any increase in sales as part of the switch." Instead, its purpose (and effect) was an "anti-generic strategy" designed to "preserve the [Doryx] franchise."[2]

It is established that such product hopping schemes are actionable. A similar anti-generic product hopping scheme survived a motion to dismiss, was tried to a jury, and ultimately settled

[1] Transcript of Doryx patent trial proceedings at 78-86, *Warner Chilcott Labs v. Mylan Pharm. Inc.*, 2:09-cv-20730WJM MF (D.N.J.), *Warner Chilcott Labs v. Impax Labs. Inc.*, 2:08-cv-6304-WJM MF (D.N.J.) (Feb. 8, 2012).

[2] *Id.*

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in *Abbott Labs. v. Teva Pharms. USA, Inc.* ("*TriCor*").[3] Warner Chilcott is not new to such product hopping allegations, having entered into a consent order with the Federal Trade Commission in 2006 precluding it from engaging in such conduct regarding an oral contraceptive ("Ovcon").[4]

Plaintiffs here allege that defendants' overall product-hopping scheme included the following sequential actions to impede generic entry:

- Switching the market from 75 and 100 mg Doryx *capsules* to 75 and 100 mg Doryx *tablets* and ceasing the marketing of the capsules.
- Later, changing the Doryx tablet label to explain how to administer Doryx by breaking up the tablet and sprinkling the contents over applesauce.
- Later still, changing the Doryx tablets to include a "score" down the center, and ceasing the marketing of unscored Doryx tablets.
- And later again, switching the market from 75 and 100 mg Doryx tablets to 150 mg Doryx tablets and ceasing the marketing of the 75 and 100 mg tablets.
- Finally, switching the market from 150 mg *single-scored* Doryx tablets to 150 mg *dual-scored* Doryx tablets, and ceasing the marketing of the single-scored tablets.

Defendants knew that because a generic drug must be the same dosage strength and form as the reference listed drug to be substitutable at the pharmacy level, these "product hopping" techniques would prevent a would-be generic competitor from obtaining an "AB" rating from FDA, and would instead require it to conform to the new manufacturing, labeling, or formulation changes in order to be substitutable for branded Doryx. Plaintiffs expressly allege that each of these product changes offered no (or no meaningful) medical or clinical benefit to consumers over the prior formulation, nor did any change boost sales, lower cost, or increase efficiency for

[3] 432 F. Supp.2d 408 (D. Del. 2006) (Rule 12 motion denied) (Jordan, J.); *id.*, No. 05-340, Mem. Ord., ECF No. 434 (D. Del. Aug. 18, 2008) (Rule 56 motion denied) (Robinson, J).

[4] Final Order and Stipulated Permanent Injunction, *FTC v. Warner Chilcott Holdings III*, No. 1:05-cv-02179-CKK (D.D.C. October 23, 2006), http://www.ftc.gov/os/caselist/0410034/finalorder.pdf.

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defendants. Rather, defendants achieved their true purpose: to suppress competition from lower-priced generic alternatives.

On the facts, defendants' formulation and labeling changes were nothing more than gamesmanship that prevented generics from competing with branded Doryx in the way generics were intended to compete: on price, via the automatic pharmacy substitution mechanism. Defendants' scheme harmed Doryx consumers and competition, and provided no clinically significant benefit from changed product design.

Defendants attempt to portray these changes as procompetitive innovations. The complaint alleges the opposite. Although defendants argue the new formulations of Doryx were "improvements" and "innovations," direct purchasers expressly allege the contrary: that the new formulations provided little or no benefit to patients.[5] Defendants cannot base a motion to dismiss on disputing or spinning facts alleged in plaintiffs' complaint.

And in *TriCor* Judge Jordan rejected defendants' arguments that product changes are generally *per se* legal "innovations" immunized by antitrust law. Given FDA regulations governing generic drug approval and automatic pharmacy substitution, and the ability of drug manufacturers to "game" them, Judge Jordan ruled that "the effect of Defendants' formulation changes" should be evaluated under the rule of reason approach:

> Contrary to Defendants' assertion, Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.[6]

[5] Complaint ¶¶ 2, 3, 5, 6, 56, 65, 68.

[6] *TriCor,* 432 F. Supp. 2d at 422 (citation omitted).

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Moreover, contrary to defendants' contention that their conduct was permissible because they did not prevent the generics from belatedly obtaining FDA approvals (and therefore making some generic sales), the Third Circuit has unambiguously held that a monopolist need not foreclose competitors from 100% of the market to violate the antitrust laws.[7] It has likewise held that impeding generic competition — and thereby minimizing substitution of lower priced generics for their expensive branded counterparts — is exclusionary conduct that inflicts classic antitrust injury on purchasers.[8]

Defendants' scheme destroyed the market for generic Doryx. The direct purchaser plaintiffs claim overcharges from being deprived of less-expensive generic doxycycline hyclate. Federal law provides this remedy precisely for abuses of this type.

II. PROCEDURAL HISTORY

The Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint was filed on August 13, 2012 [Doc. #62]. On October 9, 2012, the direct purchasers responded to defendants' motions to dismiss in a summary statement that addressed each of the defendants' seven arguments applicable to the direct purchasers [Doc. #92]. This opposition amends the prior statement.

III. FACTUAL AND REGULATORY BACKGROUND

The direct purchasers adopt Mylan's recitation of the facts. We describe the regulatory background below.

The regulatory scheme for generic drugs involves myriad laws that establish branded drug exclusivities and, with the sunset of those exclusivities, generic entry under the Drug Price

[7] *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) ("[t]he test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit").

[8] *In re Warfarin Antitrust Litig.*, 214 F.3d 397, 401 (3d Cir. 2000) (allegation of overcharges imposed by impeded generic competition represents a "formidable demonstration of an antitrust injury.").

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Competition and Patent Restoration Act of 1984, commonly known as Hatch-Waxman.[9] 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, and for less-expensive generic drugs to enter the market and be substituted, automatically, at the pharmacy counter for the more-expensive branded counterpart. Hatch-Waxman addressed the rising cost of prescription drugs by encouraging the safe and fast development, approval, and market entry of generic versions of brand drugs.[10]

Hatch-Waxman lowered the regulatory hurdles for generic companies by permitting them to file Abbreviated New Drug Applications ("ANDAs") with the FDA, shorter applications that rely on the safety and efficacy data contained in the brand-name counterpart's longer New Drug Application ("NDA").[11] And Congress enacted Hatch-Waxman shortly after every state had 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 prescribes the brand. Under this regulatory regime, after one or more generics for a given brand enters 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.[12]

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[9] Pub. L. No. 98-417, 98 Stat. 1585 (codified in pertinent part at 21 U.S.C. § 355).

[10] *See* Complaint ¶ 39; *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.").

[11] Complaint ¶ 40.

[12] *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"), available at http://www.cbo.gov/publication/10938; Complaint ¶ 52.

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AB-rated competition is not just the way generic companies (like Mylan) compete; it is the way Congress, together with state legislatures, purposely created so that purchasers could benefit from lower generic prices promptly after the expiration of any market exclusivities granted to branded companies.

The complex regulatory scheme governing generic entry and automatic pharmacy substitution, however, provides opportunities for brand companies to game the system and wrongfully extend their monopoly by manipulating their products and interfering with consumer choice. Under Hatch-Waxman and state regulatory regimes, only generic drugs that have been given an AB-rating by the FDA may automatically be 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 the brand drug.[13] Because a generic drug will be dispensed only if its brand counterpart is prescribed, if doctors are not prescribing the branded counterpart because it is no longer being marketed, there simply is no AB-rated generic.

IV. ARGUMENT

1. Direct purchasers allege antitrust injury.

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, combined with the defendants' removal of the previous Doryx formulations from the market, prevented generic substitution. Can the complaint be dismissed for failure to allege antitrust injury?

[13] Complaint ¶¶ 51-52.

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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 manipulating its product and replacing it with a "new" version while destroying the market for the prior version of the drug and thereby suppressing generic competition through automatic pharmacy substitution — an exclusionary tactic known as "product hopping" — it causes antitrust injury.[14] Such injuries include overcharges paid by direct purchasers for a product the price of which is inflated by defendants' improper exclusion or suppression of competition. Product-hopping causes the very type of harm that the Third Circuit held to be antitrust injury. Successful product hopping schemes impede the generic competition that the Hatch-Waxman Act fosters. Impeding generic competition is unarguably antitrust injury.[15]

In *TriCor*, the brand maker employed a product-hopping scheme very similar to that employed here – with similar anticompetitive effect. There, Abbott switched the market first from a capsule formulation to a tablet formulation, and then from one pair of dosage strengths to another. Plaintiffs there, as here, alleged that the new formulations were medically and clinically equivalent to the prior formulations, but were not AB-rated (and thus patients could not benefit from automatic generic substitution).[16] As planned, defendants shifted the focus of their marketing from the prior formulation to their new formulations, minimizing the number of prescriptions of the prior formulations before generic versions of the prior formulations were

[14] *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*").

[15] *In re Warfarin*, 214 F.3d at 401 (allegation that brand company "disabled [generic's] market penetration" constitutes a "formidable demonstration of antitrust injury"). *See also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 910 (6th Cir. 2003) ("[p]reventing that kind of injury [an overcharge] was undoubtedly a raison d'etre of the Sherman Act when it was enacted in 1890").

[16] *TriCor*, 432 F. Supp. 2d at 423.

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approved.[17] In ruling on the defendants' motion to dismiss, Judge Jordan held that defendants' alleged conduct could have blocked competition, and formed the basis of a claim.[18] That is, 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."[19] 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."[20] 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."[21] Once the original formulation had been removed from the market, Judge Jordan explained, "generic substitution was no longer possible."[22]

Here, as in *TriCor*, the alleged product hops "severely restricted the ambit" of generic

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[17] As the defendants have done here, the defendants in *TriCor* ignored the plaintiffs' allegations that the changes to the products were not actual improvements, and instead tried to characterize as admissions of innovation plaintiffs' averments that the products at issue were approved by FDA. 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." *TriCor*, 432 F. Supp. 2d at 423.

[18] *TriCor*, 432 F. Supp. 2d at 423.

[19] *Id.* ("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").

[20] *Id.* at 422-23 (citing *Dentsply Int'l, Inc.*, 399 F.3d at 191 and *U.S. v. Microsoft Corp.*, 253 F.3d 34, 65-67 (D.C. Cir. 2001)).

[21] *Id.* at 424 (citing *LePage's Inc. v. 3M*, 324 F.3d 141, 151-52 (3d Cir. 2003)) (internal citations and quotations omitted). Of course, direct purchaser plaintiffs do not allege that defendants had a duty to aid Mylan and other generic competitors. Rather, plaintiffs allege that defendants, given their market power in the relevant market cannot seek to suppress generic competition and consumer choice through anti-competitive means – *i.e.*, by means other than by developing truly superior or less expensive products.

[22] *Id.* at 416; *see also id*. at 424 (quoting *Berkey*, 603 F.2d 263, 287 & n.39 (2d Cir. 1979).

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competition by limiting the number of prescriptions that could be subject to AB-rated generic substitution. Schemes that foreclose lower priced competitors from the market, thereby allowing a monopolist to impose higher prices on purchasers without losing significant sales, are textbook examples of conduct that can — and must — be carefully scrutinized under Third Circuit law.[23] And "when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate."[24] Defendants' scheme impeded purchaser access to lower priced generic substitutes.

b. Brand name product-hopping is subject to antitrust scrutiny because the regulatory scheme is designed to promote generic competition.

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

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."[25] A regulatory regime may counsel for greater, or less, or neutral antitrust scrutiny. Where regulation already deters antitrust harm, less scrutiny 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."[26]

Product hopping frustrates Hatch-Waxman's effort to encourage generic competition and inject price competition into the pharmaceutical product marketplace. The system is predicated on generics receiving an AB-rating and being automatically substituted at pharmacies. When a brand company facing an AB-rated generic tweaks its drug just enough to prevent that AB-rating

[23] *Id.* at 424 (citing *LePage's Inc.*, 324 F.3d at 151-52) (internal citations and quotations omitted).

[24] *Id*. at 421. *See also U.S. v. Microsoft Corp.*, 253 F.3d 34, 65 (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").

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

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

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from applying to the "new" version, the entire automatic substitution system is destroyed, and the price benefits of generic competition are blocked. And where the prior formulation of the branded drug is no longer marketed, any comparison between the prior and allegedly "innovative" new brand product is denied, and purchasers are coerced into adopting the new formulation.[27] Competition is destroyed.

Brand name product hopping requires particular antitrust scrutiny because a generic substitute can, as a practical matter, compete only 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.[28] Thus, there is a "price disconnect" that prevents the marketplace from functioning efficiently.[29]

Brand-name companies such as Warner Chilcott exploit this inherent market defect by promoting their brand products to doctors, without reference to price.[30] Generic companies return price to the equation by offering low prices to wholesalers and pharmacies, and distributing their products, without promotion, through automatic substitution.[31] That is how generic prices stay low, as Hatch-Waxman envisions. Drug product selection (DPS) laws –

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

[28] Complaint ¶¶ 32-33.

[29] 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 (FTC 1985) at 5 ["Generic Substitution"] ("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).

[30] 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).

[31] Complaint ¶¶ 34, 36, 52.

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which permit, and in some states require, the substitution of a less-expensive generic in place of the brand drug prescribed — thus "shift the choice of [drug product] for most prescriptions from the physician to the pharmacist."[32] 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."[33]

A generic company cannot reasonably promote a generic product to doctors because the generic maker could not ensure the pharmacist would dispense its generic product rather than another company's generic. It is a generic product, after all. Upon AB-rated generic entry, Hatch-Waxman treats generic products as commodities that cannot be differentiated through marketing except on the issue of price.

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

TriCor did not, as the defendants imply, come out of thin air. *TriCor* is rooted in circuit precedent such as *LePage's*, *C.R. Bard*,[34] and *Berkey Photo*. In *LePage's*, for instance, the Third Circuit expressly recognized that, by impeding its competitors' access to the most efficient means of distribution, a monopolist can illegally maintain its monopoly. As Judge Jordan recognized, this controlling legal concept applies fully in assessing a product hopping scheme, as the very purpose and effect of a product hop is to prevent generics from accessing the efficient means of distribution of generic drugs established by Congress and state legislatures — the automatic substitution of AB-rated generics for their branded equivalents by pharmacists.

TriCor is not the only example of a successful antitrust challenge involving a product change. In *C.R. Bard*, plaintiffs challenged Bard's scheme to exclude competitors by, among

[32] Generic Substitution at 7.

[33] FTC Staff Report at 7.

[34] *C.R. Bard v. M3 Sys.*, 157 F.3d 1340 (Fed. Cir. 1998).

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other things, modifying its device to raise competitors' costs and impede doctors' use of "copycat" needles. Bard defended by arguing that its product changes were improvements. The Federal Circuit upheld a jury verdict in plaintiffs' favor, finding that "the jury could reasonably conclude that Bard's modifications to its [needle] guns constituted 'restrictive or exclusionary conduct' in a market over which it had monopoly power."[35] *C.R. Bard* provides a threshold reason that defendants' motions to dismiss here should be denied — it is a question for the jury whether competition was impeded because of an exclusionary scheme or, as defendants contend, because their replacement formulations allegedly were improvements.[36]

Defendants argue the product hopping in *TriCor* was accompanied by claims of other anticompetitive conduct, *i.e., Walker Process* fraud, sham litigation, and sham Orange Book listing.[37] The argument misrepresents the actual *TriCor* facts. 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.[38] Second, the case that went to trial in *TriCor* was based solely on the

[35] *Id.* at 1382.

[36] *See also 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).

[37] Warner Chilcott Br. at 14-15 (Doc. #84).

[38] *TriCor*, 432 F. Supp.2d at 424 (noting Teva had agreed to dismiss the Orange Book listing claim).

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product-hopping allegations, without the sham litigation or *Walker Process* claims.[39] *TriCor* demonstrates that a product-hopping claim may proceed to trial as an independent claim.[40]

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' – and with the generic substitutes for at least one of the established drugs."[41] By contrast, the direct purchasers here allege that the defendants *reduced* consumer choice, including by no longer marketing and destroying the market for earlier versions of Doryx.[42]

Finally, the defendants' argument ignores the realities of the pharmaceutical marketplace where generic drugs, by regulatory design, compete by automatic pharmacy substitution on the basis of price, not like a brand by detailing and promotion. Once the defendants stopped

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[39] Defendants also 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") (a 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*., 432 F. Supp.2d 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.

[40] *See also C.R. Bard*, 157 F.3d at 1382 (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).

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

[42] Complaint ¶¶ 58, 62, 69, 72, 74.

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marketing the prior version, doctors could prescribe only the new version and, consequently, a pharmacist could fill a Doryx prescription only with the new version.[43] Doctors did not "embrace[]" each new version of Doryx, as defendants contend.[44] They had no choice.

This case is on all fours with *TriCor* and all other cases that support the simple proposition that being deprived of the ability to purchase lower cost generic products constitutes antitrust injury.[45]

2. Direct purchasers allege exclusionary conduct.

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.[46] This is particularly true when "[d]efendants allegedly prevented such a choice by removing the prior formulations from the market while introducing new formulations."[47] The introduction of the new formulation itself can be actionable in that context when the anti-competitive harm

[43] Complaint ¶¶ 7-8, 20-22, 78.

[44] Warner Chilcott Br. at 16.

[45] Defendants misleadingly suggest that the court presiding over the Doryx patent litigation decided antitrust issues. 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).

[46] *TriCor*, 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).

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

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outweighs any procompetitive benefits from the product change.[48] To be actionable, exclusionary conduct need not completely foreclose generic competitors from the market; it is sufficient to demonstrate the generics were blocked from automatic generic substitution (which is the "cost-efficient" means of distribution) as a result of manipulative formulation changes.[49]

b. The complaint alleges that Doryx formulation switches were exclusionary because they constricted consumer choice.

When Warner Chilcott introduced its new Doryx products, its sales force aggressively detailed doctors to switch to the new formulation.[50] There was no generic yet available for the earlier 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 the "new" formulation, doctors had no reasonable alternative but to switch to the new formulation. By no longer marketing its earlier formulations,[51] defendants left doctors with no choice but to prescribe the "new" formulation if they wished to prescribe delayed release doxycycline hyclate.

For example, by discontinuing branded Doryx *capsules* and replacing them with *tablets*, defendants could (and did) block generic capsules from competing effectively because pharmacists cannot substitute a generic capsule product for a prescribed tablet product — even if the two are otherwise identical — because different dosage forms (i.e., tablets and capsules) are not AB-rated pharmaceutical equivalents automatically substitutable under the 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 except

[48] *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).

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

[50] Complaint ¶ 80.

[51] Complaint ¶¶ 58, 62, 69, 72, 74.

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to abandon any effort to market a generic Doryx product or to go back to the drawing board to formulate a generic Doryx tablet.[52] This is precisely the *TriCor* situation. As in *TriCor*, Warner Chilcott here executed a product hop several times over a short period, each time making very slight tweaks to Doryx, which offered no benefits to patients, but which allowed Warner Chilcott to sell essentially the same product without the generic competition.

Defendants 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 earlier 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.[53] Nonetheless, plaintiffs describe the exclusionary nature of each aspect of the scheme below.

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

In 2005, defendants began the first switch from Doryx capsules to tablets. Defendants took steps to "destroy the pre-existing demand for Doryx capsules" and "[b]y June 2006, the

[52] 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.

[53] 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.* 324 F.3d at 162 (*citing Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690 (1962))).

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defendants had withdrawn Doryx capsules from the market altogether."[54] This was exclusionary and anticompetitive because, by no longer marketing Doryx capsules, 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.

Moreover, Doryx tablets offered no medical or clinical benefit over capsules, meaning the anticompetitive harm outweighs any potential procompetitive benefit from the switch.[55]

Finally, reformulating Doryx from a capsule to a tablet was predatory. "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."[56]

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.[57] Defendants can seek to offer that as a procompetitive justification to be weighed against the anticompetitive effect at trial. At any rate, the implication that a tablet formulation of Doryx was required to achieve whatever benefit derives from Patent No. 6,958,161 is belied by 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

[54] Complaint ¶ 58.

[55] Complaint ¶ 56.

[56] Complaint ¶¶ 57, 80. *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").

[57] Warner Chilcott Br. at 25.

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be provided in a capsule."[58] 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, go to trial, and ultimately settle. That a product redesign is protected by a patent does not immunize the anticompetitive effects of marketing the redesigned product.[59]

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

As with the switch from capsules to tablet, defendants introduced the scored formulation of the 75 and 100 mg tablets in 2008 and 2009, and stopped marketing the prior formulation of the tablets, thereby forcing consumers to switch to the new formulation.[60] The switch to the scored tablet formulation similarly falls within the *TriCor* paradigm.

Defendants contend that the addition of scoring was not exclusionary because, they say, being able to break the tablets in half benefits consumers.[61] But the controlling allegation is that *this was not a medical or clinical benefit for consumers*.[62] 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 switch, and gave the defendants time to fully switch consumers over to the 150 mg product before generics were able to enter with generic 75

[58] Defendants correctly note an error in Plaintiffs' 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.

[59] *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).

[60] Complaint ¶ 63.

[61] Warner Chilcott Br. at 27.

[62] Complaint ¶ 65. ("The changes to branded Doryx tablets offered no medical or clinical benefits over unscored tablets and applesauce-free dosing regimens, nor did the defendants expect these changes to garner them any additional sales, lower their costs, or increase their efficiency. There was no therapeutic demand or advantage to be able to halve a 75mg tablet into two tablet halves of 37 ½ mg each.")

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and 100 mg tablets.[63] Once again, the product redesign is alleged to be predatory.[64] And, as with the earlier iterations, 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.

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. By changing their label, the newly added language would arguably give the defendants some additional period of exclusivity and, at a minimum, create a potential stumbling block for generics.

Defendants mischaracterize plaintiffs' allegations as some kind of admission that defendants did not delay seeking a labeling change related to the applesauce study.[65] To the contrary, plaintiffs specifically alleged that defendants strategically timed the submission of these studies to incorporate them into their labeling precisely when they would "maximally disrupt" efforts of their generic competitors formulating generic versions of the tablets.[66]

Unlike the tablet formulation switches, introducing this labeling did not require destruction of the sales for an existing formulation. But this conduct is also anticompetitive, particularly when viewed in the context of the entire anti-generic strategy employed by defendants. Defendants admit in their memorandum that they had conducted applesauce studies on the older capsule product.[67] If anything, it would be easier for consumers to open and

[63] Complaint ¶ 64.

[64] Complaint ¶¶ 65, 80.

[65] Warner Chilcott Br. at 29.

[66] Complaint ¶ 64.

[67] Warner Chilcott Br. at 29.

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sprinkle the contents of a Doryx capsule over applesauce, instead of trying to break up a tightly-compressed Doryx tablet. The only purpose was the disruptive effect on generic competition from strategically delaying the addition of that information to the tablet label.[68]

(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.[69] Plaintiffs allege that the introduction of the 150 mg tablet was predatory.[70]

Defendants argue that their switch to the 150 mg tablets did not delay launch of the generic 75 and 100 mg tablets, so it could not have been exclusionary. In addition to flatly contradicting plaintiffs' averments,[71] this argument reflects a complete distortion of the *TriCor* reasoning. The destruction of the sales base for the prior formulation facing imminent generic competition (in this context the 75 and 100 mg tablet product) benefits the defendants — and harms consumers — because the market is shifted to the new formulation (here the 150 mg tablet) not facing imminent generic competition. Had 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 pharmacy substitution of generic 75 and 100 mg delayed-release doxycycline hyclate tablets for branded 75 and 100 mg Doryx tablets would have proceeded, without the suppression of pharmacy substitution brought about by defendants'

[68] Complaint ¶¶ 65-66, 80.

[69] Complaint ¶¶ 68-69, 71-72.

[70] Complaint ¶¶ 71-72, 80.

[71] Complaint ¶¶ 61, 65-67.

predatory introduction of a new dosage strength. 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.

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.[72] They do not.[73] FDA regulations do not police anticompetitive behavior. Defendants selectively quote *Trinko* for the proposition that the existence of regulation in an industry militates against antitrust enforcement.[74] But *Trinko* teaches that a regulatory environment may require *greater* antitrust scrutiny.[75]

c. A monopolist's coercive product switch 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."[76] Defendants suppressed competition by delaying the introduction of a generic product through each of their product switches, the conversion of the market to the "new"

[72] Warner Chilcott Br. at 21.

[73] FDA approval of new versions of Doryx does not indicate the new formulations represent an improvement over previous 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.

[74] Warner Chilcott Br. at 21.

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

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

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product through extensive detailing efforts, and discontinuing sales of the previous formulations. Such consumer coercion is anticompetitive.[77]

Defendants cite *Berkey Photo* for the proposition that courts are reluctant to weigh in on whether a new product design is exclusionary.[78] But the *Berkey Photo* court's reluctance, as Judge Jordan recognized in *TriCor*, was based on its conclusion that the anticompetitive effects resulted from consumers' free choice, not the defendants' conduct. "Consumers who are free to choose among various products enjoy the presence of competition rather than its absence."[79] 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."[80] "In the absence of free consumer choice, the basis for judicial deference is removed"[81] and a product design change used as coercive means of extending market power is actionable.[82]

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[77] *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").

[78] Warner Chilcott Br. at 21.

[79] *TriCor*, 432 F. Supp. 2d. at 423.

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

[81] *TriCor*, 432 F. Supp. 2d. at 423.

[82] *Xerox Corp.*, 511 F. Supp. 2d at 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 Litig.*, 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").

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

Hatch-Waxman specifically enables the FDA to approve generic bioequivalent "copies" of branded drugs. Congress deliberately made it easier for generic products to obtain FDA approval by relying on safety and efficacy data generated by the branded company.

Defendants argue that brand companies should not be forced to aid generic competition, which they call "free-riding."[83] But "[t]his understanding of free-riding has no support in our case law" and is not a cognizable defense.[84] Brand drug companies are not free, through a series of meaningless product changes and the use of their detailing force, to cripple the automatic substitution system set up by Congress and the states. What defendants call "free riding" is the entire premise of Hatch Waxman.

Whatever debate there may be, in other circumstances, about the pros and cons of free riding,[85] there is no such debate here. By enacting the Hatch-Waxman framework, Congress explicitly favored the generic "piggybacking" ability to facilitate savings for consumers.[86] As the *TriCor* court explained, "I am not persuaded that . . . the prevention of 'free riding' is a legitimate business justification. Indeed, the Hatch-Waxman Act establishes and condones the opposite proposition, the 'piggybacking' of generics."[87]

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[83] Warner Chilcott Br. at 23.

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

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

[86] *See 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")).

[87] *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.")).

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3. *Noerr-Pennington* qualified immunity protects (some) petitioning, not market behavior.

Under the *Noerr-Pennington* doctrine, certain types of efforts to petition the government are protected by the First Amendment from antitrust liability; however, private commercial conduct 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 charges defendants with only private commercial activity?

The *Noerr-Pennington* doctrine protects from antitrust scrutiny genuine (i.e., not sham and not fraudulent) acts of lobbying or petitioning governmental agencies.[88] However, the scope of the doctrine only extends to *petitioning* activity; it does not protect private commercial activity or anticompetitive actions to which petitioning activity is merely incidental.[89]

Defendants contend that their scheme is immune because one aspect of one part of the scheme, defendants' application for FDA marketing approval for their "new" formulations of Doryx, is, they claim, protected by *Noerr-Pennington*.[90] This claim lacks merit.

a. *Noerr-Pennington* does not protect private actions.

The anticompetitive effects of defendants' generic-delay scheme resulted from purely private action, not government petitions, and thus are not entitled to *Noerr* protection.[91] The doctrine is "plainly inapposite" where, as here, defendants "engaged in private commercial

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[88] *E.R.R. Presidents Conf. v. Noerr Mot. Freight, Inc.*, 365 U.S. 127 (1961) (*"Noerr"*); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965) ("*Pennington*").

[89] *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).

[90] Warner Chilcott Br. at 33-35.

[91] *See Noerr,* 365 U.S. at 135 (antitrust immunity applies where anticompetitive effects are "the result of valid governmental action, as opposed to private action").

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activity" and were not "seeking to procure the passage or enforcement of laws."[92] A restraint that "is largely the result of private action directed at the government, rather than governmental action . . . is not subject to *Noerr-Pennington* protection."[93]

Moreover, because defendants had to obtain FDA approval to bring their products to market does not transform their private commercial activity into protected petitioning under *Noerr*.[94] Courts hold that a brand drug manufacturer's manipulation of regulatory approval processes constitutes private anticompetitive conduct, and thus refuse to immunize such conduct.[95]

In *Gabapentin*, the brand drug manufacturer moved to dismiss antitrust counterclaims against it that alleged a scheme to delay generic competition to the brand drug Neurontin.[96] The plaintiff, a blocked generic drug manufacturer, claimed that the brand drug manufacturer "perpetrated this scheme by (1) intentionally withholding material prior art from the Patent Office…resulting in a delayed issuance of the patent…(2) abusing FDA regulations by certifying that the '476 and '479 Patents covered the approved compounds in and uses of Neurontin, while knowing that such certifications were false; and (3) filing objectively baseless patent-

[92] *Litton,* 700 F.2d at 807.

[93] *Carpet Group Int'l v. Oriental Rug Imps. Ass'n*, 256 F. Supp. 2d 249, 268 (D.N.J. 2003).

[94] *Litton*, 700 F.2d at 807 (*Noerr Pennington* did not apply to private commercial activity of imposing and maintaining interface tariff, even though filed with FCC).

[95] *See In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 368 (D.N.J. 2009) (*Noerr* immunity did not apply where brand drug manufacturer "conducted [its applications to the Patent Office] in a manner that was ostensibly directed toward influencing governmental action, but was really meant to interfere directly with the business relationships of a competitor") (internal quotation marks omitted); *TriCor*, 432 F. Supp. 2d at 424 (rejecting defendants' argument that the First Amendment immunized parts of defendants' anticompetitive scheme to delay entry of generic TriCor).

[96] 649 F. Supp. 2d at 345.

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infringement lawsuits[.]"[97] The brand drug manufacturer argued that all of those actions were protected by *Noerr-Pennington*.[98]

The *Gabapentin* court rejected this contention.[99] With respect to the brand drug manufacturer's applications to the Patent Office, the court reasoned that, even though the applications had been granted, the timing of the filings, which is entirely private conduct, resulted in a manipulation of the Patent Office, and so were not immune. "Fraudulently delaying the issuance of a patent could lead to anticompetitive effects in the relevant market, if such delays were intended to obtain control over or exclude competitors from such market."[100] The court concluded that "[s]uch abuse of the Patent Office's administrative and regulatory process itself is not entitled to immunity."[101]

Gabapentin shows why defendants' conduct in this case is not protected by *Noerr*. The direct purchasers allege defendants timed their launch of a new tablet version of their capsule product while ANDAs for the generic capsule were pending, and subsequently ceased marketing the capsule, rendering the pending ANDAs useless and forcing generic companies to start from scratch with a new ANDA, this time for generic Doryx tablets.[102] In addition, plaintiffs allege that while ANDAs for generic Doryx tablets were pending, defendants introduced a new dosage strength (the 150 mg tablet) and subsequently ceased marketing the lower-dosage tablets, again thwarting generic substitution.[103] Separately, plaintiffs allege that, to "buy time" for the switch to the 150 mg tablet, defendants strategically timed adding a new label indication to their tablets

[97] *Id.* at 345-46.

[98] *Id*. at 360.

[99] *Id*. at 361.

[100] *Id*. at 367.

[101] *Id*.

[102] Complaint ¶¶ 6-7.

[103] Complaint ¶¶ 15, 20-24.

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for taking the tablet with applesauce, and changing the tablets to have scores on them.[104] Generic tablet ANDA filers were thereby forced to perform studies directed to taking generic Doryx tablets with applesauce, change their labels, and add scores, which delayed their ANDA approvals and thereby enhanced the anticompetitive effects of the introduction of the 150 mg tablet and the cessation of marketing of the 75 and 100 mg tablets.[105] Like the patent holder in *Gabapentin* who deliberately delayed approval of its patent application,[106] here defendants purposely timed their introduction of Doryx tablets, and their other supplemental applications, to include new scoring and applesauce labeling, until the most opportune moment for suppressing generic competition.[107] At best, defendants' conduct constitutes "private action directed at the government, rather than governmental action."[108] Just as *Noerr* was held inapplicable in *Gabapentin*, so it is inapplicable here.

The same result was reached in *TriCor*. Although the FDA had to approve the new TriCor dosage forms and strengths before they could be introduced, Judge Jordan nevertheless held that plaintiffs had successfully alleged anticompetitive conduct outside the bounds of *Noerr* protection.[109] If defendants' *Noerr* arguments had any merit, the *TriCor* case would not have survived to be tried before a jury.

The regulatory manipulations of defendants here — like those in *TriCor* and *Gabapentin* — were intended to and did suppress generic competition, and capitalized on the administrative

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[104] Complaint ¶¶ 10-12.

[105] Complaint ¶¶ 8-12.

[106] 649 F. Supp. 2d at 365

[107] Complaint ¶ 4-7, 11-12.

[108] *See Carpet Group*, 256 F. Supp. 2d at 268.

[109] *See TriCor*, 432 F. Supp. 2d at 424 ("Thus, the allegations of product removal and NDDF code changes, like the allegations related to the product changes themselves, support Plaintiffs' antitrust claims.") (citing *Cal. Motor Transp. Co. v. Trucking Unlimited,* 404 U.S. 508, 514 (1972) ("First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute")).

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delay inherent in the governmental approval process.[110] As is clear from the case law, defendants' deliberate attempts to manipulate the FDA approval process to suppress generic Doryx competition are not immunized under *Noerr*.

b. *Noerr-Pennington* does not protect commercial activity.

Another reason *Noerr-Pennington* is inapplicable here is that defendants' challenged conduct — which starts with their applications to FDA for approval to market new versions of Doryx — is commercial activity, not political activity. As the *Carpet Group* court put it, *Noerr-Pennington* "does not immunize every concerted effort that is genuinely intended to influence governmental action."[111] "Where such activity is essentially political, and cannot be segregated from the activity's impact on business, it is protected. Conversely, where such activity does 'not take place in the open political arena, where partisanship is the hallmark of decision making,' and 'can be more aptly characterized as commercial activity with a political impact,' the *Noerr-Pennington* doctrine does not apply."[112]

Though not a case involving delayed entry of generic drugs, the principles taught by *Carpet Group* are instructive here. Like the actions taken by the defendants there to dissuade the government from supporting plaintiffs' trade shows, defendants' applications to the FDA here to market a tablet form of Doryx, or for product changes related to scoring their tablets, or for labeling changes to add an indication for dosing with applesauce, or to introduce a new dosage strength tablet, self-evidently do not constitute political activity, "where partisanship is the

[110] Complaint ¶¶ 4-5, 7, 9-12.

[111] *Carpet Group*, 256 F. Supp. 2d at 262 (citing *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 503 (1988)); *see also Litton*, 700 F.2d at 807 (*Noerr* did not apply to "a mere *incident* of regulation," AT&T's filing of a tariff with the FCC, as the decision to impose and maintain the tariff "was made in the AT&T boardroom" and constituted "private commercial activity, no element of which involved seeking to procure the passage or enforcement of laws") (emphasis in original).

[112] *Carpet Group*, 256 F. Supp. 2d at 262-63 (quoting *Allied Tube*, 486 U.S. at 493, 505, 507) (internal citations omitted).

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hallmark of decision making."[113] Nor do these actions constitute an attempt to challenge a law or government policy.[114] It is therefore no wonder that *Noerr-Pennington* has never been held to apply to a drug application filed with or granted by the FDA.

c. The defendants'' FDA filings are not the primary cause of the plaintiffs' harm.

Noerr-Pennington is inapplicable for the additional reason that the defendants' submissions to FDA are not alleged to be the sole, or even the primary, cause of the plaintiffs' harm.[115] Defendants' "blame the FDA" argument contradicts plaintiffs' clear allegations that defendants' purposeful destruction of the market — not merely the introduction of a new Doryx formulation — is what caused plaintiffs' harm.[116]

Again, *Carpet Group* is instructive. There, plaintiffs, intermediaries who arranged direct sales of oriental rugs from foreign manufacturers to domestic retailers (thereby bypassing wholesalers), alleged that the defendant wholesalers conspired to sabotage their efforts to facilitate such direct sales. The defendant wholesalers had convinced foreign governments not to provide financial assistance to plaintiffs' trade shows, which undermined the trade shows and allegedly harmed them.[117] Even though government actions had caused harm to plaintiffs, the court held that *Noerr* was inapplicable, because plaintiffs' harm was not solely caused by defendants' lobbying efforts. Defendants had also taken actions that did not involve lobbying the government. "Defendants did not simply lobby [the] Pakistani government to deny

[113] *Id.* at 262-63.

[114] *See id*. at 266 n.10 (defendants "have produced no evidence tending to demonstrate that their communications…were at the very least indirect attempts to challenge Pakistani policy or laws").

[115] *See Armstrong Surg. Ctr., Inc. v. Armstrong County Mem'l Hosp.*, 185 F.3d 154, 160 (3d Cir. 1999) ("[h]ere, looking to the source of the complained of injuries, we find that all of the Surgical Center's alleged injuries arise solely from the denial of the CON"); *Carpet Group*, 256 F. Supp. 2d at 267-68 (*Noerr* immunity inapplicable where harm was not "caused solely or even primarily by government action").

[116] Complaint ¶¶ 4-7.

[117] *Carpet Group*, 256 F. Supp. 2d at 259.

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[plaintiffs] support, but [] they themselves engaged in efforts to undermine Plaintiffs' trade shows."[118]

That is precisely the case here. Plaintiffs allege that defendants engaged in a strategically-timed cessation of marketing Doryx capsules and tablets. The FDA did not approve or direct that defendants cease marketing their Doryx capsules, or cease marketing certain dosage strengths of Doryx tablets. Defendants did not petition the FDA for permission to take those actions. Nor would the FDA have the authority to pass upon the competitive effects of such actions; FDA's authority is limited to determining whether a proposed drug is safe and effective.[119] Therefore, even if defendants' applications to FDA to market new versions of Doryx could theoretically be considered *Noerr* protected — which would be an unprecedented legal result — the harm of which plaintiffs complain was not solely caused by those applications, and *Noerr* is inapplicable for that reason alone.

d. *Noerr-Pennington* does not immunize the defendants' overarching scheme.

Even if the Court were to decide that one or more elements of defendants' alleged scheme constituted petitioning activity, *Noerr* would not protect defendants' entire anticompetitive scheme, since there are portions of the scheme that not even defendants argue involve petitioning.[120]

In *Clipper Exxpress*, the defendants allegedly conspired to fix rates and allocate customers, using the protest mechanisms of the Interstate Commerce Commission (ICC) to further this conspiracy. Although protests before the ICC may constitute valid petitioning, and

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[118] *Id*. at 267.

[119] 21 U.S.C. § 355.

[120] *See Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc*., 690 F.2d 1240, 1263 (9th Cir. 1982) ("[a]n antitrust violation does not enjoy immunity simply because an element of that violation involves an action which itself is not illegal") (citing *Calif. Mot. Transp. Co.*, 404 U.S. at 513-14).

thus enjoy protection under *Noerr*, the court held that "if [those protests] were part of a larger antitrust conspiracy, the conspiracy is [still] subject to the antitrust laws."[121] The court thus rejected defendants' argument that *Noerr*-protected petitioning activity, when part of a larger antitrust violation, immunized the entire scheme, reasoning that plaintiff "is not challenging merely the petitioning activity" but rather "it challenges the defendants' entire course of conduct" and "[n]o one has contended that the alleged [overall] conspiracy was intended to influence governmental actions."[122] That is precisely the case here, where plaintiffs have alleged that defendants' destruction of the market for Doryx capsules and Doryx tablets was an integral part of the anticompetitive scheme, and not even defendants allege that their cessation of marketing prior versions of Doryx was intended to influence governmental action.

4. Direct purchasers allege that defendants' scheme caused them injuries.

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 assuming that some elements of the scheme standing alone would not be unlawful?

a. To state a violation of the antitrust laws, a plaintiff need only allege that defendants' conduct was a material cause, not the sole cause, of plaintiff's 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.[123] A scheme to manipulate Hatch-

[121] *Id.* at 1264.

[122] *Id*. at 1265.

[123] *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").

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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.[124] 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.[125]

b. The direct purchasers allege an overarching scheme that violated the antitrust laws and caused 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 more expensive branded version. The defendants' overarching, multi-faceted product hopping scheme suppressed generic competition for Doryx.[126] 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 its generic.[127] "It is difficult to imagine a more formidable demonstration of antitrust injury" than allegations of overcharges caused by conduct which impeded generic competition.[128]

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

[125] *See, e.g., In re Metoprolol Succinate*, 2010 U.S. Dist. LEXIS 36303 * 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 at 355 ("'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.").

[126] Complaint ¶¶ 55-84.

[127] *Id*.

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

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

Defendants argue it was the regulatory system – rather than defendants' successful scheme to game that system – that caused plaintiffs' harm.[129] But plaintiffs allege the opposite — that defendants took a series of deliberate, private actions that no government agency approved or required, all aimed at thwarting generic competition and keeping prices at supracompetitive levels. This dispute cannot be decided in defendants' favor on a motion to dismiss.

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 advantage. Defendants' product hopping scheme involved more than filing applications to market "new" formulations. It included 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 was never asked to determine whether defendants' new versions of Doryx were "improvements" over prior versions. Nor was FDA ever asked to 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 statutory authority nor expertise to make such determinations.[130] The anticompetitive product

[129] Warner Chilcott Br. at 38.

[130] 21 U.S.C. § 355(d).

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hopping scheme was devised and implemented entirely by the defendants, and the competitive harm caused by the scheme was caused by defendants' private actions, not government action.[131]

Defendants cite cases where plaintiffs' injuries were, as a factual matter, caused "fully" by government action, not private conduct.[132] Such cases are inapposite where, as here, plaintiffs allege that defendants' own private conduct is a "material cause" of the suppression of generic competition.[133] This principle applies in product hopping cases where, by definition, defendants hop from one FDA-approved product to another to thwart generic competition.

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.[134] But while urging the Court to consider the "realities of the regulated environment," the defendants ignore that one of the primary purposes of Hatch-Waxman is to ensure that consumers get the price benefits of effective generic competition as soon as possible.[135] Congress did not enact the system to be intentionally gamed.[136]

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[131] Defendants' citation to *Mass. School of Law at Andover, Inc. v. Am. Bar Ass'n* 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.

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

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

[134] Warner Chilcott Br. at 40.

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

[136] *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).

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5. Direct purchasers allege Mayne and Warner Chilcott unlawfully conspired.

The direct purchasers allege an unlawful conspiracy between Mayne and Warner Chilcott to prolong the Doryx monopoly through the overarching 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-intensive 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 that cannot be decided on a Rule 12(b)(6) motion.[137] The Supreme Court recently observed in *American Needle*[138] that the focus regarding the single entity issue is not upon "formalistic distinctions," but on "functional consideration of how the parties involved in the alleged anticompetitive conduct actually operate."[139] 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."[140] "[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."[141] Neither the necessity of cooperation nor that fact that the actors "operate jointly in some sense" mean that they are automatically immune from liability.[142]

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[137] *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").

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

[139] *Id.* at 2209.

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

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

[142] *Id.* at 2214.

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[143] *E.g.*, Mayne Br. at 11.

[144] *See, e.g., Eichorn v. AT&T Corp.*, 248 F.3d 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).

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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."[145] 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."[146]

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.[147] 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.[148]

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

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

[146] *Id.* (internal quotations omitted) (citing *In re Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

[147] Complaint ¶¶ 54-55.

[148] Complaint ¶¶ 75-77.

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capsules into tablets in 2005 and subsequently releas[ing] a new Doryx 150mg tablet in 2008."[149] 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,[150] 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,[151] conspired to forestall generic competition using an overarching anticompetitive product hopping scheme.[152] Each switch made as part of the scheme required coordinated effort and overt acts by each defendant. 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.[153] Likewise, Warner 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.[154]

[149] Complaint ¶ 75.

[150] Complaint ¶ 75.

[151] Complaint ¶ 53.

[152] Complaint ¶ 1.

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

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

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

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.[155]

Defendants pretend that the license at issue here is for a formulation patent that grants defendants a legal monopoly on Doryx, and therefore precludes generic competition. In reality, 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 defendants cite for the establishment of the licensee/licensor exception to antitrust conspiracy liability have no application here.

Defendants rely on dicta in *Shionogi Pharma, Inc. v. Mylan, Inc.* (involving a patent license),[156] where the court cited the summary judgment decision in *Levi Case Co. v. ATS Prods., Inc.* [157] (involving a patent license and heavily relied upon by defendants) for the proposition that patent licensors and licensees cannot conspire.[158] 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 *Townshend v. Rockwell International Corp.*, [159] 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

[155] Such an argument is belied by the cases in which courts have allowed conspiracy claims against licensees/ licensors to proceed. *TriCor*, 432 F.Supp.2d 408 (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).

[156] 2011 WL 2174499, *5 (D. Del. May 26, 2011).

[157] 788 F. Supp. 428 (N.D. Cal. 1992).

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

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

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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."[160]

Not only does *Levi Case* not create a bright-line test,[161] 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.[162] Shea and ATS were accused of conspiring to monopolize a submarket for ductwork produced using Shea's patent.[163] 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,"[164] 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 from which generics were excluded is the market for the '161 patent (akin to the ductwork in *Levi Case*); instead, the complaint alleges the market is for Doryx and its AB-rated generic equivalents, which is subject to non-infringing generic competition.[165] The alleged wrongful conduct is product hopping, not a refusal to license a patent that grants a legal monopoly. As such, *Levi Case* has no application here.

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[160] *Id.* at *6.

[161] *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*").

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

[163] *Id.* at 430.

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

[165] *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharma 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).

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6. Direct purchasers sufficiently allege a relevant market.

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."[166] "Because market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure to plead a relevant product market."[167] "[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."[168]

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

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[166] *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").

[167] *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").

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

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antitrust case is their "reasonable interchangeability."[169] 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."[170] 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.[171]

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.[172] Like the defendants here, Lilly argued that the relevant market should include all other anti-infective drugs in the therapeutic class.[173] 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.[174] 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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[169] *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997).

[170] *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").

[171] *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)).

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

[173] 427 F. Supp. at 1116.

[174] *Id.* at 1096.

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cephalosporins and other antibiotic or anti-infective drugs."[175] 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."[176] 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,[177] and *despite* finding that "[t]here is a certain degree of interchangeability among *all* antibiotic drugs."[178] 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.[179]

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[175] *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).

[176] *Id*. at 1097.

[177] *Id*. at 1097-98

[178] *Id*. (emphasis added)

[179] *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 Litig.*, 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 Litig.* 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 Pharms. Co., Inc. v. Teva Pharms. 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. 2000) (product market limited to branded and generic

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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.[180] 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,[181] and the simple fact that branded Doryx does not exhibit substantial cross-price elasticity of demand with any drug other than generic delayed-release doxycycline hyclate.[182]

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.[183] The 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."[184]

With the introduction of a generic equivalent, normal competitive pressures are restored to the pharmaceutical marketplace. This is the logic of the Hatch-Waxman Act, as discussed in Parts III and IV.A, above. Generics compete on price. Only the introduction of a competing

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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).

[180] 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").

[181] *Id.* ¶¶ 31-37, 52, 88-98.

[182] *Id.* ¶¶ 88-90.

[183] *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").

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

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AB-rated generic version of Doryx has rendered 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 impermissibly ignores cross-elasticity of demand.

Defendants agree that the ultimate question of which products belong in the relevant market is a function of cross-elasticity of demand.[185] Yet they ignore this and advocate the inclusion of products in the relevant market simply because they serve a similar therapeutic purpose.[186] 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.[187] Plaintiffs' allegations are sufficient.

7. The four-year statute of limitations does not bar plaintiffs' claims.

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

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

[186] *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).

[187] *See, e.g.*, *Telecor Commc'ns, Inc. v. Sw. Bell Tel. 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 Indus., 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); *U.S. 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 Broad. 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, Inc.*, 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").

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> 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?

Plaintiffs' complaints were filed in July of 2012. Warner Chilcott points out that much of the conduct challenged by plaintiffs occurred prior to July of 2008, and argues that plaintiffs consequently cannot recover their damages, even those they suffered after July of 2008. That is not the law.[188]

Warner Chilcott's own cited case, *Zenith*,[189] makes it clear that plaintiffs can recover damages suffered after July of 2008 even though the conduct causing those damages occurred before July of 2008.[190] Moreover, each act of defendants' scheme cannot fairly be considered in isolation, as the cumulative effect of all the acts made it impossible for competitors to enter the market over the course of several years — precisely the kind of "continuing violation" discussed in *Hanover Shoe*,[191] *Lower Lake Erie*,[192] and *Meijer*[193] that is not barred by the statute of limitations.

The four-year statute of limitations is no bar to the overcharge damages sought in this case because plaintiffs filed their complaint in July 2012 and seek certification of a class of plaintiffs who purchased "Doryx tablets directly from any of the Defendants at any time during

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[188] *See West Penn*, 627 F.3d at 105 (rejecting interpretation of limitations defense that would "improperly transform the limitations statute from one of repose to one of continued immunity") (quotations omitted).

[189] *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321 (1971).

[190] *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).

[191] *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481 (1968).

[192] *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144 (3d Cir. 1993).

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

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the period July 2008 through the present."[194] The overcharge damages sought in this case are damages that exist entirely within the four-year limitations period.

Plaintiffs' allegations are sufficient to show that defendants have taken a variety of actions as part of a continuing scheme designed to maintain monopoly power and exclude competition for Doryx. These actions, including those actions that occurred outside the limitations period, caused plaintiffs to be overcharged for Doryx purchases made within the limitations period. Plaintiffs' allegations also show, as Warner Chilcott itself acknowledges,[195] that defendants' ongoing scheme continued into the limitations period, when, in 2011, Defendants again reformulated Doryx through introduction of the dual-scored tablet.[196] The overcharge damages caused thereby are unquestionably recoverable.

a. Defendants asserting a limitations defense bear a heavy burden on Rule 12 motions.

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."[197] "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."[198] Because plaintiffs' claims are timely under either the "continuing violations" or "speculative (i.e., unaccrued) damages" doctrine, Warner Chilcott cannot meet its heavy burden and its motion must be denied.

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[194] Complaint, ¶ 22.

[195] Warner Chilcott Br. 55.

[196] Complaint, ¶ 70.

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

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

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b. The statute of limitations is no bar to claims for continuing violations of antitrust law.

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.[199] So long as overcharges continue to be incurred within the limitations period, the challenged unlawful acts can occur outside the limitations period.[200] Indeed, even forty-year old conduct can establish liability for overcharge damages incurred within the limitations period.[201]

Plaintiffs' claims are clearly timely under *Hanover Shoe*. That case involved defendant's refusal to sell specialized equipment it instead leased to plaintiff. For relief, plaintiff sought quintessential overcharge damages – the difference it paid on the lease less what it would have paid had it been able to buy the machine outright. Defendant contended that the statute of limitations started to run the moment it initiated its lease-only policy in 1912. Plaintiff sued in 1955. To the Supreme Court, the fact that plaintiff could have sued in 1912 for the identical conduct it was suing for in 1955 was irrelevant because the anti-lease conduct "constituted a continuing violation of the Sherman Act and which inflicted continuing and accumulating harm" (*i.e.*, overcharge damages) on plaintiff.[202]

Like the plaintiff in *Hanover Shoe*, plaintiffs here allege that defendants engaged in a scheme of continuing conduct that caused accumulating harm to plaintiffs in the form of

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

[200] *See, e.g., In re Lower Lake Erie*, 998 F.2d at 1172 (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").

[201] *See Hanover Shoe*, 392 U.S. at 502 n.15.

[202] *Id.*

monopoly overcharges occurring within the limitations period. It is wholly irrelevant whether any or all of the underlying continuing conduct occurred outside the limitations period because defendants' unlawful acts caused plaintiffs' damages within the limitations period. Plaintiffs' claims are therefore clearly timely.

c. The statute of limitations is no bar where damages do not accrue until after challenged pre-limitations conduct occurred.

Leaving aside for the moment any possible tolling, plaintiffs are entitled to all overcharge damages resulting from defendants' anti-competitive conduct — regardless of whether some or all of that conduct occurred outside the limitations period — incurred during the four years immediately preceding their complaint, because plaintiffs' damages did not accrue until they were actually overcharged.[203]

Zenith instructs that an antitrust claim does not accrue until the fact of injury *and* the fact of damage both occur. Or, put differently, *Zenith* reaffirms the basic black-letter principle that an antitrust claim does not accrue until all elements of the claim exist, including the element of damages. Hence, as in *Zenith*, damages occurring within the limitations period are absolutely recoverable even when the conduct causing those damages occurred outside the limitations period.[204] Following *Zenith*'s reasoning the Third Circuit expressly held in *Continental-Wirt* that the antitrust claim did not accrue until damages were actually incurred vis-à-vis a sales transaction, notwithstanding that the conduct giving rise to the sales transaction occurred entirely

[203] *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); *Continental-Wirt Elec. Corp. v. Lancaster Glass Corp.*, 459 F.2d 768, 770 (3d Cir. 1972) (holding limitations period did not start until damages were actually suffered and ascertainable through a sales transaction, notwithstanding that the antitrust violation occurred outside the limitations period); *Meijer*, 2005 WL 1660188, at *5 ("In purchaser antitrust actions, damages from future overcharges necessarily fall into the speculative damages exception to the four year statute of limitations.")

[204] *See* 401 U.S. at 339 ("the cause of action for future damages, if they ever occur, will accrue only on the date they are suffered; thereafter the plaintiff may sue to recover them at any time within the four years from the date they were inflicted").

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outside the limitations period.[205] Because plaintiffs here were not damaged by the alleged conduct until they were actually overcharged, and all such overcharges sought are entirely within the limitations period, Plaintiffs claims are clearly timely.

d. Warner Chilcott's cited cases are not to the contrary.

Warner Chilcott cites two cases in support of its argument, *Zenith* and *Klehr*.[206] As discussed above, *Zenith* does not actually support defendants' argument at all, and instead demonstrates that plaintiffs' claims are timely. Warner Chilcott also cites the RICO case *Klehr* 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."[207] The reliance is misplaced. In *Klehr*, plaintiffs sought damages in connection with an allegedly defective product purchased outside the limitations period, and were 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, and each of these overcharges represents a new, distinct harm that occurred within the limitations period. Plaintiffs' claims are therefore clearly timely and Warner Chilcott's motion must be denied.

V. 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 market for prior product versions, can violate the antitrust laws, delay generic substitution and cause higher prices to be paid for drug products. Such overcharges are a classic form of antitrust injury.

[205] *See* 459 F.2d at 770.

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

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

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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 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, and to the extent any cognizable petitioning occurred, it was not the sole or primary cause of plaintiffs' alleged injury.

4. No, the complaint should not be dismissed for lack of adequate causation pleading. The defendants' private market misconduct is sufficiently alleged to have 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, the complaint sufficiently alleges concerted action, and the license agreement itself casts Warner Chilcott and Mayne as potential horizontal competitors.

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 claims plaintiffs pursue did not accrue until the period within the four year statute applicable to antitrust claims.

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Dated: November 15, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this date I caused true and correct copies of Direct Purchaser Plaintiffs' Opposition to Defendants' Motions to Dismiss (Redacted) to be served through the CM/ECF system. An un-redacted copy of Direct Purchaser Plaintiffs' Opposition to Defendants' Motions to Dismiss, with the accompanying exhibit, were filed under seal and served by e-mail upon all counsel of record.

Dated: November 15, 2012

/s/ David S. Nalven
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