UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE ASACOL ANTITRUST LITIGATION	)	**Civil Action No. 15-cv-12730-DJC**

MEMORANDUM AND ORDER

CASPER, J. **July 20, 2016**

I. Introduction

Teamsters Union 25 Health Services & Insurance Plan, NECA-IBEW Welfare Trust Fund, United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund, Wisconsin Masons' Health Care Fund, Minnesota Laborers Health and Welfare Fund (collectively, "Health Fund Plaintiffs"), and Mark Adorney (collectively, "Plaintiffs") bring this antitrust class action on behalf of themselves and all others similarly situated against Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (collectively, "Zydus"), Allergan plc, Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, and Warner Chilcott Limited (collectively, "Warner Chilcott") (collectively, "Defendants"). Plaintiffs allege that Warner Chilcott's product hopping scheme and a reverse payment settlement agreement between Warner Chilcott and Zydus constitute monopolization (Count I) and combination and conspiracy in restraint of trade (Count II), respectively, under various state laws. D. 26.

Zydus has moved to dismiss Count II, D. 46, and the Warner Chilcott has moved to dismiss the entire complaint, D. 47. Plaintiffs have moved to strike materials attached in support of the

Warner Chilcott's motion to dismiss. D. 56. The Court ALLOWS Zydus's motion to dismiss, ALLOWS IN PART and DENIES IN PART Warner Chilcott's motion to dismiss and DENIES Plaintiffs' motion to strike.

II. Standard of Review

On a motion to dismiss under Rule 12(b)(6), the Court must conduct a two-step, context-specific inquiry. García-Catalán v. United States, 734 F.3d 100, 103 (1st Cir. 2013). First, the Court must distinguish the factual allegations from the conclusory legal allegations. Id. Factual allegations are accepted as true, while conclusory legal allegations are not. Id. Second, the Court must determine whether the factual allegations "plausibly narrate a claim for relief." Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55 (1st Cir. 2012). "Plausible, of course, means something more than merely possible, and gauging a pleaded situation's plausibility is a 'context-specific' job that compels [the Court] 'to draw on' [its] 'judicial experience and common sense.'" Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009)).

III. Factual Allegations

Unless otherwise noted, the following factual summary is based upon the factual allegations in the amended complaint, D. 26, and are accepted as true for the consideration of the Defendants' motions to dismiss.

A. Asacol, Asacol HD and Delzicol

Ulcerative colitis is a chronic inflammatory bowel disorder. D. 26 ¶ 60. The most common treatment for ulcerative colitis is a class of drugs that contain the active ingredient mesalamine. Id. ¶ 62. Asacol, Asacol HD and Delzicol are all ulcerative colitis treatments that contain mesalamine. Id. ¶¶ 66, 72, 108.

Under the Federal Food, Drug and Cosmetic Act ("FDCA"), a manufacturer must obtain

approval from the Food and Drug Administration ("FDA") to sell any drug in the United States. Id. ¶ 26. The manufacturer must submit a new drug application so the FDA can determine whether the drug is both safe and effective for its proposed uses. Id. Once the FDA approves the drug, manufacturers may protect the product by listing applicable patents in the FDA's "Orange Book," which includes all FDA-approved prescription drugs, their approved generic equivalents and any patents that purportedly protect each drug. Id. ¶ 27.

In January 1992, the FDA approved Asacol, a delayed-release oral tablet containing 400 mg of mesalamine to treat mild to moderately active ulcerative colitis. Id. ¶ 65. Five years later, the FDA approved Asacol for the maintenance of the remission of ulcerative colitis. Id. The Orange Book lists two patents for Asacol, U.S. Patent Nos. 5,541,170 ("the '170 patent") and 5,541,171 ("the '171 patent"). Id. ¶ 67. Both patents expired July 30, 2013. Id.

In May 2008, the FDA approved Asacol HD, a delayed-release oral tablet containing 800 mg of mesalamine to treat moderately active ulcerative colitis. Id. ¶¶ 72-73. Unlike Asacol, Asacol HD was not approved for mildly active ulcerative colitis or the maintenance of remission of ulcerative colitis. Id. ¶ 73. The Orange Book lists two patents for Asacol HD, U.S. Patent Nos. 6,893,662 and 8,580,302. Id. ¶ 74. Both expire on November 15, 2021. Id.

In February 2013, the FDA approved Delzicol, a delayed-release oral tablet containing 400 mg of mesalamine. Id. ¶¶ 108-11. The Orange Book lists U.S. Patent No. 6,649,180 ("the '180 patent") for Delzicol, which expires on April 13, 2020. Id. ¶ 114.

B. Hatch-Waxman Regulatory Framework

In 1984, Congress enacted the Hatch-Waxman Act to facilitate competition from low-price generic drugs. Id. ¶ 31. Once the FDA has approved a brand-name drug, the Hatch-Waxman Act allows a generic manufacturer to obtain similar approval by filing an Abbreviated New Drug

Application ("ANDA") specifying that the generic has the same active ingredient and is bioequivalent to the brand-name drug. Id. ¶ 32.

The generic manufacturer must certify that it will not infringe any of the patents listed in the Orange Book for the brand-name drug. Id. ¶ 34. One possible basis for non-infringement is known as Paragraph IV certification, in which the generic manufacturer asserts that all applicable patents are invalid or will not be infringed by the proposed generic drug. Id. If the patent owner brings an infringement suit within 45 days of receiving the Paragraph IV notice, the FDA cannot approve the generic manufacturer's ANDA for 30 months, a time when parties are supposed to litigate the infringement or validity of the patent. 21 U.S.C. § 355(j)(5)(B)(iii). The Hatch-Waxman Act bestows upon the first generic company that files an ANDA with a Paragraph IV certification a 180-day period of marketing exclusivity, during which no other generic can compete. Id. § 355(j)(5)(B)(iv); see D. 26 ¶ 52. The brand-name manufacturer, however, may release an authorized generic version of its drug during the exclusivity period. D. 26 ¶ 49. An authorized generic is chemically identical to the brand-name drug but sold as a generic product. Id.

C. Anti-Competitive Allegations

Plaintiffs allege that this case involves product hopping and a reverse payment settlement agreement. Product hopping is the practice of tweaking a brand-name drug to prevent pharmacists from substituting a generic equivalent when presented with a prescription for the newly modified brand-name drug. Id. ¶ 45; see New York ex rel. Schneiderman v. Actavis PLC ("Namenda"), 787 F.3d 638, 643 & n.2 (2d Cir. 2015) (stating that "conduct by a monopolist to perpetuate patent exclusivity through successive products" is "commonly known as 'product hopping'"). To further product hopping, a brand-name manufacturer often removes the original drug from the market

entirely, known as a "hard switch," right before patent expiration to deprive potential generic manufacturers a prescription base for their generic drugs. D. 26 ¶ 45; Namenda, 787 F.3d at 648. In a reverse payment settlement agreement, a brand-name manufacturer who holds a patent compensates a potential generic rival to delay or abandon market entry and to abandon the challenge to the brand manufacturer's patent. D. 26 ¶ 51; F.T.C. v. Actavis, Inc., __ U.S. __, 133 S. Ct. 2223, 2227 (2013) (noting that such an agreement is known as reverse payment settlement agreement because the settlement "requires the patentee to pay the alleged infringer, rather than the other way around"). Reverse payment settlement agreement raise concerns because they "insulat[e] the brand's market from competition and prevent[] consumers from accessing a more affordable generic version of the brand-name drug." In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 544 (1st Cir. 2016).

1. Promotion of Asacol HD

Plaintiffs allege that Warner Chilcott[1] acquired Asacol and Asacol HD in 2009. D. 26 ¶ 77. That year, Asacol was the 75th top-selling prescription in the United States, with sales of approximately $490 million. Id. ¶ 78. Shortly after the 2009 acquisition, Warner Chilcott sought

[1] Plaintiffs state in their complaint that "[a]ll references in the complaint to 'Warner Chilcott' include Warner Chilcott plc and "all related entities and subsidiaries that were acquired by Actavis plc (now operating as 'Allergan plc' as of June 15, 2015) and/or Warner Chilcott Limited as part of the October 1, 2013 acquisition and transaction." D. 26 n.1. Warner Chilcott argues that Plaintiffs have named the wrong entities as defendants because Warner Chilcott Company LLC (an unnamed party) signed the Settlement Agreement and therefore they should be dismissed from the case. D. 52 at 60-62. Plaintiffs acknowledge that their complaint does not name Warner Chilcott Company LLC as a defendant. D. 54 at 19. Nevertheless, they point out that "[a]lthough an improper defendant is indicated in the caption, we may consider a complaint to have named the proper defendant if the allegations made in the body of the complaint make it plain that the party is intended as a defendant." Callahan v. Wells Fargo & Co., 747 F. Supp. 2d 247, 251 (D. Mass. 2010) (internal quotation marks and citation omitted). Because the operative complaint makes clear that Warner Chilcott Company LLC is an intended party, the Court considered it named and analyzed the motions accordingly.

to switch patients from Asacol to Asacol HD before the '170 and '171 patents for Asacol expired, even though the drugs did not treat the exact same issues. Id. ¶¶ 81-87. The biggest difference is that Asacol was approved for low-dose, long-term maintenance of remission therapy, which accounts for the bulk of its prescriptions, while Asacol HD was approved only for the high-dose, short-term treatment of the most severe flares. Id. ¶ 83. Warner Chilcott's efforts to switch patients to Asacol HD was remarkably successful. Id. ¶ 97. In 2010, Asacol HD made up 9% of Warner Chilcott's total Asacol franchise sales. Id. By 2012, Asacol HD sales constituted 28% of the company's Asacol franchise sales. Id.

2. Citizen Petitions to Drive Up the Cost of Generic Entry

Warner Chilcott also allegedly submitted multiple FDA citizen petitions to make it harder for other companies to sell generic Asacol. Id. ¶ 98. A citizen petition allows a person or organization to express concerns to the FDA about the safety, efficacy or legality of a proposed or existing drug. Id. ¶ 99.

In February 2010, Warner Chilcott submitted a citizen petition that requested the FDA to require generic Asacol applicants to submit comparative clinical endpoint studies, comparative in vitro dissolution test, and comparative pharmacokinetic safety testing as a condition to FDA approval. Id. ¶ 101. In August 2010, the FDA denied Warner Chilcott's request for clinical endpoint studies. Id. ¶ 103. Two months later, Warner Chilcott submitted another citizen's petition. Id. ¶ 104. This petition requested that the FDA establish heightened bioequivalency requirements for generic competitors to Asacol and Asacol HD. Id. The FDA denied this request as well; Warner Chilcott's citizen petitions were thus "largely unsuccessful." Id. ¶¶ 105-06.

3. Promotion of Delzicol and the Hard Switch

Despite a concerted three-year effort to switch Asacol patients to Asacol HD, Warner

Chilcott realized that patients and prescribers still preferred the original product because Asacol still constituted nearly 72% of the sales of the overall franchise in 2012. Id. ¶ 107.

In 2013, Warner Chilcott began selling Delzicol. Id. ¶ 108. That same year, a few months before the expiration of Asacol's patents in July 2013, Warner Chilcott discontinued Asacol. Id. ¶ 144. Warner Chilcott did so because it knew discontinuing Asacol would weaken a generic drug's ability to convert Asacol's market share. Id. ¶¶ 144-49. Manufacturers of generics rely on state laws that often require pharmacists to substitute an AB-rated generic drug to the brand-name drug to gain market share. Id. ¶ 147. An AB-rated generic drug is a generic drug determined by the FDA to meet strict bioequivalence testing standards that show it has the same efficacy and safety profile as the brand drug. Id. ¶ 35.

During the FDA approval process, Warner Chilcott identified only two differences between the drugs: (1) Delzicol consists of a cellulose capsule around an Asacol tablet and (2) Delzicol contains dibutyl sebacate ("DBS") as an inactive coating ingredient, while Asacol contains dibutyl phthalate ("DBP") instead. Id. ¶ 112. The cellulose capsule is covered by the '180 patent, which does not expire until 2020. Id. ¶ 114.

Plaintiffs allege that Warner Chilcott created Delzicol to further its monopolization scheme.[2] Id. ¶ 116. First, the FDA approved Delzicol based on its bioequivalence to Asacol. Id.

[2] Plaintiffs, in D. 56, urge the Court to strike Exhibits 2-17 attached to the Cole Declaration, D. 53, which Defendants assert may be considered without converting the motions to dismiss into motions for summary judgment, see D. 63. The Court ALLOWS *nunc pro tunc* Plaintiffs' motion for leave to file a reply memorandum in support of their motion to strike, D. 74, and considered it in resolving the motion to strike. The Court declines to consider Exhibits 2-9 because the parties want the Court to draw competing factual inferences from these exhibits, an inappropriate task at this stage. See Evergreen Partnering Grp., Inc. v. Pactiv Corp., 720 F.3d 33, 45 (1st Cir. 2013) (noting that "[i]t is not for the court to decide, at the pleading stage, which inferences are more plausible than other competing inferences, since those questions are properly left to the factfinder"). The Court, however, takes judicial notice of Exhibits 10-11 only for the purpose that the FDA has not yet approved generics for Asacol and Asacol HD. D. 53-10, D. 53-11. The Court

¶ 117. This eliminates the possibility that the Delzicol capsule, which is triggering its patent protection, makes Delzicol a medically superior product to Asacol. Id. Second, the cellulose capsule dissolves quickly in stomach acid. Id. ¶ 118. The capsule thus provides no additional protection to the active drug ingredients in Asacol, which is already covered in a coating designed to protect the active drug ingredients from stomach acid. Id. Third, Warner Chilcott did not need to include the capsule in Delzicol to replace the DBP in Asacol with DBS. Id. ¶ 119. Warner Chilcott currently sells a DBP-free 400 mg Asacol tablet in the United Kingdom, which shows how the capsule is an unnecessary modification. Id. In fact, for many patients, the capsule has made Delzicol more difficult to swallow than Asacol. Id. ¶ 120.

Plaintiffs also allege that Warner Chilcott's purported concerns about DBP in Asacol was simply a pretext to create Delzicol. Id. ¶ 127.[3] First, Warner Chilcott was not required to remove Asacol from the market to remove DBP from the product. Id. ¶ 134. Consistent with the FDA's recommendations, the company could have simply removed the DBP from Asacol, replaced it with DBS, and then submitted the necessary regulatory submissions to establish that DBS was safe. Id. Instead, Warner Chilcott chose to introduce a new patent-protected product while simultaneously destroying the market for Asacol, which faced imminent generic competition. Id.

Second, the DBP concerns primarily applied to pregnant and nursing women and young children. Id. ¶ 135. As of May 2010, Asacol's label already recommended limited use by pregnant and nursing women and warned that the safety and effectiveness of Asacol for young children had

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did not rely on Exhibits 12-17 in considering the motions to dismiss. The request to strike Exhibits 12-17, D. 56, is thus denied as moot.

[3] In March 2012, the FDA issued draft guidance recommending that manufacturers avoid two substances (one of which was DBP) because research had suggested that the two substances were linked to poor reproductive and developmental outcomes. D. 26 ¶ 131. The FDA finalized this guidance in December 2012. Id. ¶ 132.

not been established. Id. Third, Warner Chilcott's subsidiary in Canada continued to sell Asacol and Asacol HD, both of which contained DBP, to Canadians as of December 29, 2014. Id. ¶ 136. Had the company believed that removing DBP resulted in a better product, it would have introduced DBP-free versions of both drugs. Id.

Fourth, concerns over DBP had been known since the 1990s. Id. ¶ 137. Yet Warner Chilcott and its predecessor released Asacol HD in 2008, which contains more DBP than Asacol, despite these concerns. Id. ¶¶ 128, 137. Fifth, because of Asacol HD's higher DBP content, had Warner Chilcott truly been concerned about DBP, it would have developed a replacement for Asacol HD first. Id. ¶ 138. Sixth, Warner Chilcott continued to give Asacol to children in pediatric trials as last as March 2011. Id. ¶ 139. Seventh, had Warner Chilcott been legitimately concerned about DBP, it would not have aggressively sought to switch Asacol patients to Asacol HD. Id. ¶ 140. Finally, Warner Chilcott sought, and the FDA approved, Asacol for children on October 18, 2013, after the company had removed Asacol purportedly over its concerns about DBP. Id. ¶ 141.

Shortly after Delzicol's release, doctors and patients have quickly realized that Delzicol is essentially Asacol surrounded by an unnecessary capsule. Id. ¶ 122. Members of the public have made videos, posted pictures, or written online about their frustration over the lack of differences between the two. Id. ¶¶ 122-26.

When Allergan plc acquired Warner Chilcott, Warner Chilcott's efforts to throttle generic competition received praise during the merger. Id. ¶ 163-64. Asacol HD and Delzicol had approximately $550 million in sales in 2014. Id. ¶ 166.

4. The Settlement Agreement with Zydus and Allegations of a Large and Unjustified Reverse Payment

In September 2011, Zydus filed an ANDA seeking permission from the FDA to sell a generic version of Asacol HD. Id. ¶ 170. Zydus filed a Paragraph IV certification, which meant

it intended to challenge the Asacol HD patents. Id. After two years of litigation, Warner Chilcott and Zydus announced a settlement agreement ("Settlement Agreement") in December 2013. Id. Zydus was the first Paragraph IV filer, which meant it qualified for the 180-day marketing exclusivity period under Hatch-Waxman.

Under the Settlement Agreement, Zydus has two options to sell a generic Asacol HD.[4] D. 53-1. Under the first option, Zydus can enter the market with its own generic starting November 15, 2015 (or earlier under certain conditions) if Zydus receives FDA approval of its ANDA.[5] Id. at 10-11. In exchange, Zydus would pay Warner Chilcott a 25% royalty of Zydus's net sales. Id. at 11. Warner Chilcott, however, would maintain the option to supply an authorized Asacol HD generic to its affiliates (but not third-parties) during Zydus's marketing exclusivity period. Id. at 18; D. 26 ¶ 49.

Under the second option, if the FDA does not approve Zydus's ANDA, Zydus has the option to sell an authorized generic version of Asacol HD from Warner Chilcott beginning July 2, 2016. D. 53-1 at 17. Warner Chilcott would be barred from supplying an authorized generic to its affiliates or any third party for two years. Id. at 18. In exchange, Zydus would pay 75% of its profits to Warner Chilcott. Id. at 41. If Zydus receives FDA approval, the second option terminates automatically. Id. at 53-1 at 17.

Plaintiffs allege that the Settlement Agreement between Warner Chilcott and Zydus was an improper reverse payment settlement agreement. D. 26 ¶¶ 171-75.

[4] Plaintiffs agree that the Court may consider the Settlement Agreement, referenced in the amended complaint, at this stage. D. 57 at 12.

[5] The Settlement Agreement also contains acceleration clauses, which would have allowed Zydus to sell its generic Asacol HD product even earlier than November 15, 2015 had a third party entered the market or obtained a favorable judicial decision. D. 53-1 at 10, D. 52 at 71. Plaintiffs, however, do not allege that these provisions are unlawful and concede that the Court need not consider them. D. 54 at 18 n.13.

IV. Procedural History

On December 28, 2015, six different end-payor actions filed against Defendants in the District of Massachusetts were consolidated for pretrial purposes and assigned to this Court. D. 20 at 2. On January 4, 2016, Plaintiffs filed a consolidated amended class action complaint. D. 26. Zydus subsequently filed a motion to dismiss Count II and the Warner Chilcott filed a motion to dismiss the entire complaint. D. 46, D. 47. Plaintiffs then filed a motion to strike certain materials submitted with Warner Chilcott's motion to dismiss. D. 56. The Court heard the parties on the motions and took them under advisement. D. 84.

V. Discussion

A. Standing

"The Constitution carefully confines the power of the federal courts to deciding cases and controversies." Merrimon v. Unum Life Ins. Co. of Am., 758 F.3d 46, 52 (1st Cir. 2014) (citing U.S. Const. art. III, § 2). To establish standing under the Constitution, "a plaintiff must establish each part of a familiar triad: injury, causation, and redressability." Id. (citation and internal quotation marks omitted).

A plaintiff who brings a private right of action for antitrust violations must also establish standing to bring an antitrust action. Courts consider "(1) the causal connection between the alleged antitrust violation and harm to the plaintiff; (2) an improper motive; (3) the nature of the plaintiff's alleged injury and whether the injury was of a type that Congress sought to redress with the antitrust laws . . . ; (4) the directness with which the alleged market restraint caused the asserted injury; (5) the speculative nature of the damages; and (6) the risk of duplicative recovery or complex apportionment of damages." RSA Media, Inc. v. AK Media Grp., Inc., 260 F.3d 10, 14

(1st Cir. 2001) (citation omitted).[6]

1. Count I

Warner Chilcott argues that Plaintiffs lack standing for Count I because Plaintiffs do not sufficiently allege that Warner Chilcott's product hopping conduct prevented or delayed generic entry of Asacol. D. 52 at 34-36. Plaintiffs argue that their allegations sufficiently show that had Defendants not destroyed the Asacol market with their hard switch scheme, at least one manufacturer would have introduced generic Asacol shortly after patent expiration. D. 54 at 23-26.

Plaintiffs' allegations as to this claim are plausible. In 2010, in litigation over brand-name drugs, Warner Chilcott agreed to allow a generic company to dispense an authorized generic version of Asacol once a third party introduced its own version, a fact which Plaintiffs argue reinforces that parties were expecting a generic Asacol had Warner Chilcott not torpedoed the market. D. 26 ¶ 156. By 2012, several companies were allegedly developing generic Asacol and stated that they intended to release their product once Asacol's patents expired. Id. ¶¶ 150-55. And in 2013, in a call discussing Warner Chilcott's 2012 earnings, Warner Chilcott's CEO acknowledged the anticompetitive effects of the "hard conversion" (withdrawing Asacol and introducing Delzicol), stating that those in the health care field were "all familiar with what's going on" and that once the hard switch was implemented, "[t]here won't be any Asacol out there." Id. ¶¶ 148-49. The Court cannot conclude as a matter of law at this stage that Warner Chilcott's actions in no way caused Plaintiffs' alleged injuries. Plaintiffs thus have standing to assert Count I.

[6] Because causation is an element of constitutional standing and antitrust standing, Defendants raise arguments about them together. D. 51 at 7-15, D. 52 at 13-17.

2. Count II

Count II alleges that the Settlement Agreement between Warner Chilcott and Zydus has impermissibly delayed the introduction of a generic version of Asacol HD, causing Plaintiffs to pay for Asacol HD at inflated prices since December 2013. D. 26 ¶ 202. Defendants argue that Plaintiffs lack standing to assert Count II because Zydus's failure to introduce generic Asacol HD is not due to Defendants and the Settlement Agreement, but the FDA. D. 51 at 13-14, D. 52 at 36.

For support, Defendants cite In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation, No. 14-md-02503-DJC, 2015 WL 5458570 (D. Mass. Sept. 16, 2015). In Solodyn, 2015 WL 5458570, at *9, direct purchaser plaintiffs alleged that Medicis made large and unjustified reverse payments to Lupin in exchange for Lupin's agreement to delay market entry of its generics. For one category of generics, the Legacy Strength Solodyn generics, Lupin did not receive FDA approval until a few days after the agreed-upon entry date in the settlement agreement. Id. Solodyn held that with respect to these generics, the direct purchasers did not allege a cognizable antitrust injury because the complaint did not contain "a plausible allegation of delay caused by [Medicis]." Id. Without such allegations about Medicis, "[t]he FDA's approval, not an agreement with Medicis, was the limiting factor in Lupin's ability to bring generic Solodyn in Legacy Strengths to market." Id.

Defendants argue that Solodyn's reasoning applies here too. The Court agrees. Here, Warner Chilcott and Zydus agreed that once the FDA approved Zydus's ANDA, Zydus could sell its own generic starting November 15, 2015. To date, the FDA still has not approved Zydus's ANDA for an Asacol HD generic.[7] Although Plaintiffs suggested at oral argument that Zydus did

[7] D. 53-11; see Drugs@FDA, FDA Approved Drug Products, https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (enter "Asacol HD"; then submit) (last visited July 19, 2016).

not aggressively push for FDA approval because it had a back-up option under the Settlement Agreement (i.e., the authorized generic option), the amended complaint contains no plausible allegation that Zydus or Warner Chilcott has sought to delay or sabotage FDA approval of Zydus's application. Without FDA approval, "Plaintiffs cannot claim antitrust injury on the premise that they should have paid less for a generic product that Zydus cannot have sold." D. 67 at 7. Even if Zydus could have negotiated an earlier entry date, the lack of FDA approval today remains "the limiting factor" in Zydus's ability to bring its generic drug to market. Solodyn, 2015 WL 5458570, at *9.

Plaintiffs also argue that they could have purchased a cheaper generic sooner because Zydus could have negotiated an earlier date to sell Warner Chilcott's authorized generic of Asacol HD (the second option). D. 58 at 19. But the Settlement Agreement gives Zydus the option to sell an authorized generic only if the FDA does not approve Zydus's ANDA. As Defendants stated at oral argument, this second option is a reserve parachute. Even if Zydus could have negotiated an earlier authorized generic entry date, that option would have disappeared the moment the FDA approved Zydus's ANDA.

Plaintiffs have already offered no plausible allegation that Defendants deliberately slowed the FDA approval process. They have not offered plausible allegations that Warner Chilcott and Zydus would have structured their settlement agreement so that Zydus would have come to market first as the seller of Warner's authorized generic as opposed to its own drug. Plaintiffs' failure to do so is particularly lacking because (1) litigation between Defendants began in the first place because Zydus had signaled that it intended to sell its own generic, (2) brand manufacturers are under no obligation to license authorized generics and (3) had Zydus not settled, litigated until the

end and won, Zydus still would have needed FDA approval to launch its drug. D. 67 at 9. Accordingly, Plaintiffs have not established standing to assert Count II.

B. Monopolization (Count I)

Since the Court has concluded that Plaintiffs have standing to assert Count I, the Court now turns to whether Count I states a claim for relief. As to Count I, Plaintiffs plead state law monopolization claims against Warner Chilcott. D. 26 ¶¶ 231-38. Both sides agree that the state law claims should be interpreted harmoniously with federal antitrust law. D. 52 at 22 n.1, D. 54 at 10-11.

Section 2 of the Sherman Act makes it illegal to "monopolize, or attempt to monopolize . . . any part of the trade or commerce" among several states. Diaz Aviation Corp. v. Airport Aviation Servs., Inc., 716 F.3d 256, 265 (1st Cir. 2013) (quoting 15 U.S.C. § 2) (internal quotation mark omitted). "To prove a violation of this statute, a plaintiff must demonstrate (1) that the defendant possesses 'monopoly power in the relevant market' and (2) that the defendant has acquired or maintained that power by improper means." Town of Concord v. Boston Edison Co., 915 F.2d 17, 21 (1st Cir. 1990) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570 (1966)). "Courts refer to unlawful methods of acquiring or maintaining monopoly power as 'exclusionary conduct.'" Solodyn, 2015 WL 5458570, at *10 (quoting Town of Concord, 915 F.2d at 21). Exclusionary conduct consists of "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) (quoting Grinnell, 384 U.S. at 570-71).

1. The Second Circuit in Namenda

Here, Plaintiffs allege that Defendants "willfully maintained and continue to maintain

monopoly power" through their product hopping scheme—introducing Asacol HD and Delzicol and discontinuing Asacol. D. 26 ¶ 233. In 2015, the Second Circuit stated that product hopping was a "novel question of antitrust law" and declared that determining "under what circumstances does conduct by a monopolist to perpetuate patent exclusivity through successive products . . . violate the Sherman Act" was "an issue of first impression in the circuit courts." Namenda, 787 F.3d at 643.

In Namenda, the State of New York asserted that Actavis PLC and its wholly-owned subsidiary ("Actavis") violated federal antitrust law by engaging in a product hopping scheme. Id. at 642-43. As Actavis's twice-daily drug Namenda IR (which treats moderate-to-severe Alzheimer's disease) neared the end of its patent exclusivity period in July 2015, Actavis introduced the once-daily drug Namenda XR. Id. Namenda XR's patents ensured that generics could not compete against it until 2029. Id. At the same time, Actavis moved to withdraw nearly all Namenda IR from the market to encourage its patients to switch to Namenda XR before generics for Namenda IR became available. Id. Because Namenda IR and Namenda XR have different strengths and daily dosage regimens (even though they have the same active ingredient and the same therapeutic effect), Actavis knew that pharmacists in most states could not substitute generic Namenda IR drugs for Namenda XR. Id. at 647-48.

The district court issued a preliminary injunction barring Actavis from restricting access to Namenda IR before generics of that drug joined the market. Id. at 643. The Second Circuit affirmed. Id. The Second Circuit held that the district court did not abuse its discretion by granting New York's motion for a preliminary injunction because New York had demonstrated a substantial likelihood of success on the merits of its § 2 Sherman Act claim and had made a strong showing of irreparable harm. Id.

Both sides agreed that Actavis possessed monopoly power because Namenda IR and Namenda XR constituted 100% of the relevant market, the memantine-drug market. Id. at 651-52. Accordingly, the case turned on whether Actavis willingly sought to maintain or attempted to maintain its monopoly in violation of the Sherman Act. Id. at 652. To answer that question, the Second Circuit applied the rule-of-reason framework in United States v. Microsoft Corp., 253 F.3d 34, 58-60 (D.C. Cir. 2001). Id. Under the framework, "once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer 'nonpretextual' procompetitive justifications for its conduct." Id. (quoting Microsoft, 253 F.3d at 58-59). The plaintiff "may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." Id.

First, the Second Circuit concluded that New York had established Actavis's conduct was anticompetitive and exclusionary. Although "neither product withdrawal nor product improvement alone is anticompetitive," when a monopolist "*combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act." Id. at 653-54 (citations omitted and emphasis in original). The Second Circuit agreed that Actavis's hard switch coerced consumers because it deprived doctors and their patients the freedom to decide whether the benefits of switching to Namenda XR outweighed the benefits of adhering to IR therapy with a cheaper IR generic. Id. at 654-55. The Second Circuit also agreed that Actavis's conduct impeded competition in light of "the unique characteristics of the pharmaceutical market." Id. at 655. Forcing patients to switch to Namenda XR prevented generic substitution at pharmacies, and competition through state drug substitution laws was the only cost-efficient path available to generic manufacturers. Id. at 655-56. "For there to be an antitrust

violation, generics need not be barred 'from all means of distribution' if they are 'bar[red] . . . from the cost-efficient ones.'" Id. at 656 (quoting Microsoft, 253 F.3d at 64). Although patients in theory could switch back to IR therapy after generics entered the market, evidence showed that in practice, this "reverse commute would be a highly unlikely occurrence." Id.

Second, the Second Circuit concluded that Actavis's procompetitive justifications for withdrawing Namenda IR were pretextual. Id. at 658. The record was "replete with evidence" showing that Actavis was attempting to thwart generic competition and retain its consumers before it lost Namenda IR's patent exclusivity. Id.

Finally, the Second Circuit stated that the anticompetitive harms outweighed whatever procompetitive benefits that existed. Id. at 658-59. Actavis's willingness to forsake short-term profits from Namenda IR to achieve market consolidation around Namenda XR and to undercut generic competition was indicative of anticompetitive behavior. Id. at 659. Furthermore, to immunize product hopping from antitrust scrutiny "may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations." Id. In short, the Second Circuit concluded that "the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification," violates § 2 of the Sherman Act. Id.

2. Arguments for Dismissal

Here, Plaintiffs allege that Warner Chilcott withdrew Asacol from the market and introduced reformulated versions of that drug—Asacol HD and Delzicol—to impede generic

competition. See supra Section III.C (detailing product hop allegations). Warner Chilcott argues that Plaintiffs' allegations fail as a matter of law.

First, Warner Chilcott argues that its conduct cannot be considered anticompetitive because they had a legitimate business justification for Asacol's removal: safety concerns over the DBP in Asacol. D. 52 at 38. Plaintiffs acknowledge that the FDA issued guidance concerning the safety of DBP. D. 26 ¶¶ 131-32. The parties, however, strenuously disagree whether the FDA required Warner Chilcott to remove Asacol for Delzicol. As Plaintiffs explained at oral argument, because Delzicol is medically indistinguishable from Asacol yet patent-protected, the FDA's non-binding recommendations on DBP were a pretext for Warner Chilcott's anticompetitive behavior. At this stage, Plaintiffs' detailed allegations about DBP and Warner Chilcott's actions plausibly support the inference that concerns about safety were pretextual. See supra Section III.C.3.

Second, Warner Chilcott argues that their choice to pursue Delzicol, a patented product, is innovation "inherently valuable to the public" that should not trigger antitrust scrutiny. D. 52 at 43. "To be sure, there is tension between the antitrust laws' objective of enhancing competition by preventing unlawful monopolies and patent laws' objective of incentivizing innovation by granting legal patent monopolies." Namenda, 787 F.3d at 659. But "[i]ntellectual property rights do not confer a privilege to violate the antitrust laws." Id. at 660 (quoting In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1325 (Fed. Cir. 2000)) (internal quotation marks omitted). Patent law provides "a temporary monopoly on individual drugs—not a right to use . . . patents as part of a scheme to interfere with competition 'beyond the limits of the patent monopoly.'" Id. (quoting United States v. Line Material Co., 333 U.S. 287, 308 (1948)). Here, Plaintiffs plausibly allege that the Warner Chilcott "have essentially tried to use their patent rights on [Delzicol] to extend the exclusivity period" for their ulcerative colitis drugs. Id.

Third, Warner Chilcott asserts that its actions were consistent with competition and, therefore, lawful. D. 52 at 45-51. The Court recognizes that "[a]s a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." Namenda, 787 F.3d at 652 (quoting Microsoft, 253 F.3d at 65). But "[w]ell-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition." Id. at 652. Additionally, "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." Trinko, 540 U.S. at 411. Here, "generic substitution by pharmacists . . . is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition, and by preventing the 'practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]." Namenda, 787 F.3d at 657-58 (citations omitted). Plaintiffs' allegations thus survive the motion to dismiss because "it is the *combination* of Defendants' withdrawal of [Asacol] and introduction of [Delzicol] in the context of generic substitution laws" that subjects Defendants' conduct to antitrust scrutiny. Id. at 660 (emphasis in original). Other district courts that have considered product hopping allegations at this stage concur, concluding that well-pled allegations about consumer coercion in light of the distinct nature of the pharmaceutical drug market may establish plausible antitrust liability.[8]

[8] Compare In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014) (denying motion to dismiss after noting that the "key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit," with "the somewhat unique characteristics of the pharmaceutical market in mind"); Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 422 (D. Del. 2006) (denying motion to dismiss because the "nature of the pharmaceutical drug market" supports antitrust scrutiny of the defendants' "product-switching conduct") with Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (granting motion to dismiss because "there is no allegation that AstraZeneca eliminated any consumer choices").

Finally, Warner Chilcott faults Plaintiffs for failing to plead that they possessed monopoly power in a relevant antitrust market. D. 52 at 74-79. Monopoly power can be shown directly—by showing "actual supracompetitive prices and restricted output"—or circumstantially—by showing "that the defendant has a dominant share in a well-defined relevant market and that there are significant barriers to entry in that market and that existing competitors lack the capacity to increase their output in the short run." Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196-97 (1st Cir. 1996). Here, Plaintiffs have alleged that Warner Chilcott had the power to charge supracompetitive prices for their drugs and that at competitive prices, these drugs do not exhibit significant, positive, cross-elasticity of demand with respect to price with any other mesalamine formulation other than their bioequivalent generic versions. See D. 26 ¶¶ 215-30. These allegations sufficiently withstand a motion to dismiss. In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (denying motion to dismiss after concluding that similar allegations were "more than enough" at this stage).

3. Noerr-Pennington Doctrine and Implied Preclusion

Warner Chilcott also asserts that the Noerr-Pennington doctrine and the FDCA require dismissal. Under the Noerr-Pennington doctrine, a party is "immune from antitrust liability for engaging in conduct (including litigation) aimed at influencing decisionmaking by the government." Octane Fitness, LLC v. ICON Health & Fitness, Inc., __ U.S. __, 134 S. Ct. 1749, 1757 (2014); see Davric Maine Corp. v. Rancourt, 216 F.3d 143, 147 (1st Cir. 2000) (stating that the doctrine "shields from antitrust liability entities who join together to influence government action—even if they seek to restrain competition or to damage competitors"). The doctrine "applies to 'petitions' before legislatures, administrative agencies, and courts." Rancourt, 216 F.3d at 147.

Warner Chilcott argues that their citizen petitions—allegedly filed to drive up the cost of generic entry—constitute protected conduct under the Noerr-Pennington doctrine. D. 52 at 51-53. Plaintiffs clarify that the citizen petitions "do not form an independent basis" for antitrust liability, but instead "provide context and reveal Defendants' intent." D. 57 at 16; see D. 54 at 18 n.13 (explaining that the allegations about citizen petitions here "provide background of the scheme and show recognition of imminent generic competition"). Because a plaintiff "may properly include evidence of immune lobbying activity in its antitrust allegations insofar as that evidence serves to illustrate the context and motive underlying the alleged anticompetitive conduct," the Court declines to dismiss Count I on the basis of these allegations.[9] Steward Health Care Sys., LLC v. Blue Cross & Blue Shield of Rhode Island, 997 F. Supp. 2d 142, 163 (D.R.I. 2014) (citing United Mine Workers of Am. v. Pennington, 381 U.S. 657, 670 n. 3 (1965)).

Warner Chilcott also argues that the FDCA implicitly precludes antitrust liability because the two are "clearly incompatible" here. D. 52 at 55 (quoting Credit Suisse Sec. (USA) LLC v. Billing, 551 U.S. 264, 275 (2007) (internal quotation marks omitted). As Warner Chilcott explains, "while antitrust law might prohibit a 'hard switch,' the FDA might require it for consumer safety." D. 69 at 13. As noted earlier, Plaintiffs contest the fundamental premise behind

[9] Warner Chilcott also argues that the Noerr-Pennington doctrine immunizes the hard switch scheme because the company removed Asacol from the market because of the FDA's safety concerns over DBP. D. 52 at 53-55. Because both sides dispute the link between Defendants' actions and the FDA's stance on DBP, Plaintiffs' allegations sufficiently preclude the conclusion that the Noerr-Pennington doctrine applies as a matter of law because "[t]he scope of [the Noerr-Pennington doctrine] depends . . . on the source, context, and nature of the anticompetitive restraint at issue" and "[t]he dividing line between restraints resulting from governmental action and those resulting from private action may not always be obvious." Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499, 501-02 (1988); see Abarca Health, LLC v. PharmPix Corp., 915 F. Supp. 2d 210, 216 (D.P.R. 2012) (noting that the applicability of the doctrine "is a highly factual determination[] inappropriate for a dismissal motion").

that argument: whether the FDA required Defendants to carry out its hard switch scheme. Because of this factual dispute and the nature of the allegations made by Plaintiffs in the amended complaint, the Court cannot conclude at this stage that a "clear repugnancy" exists between Plaintiffs' complaint and the FDCA as a matter of law. Billing, 551 U.S. at 275.

C. State-Specific Arguments against Count I and Count II

Plaintiffs bring two types of claims—monopolization (Count I) and combination and conspiracy in restraint of trade (Count II)—under the laws of different states. D. 26 ¶¶ 231-43. Defendants have thus made state-specific arguments against specific claims.[10]

As an initial matter, Defendants argue that Plaintiffs lack Article III standing to bring claims where they do not reside or have not purchased the products at issue. D. 51 at 21, D. 52 at 84. Nevertheless, consistent with the decisions by some courts, the Court "will consider the issue of the end payors' standing to bring claims arising under the laws of states where they are not residents and have not alleged to have suffered harm at the class certification stage."[11] Solodyn, 2015 WL 5458570, at *14 (summarizing the split among courts but deferring this issue until the class certification stage).

[10] The Court's conclusion that Plaintiffs lack standing for Count II extends to all Count II claims, particularly because, as stated above, the two sides agree that the state law claims should be interpreted harmoniously with federal antitrust law. See supra Section V.B; In re Androgel Antitrust Litig. (No. II), 687 F. Supp. 2d 1371, 1382 (N.D. Ga. 2010) (stating that "[b]ecause the Plaintiffs' allegations do not state a plausible antitrust claim under federal law, the Indirect Purchasers also do not state a plausible antitrust claim under state law"). Dismissal of Count II claims on state-specific grounds are thus an additional reason for dismissal.

[11] Plaintiffs urge the Court to strike Attachments 1-4 (D. 52 at 99-109), which were appended to Warner Chilcott's memorandum in support of their motion to dismiss, because they exceed the page limits. D. 57 at 18-19. Although Defendants should have sought leave to exceed the page limits set in this case, these charts are routinely accepted in these types of cases. See, e.g., Suboxone, 64 F. Supp. 3d at 696 n.21. Plaintiffs' request to strike these charts is DENIED. The Court, however, did not rely on Attachment 5 in considering the motions to dismiss. Plaintiffs' request to strike Attachment 5 is DENIED as moot.

1. Illinois Brick

In Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977), the Supreme Court held that "indirect purchasers of goods produced by firms engaged in anticompetitive conduct were too remote from that conduct to be regarded as injured." In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 409 (D. Mass. 2013) (citing Illinois Brick Co., 431 U.S. at 746-48). Some states have passed laws that repeal Illinois Brick and expressly grant end-payors the right to sue for antitrust violations. Solodyn, 2015 WL 5458570 at *15. Defendants, however, argue that Plaintiffs may not bring either Count I or Count II under Missouri, Montana and Utah law. D. 52 at 87-89.

The Missouri combination and conspiracy claim (Count II) should be dismissed because "Missouri's antitrust laws follow Illinois Brick and prohibit recovery by indirect purchasers." In re Pool Prods. Distribution Mkt. Antitrust Litig., 946 F. Supp. 2d 554, 570 (E.D. La. 2013) (citing Duvall v. Silvers, Asher, Sher & McLaren, M.D.'s, 998 S.W.2d 821, 825 (Mo. Ct. App. 1999)). The Missouri monopolization claim (Count I), which is brought under the Missouri Merchandising Practices Act ("MMPA"), survives because "the Missouri Supreme Court has expressly allowed suit by indirect purchasers under the MMPA." Id. at 571. Nevertheless, the MMPA limits claims to those "who purchase[] or lease[] merchandise primarily for personal, family or household purposes." Mo. Rev. Stat. § 407.025(1). The Health Fund Plaintiffs thus may not assert a claim under the MMPA. Los Gatos Mercantile, Inc. v. E.I. DuPont De Nemours & Co., No. 13-cv-01180-BLF, 2015 WL 4755335, at *23 (N.D. Cal. Aug. 11, 2015) (noting that "[c]ases in this district have interpreted the statute to confer standing only upon persons who purchase property for their *own* personal, family or household purposes") (emphasis in original); In re Cast Iron Soil Pipe & Fittings Antitrust Litig., No. 1:14-md-2508, 2015 WL 5166014, at *31 (E.D. Tenn. June

24, 2015) (rejecting view that the statute's language include businesses); cf. Solodyn, 2015 WL 5458570, at *17 (dismissing end payors' claim under the Kansas Consumer Protection Act because they were institutional purchasers who did not meet the definition of "consumer" under the statute).

The only decision from Montana state courts that either side has identified to address this issue is Olson v. Microsoft Corp., 2001-ML-652, 2001 Mont. Dist. LEXIS 2710, *14 (Mont. Dist. Ct. Feb. 15, 2001), which held that the rule in Illinois Brick does not apply to Montana's Unfair Trade Practices Act ("MUPTA"). The Court thus declines to dismiss the Montana claims.[12]

Defendants argue that the Utah claims should be dismissed because Plaintiffs do not plead that members of the putative class are citizens or residents of Utah. D. 52 at 88. Plaintiffs, however, allege in their complaint that members of the putative classes made purchases in Utah, D. 26 ¶¶ 238y, 243z, so members of the putative class presumably include Utah citizens and residents. The Court declines to dismiss the Utah claims on this ground.

2. Massachusetts Consumer Protection Law

Section 11 of Mass. Gen. L. c. 93A provides a right of action to sue for unfair practices to "[a]ny person who engages in the conduct of any trade or commerce," while § 9 provides the right to "[a]ny person, other than a person entitled to bring action under section eleven." Mass. Gen. L. c. 93A §§ 9, 11. Mass. Gen. L. c. 93A thus "distinguishes between 'consumer' claims" (brought under § 9) and "'business' claims" (brought under § 11). Frullo v. Landenberger, 61 Mass. App. Ct. 814, 821 (2004); Cont'l Ins. Co. v. Bahnan, 216 F.3d 150, 156 (1st Cir. 2000) (noting that "[b]y

[12] Both parties agree that the statute of limitations for a claim under the Montana Unfair Trade Practices Act is two years. D. 52 at 97, D. 58 at 25. Defendants argue that the Montana monopolization claim (Count I) is untimely because the first complaint was filed more than two years after the withdrawal of Asacol. D. 52 at 97. Nevertheless, courts have held that "a new cause of action accrues to purchasers upon each overpriced sale of the drug." Solodyn, 2015 WL 5458570, at *8 (quoting In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 747 (E.D. Pa. 2014)). The Court declines to dismiss this claim on statute of limitations grounds.

their terms, however, [§ 9 and § 11] are mutually exclusive"). Although the "dividing line between a consumer claim and a business claim . . . is not always clear," it "appears to turn on whether a given party has undertaken the transaction in question for business reasons, or has engaged in it for purely personal reasons (such as the purchase of an item for personal use)." Frullo, 61 Mass. App. Ct. at 821. "[A]ny transaction in which the plaintiff is motivated by business considerations gives rise to claims only under the statute's business section," § 11. Id.

Additionally, § 11 states that "[i]n any action brought under this section, . . . the court shall also be guided in its interpretation of unfair methods of competition by . . . the Massachusetts Antitrust Act." As a result, in Ciardi v. F. Hoffmann-La Roche, Ltd., 436 Mass. 53, 62-63 (2002), the Supreme Judicial Court held that indirect purchasers could bring antitrust claims under § 9 because unlike § 11, § 9 did not contain an "explicit provision" that its application had to be "guided by the provisions of the Antitrust Act, and by association, Illinois Brick."

Here, all Plaintiffs but one are organizations. Those Plaintiffs—the Health Fund Plaintiffs—cannot bring a claim under § 9 as they cannot show that they undertook the relevant transactions "for purely personal reasons (such as the purchase of an item for personal use)." Frullo, 61 Mass. App. Ct. at 821. Plaintiffs point to In re Pharmaceutical Industrial Average Wholesale Price Litigation, 582 F.3d 156, 192 (1st Cir. 2009), where the First Circuit concluded that indirect purchasers could bring claims under § 11. The indirect purchasers there, however, were not bringing antitrust claims, but misrepresentation claims, which are not guided by Illinois Brick. Id. at 193. Because Ciardi suggests that § 11 must be interpreted consistent with Illinois Brick and claims under the two sections are mutually exclusive, any claim under Mass. Gen. L. c. 93A by the Health Fund Plaintiffs must be dismissed. See, e.g., United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA,

Inc., 74 F. Supp. 3d 1052, 1086 (N.D. Cal. 2014) (concluding that an employee health and welfare plan plaintiff had no standing under Chapter 93A); In re Auto. Parts Antitrust Litig., No. 12-md-02311, 2013 WL 2456612, at *29 (E.D. Mich. June 6, 2013) (concluding that an indirect purchaser business plaintiff had no standing under Chapter 93A).

3. Intrastate Conduct

Defendants argue that claims under the laws of eleven states and the District of Columbia should be dismissed because Plaintiffs allege that Defendants' actions affected interstate commerce, while those claims require that the challenged conduct be purely or primarily intrastate conduct.[13] D. 52 at 91-94. But Plaintiffs allege that Defendants' anticompetitive conduct "occurred in part in trade and commerce within the states set forth herein" and "had substantial interstate and intrastate effects because retailers within each state have been foreclosed from offering cheaper generic versions" of Asacol and Asacol HD. D. 26 ¶ 214. This allegedly "directly impacted and disrupted commerce for end-payors within each state who have been forced to continue to pay *supra*-competitive prices." Id. With reasonable inferences drawn in Plaintiffs' favor, these allegations sufficiently allege intrastate conduct. Solodyn, 2015 WL 5458570, at *16 (D. Mass. Sept. 16, 2015) (citing In re Digital Music Antitrust Litig., 812 F. Supp. 2d 390, 407-08 (S.D.N.Y. 2011)).

4. Notice Requirements

Defendants argue that Plaintiffs should have filed a notice with the California Attorney General under Cal. Bus. & Prof. Code § 17209. D. 52 at 90-91 & n.45. That statute, however,

[13] The eleven states are the following: California, Florida, Hawaii, Massachusetts, Mississippi, Nevada, New York, Oregon, Tennessee, West Virginia and Wisconsin. D. 52 at 91-94.

does not apply here because it applies to proceedings "in the Supreme Court of California, a state court of appeal, or the appellate division of a superior court." Cal. Bus. & Prof. Code § 17209.

Defendants also argue that Plaintiffs failed to comply with four other similar notice provisions under Arizona, Hawaii, Nevada and Utah law. D. 52 at 90-91 & n.45. Plaintiffs argue that because these provisions are procedural rather than substantive, under Shady Grove Orthopedic Associates, P.A. v. Allstate Insurance Co., 559 U.S. 393 (2010), they are inapplicable here. D. 58 at 24. In Shady Grove, 559 U.S. at 402-03, a plurality concluded that a state law which precludes a lawsuit to recover a penalty from proceeding as a class action was preempted by Fed. R. Civ. P. 23. Justice Stevens concurred with the judgment because the state law at issue was procedural; he separately wrote, however, that a state procedural law would control if it were "so intertwined with a state right or remedy that it functions to define the scope of the state-created right." Id. at 423. Neither party has cited a case where a court dismissed a similar claim because of the notice provisions under Arizona, Nevada and Utah law. Courts are divided on whether Hawaii's statute necessitates dismissal.[14]

Under First Circuit law, "[i]n getting at the potential rub in the relationship between a Federal Rule of Procedure and the state law, courts now ask if the federal rule is 'sufficiently broad to control the issue before the court.'" Godin v. Schencks, 629 F.3d 79, 86 (1st Cir. 2010) (quoting

[14] Compare In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 254 (D. Conn. 2015) (declining to dismiss because the notice requirements were procedural), motion to certify interlocutory appeal on other grounds granted, No. 3:14-md-2516 SRU, 2015 WL 4459607 (D. Conn. July 21, 2015), and In re Aftermarket Filters Antitrust Litig., No. 08-cv-4883, 2009 WL 3754041, at *6 (N.D. Ill. Nov. 5, 2009) (denying dismissal because "[p]laintiffs are correct that nothing in the statutory scheme suggests that defendants may use the statute as a shield to avoid answering for alleged anti-competitive behavior"), with In re Chocolate Confectionary Antitrust Litig., 749 F. Supp. 2d 224, 232 (M.D. Pa. 2010) (dismissing indirect purchasers' claim for failing to comply with notice requirements with leave to amend), and In re Flash Memory Antitrust Litig., 643 F. Supp. 2d 1133, 1158 (N.D. Cal. 2009) (same).

Shady Grove, 130 S. Ct. at 1451) (Stevens, J., concurring)). "If so, then the federal rule must be given effect despite the existence of competing state law so long as the rule complies with the Rules Enabling Act." Id. "If a federal rule is not so broad as to control the issues raised," state law controls. Id. Yet "a federal court might nonetheless decline to apply state law if so declining would better advance the dual aims of Erie: "discouragement of forum-shopping and avoidance of inequitable administration of the laws." Id. (citing Hanna v. Plumer, 380 U.S. 460, 468 (1965)).

The Court concludes that Rule 23 is not sufficiently broad to cover the issues within the scope of these state statutory notice provisions. First, "[t]o use the language of Shady Grove," Rule 23 does not "attempt[] to answer the same question," id. at 89 (quoting Shady Grove, 130 S. Ct. at 1437) (internal quotation marks omitted), nor does it "address the same subject," id. (quoting Shady Grove, 130 S. Ct. at 1440 (internal quotation marks omitted), as the state laws. On their face, the state laws address notice provisions for antitrust-related lawsuits, while Rule 23 is a general federal procedural rule whether class actions may be maintained. "In contrast to the state statute in Shady Grove, [these state laws] do[] not seek to displace the Federal Rules or have [Rule 23] cease to function." Id. at 88. Second, to decline to apply these laws in federal court would encourage forum shopping and the inequitable administration of laws. Id. at 92. Accordingly, the Court concludes that these state laws apply and the claims brought under Arizona, Hawaii, Nevada and Utah law are dismissed without prejudice.

5. Consumer Conduct

Defendants argue that both California claims should be dismissed because Plaintiffs fail to plead consumer-directed deception or reliance under the California Unfair Competition Law ("UCL"). D. 52 at 95. Yet as Plaintiffs point out, they are asserting "well-recognized antitrust claims," and antitrust violations "can constitute 'unfair competition' under the UCL." In re

Processed Egg Products Antitrust Litig., 851 F. Supp. 2d 867, 894 (E.D. Pa. 2012) (collecting cases); see In re Ditropan XL Antitrust Litig., 529 F. Supp. 2d 1098, 1106 (N.D. Cal. 2007) (concluding that the indirect purchaser plaintiffs did not need to allege reliance because their allegations regarding anticompetitive and monopolistic conduct by pharmaceutical company sufficiently stated a claim of unfair competition). The Court thus declines to dismiss the California claims on this basis.

Defendants argue that the lack of consumer-targeted and deception allegations dooms Count I under New York and Missouri law. D. 52 at 95; see In re New Motor Vehicles Canadian Exp. Antitrust Litig., 350 F. Supp. 2d 160, 197 (D. Me. 2004) (noting that "[a]n antitrust violation may violate [New York's consumer protection statute], but only if it is deceptive"). Plaintiffs' allegations, which assert that Defendants destroyed a drug market out of pretext, sufficiently pass muster under these laws.

The Hawaii Antitrust Act provides that "[n]o person other than a consumer, the attorney general or the director of the office of consumer protection may bring an action based upon unfair or deceptive acts or practices declared unlawful by this section." Haw. Rev. Stat. § 480-2(d). The Act defines "consumer" to be "a natural person who, primarily for personal, family, or household purposes, purchases, attempts to purchase, or is solicited to purchase goods or services or who commits money, property, or services in a personal investment." Id. § 480-1. The Court thus dismisses the Hawaii claims brought by the Health Fund Plaintiffs.

Similarly, the Vermont Consumer Protection Act allows "[a]ny consumer who contracts for good or services" to seek damages. Vt. Stat. Ann. tit. 9, § 2461. A "consumer" is defined in part as "any person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale in the ordinary course of his or her trade or business but for his

or her use or benefit or the use or benefit of a member of his or her household." Id. § 2451a(a). The Health Fund Plaintiffs' Vermont claims are dismissed.

6. Tennessee Monopolization Claim

Defendants argue that Count I brought under the Tennessee Trade Practices Act ("TTPA") should be dismissed because the statute addresses only concerted antitrust conduct, not unilateral conduct. D. 52 at 97. At least two federal courts have adopted Defendants' argument. See In re Flonase Antitrust Litig., 610 F. Supp. 2d 409, 415-16 (E.D. Pa. 2009) (dismissing the TTPA claims in part after noting that the plaintiff agreed that the statute did not cover unilateral monopolization claims); In re Relafen Antitrust Litig., 221 F.R.D. 260, 284 (D. Mass. 2004) (concluding that the TTPA does not include unilateral conduct). Plaintiffs, however, point to Sherwood v. Microsoft Corp., No. M2000-01850-COA-R9-CV, 2003 WL 21780975, at *30 (Tenn. Ct. App. July 31, 2003), which allowed a claim of monopolization to go forward under the TTPA without addressing the issue. D. 58 at 20. Similarly, in Duke v. Browning-Ferris Indus. of Tennessee, Inc., No. W2005-00146-COA-R3-CV, 2006 WL 1491547, at *1 (Tenn. Ct. App. May 31, 2006), the Court of Appeals of Tennessee affirmed a trial court's grant of summary judgment on monopolization and attempted monopolization claims brought under the TTPA without raising this issue. Accordingly, the Court declines to dismiss this claim because Tennessee state courts appear to treat monopolization claims as viable under the TTPA.[15]

[15] Defendants criticize Plaintiffs for failing to cite the correct statutes for their Utah and Oregon claims. D. 52 at 99. Because Plaintiffs confess error and Defendants assumed for the purposes of their motion that Plaintiffs had cited the correct statutes, D. 52 at 99 nn.68-69, D. 58 at 23 n.32, the Court declines to dismiss these claims on this basis. Defendants also argue that claims brought under Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") should be dismissed because they do comport with the pleading requirements of Fed. R. Civ. P. 9. D. 52 at 83-84. Courts, however, disagree whether such claims must be pled with particularity. See, e.g., In re Auto. Parts Antitrust Litig., No. 12-md-02311, 2014 WL 2999269, at *19 (E.D. Mich. July 3, 2014) (concluding Rule 9 was inapplicable to FDUTPA claims based on price-fixing conspiratorial

VI. Conclusion

For these reasons, the Court rules on the pending motions as follows:

- Zydus's motion to dismiss Count II, D. 46, is ALLOWED, and Warner Chilcott's motion is ALLOWED IN PART and DENIED IN PART in that:
    - All Count II claims are dismissed;
    - Monopolization claims (Count I) under Arizona, Nevada and Utah law are dismissed without prejudice in case Plaintiffs can comply or specifically plead how they complied with each state's notice requirements;
    - Claims under Missouri, Massachusetts and Vermont law asserted by the Health Fund Plaintiffs are dismissed;
    - Claims under Hawaii law asserted by the Health Fund Plaintiffs are dismissed, but the Hawaii monopolization claim (Count I) brought by Mark Adorney is dismissed without prejudice in case he can comply or specifically plead how he complied with the notice requirements; and
    - The motions to dismiss are DENIED in all other respects.
- As explained in footnote 2, the Court DENIES Plaintiffs' motion to strike, D. 56; and
- Plaintiffs' motions to seal their opposition to Zydus's motion to dismiss, D. 55, and for leave to file a reply memorandum in support of their motion to strike, D. 74, are ALLOWED *nunc pro tunc.*

So Ordered.

/s/ Denise J. Casper
United States District Judge

conduct brought by end payors). The Court finds In re Auto. Parts persuasive and declines to dismiss the Florida claims on this basis.