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

MYLAN PHARMACEUTICALS, INC., et al.,	:	
	:	
Plaintiffs,	:	
	:	**Civ. No. 12-3824**
v.	:	**Indirect Purchaser Action**
	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	:	
	:	
Defendants.	:	
	:	

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE IBEW INDIRECT PURCHASER CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES, RULES AND REGULATIONS

OTHER AUTHORITIES

Plaintiff International Brotherhood of Electrical Workers Local 38, Health and Welfare Fund ("Plaintiff") respectfully submits this opposition to Defendants Warner Chilcott Public Limited Co., Warner Chilcott Co., LLC, Warner Chilcott (US), LLC, Warner Chilcott Holdings Co. III, LLC, and Warner Chilcott Laboratories Ireland LLC (collectively, "Warner Chilcott") and Defendants Mayne Pharma Group Ltd. and Mayne Pharma Int'l Pty. Ltd. (collectively, "Mayne") (together Warner Chilcott and Mayne shall be referred to as "Defendants") motions to dismiss (ECF Nos. 101 and 102).

I. INTRODUCTION AND STATEMENT OF FACTS AND ALLEGATIONS

This case concerns Defendants' violations of federal and state antitrust laws through a strategic "product hopping" or "product switching" scheme designed to maintain Defendants' monopoly over the drug Doryx and to exclude generic competition with Doryx. Succinctly, each time Defendants' branded-drug Doryx faced competition from generic manufacturers, Defendants made minor alterations to the existing approved version of Doryx – the product hop or switch. These minor alterations had little, if any, therapeutic benefit for those who took the drug. At the same time as the switch, Defendants withdrew from the market the pre-existing approved version of Doryx. As a result, would-be generic competitors had to start over with their approval process for a competitive generic. The end result of Defendants' scheme was Defendants' monopoly was maintained, generic competitors were excluded, and consumers, deprived of choice, paid supra-competitive prices for new versions of branded Doryx.

As Plaintiff alleges in its Complaint,[1] pursuant to federal law, branded drug manufacturers are provided with a lawful period of exclusivity on all new drugs approved by the FDA. ¶¶29 – 31. During that time, branded drug manufacturers are permitted to charge monopoly prices for their products on the principle that they expended the resources on research and development of safe, affordable and effective prescription drugs to consumers. ¶¶29 – 31. Under this statutory regime, once this period of exclusivity has expired, generic drugs with

[1] Unless otherwise identified, "¶" and "¶¶" are references to Plaintiff IBEW's Complaint.

approved Abbreviated New Drug Applications ("ANDAs") are permitted to enter the market. An ANDA will be approved by the FDA where their proposed drug is the AB-rated "bioequivalent" of the branded drug; that is, it contains identical amounts of the active ingredients in the same route of administration and dosage form, and meets applicable standards of strength, quality, purity and identity as that of the branded version.

The high cost of drugs in the United States can mean no treatment, or inadequate treatment, for many. Affordable drugs lead to better treatment and prevention. Accordingly, at the heart of the regulatory structure for pharmaceutical drugs in the United States – namely, the Federal Food Drug and Cosmetic Act ("FDCA") and the 1984 Hatch Waxman Amendments – is the basic principle that, upon the expiry of branded drug patents, competitor drug manufacturers are encouraged to produce generic bioequivalents that may be sold at a greatly lowered price than the branded versions. The result is that consumers have access to the same safe, effective, and affordable prescription drug, but with competitive prices. ¶¶32 – 35.

Plaintiff alleges that, faced with generic competition, as envisioned by the statutory regime, Defendants unlawfully maintained their monopoly on the market by blocking substitutable forms of generic competition to Doryx. ¶¶1 – 14. 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 a deliberate "product hopping" or "swapping-out strategy" scheme that Defendants' own documents characterize as an "anti-generic strategy" aimed to preserve the Doryx franchise. ¶4.

Product hopping is a well-known anticompetitive tactic of introducing new products with trivial or no substantive improvements to thwart the introduction of lower-priced generics. This scheme was not aimed at innovation or expanded output, as again, according to Defendants' own

document, "[t]hey did not expect to have any increase in sales as part of the switch."[2] A highly analogous anti-generic product hopping scheme survived a motion to dismiss, was tried to a jury, and ultimately settled in *Abbott Labs. v. Teva Pharms. USA, Inc.* ("*TriCor*"), 432 F. Supp. 2d 408 (D. Del. 2006) (Rule 12 motion denied); *see also Louisiana Wholesale Drug Co., Inc. v. Abbott Labs.*, No. 05-340, Mem. Order, ECF No. 434 (D. Del. Aug. 18, 2008) (Rule 56 motion denied). Likewise, 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. *See FTC v. Warner Chilcott Holdings Co. III et al.,* No. 1:05-cv-02179-CKK, Final Order and Stipulated Permanent Injunction (D.D.C. Oct. 23, 2006), http://www.ftc.gov/os/caselist/0410034/finalorder.pdf.

Plaintiff has plausibly alleged that Defendants' repeated reformulation of Doryx products – and withdrawal of prior formulations - constitutes unlawful product hopping in direct violation of state and federal antitrust laws. ¶¶1 – 14. Plaintiff alleges that each reformulation of Doryx offered no (or no meaningful) medical or clinical benefits to consumers over the prior formulation, nor did they boost sales, lower cost, or increase efficiency for Defendants. ¶¶4, 83. Rather, the purpose of the changes was to delay entry into the marketplace of lower-priced generic alternatives; a purpose that was achieved by Defendants. ¶¶5 – 6. Defendants also knew that they could exploit the price disconnect that characterizes the pharmaceutical marketplace – *i.e.*, doctors, not consumers, select which products will be bought, but consumers (or their insurers), not the doctors, pay for the products. ¶2. Plaintiff alleges that Defendants' product hopping scheme included the following actions specifically timed to impede generic entry:

- switching the market from 75 and 100 mg Doryx ***capsules*** to Doryx ***tablets***, a design change without therapeutic significance but carrying the consequence of imposing late-

[2] Transcript of Doryx patent trial proceedings at 78-86. *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharms. Inc.* 2:09-cv-02073-WJM (D.N.J.); *Warner Chilcott Labs. Ireland Ltd. v. Impax Labs., Inc.*, 2:08-cv-6304-WJM (D.N.J.) (Feb. 8, 2012). The portions of the trial transcript cited in this Report have not been sealed by the Defendants and are part of the public record.

stage design changes on would-be generics seeking AB-rated generic status. The result: delayed approval of generic substitutes for branded Doryx. ¶¶71 – 75.

- changing the Doryx tablet label to explain how to administer Doryx by breaking up the tablet and sprinkling the contents over applesauce, imposing additional requirements on generic manufacturers to chase the label to obtain status for ready substitution of their generic products. ¶¶76 – 78.
- changing the Doryx tablets to include a "score" down the center, and immediately discontinuing production of unscored Doryx tablets, once again, in an effort to force would-be generics to chase a late-stage design change to delay the entry of substitutable generic products. ¶¶79 – 84.
- switching the market from 75 and 100 mg Doryx tablets to 150 mg Doryx tablets and withdrawing the 75 and 100 mg tablets from the market, thereby destroying any demand for generic formulations of 75 and 100 mg Doryx tablet. ¶¶79 – 84; and
- switching the market from 150 mg ***single-scored*** Doryx tablets to 150 mg ***dual-scored*** Doryx tablets, in a further effort to impede generic competition to branded Doryx.

Defendants knew that because a generic drug must be the same dosage strength and form. ¶¶88 – 94.

Defendants combined each of these timed switches with the withdrawal of the previous version from the market so that would-be generic competitors had no bioequivalent form of Doryx on which to substitute their product.

As a result, these "product hopping" techniques required any would-be generic competitor to chase the new manufacturing, labeling, or formulation changes in order to obtain FDA approval of substitutable forms of generic products. In effect, they use their monopoly power to exclude competitors.

The facts alleged by Plaintiff are sufficient under *Twombly,* to show that Defendants entered into a naked product hopping scheme, resulting in the exclusion of generic competition

and forcing purchasers of Doryx to pay more for the products than they would have, absent Defendants' anticompetitive conduct. ¶¶1 – 14.[3]

II. LEGAL STANDARD

A. Plaintiff Needs Only Plausibly Allege a Claim

Federal Rule of Civil Procedure 8(a)(2) requires a plaintiff to provide "'short and plain statement of the claim showing that the pleader is entitled to relief' in order to 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).[4] To defeat a Rule 12(b)(6) motion, plaintiffs must allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. A complaint satisfies the plausibility standard when the factual pleadings "allow[ ] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). When reviewing a motion to dismiss, courts are to construe the complaint "'in the light most favorable to the plaintiff.'" *In re Ins. Brokerage Antitrust Litig*., 618 F.3d 300, 314 (3d Cir. 2010). In the Third Circuit, Rule 8 "'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *Phillips v. County of Allegheny,* 515 F.3d 224, 234 (3d Cir. 2008). A complaint need only allege sufficient allegations so as to test whether "'plaintiffs ... have ... nudged their claims across the line from conceivable to plausible' to survive a Rule 12(b)(6) motion." *In re Processed Egg Prods. Antitrust Litig*., 851 F. Supp. 2d 867, 879 (E.D. Pa. 2012) (citing *Twombly*, 550 U.S. at 570).

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[3] In their motion to dismiss, Defendants raise numerous issues of fact, including, *e.g.*, whether any of their switches added therapeutic benefits to the Doryx products, the timing of Defendants' withdrawals of prior formulations, or whether the FDA sanctioned Defendants' various switches. *See, e.g.*, Def's Brief at 7 – 10. While Plaintiff disputes Defendants' version of the facts, such merits-based arguments are inappropriate for a motion on the pleadings.

[4] Unless otherwise noted, all citations are omitted and emphasis is added.

To survive a motion to dismiss a claim under Section 1 of the Sherman Act, and its state law equivalents, Plaintiff must plausibly allege that the "challenged conduct" constitutes a contract, combination or conspiracy to unreasonably restrain trade, resulting in antitrust injury. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 530 (D.N.J. 2004) (citing *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 761 (D.N.J. 1999)); *see also* 15 U.S.C. §1. To survive a motion to dismiss a violation of Section 2 of the Sherman Act, Plaintiff must plausibly allege that "(1) defendants 'possessed monopoly power in the relevant market,' and (2) defendants 'willfully acquired and maintained monopoly power and did not acquire its monopoly share due to 'growth or development as a consequence of a superior product, business acumen or historical precedent.'" *K-Dur*, 338 F. Supp. 2d at 530 (quoting *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 749 (3d Cir. 1996)).[5] When assessing the plausibility of plaintiff's allegations, "'the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation.'" *TriCor*, 432 F. Supp. 2d at 428 (quoting *LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003)).

B. The Court May Only Consider IBEW's Complaint and Documents Central to Its Claim

Plaintiff does not object to the proposition that "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *See Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F. 2d 1192, 1196 (3d Cir. 1993). However Defendants' erroneous paraphrasing of the law – that the Court may consider "facts contained in the documents that Plaintiff quotes, cites or relies on in the complaint" – calls for a legal standard that could produce an almost endless number of documents which the Court could consider, many of which could be far beyond Plaintiff's allegations. Rather, the Court must ***only*** consider "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record."

[5] As Defendants point out, both Florida and Nevada look to federal antitrust law for guidance. Def's Brief at 12.

Pension Benefit Guar. Corp., 998 F.2d at 1196. Considering facts contained in documents that are not cited or have not been pled as allegations inappropriately converts the present motion into a motion more appropriately considered via Fed. R. Civ. P. 56.[6]

Furthermore, on a motion to dismiss, a court may only take judicial notice of a public record "to establish the existence of the opinion, not for the truth of the facts asserted in the opinion." *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp., Ltd.*, 181 F.3d 410, 427 n.7 (3d Cir. 1999) (finding that courts may take notice of a judicial record to establish its existence, not the "truth of facts averred") (cited in *Processed Eggs,* 2012 WL 4717963, at *4, "refusing to consider the "factual averments of the SAC simply because it is a 'public record'"). Accordingly, Plaintiff objects to Defendants' petition to the Court to consider anything other than quotations directly cited in Plaintiff's Complaint or taking as true the "factual averments" of SEC or FDA documents.

III. ARGUMENT

A. Plaintiff Plausibly Alleges Antitrust Injury

Defendants appeal to the Court to dismiss Plaintiff's Complaint for lack of antitrust injury, yet fail to identify any reason related to antitrust injury for which Plaintiff's claims should

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[6] Defendants cite to *Mayer*, in which the Third Circuit held that in determining a motion to dismiss for failure to state a claim, a court "must accept all factual allegations in the complaint as true [and] construe the complaint in the light favorable to the plaintiff, and ultimately determine whether plaintiff may be entitled to relief under any reasonable reading of the complaint." *Mayer v. Belichick,* 605 F.3d 223, 229 (3d Cir. 2010). That case does not, however, support Defendants' assertion that the Court is virtually unlimited in the number of documents it is permitted to consider. In that case, defendants attached the ticket stub containing the contractual obligation in question; a core document in the case the consideration of which was uncontested by plaintiff. *Id.* at 228; *see also Processed Egg Prods. Antitrust Litig.*, 2012 WL 4717963, at *4 (considering only documents "'are central to the claim at issue, such as contracts for breach of contract claims or public offering documents containing alleged fraudulent statements in securities misrepresentation suits'"); *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994) (In determining whether a claim should be dismissed under Rule 12(b)(6), a court looks only to the facts alleged in the complaint and its attachments without reference to other parts of the record."). Furthermore, a court "'may not consider matters extraneous to the pleadings'" but may only consider, "'a document ***integral*** to or explicitly relied upon in the complaint … without converting the motion to dismiss into one for summary judgment.'" *Westchester Surplus Lines Ins. Co. v. Safe Auto Ins. Group, Inc.,* No. 3:09-cv-1744, 2010 WL 2640196, at *4 (M.D. Pa. June 30, 2010) (emphasis in original).

fail. Indeed, Defendants fail to even identify the components of antitrust injury. Antitrust injury is the requirement that, in order to recover for anticompetitive conduct, plaintiffs must have suffered an "'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 101 (3d Cir. 2010) (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)); *Ins. Brokerage Antitrust Litig.*, 618 F.3d at 315.

B. The Antitrust Laws Were Intended to Address Monopolistic Conduct Such as Pharmaceutical Product Hopping Schemes

Plaintiff satisfies the requirements for antitrust standing because Plaintiff has suffered an injury of the type the antitrust laws were intended to prevent: preclusion of generic competition resulting in their payment of supracompetitive and monopolistic prices for branded pharmaceutical products. The Supreme Court observed in *Trinko* that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). The background regulatory regime may counsel for greater, or less, or neutral antitrust scrutiny. Where regulation already deters antitrust harm, less may be warranted. But "[w]here, by contrast, 'there is nothing built into the regulatory scheme which performs the antitrust function' … the benefits of antitrust are worth its sometimes considerable disadvantages." *Id*. at 12.

Here, the regulatory scheme establishes branded drug exclusivities and, with the sunset of those exclusivities, generic entry under Hatch-Waxman. On the one hand, federal patent and drug laws create opportunities for branded drug exclusivity; statutorily created monopolies provide brand name makers with a time-limited opportunity to charge monopoly prices. On the other hand, the law expects the statutorily created monopoly to end. Hatch-Waxman addressed the rising cost of prescription drugs by encouraging the safe and fast development and approval of generic versions of brand drugs. Hatch-Waxman lowered the regulatory hurdles for generic companies by permitting them to file Abbreviated New Drug Applications ("ANDAs") with the FDA, relying on the safety and efficacy data submitted by the proposed generic's brand-name

counterpart in its New Drug Application ("NDA"). And Congress enacted Hatch-Waxman shortly after every state enacted generic substitution laws (also known as "Drug Product Selection" or "DPS" laws) permitting or requiring pharmacists to automatically dispense lower cost generics, even when the physician's prescription listed the brand. Under this regulatory regime, after multiple generics for a given brand enter the market, the prices for the molecule (that is, the brand and corresponding generic together) can reach discounts of up to 90% off the pre-generic brand price, and generics capture as much as 90% of the brand's pre-generic sales.

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

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

Brand name product hopping requires particular antitrust scrutiny because a generic substitute can only, as a practical matter, compete on price. In efficient markets, price plays an important role in product selection because the person selecting the product also pays for the product. In the pharmaceutical marketplace, however, the person selecting the product − the

doctor − does not pay for the product. Thus, there is a "price disconnect" that prevents the marketplace from functioning efficiently.

Brand-name companies, such as Warner Chilcott, exploit this market defect by promoting their brand products to doctors, without reference to price. Generic companies return price to the equation by offering low prices to wholesalers and pharmacies and distributing their products, without promotion, through automatic substitution. That is how generic prices stay low, as Hatch-Waxman envisions. DPS laws thus "shift the choice of [drug product] for most prescriptions from the physician to the pharmacist." *See* Allison Masson and Robert L. Steiner, *Federal Trade Comm'n, General Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws 5* (1985). 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." *Id.*

When a brand pharmaceutical company seeks to extend its statutory monopoly by repeatedly tweaking its product and replacing it with a "new" version, while destroying the market for the prior version of the drug – an exclusionary tactic known as "product hopping" – it impedes generic competition, in violation of the antitrust laws. *TriCor*, 432 F. Supp. 2d 408; *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 397, 401 (3d Cir. 2000) (allegation that brand company "disabled [generic's] market penetration" constitutes a "formidable demonstration of antitrust injury"). In the absence of generic competition, purchasers of pharmaceuticals are forced to overpay for branded drugs when they would otherwise have access to less expensive generic versions. Plaintiff has alleged a classic antitrust injury – overpayment – flowing directly from Defendants' misconduct. *See Id.* at 516 ("Notably, [third-party payors], like individual consumers, suffered direct economic harm when, as a result of [defendant's] alleged misrepresentations, they paid supracompetitive prices for the [brand name drug].").[7]

[7] Moreover, concerns regarding direct purchasers or duplicative recovery are irrelevant where, as here, the state antitrust statutes specifically provide for indirect purchaser standing. *See, e.g., D.R. Ward Constr. Co. v. Rohm & Haas Co.,* 470 F. Supp. 2d 485, 503-05 (E.D. Pa. 2006) ("refus[ing] to find as a matter of law that damages to indirect purchasers under the [state

In *TriCor*, the brand maker employed a very similar product hopping scheme that switched the market first from a capsule formulation to a tablet formulation, and then, from one pair of dosage strengths to another. With each hop to a new formulation, the defendants stopped selling the prior formulations.[8] In ruling on the defendants' motion to dismiss, the court held that defendants' conduct, "if true, arguably could have blocked competition and formed the basis of a claim." Def's Direct Pls. Brief (ECF No. 84) at 14, incorporated by reference in Def's Brief at 11. It caused cognizable antitrust injury.

The *TriCor* defendants argued that because the generics "have 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. *TriCor*, 432 F. Supp. 2d at 423 ("Defendants are correct that, according to Plaintiffs' allegations, Teva and Impax have not been prevented from marketing the formulations that were the subject of their ANDAs, i.e., the old TriCor formulations."). In rejecting the argument, the court 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." *Id.* at 422-23 (citing *U.S. v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005). *U.S. v. Microsoft Corp.*, 253 F.3d 34, 65-67 (D.C. Cir. 2001) ("[j]udicial deference to product innovation, [however], does not mean that a monopolist's product design decisions are per se lawful")). 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.'" 432 F. Supp. at 424 (citing

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antitrust statutes were] *per se* too speculative or too tenuously connected to the alleged wrongdoing to confer antitrust standing").

[8] As Defendants have done here, the defendants in *TriCor* ignored the plaintiffs' allegations that the changes to the products were not actual improvements. The court in that case 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.

LePage's, 324 F.3d at 151-52). Once the original formulation had been removed from the market, the court explained, "generic substitution was no longer possible." 432 F. Supp. at 416; *see also Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 & n.39 (2d Cir. 1979) (finding no liability but stating that "the situation might be completely different" if the defendant stopped producing old products or removed them from the market).

Similarly, Plaintiff alleges that – against the background of Hatch-Waxman's intent to promote generic substitution – it suffered such overcharges as a direct and foreseeable result of Defendants' anticompetitive product hopping scheme. *See, e.g.*, ¶¶32 – 35, 100. The Complaint alleges Warner Chilcott and Mayne made useless product changes to Doryx (*e.g.*, tablet to capsule, unscored to single-scored) and that these changes were combined with the Defendants' removal of the previous Doryx formulations from the market, thereby preventing generic substitution. ¶¶4 – 14.

C. *TriCor* and Other Product Hopping Cases Support the Imposition of Liability Here

Defendants seek to distinguish *TriCor* by arguing that product hopping was accompanied by claims of other anticompetitive conduct, *i.e.*, *Walker Process* fraud, sham litigation and Orange Book listing. Def's Brief at 11 – 16. But this argument mischaracterizes *TriCor*. First, the party asserting the Orange Book listing claim in *TriCor* had already agreed to drop that claim before the motion to dismiss was decided. *TriCor*, 432 F. Supp. 2d at 424 (noting Teva had agreed to dismiss the Orange Book listing claim). Second, the case that went to trial in *TriCor* was solely based upon the product hopping allegations, without the sham litigation or Walker Process claims. As *TriCor* demonstrates, a product hopping claim is sufficient to proceed to trial as an independent claim. *See also C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382 (Fed. Cir. 1998) (where Bard contended that its product modification was an improvement, but there was substantial evidence "that Bard's real reasons for modifying the gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of 'copycat' needles." "[T]he 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).

Walgreen Co. v. AstraZeneca Pharmaceuticals L.P. 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." 534 F. Supp. 2d 146, 151 (D.D.C. 2008). Plaintiff here alleges Defendants reduced consumer choice, including by no longer marketing prior versions of Doryx. ¶¶4 – 12.

Finally, Defendants' argument ignores the realities of the pharmaceutical marketplace where generic drugs, by regulatory design, compete on the basis of price via automatic substitution, not via detailing. Once they stopped marketing the prior version, when a doctor prescribed Doryx, the pharmacist could only fill it with the new version. Doctors did not embrace each new version of Doryx, as Defendants contend. Def's Brief at 25. They had no choice. And, in any event, such a contention is clearly an issue of fact inappropriate for a motion to dismiss.

1. Exclusionary Conduct

a. Product hopping that constricts consumer choice is exclusionary.

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. As the court held in *TriCor*, when a monopolist

switches from one formulation to another and constricts consumer choice, a claim for actionable exclusionary conduct lies. *TriCor*, 432 F. Supp. 2d at 421 ("[W]hen 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). This is particularly true when "[d]efendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations."[9] The introduction of the new formulation itself can be actionable in that context when the anti-competitive harm outweighs any procompetitive benefits from the product change. *TriCor*, 432 F. Supp. 2d at 422 (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). To be actionable, exclusionary conduct need not completely foreclose generic competitors from the market; it is sufficient to demonstrate the generics were blocked from generic substitution (which is the "cost-efficient" means of distribution) as a result of manipulative and unjustifiable formulation changes. *Id.* at 423 (citing *Dentsply*, 399 F.3d at 191, and *Microsoft*, 253 F.3d at 64).

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[9] *TriCor*, 432 F. Supp. 2d at 422. Defendants argue that a critical anticompetitive act in *TriCor* was the added step of obsoleting the older formulation of *TriCor* from the National Drug Data File ("NDDF") (which is a private commercial database commonly used in the pharmaceutical market). Def's Brief at 15. While that did occur in *TriCor*, the court focused on both the NDDF obsolescence and the discontinuation of the older formulation. *See id.* at 424 ("By 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 did *TriCor* single out the code changes as the only (or necessary) exclusionary conduct.

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

Plaintiff 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. ¶¶4, 6, 68 – 70. Each time that Warner Chilcott introduced a new product, there was no generic yet available for the prior version, and therefore no price-based reason for the market to remain with the prior formulation. With no generic competition, doctors had no reasonable alternative but to switch to the new formulation. By withdrawing their prior formulations, Defendants forced doctors to prescribe the "new" formulation if they wished to prescribe delayed release doxycycline hyclate. ¶¶4 – 12.

The system designed by Congress and the states permits and encourages generic companies to obtain sales through automatic substitution, and a generic that is AB-rated and substitutable for one branded formulation is not AB-rated and substitutable for another. Thus, for example, by no longer marketing branded Doryx capsules and replacing them with tablets, Defendants could (and did) block generic capsules from competing effectively because pharmacists cannot substitute a capsule product for a tablet product (different dosage forms are not AB-rated pharmaceutical equivalents automatically substitutable under the well-known DPS laws). This eliminated the most efficient means of competition for generic companies that had, or were seeking approval for, generic Doryx capsules. Those companies had no viable alternative except either to abandon any effort to market a generic Doryx product, or to go back to the drawing board to formulate a generic Doryx tablet.[10]

This is exactly the situation that occurred in *TriCor*, which survived a motion to dismiss, and ultimately went to trial solely on product hopping claims. Warner Chilcott executed a

[10] 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.

product hop several times over a short period, each time making very slight modifications to Doryx, which offered no benefits to patients, but which allowed Warner Chilcott to sell essentially the same product without the generic competition that the Hatch-Waxman Act and state substitution laws were enacted to foster and encourage.

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

Defendants' cases do not support their argument; procedurally or substantively. In *Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, the Ninth Circuit Court of Appeals was reviewing the district court's decision on defendants' Rule 56 motion for summary judgment. 592 F.3d 991, 996 (9th Cir. 2010). Accordingly, the court was called on to "balance the benefits of Tyco's alleged product improvement against its anticompetitive effects" based on a fully developed evidentiary record. *Id.* at 998. In that case, the court noted that "changes in product design are not immune from antitrust scrutiny." *Id.* Unlike the present case, affirmation of the district court's decision was warranted because there was "undisputed evidence" that defendants' new product was an "improvement" that outweighed any anticompetitive effects of defendants' switch; "[defendant's] new sensor design allows it to introduce new types of sensors without requiring its customers to purchase new monitors or reprogram their installed base of monitors. This added flexibility promotes the introduction of new types of sensors, such as Max-Fast, and reduces costs for consumers…. It also allows new functions, such as sensor event reporting and sensor messaging, to be included in the sensors themselves." *Id.* at 1001. By contrast, Plaintiff alleges Defendants' product switches had little, if any, benefit and did not outweigh the anticompetitive effects of restricting consumer access to lower-priced generics. Finally, plaintiffs in that case also "provided no evidence that Tyco used its monopoly power to

force consumers of pulse oximetry products adopt its new OxiMax technology." *Id.* at 1002. Plaintiff here has plausibly alleged that such coercion did occur as a result of the absence of any available bioequivalent generic products on the market. ¶¶4 – 12. In any case, a determination of fact on either of these issues is wholly inappropriate for a motion to dismiss.[11]

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. Nonetheless, Plaintiff describes the exclusionary nature of each aspect of the scheme below. The alleged harm to consumers is not offset by any alleged benefits from the new formulations, which offered no clinical or medical benefits to consumers.

i. The switch from Doryx capsules to Doryx tablets was exclusionary.

In 2005, Defendants began the first switch from Doryx capsules to tablets. The Defendants took steps to destroy the pre-existing demand for Doryx capsules and by June 2006, the Defendants had withdrawn Doryx capsules from the market altogether. ¶¶71 – 75. This was exclusionary and anticompetitive because, by no longer marketing Doryx capsules, the Defendants deprived consumers of the opportunity to determine whether Doryx tablets were an improvement, and it foreclosed the cost-efficient means of competition for generic (capsule)

[11] *Berkey* was an appeal on a judgment for plaintiff based on a fully-developed factual record; the Court of Appeals determined that plaintiff's claims were not "sufficient on the facts of this case to justify an award of damages." *Berkey Photo*, 603 F. 2d at 279. Moreover, that case is factually distinguishable; defendants had not engaged in coercion because, unlike the present case, consumers "were not compelled to purchase Kodacolor II especially since Kodak did not remove any other films from the market when it introduced the new one." *Id.* at 287. The court noted that defendants' introduction of the new product was lawful "so long as the free choice of consumers is preserved." *Id.* In the present case, Plaintiff alleges that consumers are not in a position to exercise free choice with respect to pharmaceuticals prescribed to them, especially where prior formulations have been withdrawn from the market. ¶¶65-66, 80. Similarly, *ILC Peripherals*, was determined on defendants' motion for directed verdict based on evidence presented by the parties, and the court was able to weigh "uncontroverted" expert witness testimony. *ILC Peripherals Leasing Corp. v. IBM Corp.*, 458 F. Supp. 423, 439 (N.D. Cal. 1978). Moreover, in that case, the court's decision rested on the fact that it could "not see how Memorex was injured by [IBM's] interface change" when the competitor would have had to alter its interface regardless of whether IBM had chosen to update its product in the way Memorex advocated. *Id.*

competitors – AB-rated generic substitution. Additionally, Doryx tablets offered no medical or clinical benefit over capsules, meaning the anticompetitive harm outweighs any potential procompetitive benefit from the switch. ¶74. And reformulating Doryx from a capsule to a tablet was predatory.[12]

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. Def's Brief at 7. The Defendants are free to offer that as a procompetitive justification to be weighed against the anticompetitive effect on a merits-based motion. Notably, however, the implication that a tablet formulation of Doryx was required to achieve whatever benefit derives from Patent No. 6,958,161 is belied by the fact that Claim 15 of the patent says the formulation can be employed in a capsule, and the summary of the invention states that "[i]n one form, a plurality of such coated core elements may be provided in a capsule." (*See* http://patft.uspto.gov Patent No. 6,958,161, "Detailed Description of Invention") And, similarly, the defendants in *TriCor* argued that they had patent protected improvements on their new formulations, but the product hop allegations there were still sufficient to overcome the motion to dismiss and to go to trial. That a product redesign is protected by a patent does not deprive the redesign of its exclusionary character. *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).

[12] "[A] 'predatory' practice is one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor." *Covad Comm'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005). *See also Neumann v. Reinforced Earth Co.*, 786 F.2d 424, 427 (D.C. Cir. 1977) (Bork, J.) ("[p]redation 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").

ii. The Defendants' switch to a scored tablet was exclusionary.

As with the switch to the first tablet, when the Defendants introduced the scored formulation of the 75 and 100 mg tablets in 2008 and 2009, they stopped marketing the prior formulation of the tablets and forced consumers to switch to the new formulation. ¶¶80, 84. The switch to the scored tablet formulation similarly falls within the *TriCor* paradigm.

Defendants contend the addition of scoring was not exclusionary because, they say, being able to break the tablets in half benefits consumers. Def's Brief at 8. But the controlling allegation is that this was not a medical or clinical benefit for consumers. ¶¶82 – 83. This switch, particularly when combined with the applesauce study for the tablets described below, specifically disrupted the efforts of generic competitors to react to the first exclusionary switch, and gave the Defendants time to fully switch consumers over to the 150 mg product before generics were able to enter with generic 75 and 100 mg tablets. ¶81. Once again, the product redesign is alleged to be predatory. *Id*. And as with the prior versions, this formulation switch requires scrutiny under the rule of reason because consumer choice was coerced.

iii. The applesauce study was strategically timed to exclude competition.

Defendants also conducted studies on sprinkling the Doryx tablets over applesauce in order to obtain a labeling change to instruct patients how to take Doryx in this manner. Defendants mischaracterize the Plaintiff's allegations as some kind of admission that Defendants did not delay seeking a labeling change related to the applesauce study. On the contrary, Plaintiff specifically alleges that Defendants strategically held back these studies until such time as they would maximally disrupt efforts of their generic competitors formulating generic versions of the tablets. ¶¶76 – 78. This conduct is different from the tablet formulation switches in that introduction of this labeling did not require destruction of the sales for an existing formulation. However, this conduct is anticompetitive when viewed in the context of the entire anti-generic strategy employed by Defendants. Indeed, Defendants admit in their memorandum that they had conducted applesauce studies on the older capsule product. Def's Brief at 29.

Tablets, scored or not, were not required for taking Doryx with applesauce; that was a feature available with the subsequently discontinued Doryx capsules. Indeed, requiring consumers to break apart the compressed tablet formulation in order to sprinkle it over applesauce likely made it harder for consumers to take Doryx tablets in that fashion compared with Doryx capsules. The only benefit was the disruptive effect on generic competition from strategically delaying the addition of that information to the tablet label. ¶¶76 – 78.

iv. 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. ¶¶88 – 94. Plaintiff alleges that the introduction of the 150 mg tablet was predatory. *Id*.

Defendants argue that their switch to the 150 mg tablets did not delay launch of the 75 and 100 mg tablets, so it could not have been exclusionary. In addition to contradicting the Plaintiff's averments to the contrary, this argument reflects a complete misunderstanding of the *TriCor* decision. The destruction of the sales base for the prior formulation facing imminent generic competition (in this context, the 75 and 100 mg tablet product) results in the benefit to the Defendants in the shift of the sales to the new formulation not facing imminent generic competition (here, the 150 mg tablet). ¶¶88 – 94. 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 generic substitution of generic 75 and 100 mg delayed-release doxycycline hyclate tablets for branded 75 and 100 mg Doryx tablets would have proceeded apace, without the suppression of pharmacy substitution brought about by Defendants' introduction of a new dosage strength that was not substitutable with generic 75 and 100 mg delayed-release doxycycline hyclate. Although the generic companies were able to get

approval for generic equivalents to the prior formulations despite the formulation changes, they were nevertheless foreclosed from the cost-efficient means of distribution, and generic substitution could not occur.

Defendants argue that the existence of the FDA's drug approval process itself counsels against enforcing antitrust laws here – implying that the FDA's regulations provide a safe haven for anticompetitive behavior. Def's Brief at 3. They do not.[13] FDA regulations are not concerned with anticompetitive behavior. Defendants selectively quote *Trinko* for the proposition that the existence of regulation in an industry militates against antitrust enforcement. But *Trinko* teaches that a regulatory environment may require greater antitrust scrutiny. *Trinko*, 540 U.S. at 412.

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

"'[A] monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior.'" *Dentsply*, 399 F.3d at 187 (quoting *LePage's*, 324 F.3d at 151-52). Defendants suppressed competition by delaying the introduction of a generic product through each of their "innovations," the conversion of the market to the "new" product through extensive detailing efforts, and the discontinuance of the previous formulations.

Such conduct, which results in consumer coercion, is anticompetitive. *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

[13] 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.

to tighten its hold on the market"); *Dentsply*, 399 F.3d at 187 ("Unlawful 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."). The Defendants cite *Berkey Photo* for the proposition that courts are reluctant to weigh in on the question of whether a new product design is exclusionary. Def's Brief at 16. But the reluctance of the court in *Berkey Photo* was based on the conclusion that the anticompetitive effects resulted from consumers' free choice. "Consumers who are free to choose among various products enjoy the presence of competition rather than its absence." *TriCor,* 432 F. Supp. 2d at 421. 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." *Berkey Photo*, 603 F.2d at 287 n.39. "In the absence of free consumer choice, the basis for judicial deference is removed" and innovation used as coercive means of extending market power is actionable. *TriCor*, 432 F. Supp. 2d at 421; *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 Devices Antitrust Litig.*, 481 F. Supp. 965, 1003 (N.D. Cal. 1997) ("It is not difficult to imagine situations where a monopolist could utilize the design of its own product to maintain market control or to gain competitive advantage … if those [] changes had no purpose and effect other than the preclusion of [competitors], this Court would not hesitate to find that such conduct was predatory [and] … that use of monopoly power would be condemned.").

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

Defendants bemoan "free riding" and argue that innovators should not be forced to aid generic competition. Def's Brief at 16. But "[t]his understanding of free-riding has no support in our case law" and is not a cognizable defense. *Eastman Kodak Co. v. Image Tech. Servs.*, 504

U.S. 451, 485 (1992). Drug companies are not free to cripple the automatic substitution system set up by Congress and the states through a series of meaningless product changes and the use of their detailing force. The statutory framework constructed by Hatch-Waxman explicitly contemplates the ability of generics to create bioequivalent copies of branded drugs. As the Supreme Court itself has noted, there is sometimes considerable debate in many circumstances whether "free-riding" is harmful or beneficial. *See, e.g., Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 915-16 (2007). There is no such debate here. By enacting the Hatch-Waxman framework, Congress explicitly favored the "piggybacking" ability of generics in order to facilitate savings for consumers. "I am not persuaded that … the prevention of 'free riding' is a legitimate business justification. Indeed, the Hatch-Waxman Act establishes and condones the opposition proposition, the 'piggybacking' of generics." *Teva Pharms. USA, Inc. v. Abbott Labs.*, No. 02-1512, 2008 WL 4809116 (D. Del. Nov. 5, 2008) (citing *Teva Pharms. USA, Inc. v. Novartis Pharm. Corp.,* 482 F.3d 1330, 1344 (Fed. Cir. 2007)) ("A central purpose of the Hatch-Waxman Act … is to enable competitors to bring cheaper, generic … drugs to market as quickly as possible."). *See also SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) ("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.")).

D. Plaintiff Adequately Alleges Causation

1. Causation Is a Fact-Intensive Inquiry Not Supported in the Rule 12 Context

Defendants' causation arguments are essentially repackaged versions of their antitrust injury arguments. Whether described as causation or antitrust injury, Defendants argue that the FDA's regulatory scheme – and not Defendants' actions – prevented generics from entering the market, thereby causing Plaintiff's injury. Defendants' argument wholly ignores Plaintiff's

allegations that Defendants timed their product hopping and removed prior versions of Doryx from the market. It is this combination of action by Defendants that materially caused Plaintiff's injury.

First, whether particular elements of Defendants' scheme were the proximate cause of an antitrust injury is a fact-intensive inquiry that will not support dismissal in the Rule 12 context. *See, e.g., In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, CIV. A. 06-52, 2010 WL 1485328, at *8 (D. Del. Apr. 13, 2010) ("As it is not clear at this stage whether Sandoz diverted resources in this case, or whether the FDA's grant of tentative approval was slowed as a result of diverted resources, the court cannot resolve this issue on a Rule 12(b)(6) motion."); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 355 (D.N.J. 2009) ("'the existence of antitrust injury is not typically resolved through motions to dismiss'"); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) ("Defendants' ability to pose a plausible and legally permissible version of events that explains why generic manufacturers of Wellbutrin SR have not yet entered the market does not compel this Court to grant their Motion. Rather, because this is a motion to dismiss, the Court must draw all reasonable inferences in favor of Plaintiffs.").

2. Defendants' Conduct Is the Material Cause of Plaintiff's Harm

Plaintiff adequately alleges that Defendants' conduct was a material cause of the exclusion of generic competition, and thus forced Plaintiff to pay supra-competitive prices for Doryx. *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) ("An antitrust violation can be the proximate cause of a plaintiff's injury even if there are additional independent causes of the injury.").

Plaintiff is not required to "allege (or dispose of) all alternative theories of causation to survive a motion to dismiss." *K-Dur*, 338 F. Supp. 2d at 535. "Plaintiffs are simply required to allege facts showing that they suffered the type of injury or harm the antitrust laws were intended

to prevent, and that their injury flows from the Defendants' anti-competitive conduct." *Id.* Defendants in *K-Dur*, like Defendants here, argued that injury flowed from the regulatory scheme. *Id.* The court held that the regulatory scheme was not designed to prevent competition and that by "drawing all reasonable inferences in the light most favorable to Plaintiffs, this Court finds that a reasonable trier of fact could conclude that but for the allegedly anti-competitive agreements, generic drugs may have entered the market sooner." *Id.*

Plaintiff alleges that purchasers paid supra-competitive prices for Doryx because the Defendants' product hopping scheme destroyed the market for therapeutically equivalent generics, forcing indirect purchasers to buy the much more expensive branded version at the pharmacy counter. The Defendants' overarching, multi-faceted product hopping scheme suppressed generic competition for Doryx. ¶4. The alleged scheme included the Defendants' efforts to (1) delay generic entry by converting the relevant market to new versions of Doryx; and (2) destroy the market for prior-branded versions before competitors, such as Mylan could launch approved generics. *Id.* A scheme to manipulate Hatch-Waxman to suppress generic competition can result in significant overcharges that are recoverable under the antitrust laws. *See, e.g., Cardizem*, 105 F. Supp. 2d at 663. "It is difficult to imagine a more formidable demonstration of antitrust injury" than allegations of overcharges caused by conduct which impeded generic competition. *Warfarin Sodium Antitrust Litig.*, 214 F. 3d at 401.

Contrary to Defendants' accusations, filing applications for the new formulations, by itself, would not have successfully suppressed generic competition, especially where, as Plaintiff alleges here, the "new" formulations provide no meaningful therapeutic benefits. ¶4. The Defendants' product hopping scheme involved more than filing of applications to market "new" formulations. It included coercing consumer choice by destroying the market for the prior versions that forced Plaintiff to pay higher brand prices rather than lower generic prices for most of their customers' Doryx requirements. ¶¶6, 8. 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. The FDA never

determined – and was never asked to determine – whether Defendants' new versions of Doryx were "improvements" over the prior versions. Nor did the FDA ever determine whether Defendants' efforts to convert doctors to the "new" versions while destroying the market for the old versions were anticompetitive. The FDA has neither the authority nor the expertise to make such determinations. 21 U.S.C. §355(d). The anticompetitive product hopping scheme was devised and implemented entirely by the Defendants, and the competitive harm caused by this scheme was clearly caused by Defendants' private actions, rather than government action.

Defendants' citation to *Massachusetts School of Law at Andover, Inc. v. American Bar Association* is not to the contrary. Def's Brief at 31. 937 F. Supp. 435 (E.D. Pa. 1996). 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. *Id.* at 438. The court held that it was the decision by various states to adopt the requirements that were the direct cause of plaintiff's harm. *Id.* at 440-41. 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. Plaintiff here has 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.

Defendants cite cases where plaintiffs' injuries were, as a factual matter, caused "fully" by government action, rather than the private defendants' conduct. Def's Brief at 28 (citing, *inter alia, City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998)). Such cases are inapposite where, as here, the private Defendants' conduct is a "material cause" of the suppression of generic competition. *Cardizem*, 105 F. Supp. 2d at 649. This principle applies in product hopping cases where, by definition, defendants hop from one FDA-approved product to another to thwart effective generic competition.

While urging the Court to consider the "realities of the regulated environment," Defendants ignore the fact that one of the primary purposes of the Hatch-Waxman regulatory system is to ensure that consumers get the price benefits of effective generic competition as soon as possible, after the expiry of any legitimate exclusivity periods. Def's Brief at 27; *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."). Congress did not enact the system to be gamed. *K-Dur,* 338 F. Supp. 2d at 531 ("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). Because Defendants' product hopping scheme was a material cause of Plaintiff's injury, the Court should reject Defendants' causation argument.

E. The Noerr-Pennington Doctrine Does Not Preclude Plaintiff's Claims

The Noerr-Pennington Doctrine provides that genuine and legitimate efforts to petition the government will be protected from liability under the antitrust laws. Noerr-Pennington, however, does not apply to the conduct challenged in the present case. Plaintiff does not challenge Defendants' September 2011 Citizen Petition, nor its NDAs, as "sham petitions". Moreover, even if the Doctrine were applicable in the present matter, it requires the Court to delineate factual matters that are inappropriate for a Rule 12(b)(6) motion.

1. Noerr-Pennington Provides Immunity Only for Petitioning Activity, not Market Behavior or NDA Applications

The Noerr-Pennington Doctrine provides First Amendment protection for genuine (*i.e.*, not sham and not fraudulent) acts of lobbying or petitioning "the Government for a redress of grievances." *See Flonase Antitrust Litig.,* 795 F. Supp. 2d at 309 (citing U.S. Const. Amend I). The scope of the doctrine only extends to petitioning activity; it does not license private commercial conduct following petitioning activity that are only arguably subject to Noerr-Pennington themselves. *See, e.g., Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 707-08 (1962) ("Respondents 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 the FCC; the FCC's failure to strike down tariff does not make the conduct lawful.).

The Supreme Court has clearly identified the types of activity that would justify protection under the First Amendment. *See E. R. R. Presidents Conference v. Noerr Motor Freight, Inc.,* 365 U.S. 127, 129, 139 (1961) (concerning activities "designed to foster the adoption and retention of laws and law enforcement practices," and efforts by railroads to "inform their representatives in government of their desires with respect to the passage or enforcement of laws cannot properly be made to depend upon their intent in doing so"); *United Mine Workers of America v. Pennington,* 381 U.S. 657, 665-66 (1965) (immunity enforced because of the "national policy expressed in the National Labor Relations Act of promoting 'the peaceful settlement of industrial disputes by subjecting labor-management controversies to the mediatory influence of negotiation,'" but noting that a "group of employers may not conspire to eliminate competitors from the industry and the union is liable with the employers if it becomes a party to the conspiracy"). Private commercial conduct, however, is not petitioning activity protected under Noerr-Pennington. The conduct challenged in this case concerns Defendants' private commercial activity in switching Doryx formulations and destroying the market for older Doryx formulations to impede generic competition to the older Doryx formulations. ¶¶4, 6 – 7. Therefore, the Noerr-Pennington Doctrine is inapplicable in the present case.

Moreover, merely because the Defendants had to submit a supplemental NDA to the FDA for approval of their successive versions of Doryx does not immunize their product changes or the destruction of the market for the prior formulations of Doryx that Defendants undertook after FDA approval. In fact, there is not a single reported decision characterizing a drug

company's submission of an NDA – by itself – as petitioning activity under Noerr-Pennington, and Defendants cite none in their briefs. If filing an NDA were protected petitioning activity under Noerr-Pennington, then *TriCor* — where defendants filed NDAs to change the formulation of *TriCor* from a capsule to a tablet, and then from a tablet of one dosage strength to a tablet of another dosage strength — would have been subject to Noerr-Pennington and dismissed.[14] Instead, *TriCor* went to trial. Indeed, if Defendants' proposition were true, there would be no basis upon which a plaintiff could bring ***any*** antitrust claims against a drug manufacturer who had sought approval from the FDA to market their drug under ***any*** set of facts. This would be an absurd result. Defendants provide the Court with no reason to entertain their proposition that Defendants' NDAs and their anticompetitive market switching activities are protected by the Noerr-Pennington Doctrine.

2. Plaintiff Does Not Challenge Petitioning Activity; It Challenges Defendants' Market Behavior

Defendants further fixate their Noerr-Pennington argument on conduct that Plaintiff does not contend is unlawful. Def's Brief at 17-23. Defendants clearly mischaracterize the gravamen of Plaintiff's claims. Plaintiff does not assert that Defendants' mere ***filing*** of NDAs with the FDA violated the antitrust laws. Plaintiff challenges the market conduct of Defendants in connection with products that were the subject of NDAs and supplemental NDA filings. ¶¶4 – 14.

Plaintiff is not claiming the Defendants should not have been able to file applications with the FDA for their "new" formulations of Doryx; nor that Defendants made misrepresentations to the FDA to achieve their unlawful goals. Plaintiff is not challenging Defendants' NDA applications as fraudulent or "shams." Rather, Plaintiff alleges that in the process of effectuating their unlawful scheme, Defendants obtained FDA approvals in order to

[14] Even in *Walgreen v. AstraZeneca*, the court did not consider the FDA's approval of new versions of omeprazole – as distinct from plaintiffs' product hopping allegations – as conduct warranting Noerr-Pennington consideration. The fact that the FDA approved the new versions of omeprazole (Nexium) was irrelevant. *Walgreen Co.*, 534 F. Supp. 2d at 151.

successfully sell their reformulated Doryx products, offering no medical or clinical benefits over the prior formulations of Doryx. ¶¶4 – 14. Combined with the withdrawal of prior formulations of Doryx, this resulted in the foreclosure of generic competition and ultimately caused Plaintiff to pay more for Doryx products than it would have, but for Defendants' anticompetitive conduct. ¶¶4 – 14. Contrary to Defendants' constant mischaracterizations of the allegations as "sham petitioning," it is this market switching that is the substance of Plaintiff's claims. Market switching is not petitioning activity protected under Noerr-Pennington.

Defendants' argument is highly analogous to the arguments rejected by the court in *Cardizem CD Antitrust Litig.,* 105 F. Supp. 2d at 636. In that case, defendants asserted that a patent settlement agreement (underpinning plaintiff's "pay-for-delay" market allocation allegations) achieved Noerr-Pennington immunity because it was "reasonably and normally attendant upon effective litigation" between branded and generic drug manufacturers. *Id.* Rejecting this proposition, the court held that "the source of the alleged anticompetitive harm is a private market allocation agreement between horizontal competitors who were adversaries in the pending HMRI/Andrx patent infringement action. Defendant does not explain how *Noerr* advances its claim that the purely private HMRI/Andrx Agreement is an "incidental effect" of pending litigation and thus entitled to immunity from antitrust liability."

Similarly, in the present case, Defendants do not explain how Defendants' purely private market switching allegations are an "incidental effect" of their NDAs, nor how NDAs are the source of the anticompetitive harm alleged in the case. *See also In re Neurontin Antitrust Litig.,* MDL No. 1479, 2009 WL 2751029, at *19 (D.N.J. Aug. 28, 2009) (holding that sham petitioning "'encompasses situations in which persons use the governmental ***process*** – as opposed to the ***outcome*** of that process – as an anticompetitive weapon. A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay'") (emphasis in original).

Defendants cite to *California Motor Transp. Co. v. Trucking Unlimited,* 404 U.S. 508, 515 (1972) which actually supports Plaintiff's position. In that case, the Supreme Court denied defendants' motion to dismiss under Noerr-Pennington because "First Amendment rights may not be used as the means or the pretext for achieving 'substantive evils.'" *Id.* The Court further refused to substantively inquire as to whether the petitions in question were baseless, because they were required to "of course, take the allegations of the complaint at face value for the purposes of that motion."

Moreover, none of Defendants' other cases support their argument here. Unlike the present matter, each case concerned allegations that the actual petitioning constituted the anticompetitive activities in question: *Cheminor Drugs, Ltd. v. Ethyl Corp.,* 168 F.3d 119, 120 (3d Cir. 1999) (affirming summary judgment where "[defendants'] administrative complaints to the ITC about Cheminor's below-market pricing and the resultant injuries to Ethyl were baseless, made in bad faith, contained false statements, and were brought only for anti-competitive reasons*"); Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.,* 508 U.S. 49, 63, (1993) (affirming summary judgment on allegations that defendants had brought an objectively baseless copyright infringement lawsuit).

Defendants' repeated conclusory assertion that "*Noerr* immunizes that [FDA] petitioning and the consequences of that petitioning" (Def's Brief at 20) is markedly unsupported by any legal authority. The only case Defendants cite in support of this erroneous proposition is *Allied Tube,* which only proves Plaintiff's point; Noerr-Pennington applies to restraints that are "the result of valid governmental action, as opposed to private action," as distinct from those restraints that are "independent of any government action [and] result directly from private action." *Allied Tube & Conduit Corp. v. Indian Head, Inc.,* 486 U.S. 492, 493 (1988) (citing *Noerr*, 365 U.S. at 143).

Indeed, as the Supreme Court noted, the applicability of the doctrine depends "on the source, context, and nature of the anticompetitive restraint at issue." *Id*. at 499. Here, Plaintiff alleges that a monopolist brand drug manufacturer undertook to produce and sell new

formulations of the same drug, adding no therapeutic benefit, and withdraw previous formulations of Doryx. ¶¶4 – 14. This is private commercial exclusory conduct. Further, Plaintiff never alleges that the NDA process was a sham or forms part of Defendants' exclusory conduct. ¶¶1 – 14. Accordingly, the Noerr-Pennington doctrine is inapplicable here.

3. Plaintiff Does Not Challenge the September 2011 Citizen Petition as a Sham

Defendants further assert that Plaintiff's reference to the September 23, 2011 Citizen Petition immunizes their antitrust liability under the Noerr-Pennington. Defendants are wrong.

Plaintiff's allegations concerning Defendants' filing of the Citizen Petition were brought under the heading "Defendants' Third Market Switch" and were pled to underscore Plaintiff's allegations that the Defendants' scoring changes had no therapeutic benefit and "yielded no safety or dosing benefits." ¶¶91, 93. Contrary to Defendants' repeated mischaracterizations of Plaintiff's Complaint, Plaintiff does not allege a "sham" or "objective baselessness" with respect to the September 2011 Citizen Petition. Plaintiff's allegations concern Defendants' private conduct in switching out the market with new products offering no additional therapeutic benefit, and simultaneously withdrawing prior versions of the products from the market. *See* ¶¶4 – 14. Accordingly, the FDA's "post-approval requirement" eliminating the "possibility of 'sham' under *Noerr-Pennington*" is entirely irrelevant to whether Plaintiff has plausibly alleged exclusionary conduct by the monopolist under *Twombly*.

Because Plaintiff does not allege that the September 2011 Citizen Petition was a "sham petition" attracting Noerr-Pennington analysis, Defendants' citations to *Dentsply* and *Nazir* are entirely inapposite. However, even if Plaintiff alleged a sham, *Dentsply* would support its proposition that the non-sham aspect of its antitrust claim – the market switching allegations – could be assessed independently from the sham claims, and survive even if the latter did not. As Defendants point out, the "sham" allegation is just one aspect of their antitrust counterclaim. Def's Brief at 23. *See Dentsply Int'l Inc. v. New Tech. Co.,* Civ. A. No. 96-272, 1996 WL 756766, at *3 (D. Del. Dec. 19, 1996) ("Defendants also allege two other instances of unlawful

behavior by plaintiffs: the unlawful acquisition of competitors and the use of monopoly power to coerce customers into long-term supply contracts … Even if plaintiffs prevail in a first trial, defendants argue, these two bases for an antitrust claim would still be viable and ripe for determination."). *Nazir* is entirely inapplicable in the present case, where, unlike the present case, "[p]laintiff argues that Defendant is not entitled to Noerr–Pennington protection because its petitioning activity was a sham." *Nazir v. United Air Lines,* CV 09-01819, 2009 WL 2912518, at *3 (N.D. Cal. Sept. 9, 2009). Plaintiff simply does not make that allegation regarding Defendants' September 23, 2011 Citizen Petition.

4. *Sorrell* Is Inapplicable Because Plaintiff Does Not Challenge Defendants' Pharmaceutical Detailing as Anticompetitive

Defendants assert that Plaintiff's "pharmaceutical detailing" to doctors is protected commercial speech immunized from the operation of the antitrust laws. Def's Brief at 24-25. Once again, Defendants mischaracterize the gravamen of Plaintiff's claims in a conspicuous attempt to jam them into a free speech-exception under the First Amendment. And Defendants are, once again, wrong. First, Defendants cannot point to a single allegation in the Complaint stating that Plaintiff's antitrust claims rest on pharmaceutical detailing; described in *Sorrell* as "'[p]harmaceutical manufacturers promote their drugs to doctors through a process called 'detailing'…[whereby] Pharmacies receive 'prescriber-identifying information" when processing prescriptions and sell the information to "data miners," who produce reports on prescriber behavior and lease their reports to pharmaceutical manufacturers…[and] '[d]etailers' employed by pharmaceutical manufacturers then use the reports to refine their marketing tactics and increase sales to doctors." *Sorrell v. IMS Health Inc.,* 131 S. Ct. 2653, 2656 (2011). Nowhere in Plaintiff's Complaint does Plaintiff allege an antitrust violation arising from these activities. Plaintiff's allegations plainly do not rest on "speech in aid of pharmaceutical marketing" and cannot be viewed as synonymous with its claims that Defendants repeatedly reformulated Doryx, adding no new therapeutical benefit, and withdrew prior versions of the product from the market. ¶¶4, 6 – 8. To construe Plaintiff's product hopping allegations as grounded in the activities of

"details reps of the brand firms" would actually require the Court to consider factual allegations that simply do not exist in this case. Def's Brief at 24.

Second, to the extent that Plaintiff's claims incidentally relate to such activities as in the *Sorrell* case is entirely inapposite. In that case, the Court denied injunctive and declaratory relief to data miners and drug manufacturers challenging a Vermont State law that prohibited them from selling prescriber-identifying information for marketing purposes. 131 S.Ct. at 2660. The Supreme Court upheld the Second Circuit's determination that the law "unconstitutionally burdens the speech of pharmaceutical marketers and data miners without adequate justification." *Id.* at 2656. In other words, actual speech was the subject of the law infringing on the plaintiffs' rights. Defendants claim that "switching markets" is free speech because it "only occurred because doctors chose to exercise their professional judgment." Def's Brief at 25. Once again, however, the logical conclusion of Defendants' reasoning would lead to the absurd result that any company that had engaged in ***any*** marketing of their products would be immune from the operation of the antitrust laws for anticompetitive conduct in relation to that product. This simply cannot be the reach of the First Amendment nor the Noerr-Pennington Doctrine.

5. Plaintiff's State Law Claims Also Survive Noerr-Pennington

Defendants bring no new argument that Noerr-Pennington bars Plaintiff's state law claims and their motion to dismiss on this basis should be denied for the same reasons.[15]

[15] As with Defendants' Noerr-Pennington arguments under Plaintiff's federal antitrust claims, Defendants cite to no case law supporting their argument for immunity. *Brownsville* and *Globetrotter* were decisions on motions for summary judgment based on fully-developed evidentiary records and in any case are inapplicable because Plaintiff simply does not seek "damages for injuries allegedly caused by the defendants' actions directed to influencing government action" nor challenges Defendants' attempts "to petition the government for redress through litigation in the courts." *Brownsville Golden Age Nursing Home, Inc. v. Wells*, 839 F.2d 155, 160 (3d Cir. 1988); *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1375 (Fed. Cir. 2004). Similarly, *IGEN* and *Honeywell* were based on fully-developed evidentiary records, and concerned challenges that a party's pursuit and involvement in litigation was objectively baseless. *IGEN Int'l, Inc. v. Roche Diagnostics GmbH*, 335 F.3d 303, 310 (4th

6. Determination of Noerr-Pennington "Shams" Are Inappropriate for a Motion to Dismiss

Finally, even if Plaintiff had alleged a sham petition – which it has not – an inquiry as to whether Defendants' conduct was a "sham" or "objectively baseless" is a "question of fact for the jury." *Flonase Antitrust Litig.,* 795 F. Supp. 2d at 310 (citing *Indep. Taxicab Drivers' Emps. v. Greater Hous. Transp. Co.,* 760 F.2d 607, 612 n.9 (5th Cir.1985)); *see also Catch Curve, Inc. v. Venali, Inc.,* 519 F. Supp. 2d 1028, 1037 (C.D. Cal. 2007) ("'[W]hether something is a genuine effort to influence governmental action, or a mere sham, is a question of fact.'") (quoting *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.,* 690 F.2d 1240, 1253 (9th Cir. 1982); *Kravco Co. v. Valley Forge Ctr. Assocs.,* No. 91–cv–4932, 1992 WL 97926, at *3 (E.D. Pa. Apr. 30, 1992) ("Whether or not the acts of the defendants fit the sham exception is a factual issue."). A court should only rule on the objective baselessness prong as a matter of law "[w]here there is no dispute over the predicate facts of the underlying [petitions]." *Flonase Antitrust Litig.,* 795 F. Supp. 2d at 300.

F. The Complaint Adequately Alleges a Plausible Conspiracy

1. The Complaint Adequately Alleges Defendants' Conspiracy to Prolong the Doryx Monopoly Through Product Hopping

To state a cognizable claim, "a complaint must contain factual allegations that, taken as a whole, render the plaintiff's entitlement to relief plausible." *West Penn Allegheny Health Sys.*, 627 F.3d. at 98. 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.'" *Id.* Moreover, to show a conspiracy claim, a plaintiff must allege (1) an overall unlawful plan or common design; (2) knowledge that others are involved is inferable as to each member of the alleged conspiracy because of the party's knowledge of the unlawful nature of the subject of the conspiracy; and (3) a showing of each alleged member's participation. *K-Dur*, 338 F. Supp. 2d at 536.

Cir. 2003); *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.,* 343 F. Supp. 2d 272, 325 (D. Del. 2004). Plaintiff brings no such claim here.

Plaintiff alleges a conspiracy by Mayne and Warner Chilcott to restrain trade, specifically to exclude generic competition for Doryx. ¶¶68-70. Plaintiff alleges the President and CEO of Warner Chilcott publicly boasting about the Company's ability to move the market to new formulations of Doryx on the eve of generic entry. ¶68. Plaintiff alleges Defendants admitted their strategy to thwart generic competition to Doryx through multiple strategies to shift the market by changing formulations in an earnings call with stock analysts. ¶69. Plaintiff alleges Mayne admitted to collaborating with Warner Chilcott to use "life cycle strategies" to prevent generic competition in its annual reports. *Id*.

Plaintiff alleges 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. ¶6. 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. ¶12. Each switch made as part of the scheme required coordinated efforts and overt acts by each of the Defendants. For instance, the switch from capsules to tablets required Mayne, as the manufacturer of Doryx, to expend significant resources (1) developing and seeking FDA approval of the tablet formulation and (2) changing the manufacturing process to effectuate the market switch. ¶¶71-75. 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. ¶62. These allegations plead a plausible conspiracy to violate state and federal antitrust laws.

2. Capacity to Conspire Is a Fact-Intensive Inquiry Not Supported in the Rule 12 Context

Defendants ask this Court to decide upon a motion to dismiss, without any factual record, that Warner Chilcott and Mayne, who are not part of the same corporate family, should be treated as a single entity under the antitrust laws, and thus, are incapable of conspiring. Defendants' argument is premature.

Defendants' capability of conspiring is a question of fact not capable of resolution on a Rule 12(b)(6) motion. *Los Angeles Mem'l Coliseum Comm'n v. Nat'l Football League*, 726 F.2d 1381, 1387 (9th Cir. 1984). The Supreme Court recently observed in *American Needle* that the focus regarding the single entity issue is not upon "formalistic distinctions," but instead, on "functional consideration of how the parties involved in the alleged anticompetitive conduct actually operate." *Am. Needle, Inc. v. NFL*, 130 S. Ct. 2201, 2209, 176 L. Ed. 2d 947 (2010). 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.'" *Id.* at 2212. "'[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 cartels." *Deutscher Tennis Bund v. ATP Tour, Inc*., 610 F.3d 820, 835 (3d Cir. 2010). Neither the necessity of cooperation nor that fact that the actors "operate jointly in some sense" mean that they are automatically immune from liability. *Id.* at 837.

The Supreme Court requires "the courts to analyze the substance, not the form, of economic arrangements when faced with allegations of intra-corporate conspiracies." *Siegel Transfer, Inc. v. Carrier Exp., Inc.*, 54 F.3d 1125, 1132-33 (3d Cir. 1995) (citing *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 772-73, 104 S. Ct. 2731, 81 L. Ed. 2d 628 (1984)). In *Copperweld*, the Court determined that a parent company and its wholly owned subsidiary are incapable of conspiring. *Copperweld*, 467 U.S. at 759-77. *Copperweld* does not apply here because Mayne and Warner Chilcott are not in the same corporate family. *See Siegel*, 54 F. 3d at 1132-33.

On a motion for summary judgment, *Siegel* held that a contract carrier managed by its corporate principle consisted of one economic unit that could not conspire. *Siegel*, 54 F. 3d at 1135. Mayne and Warner Chilcott are completely separate entities with independent

management. Moreover, a fact-intensive inquiry into the relationship between Warner Chilcott and Mayne is required to determine the level of control between them.[16]

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

The Defendants rely on *dicta* in *Shionogi Pharma, Inc. v. Mylan, Inc.* (involving a patent license), where the court cited the summary judgment decision in *Levi Case Co. v. ATS Prods., Inc.* (involving a patent license and heavily relied upon by Defendants) for the proposition that patent licensors and licensees cannot conspire. *Shionogi Pharma, Inc. v. Mylan, Inc.,* No. 10-1077, 2011 WL 2174499, at *5 (D. Del. May 26, 2011); *Levi Case Co., Inc. v. ATS Prods., Inc.* 788 F. Supp. 428 (N.D. Cal. 1992). 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 Int'l Corp.*, which held that "[w]hile the facts in *Levi Case* resulted in a finding by that court that a patent holder and its exclusive licensee were incapable of entering into a conspiracy with respect to their conduct with sublicensees, the court did not set forth a bright-line rule that patent holders and their licensees could never conspire." *Townshend v. Rockwell Int'l Corp.*, No. C99-0400, 2000 WL 433505, at *6 (N.D. Cal. Mar. 28, 2000).

Furthermore, as the Northern District of California recently explained, in *Levi Case*, "[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

[16] Numerous cases allow conspiracy claims against drug makers and distributors to proceed. *See, e.g., In re Nifedipine Antitrust Litig.,* 246 F.R.D. 365, 367 (D.D.C. 2007) (Biovail and Teva were Elan's exclusive distributors); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 147 (E.D. Pa. 2009) (SmithKline and Glaxo were Biovail's distributors).

restraint on trade," thus, justifying the *Levi Case* court's single entity finding based on the facts before it. *Pecover v. Electronic Arts Inc*., 633 F. Supp. 2d 976, 984 (N.D. Cal. 2009). Here, of course, there is no legally-sanctioned restraint on trade. Plaintiff does not allege that the market generics are kept out of is for the '161 patent (akin to the ductwork in *Levi Case*); instead, the Complaint alleges the market is for Doryx, which is subject to non-infringing generic competition. *Warner Chilcott Labs. Ireland Ltd. v. Impax Labs*, No. 08-06304, 2012 WL 1551709 (D.N.J. Apr. 30, 2012) (finding that Mylan's generic Doryx did not infringe the '161 patent). The alleged conduct is product hopping, not a refusal to license a patent that grants a legal monopoly. As such, *Levi Case* has no application here.

G. Federal Law Does Not Preempt Plaintiff's State Law Claims[17]

Defendants mischaracterize Plaintiff's state law claims, particularly its FDUTPA claim, as a fraud-on-the-FDA claim in order to fit it within *Buckman*. Plaintiff's claims, properly characterized, are not for fraud-on-the-FDA, and therefore, are outside of *Buckman*.

In *Buckman*, plaintiffs brought a claim against a consulting company that assisted with the filing of an FDA application. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 121 S.Ct. 1012 (2001). Plaintiffs' claim was simply that "but for" the consulting company's alleged fraud during the application process, the FDA would not have approved the application, and plaintiffs would not have been injured. *Id.* That was the entirety of plaintiffs' claim. *See id.* The Supreme Court deemed such a claim to be nothing more than a "fraud-on-the-FDA" claim because it "exist[ed] solely by virtue of the FDCA disclosure requirements," which interfered with the FDCA's objective to allow the FDA to police fraud on the agency, but claims that are based on traditional common-law torts do not interfere with that particular FDCA objective. *Id.* at 1017-20.

[17] Plaintiff pled state law claims under Nevada's antitrust law (Counts III-IV), Nevada's Deceptive Trade Practice Statute (Count V), and the Florida Deceptive and Unfair Trade Practices Act (Count VI). Through this opposition, Plaintiff withdraws its claim under Nevada's Deceptive Trade Practice Statute (Count V).

In contrast, courts hold that state law claims, such as those plead by Plaintiff, endure if they are premised on traditional common law principles, and incorporate, but do not depend entirely upon an FDCA violation. *In re DDAVP Indirect Purchaser Antitrust Litig.*, No. 05-cv-2237, 2012 WL 4932158, at *15 (S.D.N.Y. Oct. 17, 2012); *In re Bayer Corp. Combination Aspirin Prods. Mktg. and Sales Practices Litig.*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010) (The court held that pharmaceutical buyers' state law claims, which alleged the manufacturer made misrepresentations, were not preempted by the FDCA); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 87-88 (2d Cir. 2006) (The court did not preempt a state statute that granted immunity to drug makers who complied with FDA requirements and exempted drug makers who committed fraud on the FDA), *aff'd by Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440, 128 S.Ct. 1168, 170 L.Ed.2d. 51 (2008).

DDAVP is instructive for non-fraud-on-the-FDA claims, such as those alleged by Plaintiff. In *DDAVP*, the court held plaintiffs' indirect purchaser antitrust and consumer protection state law claims were not preempted, because plaintiffs were "not merely suing on a claim where 'proof of fraud against the FDA is ***alone sufficient*** to impose liability.'" *DDAVP*, 2012 WL 4932158, at *15 (quoting *Desiano*, 467 F.3d at 95) (emphasis in original). Plaintiffs in *DDAVP* claimed "anticompetitive conduct designed to maintain a fraudulent monopoly through a knowingly invalid patent – sufficient for these claims not to be preempted." *Id.* *DDAVP* distinguished *Buckman* on the grounds that plaintiffs "sought to bring claims that would remedy the misconduct before a federal agency," whereas, the *DDAVP* plaintiffs brought antitrust consumer protection claims with "alleged conduct that had the effect of keeping generic DDAVP manufactures out of the marketplace, which in turn enabled Defendants to sell DDAVP to Plaintiffs at supra-competitive prices." *Id.,* n.11. Furthermore, *DDAVP* held that "proof of fraud on the FDA is not an element of an antitrust claim. It may be ***evidence*** of such a claim… but it is not an affirmative element that Plaintiffs are required to prove to make out an antitrust claim." *Id.* at 15 (emphasis in original).

Like *DDAVP*, Plaintiff here alleges anticompetitive conduct designed to maintain an unlawful monopoly through timed product hopping and product withdrawal. ¶¶4 – 14. Plaintiff's state law claims are not an attempt to enforce or police the FDA's requirements. Instead, they seek remedy for Defendants' unfair acts – by replacing existing versions of Doryx on the eve of generic entry and manipulating the FDA regulatory process to delay or prevent generic competition to Doryx. ¶¶4 – 14. These are antitrust allegations against monopolistic behavior, not a sole allegation of fraud-on-the-FDA. As *DDAVP* found, Plaintiff's allegation regarding FDA manipulation "is not an element of [the FDUTPA] claim. It may be evidence of such a claim … but it is not an affirmative element … ." *See DDAVP*, 2012 WL 4932158 at *15. Plaintiff alleges state law claims that are not preempted by the FDCA because Plaintiff's claims do not "exist solely by virtue of the FDCA disclosure requirements." *Buckman*, 531 U.S. at 353.

To support preemption, Defendants cite *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011) and *Prohias v. AstraZeneca Pharms., L.P.*, 958 So. 2d 1054 (Fla. Dist. Ct. App. 2007). Both cases are inapposite as the courts in those cases held that state drug labeling laws were preempted because those laws directly conflicted with federal law, so that it was impossible for a private party to comply with both state and federal requirements. *Pliva, Inc.*, 131 S. Ct. at 2577-78; *Prohias,* 958 So. 2d at 1056. Plaintiff's state law claims do not involve drug labels and do not conflict with the FDCA or the FDA's role in regulating approval of drugs. Accordingly, the Court should reject Defendants' preemption argument.

H. Plaintiff Pleads a Relevant Market Definition

1. The Relevant Market Is a Fact-Intensive Inquiry Not Supported in the Rule 12 Context

Courts disfavor dismissal for failure to plead a relevant product market because the relevant product market definition is a fact intensive analysis to be made by the trier of fact. *Eastman Kodak Co.*, 504 U.S. at 482 ("The proper market definition in this case can be determined only after a factual inquiry into the 'commercial realities' faced by consumers."); *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"). ("[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."); *Peerless Heater Co. v. Mestek, Inc.*, No. Civ. A. 98-6532, 1999 WL 624481, at *1 (E.D. Pa. Aug. 6, 1999).

Moreover, if Plaintiff can demonstrate through direct evidence that Defendants enjoyed monopoly power with respect to Doryx, it 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"); *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").

2. 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 standard for deciding what products belong in a relevant product market in an antitrust case is their "reasonable interchangeability." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). 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 causes substantial shifts in the quantities demanded for another – commonly referred to as "cross-elasticity of demand." *Id.* at 437-38; *Babyage.com, Inc. v. Toys "R" Us, Inc.*, 558 F. Supp. 2d 575, 580-82 (E.D. Pa. 2008); *Brown Shoe Co. v. U.S.*, 370 U.S. 294, 325 (1962).

In *SmithKline*, the district court held that the relevant market was limited to "cephalosporins," and did not include other antibiotics or anti-infectives. *See SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d Cir. 1978). Like the Defendants here, Lilly argued that the relevant market should include all other anti-infective drugs in the therapeutic class. *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1096, 1100, 1116 (E.D. Pa. 1976), *aff'd*, 575 F.2d 1056, 1063 (3d Cir. 1978). 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. *Id.* at 1096. 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 cephalosporins and other antibiotic or anti-infective drugs." *Id.*

In *SmithKline,* 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." *Id.* at 1097. 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, and despite finding that "[t]here is a certain degree of interchangeability among all antibiotic drugs." *Id.* The Third Circuit affirmed.

Plaintiff defines the relevant product market (assuming such a definition is ultimately required) to include Doryx and all AB-rated generic versions of Doryx. ¶57. The exclusion of other (non-AB-rated) Doryx products and other antibiotics from the relevant market is a function of the unique characteristics of the pharmaceutical marketplace, 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.[18] *Id*.

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.[19]

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[18] Defendants state without any explanation that Plaintiff's relevant market definition "hinges" upon automatic substitution laws. Def's Brief at 38. As set forth above, Plaintiff's relevant market definition does not hinge upon those laws. Those laws, however, provide Defendants with a powerful motive to suppress generic competition.

[19] *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

In most other industries, manufacturers have a strong incentive to lower their product's price to maintain profitability when faced with the availability of products that function similarly to their product. Branded pharmaceutical manufacturers do not face the same incentives because physicians do not pay for the product. 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." *Columbia Metal Culvert Co., Inc. v. Kaiser Alum. & Chem. Corp.*, 579 F.2d 20, 28 n.22 (3d Cir. 1978). As a result of the disconnect between product choice and payment obligation, products that serve a similar medical function often exhibit little or no downward price competition with one another.

Defendants ignore that the relevant market is a function of cross-elasticity of demand and advocate the inclusion of products in the relevant market because they serve a similar therapeutic purpose. Courts hold that products with similar functionality, but without sufficient cross-elasticity of demand to constrain prices to competitive levels should not be included in the relevant product market. *See, e.g., Telecor Commc'ns, Inc. v. Southwestern Bell Tel. Co.*, 305 F.3d 1124, 1132 (10th Cir. 2002) ("[r]easonable interchangeability does not depend upon

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warfarin sodium); *La. Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-Civ.-7343, 2008 WL 169362, *7 (S.D.N.Y. Jan. 18, 2008) (product market limited to branded and generic versions of rheumatoid arthritis drug Arava, and excluding all other rheumatoid arthritis drugs, was cognizable); *In re Lorazepam & Clorazepate Antitrust Litigation*, 467 F. Supp. 2d 74, 81-82 (D.D.C. 2006) (relevant markets limited to generic versions of lorazepam and clorazepate, respectively and excluding other anti-anxiety agents); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522-23 (E.D.N.Y. 2005) (relevant market limited to drug product ciprofloxacin, excluding other antibiotics, including other flouroquinolone antibiotics); *In re Terazosin Hydrochloride Antitrust 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 Pharmaceuticals Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 01-C-1646, 2001 WL 1001117, at *3-*4 (N.D. Ill. Aug. 24, 2001) (product market limited to hydrocodone bitartrate/ibuprofen was cognizable); *Cardizem*, 105 F. Supp. 2d at 680-81 (product market limited to branded and generic versions of Cardizem CD was cognizable); *Mutual Pharm. Co., Inc. v. Hoechst Marion Roussel, Inc.*, No. Civ. A. 96-1409, 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).

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); *Hayden Publ'g Co. v. Cox Broadcasting Corp*., 730 F.2d 64, 70 (2d Cir. 1984) (district court committed reversible error in "neglect[ing] the factor of cross-elasticity of demand," which directs that the court to determine "'***how far buyers will go to substitute one commodity for another***'"). (Emphasis in original).

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

I. Plaintiff Adequately Pled FDUTPA'S Requirements (COUNT VI)

Under FDUTPA, "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts of practices in the conduct of any trade or commerce are hereby declared unlawful." Fla. Stat. §501.204. A stated purpose of FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. §501.202(2). *See also In re Flonase Antitrust Litig*., 692 F. Supp. 2d 524, 537 (E.D. Pa. 2010) (noting FDUTPA is to be construed liberally to protect the consuming public).

The three elements of a FDUTPA claim are: (1) a deceptive act or unfair practice; (2) causation; and (3) actual damages. *Processed Egg Products Antitrust Litig*., 851 F. Supp. 2d at 900. As this Court has repeatedly ruled, FDUTPA's first element encompasses antitrust violations. *Id.* (collecting case); *Flonase Antitrust Litig*., 815 F. Supp. 2d at 887; *RDK Truck*

Sales and Serv. Inc. v. Mack Trucks, Inc., No. 04-4007, 2009 WL 1441578, at *20 (E.D. Pa. May 19, 2009).

Here, Plaintiff's FDUTPA claim is based upon Defendants' alleged violations of the antitrust laws in monopolizing and attempting to monopolize the market for Doryx through their unlawful product hopping scheme. Defendants' scheme caused Plaintiff and the putative class of Florida indirect purchasers to pay supra-competitive prices for Doryx. Thus, the Complaint adequately states each element of a claim for relief under FDUTPA. *See Processed Egg Products Antitrust Litig*., 851 F. Supp. 2d at 900.

Defendants raise three other arguments against Plaintiff's well-plead FDUTPA claim. First, Defendants argue FDUTPA's safe harbor provision bars Plaintiff's FDUTPA claim. Second, Defendants argue federal law preempts Plaintiff's FDUTPA claim. Plaintiff has sufficiently argued that preemption does not apply. Finally, Defendants argue that Plaintiff's FDUTPA claim seeks relief for injuries outside of Florida. Each of Defendants' arguments is without merit.

1. FDUTPA's Safe Harbor Provision Does Not Apply

Defendants seek shelter from Plaintiff's FDUTPA claim in the statute's safe harbor provision claiming their actions were "specifically permitted by federal law." *See* Fla. Stat. §501.212(1). Like their preemption argument, Defendants mischaracterize Plaintiffs' FDUTPA claim as one of "fraud-on-the-FDA." Plaintiff's claim is not for fraud-on-the-FDA, but for relief from Defendants' unlawful product hopping scheme. Their scheme was not specifically permitted by federal law, and in fact, violates federal law. Accordingly, Defendants cannot anchor their defense in FDUTPA's safe harbor.

In support of their argument, Defendants cite two cases where the safe harbor provision of FDUTPA applied to defendants' advertisements based on approved FDA drug labels. MTD pg. 34-35. In *Kuenzig v. Kraft Global Foods, Inc.*, the court held that defendants could not violate FDUTPA by including pictures of its USDA-approved labels in its advertising. *Kuenzig v. Kraft Global Foods, Inc.*, No. 8:11-cv-838-T-24, 2012 WL 366927, at *3 (M.D. Fla. Feb. 3,

2012). In *Prohias v. AstraZeneca Pharm.*, the court held that certain promotional and advertising activities fell within FDUTPA's safe harbor provision because labeling was "specifically permitted" and approved by federal law. *Prohias v. AstraZeneca Pharm.*, 958 So. 2d at 1056. In both cases, plaintiffs' claims were preempted because the FDA had approved the labels that were contested. Plaintiff is not contesting Doryx's labels. Defendants also cite cases where Florida courts have held that FDUTPA is preempted where federal laws regulate securities, patents, maritime, and national flood insurance laws. Def's Brief at 35. None of these cases are relevant here because Plaintiff's FDUTPA claim does not interfere with the FDA's responsibility for ensuring safe and effective drugs.[20]

2. Federal Law Does Not Preempt Plaintiff's FDUTPA Claims

For the reasons set forth in Section G, *supra*, Plaintiff's FDUTPA claim is not preempted.

3. Plaintiff Seeks Relief for Injuries in Florida

Finally, Defendants argue that only a plaintiff who has been injured in Florida can pursue a claim under FDUTPA. Again, Defendants mischaracterize Plaintiff's FDUTPA claim.

Plaintiff, who is a citizen of Ohio, alleges that it is responsible for reimbursing or paying for members' purchases of Doryx and that it reimbursed beneficiaries for purchases of Doryx in, among other places, Florida. ¶17. Plaintiff brings a FDUTPA claim on its own behalf and on behalf of a putative class of indirect purchasers who purchased Doryx in Florida. ¶108. Plaintiff does not allege or seek relief under FDUTPA for a nationwide class of indirect purchasers regardless of where they purchased Doryx.

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[20] This Court has permitted claims under FDUTPA brought on behalf of indirect purchasers of drugs to proceed. *See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 409 (E.D. Pa. 2010) ("Courts in this district have held that indirect payor plaintiffs may assert a cause of action under the FDUTPA for claims arising in Florida based on reimbursement for purchases of over-priced drugs."); *Wellbutrin XL*, 260 F.R.D. at 162 (the court allowed the FDUTPA claim to proceed where indirect purchasers – through employee benefit plans – alleged that defendants conspired to prevent generic versions of the drug from entering the market); *Flonase*, 692 F. Supp. 2d at 537-38 (The court allowed the antitrust claim under FDUTPA brought on behalf of multiple employee welfare benefit plans to proceed).

As alleged, Plaintiff's FDUTPA claim on behalf of Florida indirect purchasers falls squarely within the prior decisions of this Court. *See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp.2d 380, 409 (E.D. Pa. 2010) ("Courts in this district have held that indirect payor plaintiffs may assert a cause of action under the FDUTPA for claims arising in Florida based on reimbursement of purchases of over-priced drugs, even when the alleged injuries did not take place entirely within Florida."); *See also Flonase*, 692 F. Supp. 2d at 537-38 (same); *Wellbutrin XL*, 260 F.R.D. at 161-62 (same). Accordingly, Defendants' motion to dismiss Plaintiff's FDUTPA claim on the grounds that it seeks relief for injuries outside of Florida should be denied.

J. The Statute of Limitations Does Not Bar Recovery for Purchases Made Within Four Years of the Filing of the Complaint

Defendants argue that Plaintiff's claims seeking damages arising out of events more than four years old are time-barred under Fla. Stat. Ann. §95.11(3)(f) (Florida deceptive and unfair trade practices claim), Nev. Rev. Stat. §598A.220 (Nevada antitrust claims), and 15 U.S.C. §15b (federal antitrust claims), even though Plaintiff and other indirect purchaser class members purchased Doryx within the past four years. Defendants' arguments are contrary to the well-established Third Circuit precedent and the decisions of this Court.

An antitrust cause of action generally "accrues and the statute [of limitations] begins to run when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Crop. v. Hazeltine Research, Inc.*, 401 U.S. 321, 91 S. Ct. 795, 28 L. Ed. 2d 77 (1971). However, "[i]n the context of a continuing conspiracy to violate the antitrust laws, … each plaintiff is injured by an act of the defendants a cause of action accrues to [it] to recover the damages caused by that act and … as to those damages, the statute of limitations runs from the commission of the act." *Id.* at 338.; *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 502 n.15, 88 S.Ct. 2224, 20 L. Ed. 2d. 1231 (1968); *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d Cir. 1993) ("[A]n injurious act within the limitations period may serve as a basis

for an antitrust suit."); *see also Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189-90, 117 S.Ct. 1984, 138 L. Ed. 2d 373 (1997).

In this case, relief is sought for overcharges which occurred within the four year limitations period. The Third Circuit recently reaffirmed that the statute of limitations does not bar recovery for injurious acts causing damages within the limitations period. *See West Penn Allegheny health Systems, Inc. v. UPMC*, 627 F. 3d 85, 105-6 (3rd Cir. 2010). And this Court has specifically found that "[i]n purchaser antitrust actions, the requisite injurious act within the limitations period can include being overcharged as the result of an unlawful act which took place outside the limitations period but continues to allow the defendants to maintain market control. *Meijer, Inc. v. 3M*, No. Civ. A. 04-5871, 2005 WL 1660188, at *4 (E.D. Pa. July 13, 2005) (citing *K-Dur*, 338 F. Supp. 2d at 551)). Accordingly, Defendants' statute of limitations argument is without merit.[21]

Finally, 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." *Meijer, Inc. v. 3M*, 2005 WL 1660188, at *2 (E.D. Pa. July 13, 2005). "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." *In re Linerboard Antitrust Litig.*, No. MDL 1261, 2000 WL 1475559, at *4 (E.D. Pa. Oct. 3, 2000). The Complaint should not be dismissed at the pleading stage by the statute of limitations.

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[21] Plaintiff seeks damages from overcharges paid within the limitations period from September 2008 to September 2012. Florida and Nevada law are in accord. Under FDUTPA, "a cause of action accrues, for statute of limitations purposes, 'when the last element constituting the cause of action occurs'" and the final element of a FDUTPA claim is "actual damages." *Sundance Apts., I, Inc. v. Gen. Elec. Capital Corp.*, 581 F. Supp. 2d 1215, 1223 (S.D. Fla. 2008); *Nelson v. Mead Johnson Nutrition Co.*, 270 F.R.D. 689, 696 (2010) ("Because Plaintiff purchased Enfamil within the four-year statute of limitations, the Court find that Plaintiff has standing to assert a FDUTPA… claim against Defendant.") Under Nevada's Unfair Trade Practices a cause of action "for a continuing violation arises at any time during the period of such violation." Nev. Rev. Stat. §598A.220(3).

IV. CONCLUSION

For the foregoing reasons, the Court should deny Defendants' motion to dismiss.

Dated: November 15, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2012, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List, and I hereby certify that I caused the foregoing document or paper to be mailed via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice List.

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