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

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

MEMORANDUM IN SUPPORT OF DEFENDANT WARNER CHILCOTT'S MOTION TO DISMISS THE IBEW INDIRECT PURCHASER CLASS ACTION COMPLAINT

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INTRODUCTION

Indirect Purchaser Plaintiff's me-too class action complaint premised on "product hopping" raises no new issues and must be dismissed for the reasons set forth in Warner Chilcott's Motion to Dismiss the Mylan and Direct Purchaser Complaints, Docket Nos. 83-84. Those grounds are expressly incorporated here.

Indirect Purchaser Plaintiff ("Indirect Plaintiff" or "IBEW") simply alleges the same fact pattern asserted by Mylan and the Directs, and no illegal acts of monopolization. Indirect Plaintiff claims that Defendants created new Doryx pharmaceutical products, obtained FDA approval to market those products, and marketed them under those FDA approvals. In addition, Plaintiff claims that Defendants stopped marketing their older products. Fatally, these allegations do not describe illegal acts and cannot state an antitrust claim. Any pharmaceutical company can be accused of modernizing or updating its drug products. No exclusionary conduct is alleged here. That was the conclusion of the two most recent courts to evaluate claims that launching a new pharmaceutical product was illegal "product switching" (the *Mylan* and *Walgreen* cases regarding Prilosec/Nexium). Unlike the only antitrust case ever to proceed past a motion to dismiss at the district court level on a "product switching" theory (*Abbott-Tricor*), there is no allegation here of any deletion of an NDDF code to prevent generic prescriptions or of any of the other anticompetitive conduct alleged in the *Abbott* case.

The antitrust laws encourage the independent, competitive action of competitors. The antitrust laws protect competition, not competitors like Mylan. Nothing in state or federal antitrust law creates a duty in a brand company to concern itself with whether its innovations will benefit generic competitors — particularly not one as large as Mylan. No antitrust case has held that a brand firm should slow its innovation to help out the generic competition.

Indirect purchasers (*i.e.*, the three proposed indirect classes described at Indirect Compl. ¶¶ 105-108) are barred under the federal Sherman Act from seeking any damages under *Illinois Brick* (which limits Sherman Act damages recoveries to direct purchasers only). 431 U.S. 720, 734-35 (1977). Thus, Indirect Plaintiff purports to seek only injunctive relief under Sections 1 and 2 of the Sherman Act for its putative U.S. indirect purchaser class. Indirect Compl. ¶ 106. These federal injunctive claims, however, are barred for the same reasons that the Mylan and Direct Purchaser claims fail, namely: 1) the fatal failure to allege any cognizable antitrust injury or exclusionary conduct under the Sherman Act; 2) the operation of *Noerr-Pennington* immunity which protects petitioning to the FDA (*e.g.*, the approval of the new versions of Doryx), including the related First Amendment principles that protect pharmaceutical detailing (*Sorrell*), and 3) the independent requirement that plaintiffs in a Sherman Act case demonstrate causation — impossible where any delay in generic entry stems from the FDA regulatory structure for bioequivalent AB-rated generics.

Indirect Plaintiff also purports to seek damages and other relief for two indirect purchaser classes under state law: one class brought under Nevada law and the other brought under Florida law. These state law damages claims fail due to: 1) the absence of any exclusionary conduct or antitrust injury; 2) the presence of *Noerr-Pennington* immunity for successful petitioning of the FDA and all the consequences of that petitioning, as well as the First Amendment protection for pharmaceutical detailing (*Sorrell*) which bars the state claims; 3) the failure to show causation; 4) federal law preemption of state law under *Buckman* and other authority; and 5) specific failures to meet the strictures of Nevada or Florida state law, such as the failure of those laws to cover indirect purchasers or other requirements (*e.g.*, Nevada law is limited to deceptive statements to *consumers*, none of which are specifically alleged here, and Florida has a safe

harbor for conduct "permitted by" federal or state law (*e.g.*, pharmaceutical marketing is within FDUTPA safe harbor: *Prohias*)).

Finally, all of Indirect Purchaser's claims are time-barred. Florida and Nevada state laws provide recourse only for acts occurring within the last four years. Federal law too has a four-year statute of limitations. Each of the "product switches" complained of occurred more than four years earlier than the filing of the Indirect Complaint on September 21, 2012. The only timely allegation — related to single vs. dual scoring of Doryx — produced no generic delay because Mylan did not have an FDA-approved drug, Citizen Petitions do not delay ANDAs, and in any event was barred by the New Jersey patent court injunction and then by Mylan's own voluntary TRO from generic entry during the pendency of the Citizen Petition.

By stipulation, Indirect Plaintiff has dropped its claim of any "anticompetitive" (¶ 5) "settlement agreements" (¶ 7) with generic drug manufacturers. *E.g.*, Indirect Compl. ¶¶ 5, 7, 85-87; *id.* at ¶ 118(2) ("enter into anti-competitive settlement agreements with generic manufacturers"); *id.* at ¶ 127(2) (same), *et seq.* (all Counts). Thus, those allegations are no longer before the Court. That stipulation was presented to the Court on October 29, 2012. *See* Stipulation of Dismissal of Claims, Dkt. No. 99 (Oct. 29, 2012).

The failings of the Indirect Complaint are inherent in the claims alleged. Neither federal nor state law acts to bar pharmaceutical innovation. Nor does federal or state law compel a branded company to innovate only at a pace that is convenient for generic companies. Any complaint about the speed or the FDA's regulation of AB-rated generic entry is one that should be directed to Congress, not to the courts. Doctors were free to choose and chose the newer Doryx products. And the state law damages claims (as well as federal injunctive claims) are time-barred. The motion to dismiss should be granted with prejudice.

STATEMENT OF FACTS

Although on a motion to dismiss the Court assumes the accuracy of the well-pled facts, the Court is not limited to the four corners of the Complaint. It is well-established that in deciding a motion to dismiss, the Court may consider facts contained in the documents that Plaintiff quotes, cites, or relies on in the Complaint.[1] Certain documents cited in the Indirect Complaint were cited in the highly-similar Mylan and Direct Purchaser Complaints and are exhibits to Warner Chilcott's motion to dismiss those complaints.[2] Additionally, the Court may take judicial notice of SEC filings and publicly available documents on the FDA's website.[3]

A. The Parties

1. Plaintiff IBEW

Plaintiff IBEW is a health and welfare fund, and describes itself as an "employee welfare benefit plan" and "employee benefit plan" maintained under the Labor Management Relations Act. Indirect Compl. ¶ 17. IBEW alleges it is "responsible for reimbursing or paying for members' purchases of prescription drugs," and claims it has reimbursed beneficiaries for purchases of Doryx in the states of Nevada and Florida. *Id.*

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

[2] *See* Warner Chilcott's Memorandum in Support of Motion to Dismiss, Dkt. No. 84 (Oct. 1, 2012) ("Warner Chilcott Mem."). Cross-references herein to exhibits to that motion are denoted as "Ex. # Warner Chilcott Mem."

[3] *See In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (judicial notice proper on motion to dismiss for documents "integral to or explicitly relied on in complaint," documents filed with SEC, and data compiled by Dow Jones news service).

2. Defendants Warner Chilcott and Mayne

Warner Chilcott is a specialty pharmaceuticals company that is far smaller than Mylan, the generic pharmaceutical plaintiff in these cases, with less than half of Mylan's 2011 revenues.[4] Compared to Mylan's 1,100 products, just eight products made up more than 93 percent of Warner Chilcott's revenue in the most recent quarter.[5]

Mayne is an Australian specialty pharmaceuticals company, with six products.[6] Lacking a U.S.-based sales force, Mayne licensed Warner Chilcott to sell Doryx in the United States. Indirect Compl. ¶¶ 3, 62 ("Mayne granted Warner Chilcott an exclusive license.").

B. Pharmaceutical Regulatory Scheme and Petitioning the FDA

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

1. New Drugs (NDAs)

The FDA has exclusive jurisdiction to determine whether to approve a company's new drug application ("NDA") to market and sell a drug in the U.S. 21 U.S.C. §§ 355(a), (b); Indirect Compl. ¶ 29. Prior to receiving FDA approval to market and sell drugs, an NDA applicant must submit clinical studies demonstrating that the drug is both "safe" and "effective" for its proposed uses. 21 U.S.C. § 355(b)(1)(A); *see also* Indirect Compl. ¶ 29. The NDA applicant also must submit the proposed labeling, including the drug's pharmacology, indications, recommended dosage, adverse events, and contraindications. *See* 21 U.S.C. § 355(b); 21 C.F.R. §§ 314.50(c)(2), 314.126. The FDA will approve an NDA only "after it

[4] *See* Mylan 2011 Form 10-K at 52 (Ex. 1 Warner Chilcott Mem.) (reporting revenues of $6.13 billion in 2011); Warner Chilcott 2011 Form 10-K at 52 (Ex. 4 Warner Chilcott Mem.) (reporting total revenues of $2.73 billion in 2011).

[5] *See* Warner Chilcott Form 10-Q at 23 (Ex. 5 Warner Chilcott Mem.).

[6] Mayne 2011 Annual Report at 4, 5 (cited in Indirect Compl. at ¶ 12) (Ex. 6 Warner Chilcott Mem.).

determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c).

2. Generic Drugs (ANDAs)

The FDA also exclusively regulates generic drugs. Under the Hatch-Waxman Act, generic drug manufacturers may file an Abbreviated New Drug Application ("ANDA"), relying on the FDA's previous findings of safety and effectiveness made for the innovator's relevant "reference listed drug," *i.e.*, the subject of the original NDA. *See* 21 U.S.C. § 355(j); Indirect Compl. ¶¶ 32-33. To receive FDA approval, an ANDA applicant must submit data demonstrating that its proposed generic drug is, among other things, both "bioequivalent" and pharmaceutically equivalent to the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A); Indirect Compl. ¶ 32. Since the Hatch-Waxman Act was adopted, the use of generics has risen dramatically, from 19 percent of all drug prescriptions filled in 1984 to 75 percent of all prescriptions filled in 2009. Indirect Compl. ¶ 35.

Indirect Plaintiff also admits that FDA regulations force generics to have the same labeling as the reference listed brand drug. Indirect Compl. ¶ 76.

C. State Substitution Laws

State laws regulating the substitution of branded drugs with generic drugs at the pharmacy level vary considerably by state. As the Indirect Complaint acknowledges, some states have "automatic substitution" laws that require pharmacists to substitute AB-rated generic versions for prescriptions written for reference listed branded drugs." Indirect Compl. ¶ 54. Only fourteen states have automatic substitution laws. *See* Warner Chilcott Mem. at 6 & n.15.

D. The Anti-Acne Treatments at Issue

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

Doryx is an oral antibiotic widely prescribed for the treatment of acne as well as certain other bacterial infections. Indirect Compl. ¶ 52. Doryx is delayed-release doxycycline hyclate. Indirect Compl. ¶ 52. In 1985, F.H. Faulding & Company Limited ("Faulding"), a predecessor to Mayne, obtained FDA approval to market Doryx 100 mg strength capsules. *See* Indirect Compl. ¶ 61 ("Mayne Defendants received approval in 1985"). In 2001, Faulding obtained FDA approval to market for 75 mg capsules. *See* Indirect Compl. ¶ 63.

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

On May 6, 2005, the FDA approved Faulding's NDA for new 75 mg and 100 mg Doryx tablets. *See* Indirect Compl. ¶ 63. Although the Doryx capsule had been successful, the Faulding scientists had long been aware of an issue with the capsule form of Doryx, a fact U.S. District Judge William J. Martini highlighted during the 2012 Doryx tablet patent litigation, in which the '161 Patent was held to be a valid invention (but not infringed). *See Warner Chilcott Labs. Ireland Ltd. v. Impax Labs., Inc.*, No. 08-cv-06304, 2012 WL 1551709, at *1-2 (D.N.J. Apr. 30, 2012) ("*Mylan*"). The company's scientists found that the delayed-release properties of the capsule actually diminished over time, raising a concern as to the capsule's "dissolution storage stability." *See id.* Eventually, Faulding solved that problem by adding a "stabilizing coat" between the drug core and the delayed release coating of the pellets, thus prolonging the stability of the drug and allowing the Doryx active ingredient to be "contained in a tablet instead of a capsule." *See id.* at *4. Faulding applied for and received a patent (Patent No. 6,958,161, the "Doryx Tablet Patent") embodying its invention for "improv[ing] dissolution stability." *Id.* at *58.

3. FDA Approves Labeling for Applesauce Administration (2006)

The Complaint alleges that in February 2006, Defendants sought FDA approval for a labeling change for Defendants' 75 mg and 100 mg Doryx tablets, indicating that a Doryx tablet could be administered by breaking up the tablet and sprinkling the tablet contents over applesauce. Indirect Compl. ¶¶ 76-77. The Complaint acknowledges the FDA approved such labeling in December 2006. Indirect Compl. ¶ 77.

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

In June 2008, the FDA approved Defendants' 150 mg strength tablet. *See* Indirect Compl. ¶¶ 66, 80. Defendants' 150 mg strength tablet was initially introduced with a single score, allowing a patient to break the tablet into two 75 mg portions. Sept. 23, 2011 Citizen Petition at 2;[7] Indirect Compl. ¶ 80. Indirect Plaintiff blithely contends that after receiving approval for the 150 mg tablet in June 2008 Defendants were "quickly phasing out" the 75 and 100 mg "through eliminating all promotional actives" for the 75 mg and 100mg. Indirect Compl. ¶ 80. But elsewhere, Indirect Plaintiff concedes that Defendants continued marketing the 75 mg and 100 mg doses — including in 2009 by introducing scoring changes "which allow patients to break the tablets into halves" — a year after Defendants received approval for the 150 mg tablet. *See* Indirect Compl. p. 23 (unnumbered para. between ¶¶ 78 and 79) ("Defendants' Scoring Change").

[7] Defendants' petitioning of the FDA in Warner Chilcott's Sept. 23, 2011 Citizen Petition is a key basis for IBEW's Complaint and that petition is cited and discussed extensively in IBEW's Complaint at ¶¶ 8-9, and 90-93. (Ex. 9 Warner Chilcott Mem.).

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

After the FDA approved the single-scored 150 mg Doryx tablet, Defendants likewise introduced single-scoring for both their Doryx 75 mg and 100 mg tablets.[8] The FDA approved, and Defendants launched, the scored version of Defendants' 100 mg tablet in February 2009, and the 75 mg tablet in March 2009. *See* Indirect Compl. at p. 23 (unnumbered para. between ¶¶ 78 and 79). Defendants subsequently filed a supplemental NDA for the Doryx 150 mg tablet supporting a manufacturing change from single-scored to dual-scored tablets and received FDA approval in September 2011. Indirect Compl. ¶¶ 88, 90. By changing from single to dual-scoring, a 150 mg tablet could be used as a 50 mg, 100 mg, or 150 mg dose. *See* Sept. 23, 2011 Citizen Petition at 2.

E. Mylan's Generic Doryx Anti-Acne Treatment

According to the FDA website, seven AB-rated generic drugs are approved by the FDA as therapeutic equivalents to Doryx products.[9] Generic manufacturers Actavis, Impax, and Mylan each have AB-rated therapeutic equivalent generics for Doryx 75 mg and 100 mg tablets, and Mylan has an AB-rated therapeutic equivalent generic for Doryx 150 mg tablets. *Id.* According to IBEW's complaint, Mylan currently manufacturers and markets three generic Doryx tablets — the 75, 100, and 150 mg dosage strengths. Indirect Compl. ¶ 53.

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[8] Highlighting the copy-cat nature of the Indirect Complaint, just like the Mylan Complaint (*compare* Mylan Compl. ¶ 60, *with* ¶ 62) the Indirect Complaint similarly obscures the sequence of events by not presenting the various FDA approvals in chronological order (*compare* Indirect Compl. unnumbered para. between ¶ 78 and ¶ 79, *with* ¶ 80). But IBEW's Complaint does admit that the scored 150 mg tablet was approved and marketed before the scored 75 mg and 100 mg tablets. *Id.* ¶ 80 (Doryx 150 mg tablet approved in June 2008); *id.* unnumbered para. between ¶¶ 78 and 79 (Doryx single-scored 75 mg and 100 mg tablets approved in February and March 2009).

[9] The FDA website provides therapeutic equivalents data to the public, *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Generics (Ex. 10 Warner Chilcott Mem).

Indirect Plaintiff alleges that Mylan and at least one other generic manufacturer — presumably Impax — successfully formulated products bioequivalent to the Doryx 75 and 100 mg dosages and filed ANDAs in 2008. Indirect Compl. ¶ 78.[10] Indirect Plaintiff alleges Mylan received final approval from the FDA on December 28, 2010 for its 75 mg and 100 mg tablets. Indirect Compl. ¶ 81. Mylan also filed an ANDA in December 2008, seeking approval for a 150 mg generic Doryx tablet product, and received tentative FDA approval on June 10, 2011. Indirect Compl. 88. Mylan received final FDA approval to market its 150 mg generic Doryx tablet on February 8, 2012, with "a post-approval requirement to double score Mylan's next manufacturing run." Indirect Compl. ¶¶ 93-94.

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

Patent litigation between the Defendants and Mylan concerning the innovation of the Doryx tablet is referenced in the Indirect Complaint as a basis for Plaintiff's allegations. *See* Indirect Compl. at 1 (preamble). The patent litigation was conducted before Judge Martini in the U.S. District Court for the District of New Jersey, with a final trial court decision in April 2012. *See generally Mylan*, 2012 WL 1551709. Judge Martini entered a preliminary injunction against Mylan barring the sale of Mylan's 150 mg Doryx generic on September 22, 2011. *Id.* at *5. As discussed below, after the Federal Circuit vacated the injunction, Mylan agreed to a TRO pending the outcome of the February 2012 bench trial on validity and infringement; that outcome was announced in the April 30, 2012 opinion. *Id.* at *5-6.

The Indirect Complaint fails to acknowledge that Judge Martini in his April 30, 2012 opinion found the Doryx Tablet Patent ('161) to be a valid invention, and an advance over the

[10] *See also* Indirect Compl. ¶ 53 (Impax obtained FDA approval for 75 mg and 100 mg tablets).

prior art — that is, the Doryx "Tablet ***improved the dissolution stability of the Capsule*** (among other things)." *Id.* at *58 (emphasis added).

STANDARD OF REVIEW

Antitrust complaints that fail to plausibly state a claim must be dismissed at the outset. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (explaining that courts should expose deficiencies "at the point of minimum expenditure of time and money by the parties and the court") (citation omitted). It is not enough to allege that a defendant *may* have violated the law; the complaint must "nudge[] . . . [the] claims . . . across the line from conceivable to plausible." *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009) (quotation marks and citation omitted). "Naked assertion[s] devoid of further factual enhancement" or "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are insufficient to survive dismissal. *Id.* at 678 (citations omitted). "[M]erely saying so does not make it so for pleading-sufficiency purposes." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 258 (3d Cir. 2010). In evaluating plausibility, the court must consider "context" and "draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

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

ARGUMENT

I. Indirect Plaintiff Does Not and Cannot Allege Antitrust Injury or Exclusionary Acts

Warner Chilcott argued in its earlier motion to dismiss that Mylan's and the Direct Purchaser Plaintiffs' conspiracy and monopolization claims must be dismissed for failure to allege antitrust injury and exclusionary conduct. Warner Chilcott Mem. at 11-31. Indirect

Plaintiff's antitrust claims are based on the same alleged conduct and should be dismissed for the same reasons. Like the earlier plaintiffs, this Plaintiff's antitrust claims also depend entirely on the assumption that the time it takes a generic pharmaceutical manufacturer to "keep pace with" a new, Hatch-Waxman-compliant product constitutes "delay" in generic entry that violates the antitrust laws. Indirect Compl. ¶¶ 39, 46, 49. Like the earlier plaintiffs, this Plaintiff's antitrust claims also depend entirely on the assumption that launching a new product, and deciding not to market an old version, somehow "excludes" competition and triggers treble damage antitrust liability. *See, e.g.*, Indirect Compl. ¶¶ 4, 6. For these reasons and those set forth in support of Defendant's motion to dismiss the related cases, IBEW's antitrust claims must be dismissed.

A. The Florida and Nevada Antitrust Laws Follow the Sherman Act

Indirect Plaintiff asserts claims under the Florida and Nevada antitrust statutes. Fla. Stat. § 542.22; Nev. Rev. Stat. §§ 598A.060, 598A.210. Both states intended their antitrust statutes to be interpreted in a way that was consistent with Sherman Act — and therefore IBEW's claims under both statutes should be dismissed for failure to allege antitrust injury or exclusionary conduct, as discussed below.

With respect to the Florida statute, the section titled, "Rule of construction and coverage" provides that "[i]t is the intent of the Legislature that, in construing [Chapter 542], due consideration and great weight be given to the interpretations of the federal courts relating to the comparable federal antitrust statutes." Fla. Stat. Ann. § 542.32. With respect to the Nevada law, the legislature instructed that "[t]he provisions of this chapter shall be construed in harmony with prevailing judicial interpretations of the federal antitrust statutes." Nev. Rev. Stat. § 598A.050 (2011) ("Construction of chapter").

Accordingly, courts have interpreted both statutes to be subject to the same rules and interpretations governing the federal antitrust laws, including with respect to the antitrust injury

and exclusionary conduct requirements. For Nevada: *see Jensen Enters. Inc. v. Oldcastle Precast Inc.*, No. 06-247, 2009 WL 440492, at *5 n.7, 7 (N.D. Cal. Feb. 23, 2009) (granting motion for summary judgment on antitrust claims brought under federal law, Nevada state law, and California state law because, among other reasons, plaintiff "cannot prove that it suffered any antitrust injury;" "[t]he requirements for maintaining an antitrust suit under California and Nevada law mirror the federal requirements") (citing Nev. Rev. Stat. § 598A.050); *IGT v. Alliance Gaming Corp.*, No. 04-1676, 2007 WL 911773, at *11 (D. Nev. Mar. 22, 2007) ("The analysis for the Nevada claims does not differ from the federal claims."); *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 516 F. Supp. 2d 1072, 1093-96 (N.D. Cal. 2007) (granting motion for judgment on pleadings with respect to Nevada antitrust law and other statutes because, among other reasons, plaintiff failed to show antitrust injury). For Florida: *see All Care Nursing Serv., Inc. v. High Tech Staffing Servs., Inc.*, 135 F.3d 740, 745 n.11 (11th Cir. 1998) ("Federal and Florida antitrust laws are analyzed under the same rules and case law."); *QSGI, Inc. v. IBM Global Fin.*, No. 11-80880, 2012 WL 1150402, at *2-4 (S.D. Fla. Mar. 14, 2012) (granting motion to dismiss antitrust claims brought under Florida antitrust law because amended complaint failed to allege antitrust injury and noting that "federal antitrust standing law applies to Florida Antitrust Act claims"); *Pierson v. Orlando Reg'l Healthcare Sys., Inc.*, 619 F. Supp. 2d 1260, 1274 n.22, 1276-77 (S.D. Fla. 2009) (granting motion to dismiss antitrust claims brought under federal law and Florida antitrust law where "[t]he Amended Complaint alleges many detriments to Plaintiff, but it does not allege 'antitrust injury;'" holding that federal and Florida antitrust rules should be analyzed together under same case law and rules); *S.E. Fla. Laborers Dist. Health & Welfare Trust Fund v. Morris*, No. 97-8715, 1998 WL 186878, at *5-6

(S.D. Fla. Apr. 13, 1998) (dismissing antitrust claims under both federal law and Florida state law because plaintiff "has not and cannot allege antitrust injury").

B. Indirect Plaintiff's Federal and State Antitrust Claims Fail to Satisfy the Antitrust Injury Requirement

Antitrust injury is an essential element of any antitrust claim, and without it a claim cannot proceed. *See, e.g., Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 484, 488-89 (1977); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998); *Mathews v. Lancaster Gen. Hosp.*, 87 F.3d 624, 641 (3d Cir. 1996). The antitrust injury requirement ensures that antitrust law is used to protect competition and not competitors. *See Brunswick*, 429 U.S. at 488 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)); *see also Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). *See also* Warner Chilcott Mem. at 11-19 (collecting authorities).

The two most recent courts to have evaluated claims that launching and marketing a new pharmaceutical product constituted illegal "product switching" have rejected such claims. *See AstraZeneca AB v. Mylan Labs. Inc*., No. 00-CV-6749, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 148 (D.D.C. 2008). In the cases accusing AstraZeneca of violating the antitrust laws by launching Nexium and discontinuing prescription Prilosec, two separate courts have rejected two separate plaintiffs' "product-switching" theories. *Mylan*, 2010 WL 2079722, at *6 ("Mylan has failed to plausibly allege "predatory or exclusionary acts or practices" . . . because the alleged conduct introducing new products — is generally considered pro-competitive."); *Walgreen*, 534 F. Supp. 2d at 151 ("Courts and juries are not tasked with determining which product among several is superior. Those determinations are left to the marketplace."). Only one district court, in 2006, has denied

a motion to dismiss in a "product switching" case, and that case involved different facts than those alleged here. *See Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 414-19 (D. Del. 2006) (involving conduct that, unlike here, actually could have blocked competition, including fraud on PTO, sham litigation, and manipulating drug's National Drug Data File coding to prevent doctors from prescribing and pharmacies from substituting generic versions).

The antitrust laws do not impose a duty on Warner Chilcott to market Doryx in a manner most beneficial to the company's competitors. Any alleged losses resulting from Warner's Chilcott's failure to assist its competitors in this way — as well as any alleged derivative injuries, such as IBEW's here — cannot satisfy the antitrust injury requirement. IBEW's federal and state law antitrust claims should be dismissed for this independent reason.

C. Indirect Plaintiff's Federal and State Claims Fail to Allege Exclusionary Conduct

The requirement that a plaintiff asserting a claim of monopolization allege conduct that illegally "excludes" competitors is another fundamental requirement of the antitrust laws. *See Trinko*, 540 U.S. at 407 ("To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*.") (emphasis in original); *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966) (Sherman Act Section 2 requires "the willful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident"); *see also Handicomp, Inc. v. U.S. Golf Ass'n*, No. 99-5372, 2000 WL 426245, at *3 (3d Cir. Mar. 22, 2000); *Behrend v. Comcast Corp.*, No. 03-6604, 2012 WL 1231794, at *19 (E.D. Pa. Apr. 12, 2012). Innovation is competition.

Developing and marketing a new product ***cannot*** be deemed exclusionary unless accompanied by some form of ***coercion***. *See Allied Orthopedic Appliances Inc. v. Tyco Health*

Care Group LP, 592 F.3d 991, 1000 (9th Cir. 2010) ("Absent some form of coercive conduct by the monopolist, the ultimate worth of a genuine product improvement can be adequately judged only by the market itself."); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286-87 (2d Cir. 1979) ("If a monopolist's products gain acceptance in the market, therefore, it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion."); *Walgreen*, 534 F. Supp. 2d at 151-52 (same); IIB PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 781e (3d ed. 2008) ("We therefore conclude that all product innovation should be lawful in the absence of bundling . . . ."); *see also ILC Peripherals Leasing Corp. v. IBM, Corp.*, 458 F. Supp. 423, 439 (N.D. Cal. 1978) ("Where there is a difference of opinion as to the advantages of two alternatives which can both be defended from an engineering standpoint, the court will not allow itself to be enmeshed 'in a technical inquiry into the justifiability of product innovations.'") (quoting *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F.2d 1307, 1330 (5th Cir. 1976)).

Nor can stopping the marketing of an older drug (Compl. ¶¶ 65-66, 72) be considered exclusionary. The Indirect Complaint admits that "[o]nce a generic drug has entered into the market, sales switch quickly from the brand to the generic." Compl. ¶ 39. The U.S. Supreme Court in *Sorrell v. IMS Health*, 131 S. Ct. 2653, 2660 (2011)) observed that "[d]etailing is an expensive undertaking, so pharmaceutical companies most often use it to promote high-profit brand name drugs protected by patent." Once patent protection is no longer available, antitrust law recognizes that the avoidance of free riding is a legitimate aim of firms under Supreme Court precedent. *See* Warner Chilcott Mem. at 23-24 (citing *Sylvania* and *Leegin*). Federal antitrust law does not require Apple to continue to market the iPhone 2 or iPhone 4s when it brings out the iPhone 5, nor must a textbook publisher market the seventh edition of the best-selling biology

textbook when it releases the new eighth edition. And nowhere do federal or state antitrust laws require a brand manufacturer to slow its innovation in order to assist a generic firm.

II. *Noerr-Pennington* Immunity Bars Any Recovery by Indirect Plaintiff (All Counts)

The *Noerr-Pennington* doctrine provides complete immunity to petitioning of federal regulatory agencies such as the FDA from the Sherman Act and from state laws, under the authorities set forth in Defendants' motion to dismiss the Mylan and Direct Purchaser Complaints. *See* Warner Chilcott Mem. at 31-38. Warner Chilcott incorporates those precedents here by reference. *Noerr-Pennington* also bars any recovery flowing from the subsequent regulatory action taken by a federal agency after such petitioning. *See* authorities cited in Warner Chilcott Mem. at 32-34. *Noerr-Pennington* antitrust immunity flows both from the First Amendment and from the fact that Congress never sought to regulate petitioning and lobbying or the consequences of petitioning and lobbying by means of the Sherman Act. *E. R.R. Presidents Conference, Inc. v. Noerr Motor Freight*, 365 U.S. 127, 138-40 (1961) (finding that petitioning the government with anticompetitive intent cannot "transform conduct otherwise lawful into a violation of the Sherman Act").

A. Petitioning for and Obtaining Marketing Approval from the FDA Is Activity Fully Protected under *Noerr-Pennington* Immunity

At its heart, the Indirect Purchasers' Complaint alleges nothing more than that Defendants developed Doryx drug innovations, then applied for FDA approval to market those new drugs, and then marketed the drugs. *E.g.*, Indirect Compl. ¶¶ 80-81 ("seeking and obtaining FDA approval for 150 mg" Doryx Tablets, and then "shifting prescriptions" to 150 mg Tablets). Not only does this ***not*** state any exclusionary conduct under the Sherman Act, but the petitioning of FDA for new drug marketing approval, followed by marketing under that FDA approval, is fully-protected by *Noerr-Pennington* immunity. *Cal. Motor Transp. Co. v. Trucking Unlimited*,

404 U.S. 508, 510-11 (1972) (*Noerr* applies to petitioning of regulatory agencies); *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 127 (3d Cir. 1999) (pharmaceutical manufacturer of ibuprofen entitled to *Noerr* immunity for filing petitions with International Trade Commission and Department of Commerce).

Indirect Plaintiff's key product-hopping allegations expressly admit (as they must) that Defendants successfully sought and obtained FDA regulatory approval for each and every one of their innovations — petitioning activity that is protected by the First Amendment and free from the strictures of the Sherman Act:

- "Mayne Defendants ***received FDA approval for the Doryx 75 mg Capsule*** on August 13, 2001, and Warner Chilcott Defendants introduced the Doryx 75 mg Capsule in the United States in January 2002." Indirect Compl. ¶ 63 (emphasis added).

- "Mayne Defendants ***received FDA approval for the Doryx 75 mg and 100 mg Tablets*** on May 6, 2005 and began commercialization of these products soon thereafter." Indirect Compl. ¶ 63 (emphasis added).

- "Mayne Defendants ***received FDA approval for the Doryx 150 mg Tablet on June 20, 2008,*** and soon thereafter Warner Chilcott Defendants stopped promoting the Doryx 75 mg and 100 mg Tablets." Indirect Compl. ¶ 66 (emphasis added).

- "Defendants ***first obtained FDA approval to market the Doryx 75 mg and 100 mg Tablets on May 6, 2005*** and launched the Doryx 75 mg and 100 mg Tablets shortly after approval." Indirect Compl. ¶ 72 (emphasis added).

- "But Defendants waited until February 2006 . . . to release the results of the Tablet Applesauce Study and ***seek a labeling change, obtaining approval in December 2006***." Indirect Compl. ¶ 77 (emphasis added).

- "After ***seeking and obtaining FDA approval for 150 mg single-scored delayed-release tablet version of Doryx, in June 2008,*** Defendants again shifted the delayed-release doxycycline hyclate market, this time from the Doryx 75 mg and 100 mg Tablets to the Doryx 150 mg Tablets." Indirect Compl. ¶ 80 (emphasis added).

- "Defendants' intent to use this change in scoring as a means to delay generic entry is further evidenced by Mayne's press release announcing ***its September 14, 2011 FDA Approval of the dual-scored Doryx 150 mg Tablet*** . . . ." Indirect Compl. ¶ 90 (emphasis added).

Indirect Plaintiff also admits as it must that the FDA regulations directly govern the marketing and sale of new branded drugs in the United States, such as all relevant versions of Doryx mentioned in the complaint:

- "Under the Federal Food, Drug, and Cosmetic Act (FDCA), manufacturers who create a new drug product must obtain the approval of the FDA ***to sell the new drug*** by filing a New Drug Application (NDA). Indirect Compl. ¶ 29 (emphasis added).
- "The ***FDA's regulatory process for approving drugs for sale*** only in the United States . . . ." Indirect Compl. ¶ 58 (emphasis added).

Although the Indirect Complaint conclusorily asserts that Defendants conspired "to manipulate the FDA regulatory processes" (Indirect Compl. ¶ 118(3), ¶ 127(3), ¶ 135(3), ¶ 144(3), ¶ 162(3)), the only factual allegations made concerning the FDA are the Defendants' successful FDA petitions listed above. No facts of FDA "manipulate[ion]" are pled, and in any event *Noerr* immunizes advocacy before regulatory agencies. *Cheminor*, 168 F.3d at 127. Thus, quite apart from the failure to allege facts under *Twombly* and *Iqbal*, the Complaint alleges nothing more than petitioning success at the FDA for the newer Doryx formulations.

Significantly, there is no allegation of sham petitioning by Indirect Plaintiff. In fact the word "sham" does not appear at all in the Indirect Complaint. Nor can there be an allegation of "sham." To constitute a "sham," the petitioning must: 1) be "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and 2) demonstrate an improper "subjective motivation" (*i.e.*, "an attempt to interfere *directly* with the business relationships of a competitor" through the "use [of] the governmental *process*—as *opposed* to the outcome of that process—as an anticompetitive weapon"). *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) ("*PRE*") (emphasis in original). Here, Indirect Plaintiff would never be able to overcome the first prong of *PRE* —"objective baselessness" — because Plaintiff admits that in each instance of switching, Defendants

successfully petitioned FDA for the marketing approvals that permitted them to sell the newer Doryx products — *e.g.*, 150 mg single-scored Doryx, 150 mg dual-scored. Indirect Compl. ¶¶ 63, 66, 72, 77, 80, 90. Successfully petitioning of the FDA by definition ***cannot*** be "objectively baseless" and therefore is not a sham under the Supreme Court's *PRE* decision. *See PRE*, 508 U.S. at 60 n.5 (1993) ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.").

Indirect Plaintiff complains that Defendants marketed the new versions of Doryx and convinced doctors to make a "switch" to new versions of Doryx. Indirect Compl. ¶73 ("switch the market from Doryx Capsules to Doryx Tablets"). But the marketing of the newer versions of Doryx that Defendants conducted occurred only because the FDA had granted new drug marketing approval of these new Doryx drugs for sale in the United States. *Noerr-Pennington* immunity protects conduct that flows from the government regulatory action, not merely the petitioning. *See Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) ("'[W]here a restraint upon trade or monopolization is ***the result of valid governmental action***, as opposed to private action,' those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint.") (quoting *Noerr*, 365 U.S. at 136) (emphasis added).

In short, the new versions of Doryx in each instance were fully approved by the FDA for marketing to doctors, the result of Defendants' successfully petitioning FDA for the right to market these drugs and to make these labeling claims. The fact that Defendants' marketed and sold the drugs flows from the approvals FDA granted. *Noerr* immunizes that petitioning and the consquences of that petitioning.

B. The September 2011 Dual Scoring Citizen Petition Is Fully Protected by the *Noerr-Pennington* Doctrine

Indirect Plaintiff casually refers to the FDA's "reject[ion]" on February 8, 2012 of a September 23, 2011 Citizen Petition (Indirect Compl. ¶93), but Indirect Plaintiff does not and cannot make out any facts to escape the inescapable reach of *Noerr-Pennington* immunity to the September 2011 Citizen Petition. Nor can Indirect Plaintiff establish causation where, as here, Mylan was barred by the patent court injunction and subsequent voluntary TRO from entering the market during the pendency of the Citizen Petition.

1. No Allegation of Sham Petitioning Is Made

The Supreme Court's *PRE* decision sets forth a rigorous two-pronged test for the sham exception to *Noerr* for any petition: (1) objective baselessness, and (2) improper subjective motivation. *PRE*, 508 U.S. at 60-61. As noted, the Complaint does not describe the September 23, 2011 Citizen Petition as a "sham." Nor does the Indirect Complaint use the word "sham" at any point.

Nor does the Indirect Complaint plead any *facts* to support either of the two prongs of "objective baselessness" and improper "subjective motivation." This Citizen *Petition* is simply petitioning of a regulatory agency, which is protected. *Cal. Motor Transp.*, 404 U.S. at 510-11 ("[I]t would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-a-vis their competitors.").

2. The September 23, 2011 Citizen Petition Did Involve Successful Petitioning Because the FDA Required Mylan to Dual Score Going Forward

In reality, the FDA did grant Warner Chilcott some of the relief it sought in the September 23, 2011 Citizen Petition — as the Indirect Complaint admits. The FDA ruled that after Mylan sold off its existing batch of generic Doryx, Mylan had to begin double-scoring its 150 mg generic of Doryx. Indirect Plaintiff explicitly admits this in its Complaint: "On the same day as the FDA rejected Defendants' Citizen Petition, it ***approved*** Mylan's generic version of the single-scored Doryx 150mg Tablet, ***with a post-approval requirement to double score Mylan's next manufacturing run***." Indirect Compl. ¶ 94 (emphasis added).

> The FDA's response to the September 23, 2011 Citizen Petition is explicit:
>
> Today we are approving a generic single-scored 150 mg doxycycline hyclate delayed-release product, ***with a postapproval requirement to comply with the new dual scoring configuration of the referenced listed drug*** product (RLD) when it conducts its next manufacturing run.

FDA Response to Warner Chilcott Citizen Petition, at 1 (Feb. 8, 2012), attached as Exhibit 1 (emphasis added).[11] In other words, although FDA permitted Mylan to launch, the FDA also ruled that when Mylan started its next production run of 150 mg generic Doryx, Mylan had to use the dual-scored configuration in that production run and subsequent production runs. Thus, prospectively the FDA imposed a "postapproval requirement" that Mylan had to dual score the 150 mg generic Doryx. *See* Ex. 1, FDA Response to Warner Chilcott Citizen Petition, at 1 (Feb. 8, 2012).

[11] The Complaint references the FDA response to September 23, 2011 Citizen Petition (Indirect Compl. ¶ 93), which means that this Court is free to review it. *See Burlington Coat Factory*, 114 F.3d at 1426 (3d Cir. 1997) (court may rely on documents which the complaint was based upon, even if not explicitly cited). The FDA's response to the Citizen Petition is also a public record and can be found at http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0702-0003.

Any success eliminates the possibility of "sham" under *Noerr-Pennington*. *See Dentsply Int'l, Inc. v. New Tech. Co.*, No. 96-cv-272, 1996 U.S. Dist. LEXIS 19846, at *8-9 (D. Del. Dec. 19, 1996) ("A winning lawsuit cannot be considered a 'sham,' despite a subjective, anti-competitive motive by the litigant. . . . In fact, courts have indicated that litigation will not be considered a 'sham' so long as at least one claim in the lawsuit has objective merit. Therefore, if plaintiffs prevail on one of their counts, the sham aspect of the antitrust counterclaim must fail.") (citations omitted); *Nazir v. United Airlines*, No. 09-cv-1819, 2009 U.S. Dist. LEXIS 81901, at *11 (N.D. Cal. Sept. 9, 2009) ("The Court takes judicial notice of Defendant's partial success in each bankruptcy order . . . . In light of this success, it is hard to see how Defendant's bankruptcy litigation could be seen as objectively baseless.").

3. The September 23, 2011 Citizen Petition Caused No Delay in Entry

Indirect Plaintiff does not allege that the September 23, 2011 Citizen Petition caused any generic delay. Dismissal with prejudice is warranted because Indirect Plaintiff cannot allege any delay in generic entry, an independent basis for dismissal of Indirect Plaintiff's claims.

As Indirect Plaintiff expressly admits, under the 2007 legislation, a Citizen Petition cannot delay an ANDA. *See* Indirect Compl. ¶ 49 ("In relevant part, the 2007 Amendments require the FDA to not delay approval of a pending ANDA because of a Citizen Petition unless such a delay is necessary to protect the public health. The 2007 Amendments also enabled the FDA to deny summarily any Citizen Petition where the primary purpose of the petition is to delay competition entering the market."). Mylan's ANDA thus was not delayed.

In addition to the 2007 legislative command, during the less than six months that the September 23, 2011 Citizen Petition was pending, the generic, Mylan, was: (1) not in possession of final approval from the FDA until February 8, 2012 (Indirect Compl. ¶ 94); (2) had been barred by the U.S. District Court for the District of New Jersey from launching its 150 mg

generic due to the preliminary injunction (*see* Warner Chilcott Mem. at 42 (quoting *Mylan*, 2012 WL 1551709, at *5 (patent court issued injunction "to enjoin Mylan from selling its 150 mg ANDA product")); and (3) Mylan had then voluntarily extended the preliminary injunction by agreeing to a temporary restraining order until the patent litigation was resolved on its merits on April 30, 2012 — two months after the Citizen Petition was resolved. *See* Warner Chilcott Mem. at 42 (patent court discusses voluntary TRO Mylan agreed to until patent trial court's determination of infringement on April 30, 2012, citing *Mylan*, 2012 WL 1551709, at *5).

C. Plaintiffs Cannot Base an Antitrust Claim on Switching by Doctors Resulting from Pharmaceutical Detailing Because Such Detailing Is Commercial Speech Fully Protected by the First Amendment (*Sorrell*)

Independently, Indirect Plaintiff's claims of injury due to a "switch" of doctors from older Doryx to new Doryx (Indirect Compl. ¶ 73; *see also* ¶ 81 ("shifting prescriptions")) by means of the marketing efforts by Defendants' sales force — pharmaceutical detailers — are barred because such marketing/detailing to doctors is protected speech outside the realm of Sherman Act (*e.g.*, *Noerr*) or state law regulation. If there was any doubt, the U.S. Supreme Court's 2011 decision in *Sorrell v. IMS Health, Inc.*, settled the question by holding that branded companies' pharmaceutical detailing is protected commercial speech under the First Amendment to the U.S. Constitution. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011). In striking down a Vermont statute, the Court considered the role of pharmaceutical marketing by detail reps of the brand firms. *Id.* at 2659-62. In no uncertain terms, the Court held: "Speech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment." *Id.* at 2659. The Vermont statute restricting detailing was struck down. *Id.* at 2672 (concluding that "State's interest in burdening the speech of detailers instead turns on nothing more than a difference of opinion"); *id.* at 2671 ("Vermont may be displeased that detailers who use prescriber-identifying information are effective in promoting brand name

drugs. The State can express that view through its own speech . . . The State may not burden the speech of others in order to tilt the public debate in a preferred direction.") (citation omitted).

Indirect Plaintiff's claim that Doryx's reformulated product entailed no "improvement to the therapeutic character of the product or consumer welfare, generally" (Indirect Compl. ¶ 74), invites the Court to engage in precisely the sort of paternalism that the First Amendment rejects. Pharmaceutical detailing is selling activity directed at doctors, a learned profession. *Id.* at 2671 ("[T]he audience, in this case prescribing physicians, consists of 'sophisticated and experienced' consumers"). It is up to the marketplace of ideas to determine under the First Amendment the utility of any particular pharmaceutical:

> The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. ***Some of the ideas and information are vital, some of slight worth.*** But ***the general rule is that the speaker and the audience, not the government, assess the value of the information presented***.

Thompson v. Western States Med. Ctr. 535 U.S. 357, 367 (2002) (emphasis added) (quoting *Edenfield v. Fane*, 507 U. S. 761, 767 (1993)). Switching to new Doryx only occurred because doctors, after considering the detailing messages, chose to exercise their professional judgment and chose newer Doryx. The Sherman Act stops short of interfering with protected First Amendment freedoms under the *Noerr-Pennington* doctrine. *Noerr*, 365 U.S. at 138 ("The right of petition is one of the freedoms protected by the Bill of Rights, and we cannot, of course, lightly impute to Congress an intent to invade these freedoms. . . . For these reasons, we think it clear that the Sherman Act does not apply to the activities of the railroads at least insofar as those activities comprised mere solicitation of governmental action with respect to the passage and enforcement of laws."). And there is no allegation of falsity in Defendants' detailing to doctors.

D. *Noerr-Pennington* Also Bars the State Law Claims (Counts III-VI)

It is settled law in this Circuit that *Noerr-Pennington* immunity extends to Indirect Plaintiff's state law claims with equal force. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 128 (3d Cir. 1999) (finding that "the same First Amendment principles on which *Noerr-Pennington* immunity is based apply to the [state] tort claims" and dismissing New Jersey tort claims) (citing *Brownsville Golden Age Nursing Home, Inc. v. Wells*, 839 F.2d 155, 160 (3d Cir. 1988) (dismissing claims for civil conspiracy and interference with a business relationship under Pennsylvania law because "[t]he rule that liability cannot be imposed for damage caused by inducing legislative, administrative, or judicial action [articulated in *Noerr*] is applicable here")).

In *Cheminor*, the Third Circuit found that when a plaintiff relies on actions that are immunized under federal law by *Noerr-Pennington*, the Constitution clearly prevents those same actions from being be the basis for liability under state law. *Cheminor*, 168 F.3d at 128-29. Other courts have reached the same conclusion. *See Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1376-77 (Fed. Cir. 2004) (holding that state law competition and state law tort claims were both preempted by federal patent law and, absent a showing of objective baselessness, properly dismissed under the *Noerr-Pennington* doctrine); *IGEN Int'l, Inc. v. Roche Diagnostics GMBH*, 335 F.3d 303, 310, 313 (4th Cir. 2003) (finding that the *Noerr-Pennington* doctrine immunizes "the pursuit of litigation, and, although originally developed in the antitrust context, ***the doctrine has now universally been applied to business torts***" and vacating a jury verdict of compensatory and punitive damages of over $400 million) (emphasis added); *Honeywell Int'l, Inc. v. Universal Avionics Corp.*, 343 F. Supp. 2d 272, 324 (D. Del. 2004) (dismissing state law antitrust counterclaims under *Noerr-Pennington* and *PRE* when claimant had not shown objective baselessness "[b]ecause the principles of *PRE* are based on a First Amendment right of petition, those principles also apply to Universal's state law

theories.") (citing cases). The First Amendment principles expressed in *Sorrell* also prevent state interference with detailing to switch doctors from one drug to another. *Sorrell*, 131 S. Ct. at 2675-76.

E. Causation Is an Independent Ground for Dismissal of Indirect Plaintiff's Claims (Counts I-VI)

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

1. Causation Is an Essential Element of Every Claim

A private plaintiff suing under the antitrust laws must prove that it was injured "by reason of" the defendant's anticompetitive conduct. 15 U.S.C. § 15(a); *see, e.g.*, *Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc.*, 63 F.3d 1267, 1273 (3d Cir. 1995) (antitrust claim requires proof of "causal connection" between alleged antitrust violation and plaintiff's alleged injury); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (holding that city suffered no antitrust injury because "any injury suffered by the City did not flow from the defendants' conduct, but, rather, from the realities of the regulated environment in which all three were actors"); *Sound Ship Bldg. Corp. v. Bethlehem Steel Co.*, 533 F.2d 96, 98 (3d Cir. 1976) (granting summary judgment against plaintiff who "failed to develop a theory or set out any facts . . . which would show a causal link between [defendant's] acts and [plaintiff's] losses.").

The relevant state laws also require causation. The Nevada and Florida antitrust and deceptive trade practices laws (Counts II – VI) require plaintiff to establish causation. *See Picus v. Wal-Mart Stores, Inc.*, 256 F.R.D. 651, 658 (D. Nev. 2009) ("The Court therefore concludes that for a private NDTPA claim for damages, the Nevada Supreme Court would require, at a

minimum, a victim of consumer fraud to prove that (1) an act of consumer fraud by the defendant (2) caused (3) damage to the plaintiff."); *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 516 F. Supp. 2d 1072, 1095 (N.D. Cal. 2007) (NUTPA has "harmonization provisions . . . calling for the statute[] to be construed in accordance with federal law," which requires proof of causation); *Marco Island Cable, Inc. v. Comcast Cablevision of the South, Inc.*, No. 2:04-CV-26-29DNF, 2006 WL 1814333, at *3-4, 11 (M.D. Fla. July 3, 2006) (dismissing FAA claim where FAA mirrors Sherman Act and where defendant failed to establish causation under Sherman Act); *Montgomery v. New Piper Aircraft, Inc.*, 209 F.R.D. 221, 229 (S.D. Fla. 2002) ("FDUTPA requires proof of causation."); *see also* Section I (collecting authorities that Nevada and Florida antitrust law follow federal law).

Dismissal is required when an independent cause — such as FDA approval and a binding court order in this case — fully accounts for the plaintiff's alleged injury and breaks the causal connection between the alleged antitrust violation and the plaintiff's alleged harm. *See, e.g., City of Pittsburgh*, 147 F.3d at 265. This is true even where a defendant has committed a *per se* antitrust violation, which is not the case here. *See Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328 341-42 (1990) (even *per se* violation require antitrust injury as an element).

Courts routinely dismiss antitrust claims where the claimed injury is not caused by the alleged antitrust violation, particularly where the alleged injury results from lawful government action. *See City of Pittsburgh*, 147 F.3d at 265 (affirming dismissal where injury caused by regulatory aspects of industry and not by defendants' conduct); *Midland Export, Ltd. v. Elkem Holding, Inc.*, 947 F. Supp. 163, 166 (E.D. Pa. 1996) (holding "ITC's action was still the direct cause of the harm alleged here. Defendants' conspiracy, even if a significant influence on the ITC's determination, was nonetheless an indirect cause of Midland's harm."); *In re Canadian*

Import Antitrust Litig., 470 F.3d 785, 791 (8th Cir. 2006) (affirming dismissal where injury caused by FDA's import restrictions, not defendants' conduct); *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (affirming summary judgment because alleged injury was caused by regulatory scheme that prevented plaintiff's construction of new billboards, not defendant's threats).

2. Indirect Plaintiff Does Not and Cannot Allege that Defendants' Conduct Caused Its Alleged Injuries; FDA Regulation is the Intervening Cause

Indirect Plaintiff has failed to allege the causal link required for its antitrust claims. For each of the alleged "switches," the Indirect Complaint makes clear that government approval of the Doryx new drug formulations caused whatever delay in approval for the AB-rated generic that Indirect Plaintiff claims as injury. In addition, with respect to Indirect Plaintiff's challenge to Warner Chilcott's FDA citizen petition regarding dual-scored tablets — a challenge the Direct Purchasers tellingly chose *not* to pursue — any delay in generic entry was caused by the independent, intervening event of a court-ordered preliminary injunction and TRO, not the citizen petition. Indirect Plaintiff's own allegations demonstrate that any alleged harm flowed directly from the FDA's *government* action, rather than Defendants' private conduct.

Indirect Plaintiff admits that Defendants sought and obtained government approval of each new Doryx product at issue. *See* Section II.A above; *see also* Indirect Compl. ¶ 63 (FDA approval to market Doryx 75 mg and 100 mg tablets); Indirect Compl. ¶ 77 (FDA approval for the applesauce label); Indirect Compl. ¶ 66 (FDA approval to market 150 mg Doryx tablets); Indirect Compl. ¶ 72 (FDA approval to market scored 75 mg and 100 mg Doryx Tablets). Plaintiff further admits that any alleged "delay" in the entry of generic tablets resulted from government (FDA) action and regulatory restrictions. *See, e.g.*, Indirect Compl. ¶ 59 ("There are

substantial barriers to entry in the relevant market, ***including the FDA's regulatory requirements***.").

Paragraph 4 of the Indirect Complaint is clear that it is the FDA regulation that is the cause for the delay of the entry of AB-rated generics to Doryx:

> *Because a generic drug must be identical in dosage form and route of administration to its reference listed drug*, these switches, along with other carefully-timed exclusionary conduct, *prevented generic manufacturers* from launching commercially viable competing generic versions of delayed-release doxycycline hyclate products.

Indirect Compl. ¶ 4 (emphasis added).

Paragraph 32 of the Complaint is to the same effect, describing the FDA's Hatch-Waxman Act ANDA regime, which requires that AB-rated generics must be "bioequivalent" to the new drug:

> ANDAs rely on the scientific findings of safety and effectiveness included in the brand-name drug manufacturer's original NDA, but must show that the generic drug *contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug* — that is, that the generic drug is *bioequivalent* to the brand-name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.

Indirect Compl. ¶ 32 (emphasis added).

Thus, once the FDA approved the New Drug Applications applicable to the newer versions of Doryx, it was the FDA regulatory scheme for ANDAs which barred generic entry of AB-rated generic to the new Doryx drugs until "bioequivalence" was demonstrated. Indirect Compl. ¶¶ 32, 33 ("bioequivalence"), 36-37. It is the Hatch-Waxman requirements for the generic to be "bioequivalent" that is the source of this delay in FDA approval of AB-rated generics to the new Doryx drugs (¶ 32) — which is the injury claimed by Indirect Plaintiff's claimed anti-competitive effect. Indirect Compl. ¶ 99 (claiming injury due to delay of lower-

priced "AB-rated equivalents to Defendants' branded Doryx products"); *see, e.g., id.* at. ¶ 159 (alleging "strategies to keep generic AB-rated substitutes for Doryx off the market").

As for the applesauce study — another successful example of petitioning the FDA — Indirect Plaintiff is also explicit that the injury flowed ***from*** the FDA's decision to approve the petitioned-for labeling:

> But Defendants waited until February 2006 . . . . to release the results of the Tablet Applesauce Study ***and seek a labeling change, obtaining approval in*** December 2006. Defendants' ***change in labeling*** to include the Tablet Applesauce Study was designed to, and ***had the effect of***, delaying generic manufacturers' ANDAs for their generic Doryx 75 mg and 100 mg Tablets . . . .

Indirect Compl. ¶ 77 (emphasis added); *id*. at ¶ 76 ("Because a generic must be identical").

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

Thus, there can be no allegation that Defendants' citizen petition caused any delay. Where, as here, "anticompetitive harm is caused by the decisions of a court, even though granted at the request of a private party, no private restraint of trade occurs because the intervening government action breaks the causal chain." *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 818 (D.C. Cir. 2001); *Egervary v. Young*, 366 F.3d 238, 246-47 (3d Cir. 2004) (observing that "the actions of a judicial officer may sever the chain of causation. . . . *In the usual case, the order of the court would be the proximate cause and the various preliminary steps would be*

remote causes of any injury from imprisonment or restraint under the court order.") (citation omitted).

III. Indirect Plaintiff's State Law Claims Are Preempted by the FDCA Act and Hatch-Waxman Amendments Regulatory Regime (Counts V-VI)

The Federal Food, Drug and Cosmetics Act (the "FDCA"), as amended by the Hatch-Waxman Act" preempts and cuts off Indirect Plaintiff's antitrust and consumer protection claims based on the state laws of Nevada and Florida in Counts III-VI. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (affirming dismissal by E.D. Pa. of "state-law fraud-on-the-FDA claims" as preempted by federal law); *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011) (FDCA Act and Hatch-Waxman Amendments preempting state-law duty-to-warn claims); *Prohias v. Astrazeneca Pharm.*, 958 So.2d 1054 (Fla. Dist. Ct. App. 2007) (plaintiffs' FDUTPA claims preempted by FDA labeling regulations and FDUTPA safe harbor provision prevents claim where conduct complies with federal law).

A. The Supreme Court in *Buckman* Held Federal Law Preempts State-Law Fraud-on-the-FDA Claim Such As Plaintiff's Nevada Deceptive Trade Practices Claim (Count V)

The Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001), squarely held that federal law preempts state-law "fraud-on-the-FDA" claims such as Indirect Plaintiff's claims under the Nevada Deceptive Trade Practice statute (Count V). Paragraph 153(1) of Count V makes the conclusory allegation that Defendants engaged in deceptive trade practices, by, *inter alia*, "fraudulently representing to . . . the FDA that their multiple reformulations of Doryx . . . added some therapeutic benefit for consumers." *See also* Indirect Compl. at ¶ 153(2), ¶ 153(3) (two other conclusory allegations of Defendants' "fraudulently representing . . . to the FDA").

In *Buckman*, the Supreme Court rejected state-law "fraud-on-the FDA" claims holding: "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. The Court in *Buckman* reasoned that: "[T]he relationship between a federal agency and the entity it regulates is ***inherently federal in character*** because the relationship originates from, is governed by, and terminates according to federal law." *Id* at 347 (emphasis added). *See also Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1382 (Fed. Cir. 2000) (holding as preempted by federal patent law state-law claims based on "no more than bad faith misconduct before the PTO"); *see also Pliva*, 131 S. Ct. at 2577 (federal drug regulations preempting state-law duty-to-warn claims).

The *Buckman* case arose from an MDL litigation consolidated in the Eastern District of Pennsylvania, where plaintiffs alleged that a manufacturer of screws that go into medical devices had made fraudulent representations to the FDA "in the course of obtaining approval to market the screws." 551 U.S. at 344. According to the plaintiffs in *Buckman*, the representations to the FDA were a "but for" cause of the plaintiffs' injuries sustained from the implementation of the medical devices. *Id.* Plaintiffs' argument was that: "Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* The Supreme Court observed that "[p]olicing fraud against federal agencies is hardly 'a field which the states have traditionally occupied' such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Id*. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In reversing the appellate court decision, the Supreme Court in *Buckman* — agreeing with the trial court's holding — reasoned that: "State-law fraud-on-the-FDA claims ***inevitably conflict*** with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350 (emphasis added).

Here, Indirect Plaintiff claims in conclusory fashion — devoid of any factual allegations — that Defendants "engaged in deceptive trade practices, by . . . fraudulently representing to consumers and the FDA" that: (1) "the multiple reformations of Doryx . . . added some therapeutic benefits"; (2) the Applesauce Studies improved consumption of Doryx; and (3) dual scoring "provided 'greater flexibility and treatment options.'" Indirect Compl. at ¶ 153. Indirect Plaintiff's fraud-on-the FDA claims are precisely the sort of state law "fraud-on-the-FDA" claims the Court in *Buckman* held to be preempted by federal law: Had Defendants here not made supposedly fraudulent representations to the FDA, the FDA would not have approved the dosage, labeling, or scoring changes to Doryx, generic manufacturers could have entered the market earlier, and Plaintiff would not have been injured. As in *Buckman*, the state-law "fraud-on-the-FDA" claims in Count V are squarely preempted by federal law here and must be dismissed.

B. Federal Law Preempts the Florida FDUTPA Claim (Count VI)

Courts in Florida consistently have held that FDUTPA claims like those in Indirect Plaintiff's Count VI complaining about conduct related to FDA approvals are preempted by federal law.[12] In *Kuenzig v. Kraft Global Foods, Inc.*, the federal district court in Florida held that plaintiffs' FDUTPA state law claims for misleading advertising as to Hormel meats were preempted by FDA and USDA labeling regulations, with which defendant had complied. No. 8:11–cv–838–T–24, 2012 WL 366927, at *2-4 (M.D. Fla. Feb. 3, 2012). Likewise, in *Prohias v. Astrazeneca Pharm.*, which involved product hopping allegations as to Prilosec and Nexium, the Florida court found that plaintiffs' FDUTPA claims were preempted because "Plaintiffs state law

[12] Plaintiff alleges that under Florida law, that Defendants engaged in unfair business practices by "replacing existing versions of Doryx with new versions of Doryx" and "***manipulat[ing] the FDA regulatory processes***." Indirect Compl. ¶ 162 (emphasis added).

claims would conflict with federal law and the FDA-approved Nexium labeling . . . ." 958 So. 2d at 1056. Moreover, courts in Florida routinely have held that FDUTPA is preempted where federal laws regulate a given field, such as for claims as to securities regulations, federal patent law, federal maritime law, and national flood insurance laws. *See, e.g.*, *Riley v. Merrill Lynch*, 168 F. Supp. 2d 1352 (M.D. Fla. 2001) (Securities Litigation Uniform Standard Act preempts FDUTPA claims); *In re Pariseau*, 395 B.R. 492, 495 (Bankr. M.D. Fla. 2008) (Bankruptcy Code preempts FDUTPA claims); *F.W.F. Inc. v. Detroit Diesel Corp.*, 494 F. Supp. 2d 1342, 1352-56 (S.D. Fla. 2007) (maritime law preempts FDUTPA claims); *Stapleton v. State Farm Fire & Cas. Co.*, 11 F. Supp. 2d 1344, 1347 (M.D. Fla. 1998) (National Flood Insurance Act preempts FDUTPA claims). Accordingly, Indirect Purchaser's claims under FDUTPA in Count VI must be dismissed as preempted.

IV. Indirect Plaintiff Fails to Allege an Illegal Conspiracy in Violation of the Sherman Act and State Law in Light of the Supreme Court's Holdings in *Copperweld* and *Iqbal/Twombly* (Counts I-IV, VI)

Like Mylan and the Direct Purchasers, Indirect Plaintiff's contention that Warner Chilcott's IP license somehow constitutes an illegal agreement under either Section 1 or Section 2 of the Sherman Act fails to state a claim. Warner Chilcott incorporates here the arguments set forth in its October 1, 2012 Memorandum (at 44-46) as well as the arguments in Mayne's Memorandum in Support of its Motion to Dismiss the Mylan and Direct Purchaser Complaints. *See* Warner Chilcott Mem. at 44-46; Mayne Mem. at 3-10).

First, as detailed in those memoranda, under *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984), and related precedent, exclusive licensees and licensors such as Warner Chilcott and Mayne are a single entity under the antitrust laws, and thus incapable as a matter of law of conspiring to violate Section 1. *See* Warner Chilcott Mem. at 44-45 (collecting

authorities such as *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499 (D. Del. May 26, 2011)). The antitrust laws are designed to encourage the dissemination of technology via license — here by an Australian company so that its products can reach American patients.

Second, like Mylan, Indirect Plaintiff fails to allege plausibly — as required by *Iqbal* and *Twombly* — that Defendants reached some other illegal agreement to *restrain trade*, where the Complaint is devoid of facts as to any such agreement, relying instead on selected public statements made separately by each of Warner Chilcott and Mayne that Plaintiff claims somehow reflect a joint "anti-generic" strategy. *See* Warner Chilcott Mem. at 44-45, *citing Ashcroft v. Iqbal*, 556 U.S. at 680*; Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499, at *5 (D. Del. May 26, 2011) (dismissing on pleadings Mylan's Section 1 claim because "Mylan has not pled any factual allegations concerning an agreement" between licensor-licensee) (Baylson, J.).

Just as for Section 1, Indirect Plaintiff fails to allege an illegal conspiracy under Section 2 where: (a) Defendants must be treated as single entity for purposes of Section 2; (b) like Mylan, Indirect Plaintiff has failed to allege any facts that plausibly suggest to *Iqbal*'s standards an illegal agreement under Section 2; and (c) Indirect Plaintiff has failed to plead a plausible relevant product market. *See* Warner Chilcott Mem. at 46.

Because the antitrust laws of Nevada and Florida both follow federal antitrust law (*see* Section I.A above), Indirect Plaintiff's state law antitrust claims in Counts III, IV and VI must be dismissed for these same reasons.

V. Indirect Plaintiff's Allegations of the Relevant Product Market Are Implausible and Contrary to Settled Law (Counts I-IV, VI)

The Indirect Complaint also must be dismissed because — like Mylan and the Direct Purchasers — Indirect Plaintiff alleges an implausible product market that is contrary to law and fails to include obvious alternatives for use. *See* Warner Chilcott Mem. at 47-53 (incorporated by reference, collecting authorities).

Indirect Plaintiff's market allegations are stunningly devoid of factual allegations regarding the acne market or competing acne treatments. *See* Indirect Compl. ¶¶ 52-60. After a brief discussion of principles of automatic substitutability (at ¶¶ 54-55) that could apply to any FDA-approved drug and its generic, the Complaint defines the relevant product market as "Doryx and its AB-rated equivalents" as follows:

> 57. ***Because of the competitive relationship between branded drugs and their generic competitors***, such products comprise a distinct product market for antitrust purposes. Thus, ***the product market*** in which to assess the effects of Defendants' conduct ***is the market for Doryx and its AB-rated equivalents***, i.e. the delayed-release doxycycline hyclate market.

Indirect Compl. ¶ 57 (emphasis added). The market definition is not tethered to any facts specific to Doryx or the acne treatment market. *See id*. at ¶¶ 52-60.

Permitting Indirect Purchaser's market definition (a partial molecule — only delayed release doxycycline), which is based entirely on branded and generic drugs having a "competitive relationship," means that ***any branded drug*** could be plugged into Indirect Plaintiff's market definition of the branded drug and its AB-equivalent. Under Plaintiff's approach, this would mean that each and every time a brand name drug manufacturer launched a new version of a branded drug — whether a new strength, dosage form, or scoring — the manufacturer is a monopolist. The Third Circuit long ago rejected such a narrow view of product markets and monopoly in *Sweeney*. *See Sweeney & Sons, Inc. v. Texaco, Inc.*, 637 F.2d

105, 118 (3d Cir. 1980) ("Accepting these arguments would lead to the conclusion that every manufacturer of a trademarked product has monopoly power over that product. No legal precept stands for this proposition, as the Supreme Court has emphatically held . . . .") (citing *United States v. E.I. duPont de Nemours & Co.*, 351 U.S. 377, 393 (1956)). In other words, for every new drug improvement, this Court and other courts could be asked to analyze whether the new FDA-approved drug was a ***sufficient*** innovation so as not to be anticompetitive under the Sherman Act. Indirect Plaintiff's approach is not only contrary to law, unmanageable, and itself an anticompetitive restriction on innovation.

Further, in cribbing from the Mylan/Direct Purchaser product market definition Indirect Plaintiff's product market is implausible for numerous reasons including: 1) Indirect Plaintiff proposes a product market that is a subset of the doxycyline molecule — it excludes both immediate release doxycycline hyclate and doxycycline monohydrate (*see* Warner Chilcott Mem. at 48-49); 2) Indirect Plaintiff's product market hinges on principles of "automatic substitution" (present in only 14 states), but this is not a market test (*see id*. at 49-50)); and 3) Indirect Plaintiff, like Mylan and the Direct Purchaser Plaintiffs, fails to explain its rationale for limiting the relevant product market to a subset of the single molecule and excluding the broad range of acne treatments that a consumer or doctor may view as adequate substitutes (*see id*. at 50-53). For these reasons, the Court should dismiss the Indirect Complaint's antitrust claims for failure to allege a plausible relevant product market. *Id*. at 47, 49-50 (discussing *Queen City*).

VI. Indirect Plaintiff's Florida and Nevada Claims Fail to State a Claim under Specific State Law Requirements (Counts III-VI)

The Indirect Complaint's claims in Counts V and VI under Nevada and Florida consumer deception laws also must be dismissed because they fail in any way to meet those laws'

requirements. These fundamental state law failings provide independent grounds for dismissal under Nevada and Florida law, as set forth below.[13]

In particular, as alleged in the Indirect Complaint, this is not a consumer fraud case. The Nevada and Florida state law deceptive practice claims in Counts V and VI require that a plaintiff allege deception. As a result, Indirect Plaintiff attempts to force-fit its allegations of "product-hopping" and detailing of doctors into a "fraud" theory in a futile effort to satisfy the state law requirements. But, at no time does Indirect Purchaser ever identify a single statement to consumers — as opposed to statements to the FDA or doctors — let alone a statement that could be deemed deceptive. This is frivolous, and the claims under the Nevada and Florida deceptive practices statutes in Counts V and VI requiring deceptive conduct must be dismissed.

A. Indirect Complaint's Nevada Deceptive Trade Practices Statute Claims Must Be Dismissed (Count V)

The Nevada Deceptive Trade Practices Act invoked by Indirect Plaintiff prohibits deception of consumers, but Indirect Plaintiff fails to allege anything like that here. In fact, as discussed below, the only form of communication mentioned at all in the Complaint is marketing or detailing to physicians, which for multiple reasons cannot form the basis for a "deception" claim.

Courts accept well-pled *facts* on a motion to dismiss, but they need not accept conclusions nor draw unreasonable inferences. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.") (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

[13] Moreover, as discussed above, Section III, the Supreme Court has held that state law claims are not the appropriate mechanism to police alleged fraud-on-the-FDA, and such claims therefore are preempted by federal law. *See Buckman*, 531 U.S. at 348, 350.

Moreover, claims sounding in fraud under § 598.0903 of the Nevada statute must meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *See Weinstein v. Home Am. Mortg. Corp.*, No. 2:10-cv-1552, 2010 WL 5463681, at *3 (D. Nev. Dec. 29, 2010). Rule 9(b) requires that, "[i]n alleging fraud or mistake, a party must state *with particularity* the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b) (emphasis added). To set forth the "particularized factual bases for the allegation," plaintiffs must plead "'who, what, when, where, and how' of the alleged fraud." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327-1328 (Fed. Cir. 2009) (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)).

The Nevada Act also requires a plaintiff to allege that "(1) an act of consumer fraud by the defendant (2) caused (3) damage to the plaintiff." *Picus v. Wal-Mart Stores, Inc.*, 256 F.R.D. 651, 658 (D. Nev. 2009); *see* Nev. Rev. Stat. §§ 41.600 and 598.0903, *et seq*. Indirect Plaintiff does not identify which subsection of the Nevada Act it believes could have been violated here and instead cites only §§598.0915 and 598.0923 (Indirect Compl. ¶ 153), which provide lists of different kinds of "deceptive trade practices." In any event, whichever subsection of the Nevada Statute Indirect Plaintiff attempted to invoke, all of them require some form of "deception," which Plaintiff cannot allege or prove.

A Nevada plaintiff also must show that the allegedly deceptive conduct was *relied upon* by consumers. Nev. Rev. Stat. § 598.015, *et. seq.*; *Picus*, 256 F.R.D. at 658. "Under the NDTPA's plain language, to establish a private cause of action, a plaintiff must show a defendant engaged in consumer fraud of which the plaintiff was a victim." *Picus*, 256 F.R.D. at 657; *id*. at 658 (NDTPA claim requires showing of reliance on alleged misrepresentations).

Here, the beginning, middle, and end of Indirect Plaintiff's "fraud" allegation is the following conclusory language from the Complaint:

> Defendants have willfully and unlawfully engaged in deceptive trade practices, by (1) fraudulently representing to consumers and the FDA that their multiple reformulations of Doryx, including changes from capsules to tablets, from 75 mg to 100 mg tablets to single-scored 150 mg tablets, and from single-scored 150 mg tablets to dual-scored 150 mg tablets of Doryx, added some therapeutic benefit for consumers justifying the changes; (2) fraudulently representing to consumers and the FDA that the Tablet and Capsule Applesauce Studies were designed to improve consumption of Doryx, justifying a change in labeling, but only releasing the results of these studies years later on the eve of generic entry; and (3) fraudulently representing to consumers and the FDA, that dual scoring of its 150 mg tablets provided 'greater flexibility and treatment options for patients' when 50 mg and 100 mg dosage options were had [sic] already been available to consumers via 100 mg versions of Doryx.

Indirect Compl. ¶ 153. As noted above (*see* Section III above), *Buckman* completely preempts each of the "fraud-on-the-FDA" portions of ¶ 153(1)-(3), so at most only the fraudulent representation to "consumers" might remain.

Nowhere in the above language, or anywhere else in the Complaint, does Indirect Plaintiff point to any actual false statement made by any Defendant on which a "fraud" theory could be based. *See* Fed. R. Civ. P. 9(b). Nor is the recipient of any false or deceptive statement identified. In fact, Plaintiff fails to allege *any statement at all* — much less a false one.

1. The Indirect Complaint Fails to Allege Any Conduct Directed at Consumers

Indirect Plaintiff also fails to allege any statement or other conduct directed in any way toward *consumers*. Plaintiff's Complaint does not allege any direct-to-consumer advertising for Doryx (*e.g.*, television, radio ads) nor could they.[14] Indirect Plaintiff fails to allege any statement

[14] Direct to consumer advertising, like many other aspects of the pharmaceutical industry, specifically is overseen and reviewed by the FDA and governed by a unique set of rules and regulations. *See* 21 C.F.R. § 202.1.

of any kind to a consumer that conceivably could form the basis of a claim under the Nevada Act.

The only *fact* alleged concerning communications of any kind is that Warner Chilcott used detailing to persuade doctors to prescribe its new versions of Doryx. Indirect Compl. ¶ 81 ("Defendants eliminated the market for the generic products, *shifting prescriptions* from Doryx 75 mg and 100 mg Tablets to the 150 mg Tablets.") (emphasis added). In other words, at most, Indirect Plaintiff is attacking Warner Chilcott's communications *with doctors* concerning Doryx and their effects on prescriptions — but not alleging any of those communications were false. This fails to state a claim under the Nevada Act where the target of these communications is not the consumer, and for that reason alone the claim fails. *See* Nev. Rev. Stat. § 41.600 ("An action may be brought by any person who is a victim of ***consumer fraud***.") (emphasis added).

2. The Indirect Complaint Only Alleges Marketing to Doctors, Which Is Not Covered by the Nevada Statute

The Nevada Act does not even reach pharmaceutical detailing or marketing to doctors. None of the enumerated forms of "deceptive trade practices" listed in the statute describe this form of marketing. And "advertising" under the statute means attempting to "induce, directly or indirectly, any person to enter into any obligation to lease or *to acquire any title or interest in* any property." Nev. Rev. Stat. § 598.0905 (emphasis added). Unlike consumer purchases which are the target of Nevada law, doctors take no "title or interest" in the treatments they prescribe.[15] *See SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978) ("Prescribing

[15] Interpreting the Act so as not to address pharmaceutical detailing is also appropriate because otherwise it would conflict with the First Amendment, which as discussed below protects this activity. *See Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.").

physicians are not cost-conscious in their choices of an antibiotic for a hospitalized patient, and so do not opt for a less expensive over a more costly medication.").

Communications with doctors cannot form the basis of a Nevada claim — particularly where the statements are not alleged to be false. Pharmaceutical detailing is commercial speech protected by the First Amendment. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing [ ] is a form of expression protected by the Free Speech Clause of the First Amendment."). And these communications are made to physicians acting as learned intermediaries exercising their expert professional judgment in making prescription decisions. *See Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 851 (10th Cir. 2003) ("[P]hysicians, based upon knowledge of their own patients, bear the final responsibility for the decision to prescribe medications and to warn the patient of possible side effects."); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 382 (D.N.J. 2004) ("It is for the prescribing physician to use his own independent medical judgment . . . [in deciding] whether to prescribe a given drug"). Any claim, therefore, that the detailing vaguely referenced in the Complaint could be the basis for a claim of deceptive conduct is implausible.

3. The Indirect Complaint Fails to Allege Any Consumer Reliance

Indirect Plaintiff also ignores and fails to allege any form of consumer reliance. Plaintiff claims only that it, a third-party health insurance payor, was forced to pay "supra-competitive and artificially inflated prices for Doryx in the absence of a competing generic doxycycline hyclate product." Indirect Compl. ¶ 155. But this is missing the critical connection to *consumers* required by the Nevada law. Nev. Rev. Stat. § 41.600 ("An action may be brought by any person who is a victim of ***consumer fraud***.") (emphasis added). Indeed, a vague statement of paying "inflated prices" without more does not adequately allege any reliance on any statement, let alone consumer reliance. Nor does Indirect Plaintiff IBEW claim that any false or

deceptive statement was made to it, or even that the IBEW is a "consumer" for purposes of the Nevada deceptive practices statute.

4. The Indirect Complaint Fails to Allege Any Purported Statements Were Untrue

Moreover, even if Indirect Plaintiff had alleged any of the elements of fraud — and it has not despite the requirements of Rule 9(b) — the Complaint would still fail to state a fraud claim. That is because, with respect to many of the alleged subjects of the "fraud," Indirect Plaintiff cannot allege that Defendants made any statement that was untrue.

First, Indirect Plaintiff cannot challenge as "fraudulent" a statement that the launch of a tablet product represented a "benefit" or was "justified." Indirect Compl. ¶ 153. As discussed in Warner Chilcott's motion to dismiss the Mylan and Direct Purchaser Complaints, the court presiding over the earlier patent litigation concerning Doryx flatly *rejected* any claim that there was no benefit in the development from capsules to tablets. *See Mylan*, 2012 WL 1551709; Warner Chilcott Mem. at 25-26. Judge William Martini of the United States District Court for the District of New Jersey held that the tablets represented a novel *invention*, finding that: "To the extent that Defendants are arguing that the Capsule and the Tablet have identical properties, that is plainly incorrect. The Tablet ***improved the dissolution stability*** of the Capsule (among other things)." *Mylan*, 2012 WL 1551709 at *58 (emphasis added). Judge Martini ruled that the patent over the Doryx tablet was valid, and the generic defendant did not appeal that ruling. Indirect Plaintiff cannot claim fraud with respect to a statement — again, holding aside that Plaintiff fails to allege any statement at all — that has been found by a the District Court and Federal Circuit to be true. The Doryx Tablet Patent ('161) is a valid invention, representing an advance over the prior art.

Second, Indirect Plaintiff alleges that Defendants "fraudulently represent[ed] to consumers and the FDA that the Tablet and Capsule Applesauce Studies were designed to improve consumption of Doryx, justifying a change in labeling, but only releasing the results of these studies *years later* on the eve of generic entry." Indirect Compl. ¶ 153 (emphasis added). But the Complaint itself reveals this claim to be baseless. Indirect Plaintiff admits that Defendants first received FDA approval for a tablet product on May 6, 2005. *See* Indirect Compl. ¶ 72. Plaintiff further admits that the tablet applesauce study was released the following year. Indirect Compl. ¶ 76. The Complaint therefore concedes that there is no basis for the assertion that Defendants somehow delayed and waited "over three years" to release the tablet applesauce study. Indirect Compl. ¶ 77.

Finally, Indirect Plaintiff also admits that any communications with the FDA regarding the development of dual-scored 150 mg tablets were not only not fraudulent, but in fact *adopted by the FDA*. Indirect Compl. ¶ 94. As the Complaint alleges, the FDA required Mylan to dual-score its generic Doryx tablet and "approved Mylan's generic version of the single-scored Doryx 150 mg Tablet, with a post-approval requirement to double score Mylan's next manufacturing run." *Id.*; Exhibit 1 (FDA Response to Warner Chilcott Citizen Petition, Feb. 8, 2012 at 1). Presumably, the FDA would not require generic manufacturers to switch to dual-scored tablets if it concluded there was no benefit to doing so. Any alleged communications regarding this subject, therefore, cannot be the basis for a fraud claim.

5. NDTPA Claims Are Barred Because Indirect Plaintiff Is Not "Elderly" or a "Person with a Disability"

Courts have held that the Nevada Deceptive Trade Practices Act allows private enforcement only by an "elderly person" or "a person with a disability." *See, e.g.*, Nev. Rev. Stat. § 598.0977; *In re Chocolate Confectionary Antitrust Litig.*, 749 F. Supp. 2d 224, 234

(M.D. Pa. 2010) (dismissing NDTPA claims where indirect purchaser plaintiffs did not allege to be either elderly or disabled). Even where proposed indirect purchaser classes include members who are elderly or disabled, where the proposed class representatives are not elderly or disabled themselves, a private action under the NDTPA cannot proceed. IBEW does not and of course cannot allege itself to be a qualified "elderly" or "disabled" plaintiff. IBEW therefore may not pursue a claim under this statute.

6. Indirect Plaintiff Fails to Allege Compliance with Pre-Filing Notice Requirements of the Nevada State Antitrust Law

The Nevada antitrust law requires a plaintiff, prior to bringing a claim, to notify the state attorney general of its intentions. Under the NUTPA, a party "commencing an action" under the NUTPA must "simultaneously with the filing of the complaint with the court, mail a copy of the complaint to the Attorney General." Nev. Rev. Stat. § 598A.210. A failure to do so warrants dismissal.

Indirect Plaintiff has not alleged that it has notified the Attorney General. For this additional reason, Indirect Plaintiff's Nevada antitrust claim should be dismissed.

B. Indirect Complaint's Claims Under Florida's Deceptive and Unfair Trade Practices Act Must Be Dismissed (Count VI)

Plaintiff's claim under the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") are fatally flawed for several reasons and must be dismissed.

1. FDUTPA Safe Harbor Bars Claims Regarding Defendants' FDA Petitioning and Marketing of FDA-Approved Doryx (*Prohias*)

Indirect Plaintiff's claims regarding Defendants' marketing of FDA-approved Doryx Products falls within the FDUTPA safe harbor provision and are barred. FDUTPA that provides that no claim arises under FDUTPA where the conduct alleged is required or permitted by federal law: "This part does not apply to: (1) an act or practice required or specifically permitted

by federal or state law." Fla. Stat. § 501.212. Applying this provision, courts in Florida have rejected claims under FDUTPA (such as the one here) based on marketing efforts of federally approved products. The Florida appellate court decision referenced above, *Prohias v. Astrazeneca Pharm.*, 958 So.2d 1054 (Fla. Dist. Ct. App. 2007), is squarely on point. *Prohias* is related to the *Walgreens v. AstraZeneca* decision from the District Court for the District of Columbia that dismissed on the pleadings product hopping claims similar to those alleged here related to Prilosec and Nexium. *See* Section I.B above. The Florida court in *Prohias* considered FDUTPA claims virtually identical the ones asserted here regarding allegations that the Defendant's switching of prescriptions from Prilosec to Nexium, (the alleged "product hopping"), stated a claim under FDUTPA. *Prohias,* 958 So. 2d at 1056. The Florida appellate court upheld the dismissal of the FDUTPA claims because the pharmaceutical promotional marketing was permitted by the FDA:

> [T]he conduct that Plaintiff challenges falls within the safe harbor of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.212(1), because the promotional and advertising activity attacked in the Complaint is supported by the FDA-approved labeling for Nexium® and thus is "specifically permitted" by federal law.

Id. at 1056. In support of this holding, the *Prohias* court cited the Seventh Circuit's decision in *Bober v. Glaxo Wellcome PLC,* 246 F.3d 934 (7th Cir. 2001). In *Bober*, the Seventh Circuit held that state law deception claims regarding pharmaceutical marketing of Zantac could not be brought under Illinois' parallel consumer deceptive practices statute ("CFA") due to the safe harbor provision in that statute, ruling:

> But, recognizing the primacy of federal law in this field, the Illinois statute itself protects companies from liability if their actions are authorized by federal law. . . . Because Glaxo's statements fall with the boundaries established by federal law, under *Weatherman* and *Martin* they are entitled to protections under section 10b(1) of the CFA.

Bober, 246 F.3d at 940. Federal courts in Florida have similarly found such claims regarding marketing of federally regulated products to be outside the scope of FDUTPA. S*ee Kuenzig*, 2012 WL 366927, at *3 (dismissing plaintiff's FDUTPA claim for misleading advertising as within the safe harbor where USDA had approved defendant's label).

Here, each and every action about which Indirect Plaintiff complains — the approvals of versions of Doryx and the marketing of the new Doryx products — was approved by the FDA. *See* Section II above on *Noerr-Pennington* and causation. Defendants' detailing activity (challenged at paragraph 81 of the Indirect Complaint) also is protected by the safe harbor, as it is not only "permitted by federal law" but also is First Amendment protected speech. *See Sorrell*, 131 S. Ct. at 2659 (2011); *see also Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-13 (2004) (holding that presence a comprehensive of regulatory regime (like FDA drug approval process here) was a factor counseling against using antitrust laws to compel sharing by competitors).

Moreover, with respect to the challenged detailing activity, we are not aware of any case explicitly holding that FDUTPA applies to the detailing of doctors or other similarly protected conduct.

2. FDUTPA Claims Are Preempted by FDCA Act and Hatch-Waxman Amendments

Indirect Plaintiff's FDUTPA claims are preempted by the FDCA and Hatch-Waxman Acts, as set forth above in Section III.B. Indirect Plaintiff claims in conclusory fashion that Defendants engaged in unfair and deceptive practices by making certain representations to the FDA. Indirect Compl. ¶ 153. But such "fraud-on-the FDA" claims are preempted by *Buckman* and the other authority discussed above, and Plaintiff's FDUTPA claim must be dismissed on this basis alone.

3. Indirect Complaint Fails to Allege Elements of FDUTPA Claim

To state a claim under FDUTPA, a plaintiff must allege adequately: (1) an unfair practice or deceptive act; (2) causation; and (3) actual damages. *See In re Fla. Cement and Concrete Antitrust Litig.*, 746 F. Supp. 2d 1291, 1320 (S.D. Fla. 2010) (citing *Rollins, Inc. v. Butland*, 951 So. 2d 860, 869 (Fla. 2d DCA 2006)); Fla. Stat. §§ 542.22 and 501.204.

First, to the extent Indirect Plaintiff's FDUTPA claim is based on the portion of the statute addressing deception, the claim should be dismissed for the reasons discussed above. Courts have applied the standards of Rule 9(b) to FDUTPA claims directed at "deceptive" conduct. *See, e.g.*, *Sunoptic Tech., LLC v. Integra Luxtec, Inc.*, No. 3:08-cv-878-J-16JRK, 2009 WL 722320, at *2 (M.D. Fla. Mar. 18, 2009) (dismissing fraud claims under FDUTPA where fraud claims failed to "meet the heightened pleading standard under Rule 9(b)"); *Wrestlereunion, LLC v. Live Nation Tel. Holdings, Inc.*, No. 8:07-cv-2093, 2008 WL 3048859, at *3 (M.D. Fla. Aug. 4, 2008) ("Plaintiff's contention, without citation to authority, that its FDUTPA claim is not required to be pled with particularity is rejected."); *Fla. Digital Network, Inc. v. N. Telecom, Inc.*, No. 6:06-cv-899, 2006 WL 2523163, at *5 (M.D. Fla. Aug. 30, 2006) ("claims arising under the FDUTPA must be pled with particularity"; dismissing claims of "unconscionable, unfair and deceptive" acts that failed to satisfy 9(b)).

Here, Indirect Plaintiff fails to plead any element of fraud or provide any specific factual allegations to support a claim that Defendants' alleged conduct was deceptive under the statute. Indirect Plaintiff merely restates the statutory language and states in conclusory fashion that "deceptive acts" must have occurred. Indirect Compl. ¶ 162. That does not state a claim for fraud under FDUTPA or any other law. *See also* Rule 9(b); *Twombly*.

Second, to the extent Plaintiff IBEW's claim is based on the portion of the statute prohibiting "unfair" conduct, this claim also should be dismissed. Indirect Plaintiff alleges three

bases for its FDUTPA claim: (1) "replacing existing versions of Doryx with new versions of Doryx," (2) "anti-competitive reverse payment settlement agreements," and (3) "manipulat[ing] the FDA regulatory processes to delay or prevent generic competition to Doryx." Indirect Compl. ¶ 162. All three bases fail to state to claim.

The first reason (¶ 162(1), restating the "product hopping" allegation) should be dismissed for the many reasons set forth in this memorandum (Section I above) and Warner Chilcott's earlier motion to dismiss. The second reason (¶ 162(2), alleged "anti-competitive settlement agreements") has been withdrawn by Indirect Plaintiff and is no longer pending, as discussed below. *See* Section VIII above. And the third reason (¶ 162(3), "manipulating the FDA regulatory processes") is FDA petitioning protected by *Noerr* (*see* Section II above), and any state law claim for "fraud-on-the-FDA" is preempted. *See Buckman*, 531 U.S. 341, 347 (2001) ("Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'") (citation omitted); *id.* ("the relationship between a federal agency and the entity it regulates is inherently federal in character"); *id.* at 348 ("we hold that the plaintiff's state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law."); *see* Section III above.

As discussed above, Indirect Plaintiff attacks nothing more than seeking approval to market new products, obtaining that approval, and marketing the products — all in a manner consistent with the governing Hatch-Waxman regulatory scheme. Any claim under FDUTPA based on such conduct is preempted. *See Buckman*, 531 U.S. at 348 ("[S]tate-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law."); *Kuenzig*, 2012 WL 366927, at *2-4 (plaintiffs' FDUTPA state law claims for misleading advertising as to

Hormel meats were preempted by FDA and USDA regulations); *Prohias*, , 958 So. 2d at 1056 (FDUTPA claims preempted by FDA labeling regulations).

Such conduct cannot be deemed "unfair" under FDUTPA under any interpretation of that statute. If Plaintiff is right, then *Florida law* imposes a requirement — over the top of and contrary to Hatch Waxman — that Warner Chilcott keep old versions of its pharmaceutical products on the market as long as necessary to help Warner Chilcott's competitors. If Plaintiff is right, then the launch of a tablet product — even though recognized by a trial court and the Federal Circuit as an invention — is illegal under *Florida law*. If Plaintiff is right, then dual-scoring — even though, as Plaintiff admits, the FDA required the generic manufacturer here to switch to dual-scored tablets — is illegal under *Florida law*. This cannot be what the Florida legislature intended when it sought to protect consumers from "unfair" conduct in FDUTPA, and to make that clear Florida enacted the Safe Harbor for activities "permitted" under federal law. *See Prohias*, *Bober*, above. Accordingly, Plaintiff's claim FDUTPA claim must be dismissed.

4. FDUTPA Claim Must Be Dismissed to the Extent It Seek to Recover for Alleged Injuries Outside of Florida

Only a plaintiff who has been injured in Florida may pursue a claim under FDUTPA; a plaintiff who has purchased a product outside of Florida cannot invoke FDUTPA to seek relief based on those purchases. *See Montgomery v. New Piper Aircraft, Inc.*, 209 F.R.D. 221, 227 (S.D. Fla. 2002) (finding that plaintiff whose purchase of relevant product and alleged injury occurred in Texas lacked standing to bring a claim under FDUTPA and denying class certification in part because "there is no evidence in the record of any putative class members having suffered any alleged injury in Florida."); *Coastal Physician Servs. of Broward Cnty. v. Ortiz*, 764 So. 2d 7, 8 (Fla. Dist. Ct. App. 1999) (concluding that FDUTPA is "for the protection of in-state consumers").

Here, Indirect Plaintiff seeks relief on behalf of the purported Florida Indirect Purchaser Class in a manner that suggests that it is claiming damages for reimbursements that the IBEW has made outside of Florida. Specifically, Indirect Plaintiff claims that it and the Florida Indirect Purchaser Class assert claims as to Doryx "that was manufactured, produced, marketed, sold or purchased, in the state of Florida." Indirect Compl. ¶ 108. Such a broad category of claims clearly could include reimbursements made outside of the state (*e.g.*, product "marketed" in Florida but purchased out of state) and therefore outside the reach of FDUTPA. For this additional reason, the FDUTPA claim should be dismissed.[16]

C. Any Florida Antitrust Act Claims Must Be Dismissed Because Florida Does Not Permit Indirect Purchaser Damages Claims (Count VI, Prayer for Relief)

It appears that Indirect Plaintiff also seeks to bring antitrust damages claims under Florida law, based on an oblique reference in Count VI to § 542.22 of the Florida statutes (Indirect Compl. ¶ 166) and a reference in the Demand for Judgment for "three-fold" damages based on Florida state law claims (Demand ¶ 4). Section 542.22 is part of the Florida Antitrust Act of 1980. Such a claim for three-fold damages by indirect purchasers must be dismissed as not permitted by Florida law.

The Supreme Court's decision in *Illinois Brick* bars indirect purchasers from pursuing antitrust claims for damages under the Sherman Act. *Illinois Brick*, 431 U.S. at 740 ("[A]llowing indirect purchasers to recover using pass-on theories . . . would transform treble-damages actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant."). Thus, only if a state

[16] To the extent Indirect Plaintiff asserts a claim for any purported class members who did not suffer injury in Florida or Nevada, such class claims should be stricken, as plaintiffs would not have standing to pursue such claims.

has enacted a separate baby state Sherman Act with an *Illinois Brick* repealer provision may an indirect purchaser sue for damages under a state antitrust law. Florida has not enacted such a *Illinois Brick* repealer statute, and, accordingly, courts have held that *Illinois Brick* bars indirect purchaser standing under the Florida antitrust law. *See Mack v. Bristol-Myers Squibb Co.*, 673 So. 2d 100, 108 (Fla. Dist. Ct. App. 1996) ("Florida Legislature has declined to adopt" an *Illinois Brick* repealer statute). Thus, the Florida baby Sherman Act does not permit indirect purchasers, such as IBEW, to pursue a damages claim in federal court. Accordingly, Indirect Plaintiff's Florida Antitrust Act claim, and with it the demand for treble damages, must be dismissed.

VII. The Four-Year Statutes of Limitations Bar Plaintiff from the Damages Recovery It Seeks (Counts I-VI)

A. All of the Challenged New "Product Switches" (Except Dual-Scoring) Occurred Prior to the State and Federal Four-Year Statutes of Limitations

All of the Doryx "product-switching" conduct alleged by Indirect Plaintiff is outside the applicable four-year statutes of limitations and therefore time-barred, except for dual-scoring, which is addressed below.

The statute of limitations is four years for all the Florida and Nevada claims asserted by Plaintiff — the only statutes for which Indirect Plaintiff seeks damages. Fla. Stat. Ann. § 95.11(3)(f) (four-year statute of limitations for any "action founded on a statutory liability"); Nev. Rev. Stat. § 598A.220 (four-year statute of limitation for an action under 589A.210); Nev. Rev. Stat § 11.190(2)(d) (four-year period of limitation for deceptive trade practice action); *see also Bosuwan v. First Option Mortgage, LLC*, No. 2:09-cv-2292, 2012 WL 1330424, at *2 (D. Nev. Apr. 16, 2012) ("A claim for consumer fraud must be filed within four (4) years after an event which would constitute consumer fraud under NRS 41.600(2)."). The federal antitrust statute is also subject to a four-year statute of limitations. 15 U.S.C. § 15b; *see* Warner Chilcott Mem. at 53-55 (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971);

Klehr v. A.O. Smith Corp., 521 U.S. 179, 189 (1997) (analogizing civil RICO statute of limitations to antitrust cases)).

Indirect Plaintiff filed its Complaint on September 21, 2012, so the four-year limitations period goes back to September 21, 2008. Thus, all of Indirect Plaintiff's claims (except for the dual-scoring) fail based on the four-year statutes of limitations for the same reasons Mylan's and Direct Purchaser Plaintiffs' claims fail — the complaint seeks damages arising from events more than four years old, and such claims are thus time-barred:

- Specifically, Indirect Plaintiff admits that Defendants received FDA approval for the 75 and 100 mg tablet products on May 6, 2005 (Indirect Compl. ¶¶ 63, 70, 72; *see also* ¶ 6), and any claim based on the tablets thus is time-barred, being over *three* years outside the four-year statute of limitations period.

- Indirect Plaintiff also admits that the discontinuation of the marketing of capsules occurred by the end of June 2006 (Indirect Compl. ¶¶ 65, 72), and any claim based on that conduct is time-barred, having occurred over *two* years outside the statute.

- Indirect Plaintiff further concedes that the applesauce labeling change attacked in the Complaint took place in February 2006 (Indirect Compl. ¶¶ 76-77; *see also* ¶ 6), which also is time barred because it took place more than *two* years outside the four-year statute of limitations period.

- Indirect Plaintiff admits that Defendants obtained FDA approval for the 150 mg tablet on June 20, 2008 (Indirect Compl. ¶ 66, 80) and "soon thereafter" stopped promoting the 75 mg and 100 mg tablets (*id*. at ¶ 66). Claims arising from these events are also time-barred, having occurred almost three months outside the limitations period (September 21, 2008).

Accordingly, any claims based on the above conduct (the launch of tablets, applesauce labeling, the launch of 150 mg tablets) are each time-barred and cannot form the basis for any relief requested in this action.

B. The Only In-Time Conduct Is the Introduction of the Dual-Scored Product Which Caused No Damages and Can Form the Basis for No Liability under State or Federal Law

The only "product switch" or "product hop" to have occurred after September 21, 2008 was the so-called "third switch" (Indirect Compl. ¶ 8) "from a single scored version of Doryx

150 mg tablets to a dual-scored version of Doryx 150 mg tablets." *Id.* This third "switch" was accomplished allegedly by means of a September 2011 Citizen Petition. *Id.*

But Indirect Plaintiff suffered no damages due to the Citizen Petition. First, the FDA did not approve Mylan's generic for sale until February 8, 2012, the same date on which the FDA responded to Warner Chilcott's Citizen Petition. Indirect Compl. ¶ 94 ("On the same day as the FDA rejected Defendants' citizen petition, it approved Mylan's generic version of the single-scored Doryx 150 mg Tablet, with a post-approval requirement to double score Mylan's next manufacturing run."). Not only did Mylan lack FDA approval prior to that date, Mylan was barred during the pendency of the Citizen Petition due to the Patent Court's Injunction and Mylan's own voluntary TRO, which kept Mylan off of the market until April 2012, well after the February 8, 2012 date that FDA ruled on the Citizen Petition. *See* Section II.B.3 above. Therefore, Indirect Plaintiff cannot allege that the dual-scored 150 mg tablet delayed the entry of any lower cost generic product that Indirect Plaintiff could have purchased.

Second, no state statute can overcome the *Noerr-Pennington* bar on petitioning of government agencies. *See* Section II.D above. For these reasons, there is no recovery available to Indirect Plaintiff at all.

VIII. Indirect Plaintiff Has Voluntarily Dismissed Allegations Concerning Patent Settlements With Generic Firms (*E.g.*, Paras. 5-8, 85-87, 118(2))

Although Indirect Plaintiff originally included in its Complaint certain allegations challenging alleged "anti-competitive agreements with generic drug manufacturers" (Indirect Compl. ¶ 5; *see also* ¶ 7) — that is, patent settlements between Defendants and generic manufacturers Heritage and Sandoz — Plaintiff has voluntarily dismissed those allegations, and they no longer form part of the Complaint. The allegations regarding the patent settlement agreements with Heritage and Sandoz were set forth primarily in the Indirect Complaint at

Paragraphs 5-8, 85-87, with subsequent references appearing for example in paragraphs 100, 114(i), 118(2) ("anti-competitive settlement agreements"), 127(2), 135(2), 144(2), 162(2) ("anti-competitive reverse payment settlement agreements") and generally in Counts I-IV and VI.

Plaintiff's allegations had been made "upon information and belief." Prior to the filing of this motion, Defendants provided to Plaintiff information regarding the settlement agreements with Heritage and Sandoz, and Plaintiff subsequently agreed to dismiss from the Complaint claims challenging those settlements. On October 29, 2012, Plaintiff and Defendants filed a stipulated voluntary notice of dismissal of claims relating to the patent settlements. *See* Stipulation of Dismissal of Claims, Civ. No. 12-3824, Dkt. No. 99 (Oct. 29, 2012). As a result, those claims and challenges to the patent settlements are no longer part of the Indirect Complaint or any of the Counts of the Indirect Complaint.

CONCLUSION

For the foregoing reasons, Warner Chilcott respectfully requests that this Court dismiss all of Plaintiff's claims with prejudice.

Respectfully submitted this 31st day of October, 2012.

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