UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: Ranbaxy Generic Drug Application Antitrust Litigation,	)	**MDL No. 19-md-02878-NMG**
This Document Relates To:	)	
All Cases	)	

MEMORANDUM & ORDER

GORTON, J.

This multi-district ligation involves five actions which are centralized in this Court and have been divided into two putative classes against Ranbaxy Inc. and Sun Pharmaceutical Industries Limited (collectively, "Ranbaxy" or "defendants") for allegedly causing the delayed market entry of three generic drugs (Diovan, Valcyte and Nexium).

Direct purchaser plaintiffs ("DPPs"), such as wholesalers, purchased brand name and generic drugs directly from drug manufacturers. End-payor plaintiffs ("EPPs"), such as consumers and third-party payors, purchased brand name and generic drugs at the end of the distribution chain from retailers and other financial intermediaries. The DPPs and EPPs (collectively,

"plaintiffs") bring claims for violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), federal and state antitrust law and state consumer protection law.

Following centralization, both the DPPs and the EPPs filed amended consolidated complaints (Docket Nos. 20, 22) (collectively, "the Consolidated Complaints"). Pending before the Court are the motions of Ranbaxy to dismiss both Consolidated Complaints (Docket Nos. 63, 65).[1]

I. Background

The facts of this case are described in detail in the Report and Recommendation of Magistrate Judge Page Kelley with respect to Ranbaxy's motion to dismiss the complaint of plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") in the original action in this Court prior to centralization. See Meijer, Inc. v. Ranbaxy, Inc., No.1:15-cv-11828-NMG (D. Mass. Sept. 7, 2016) ("Meijer I"). For that reason, the Court provides only an abbreviated background here.

[1] The Consolidated Complaints name Ranbaxy Laboratories Limited and Ranbaxy USA, Inc. as additional defendants. These entities no longer exist and, therefore, will be dismissed.

A. Statutory and Regulatory Framework

The Food and Drug Administration ("FDA") is charged with regulating prescription drugs under the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. §§ 301 et seq. The FDCA requires drug manufacturers that create a new drug product to seek approval to sell the drug by filing with the FDA a New Drug Application. 21 U.S.C. §§ 301-392.

Recognizing that the drug approval process is an onerous one, Congress passed the Hatch-Waxman Amendments to the FDCA in 1984 ("the Hatch-Waxman Act"). Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act created the Abbreviated New Drug Application ("ANDA") as a "fast-track" for manufacturers seeking to launch generic versions of branded drugs previously approved by the FDA. 21 U.S.C. § 355. The ANDA process allows a manufacturer to demonstrate that its proposed generic has the same therapeutically active ingredient and releases it at the same rate and to the same extent as an FDA-approved drug. § 355(j)(2)(A)(vii).

The ANDA approval process proceeds in three phases. Ranbaxy Labs., LTD. v. Burwell, 82 F. Supp. 3d 159, 170 (D.D.C. 2015). In phase I, a generic drug manufacturer must "perfect" its application. Id. This requires the generic manufacturer to

certify that the marketing of its generic drug will not infringe upon any existing patents. § 355(j)(2)(A)(vii)(I)-(IV). If a generic manufacturer certifies its application pursuant to § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), it claims that either an existing patent is invalid or will not be infringed upon by the generic. Id.

A Paragraph IV certification is a per se patent infringement upon the preexisting patent and prompts a 45-day window for the patent holder to file suit. 35 U.S.C. § 271(e)(2). To compensate for this risk, the first generic manufacturer to file a successful ANDA with a Paragraph IV certification ("first filer") is rewarded with a 180-day exclusivity period during which no other manufacturers, with the exception of those authorized by the branded drug manufacturer, may market competing generics. 21 U.S.C. § 355(j)(5)(B)(iv). This period of exclusivity is the most profitable time for a new generic drug because the first filer typically procures an overwhelming majority of the sales of the drug while offering only a modest discount off the brand drug price.

Phase II is tentative approval ("TA"). An ANDA may be tentatively approved if it could be unconditionally approved but for the presence of blocking patents or other existing periods

of exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). A TA does not authorize the drug to be marketed but serves to preserve the 180-day exclusivity period. Id.

Phase III is final approval which may be granted once the manufacturer has met the FDA's requirements. 21 U.S.C. § 355(j)(4).

B. Factual Background

Plaintiffs allege that Ranbaxy violated RICO, federal and state antitrust laws and state consumer protection laws by submitting multiple ANDAs with missing, incorrect or fraudulent information, thereby wrongfully acquiring exclusivity periods and delaying the market entry of generic drugs.

The Consolidated Complaints focus on Ranbaxy's manufacture of generic versions of three drugs branded Diovan, Nexium and Valcyte. Diovan is the generic valsartan ("generic Diovan") and is used to treat high blood pressure and heart failure. Valcyte is the generic valganciclovir hydrochloride ("generic Valcyte") and is an antiviral medication. Nexium is the generic esomeprazole magnesium ("generic Nexium") and is a proton-pump inhibitor used to treat gastroesophageal reflux disease.

In late 2005, a whistleblower alerted the FDA to serious and systemic issues of noncompliance with the FDA's current Good

Manufacturing Practices at various Ranbaxy manufacturing facilities. Following the whistleblower's complaint, the FDA began a series of detailed inspections at Ranbaxy's facilities. In response, Ranbaxy hired the law firm of Buc & Beardsley LLP ("Beardsley") and an auditor, Parexel Consulting LLC ("Parexel"), pursuant to an agreement whereby Beardsley and Ranbaxy could control what information Parexel shared with the FDA. Beardsley reviewed Parexel's audit reports and designated them as privileged.

In June, 2006, the FDA issued a warning letter to Ranbaxy's facility in Paonta Sahib, India ("the Paonta Sahib facility") and recommended placing a hold on all ANDAs originating from that facility. Nearly one year later, Ranbaxy notified the FDA that the identified compliance issues were resolved. The FDA, relying on Ranbaxy's attestations, granted TAs for Ranbaxy's ADNAs for generic Diovan (in October, 2007), generic Nexium (in February, 2008) and generic Valcyte (in June, 2008).

In July, 2008, the government subpoenaed the Parexel audits and, upon examination, issued additional warning letters. In February, 2009, the FDA froze all ANDAs originating from the Paonta Sahib facility.

In January, 2012, Ranbaxy and the FDA entered into a consent decree and Ranbaxy withdrew several ANDAs. With respect to certain "excepted" ANDAs, Ranbaxy was permitted to retain its first filer status upon demonstrating that the ANDA had been substantially complete at the time of submission and did not reflect a pattern or practice of data irregularities. Ranbaxy's generic Diovan, generic Valcyte and generic Nexium ANDAs were among those "excepted."

1. Diovan

Ranbaxy filed its ANDA for generic Diovan in 2004. In 2007, Ranbaxy amended its ANDA to include a Paragraph IV certification, preserving eligibility for first filer status. The patent holder filed suit and, pursuant to a settlement agreement, Ranbaxy agreed to delay marketing generic Diovan until September, 2012.

Ranbaxy's generic Diovan ANDA was excepted from the FDA consent decree and Ranbaxy was permitted to retain first filer status. Plaintiffs submit that other ANDA filers had received TAs by July, 2012, but were unable to obtain final approval because of Ranbaxy's first filer status. The FDA granted final approval in June, 2014, and Ranbaxy launched generic Diovan the following month.

2. Nexium

Ranbaxy filed its ANDA for generic Nexium in August, 2005, and subsequently included a Paragraph IV certification, preserving eligibility for first filer status. The patent holder filed suit in November, 2005. In April, 2008, Ranbaxy settled with the patent holder and agreed to delay launching generic Nexium until May, 2014.

The agreed-upon entry date passed without Ranbaxy launching generic Nexium. In November, 2014, the FDA rescinded its TA for generic Nexium and stripped Ranbaxy of first filer status. That same day, the FDA issued final approval to a competitor's generic Nexium ANDA and generic Nexium entered the market a few weeks later.

3. Valcyte

Ranbaxy filed its ANDA for generic Valcyte in December, 2005 and included a Paragraph IV certification which made it eligible for first filer status. In April, 2006, the patent holder filed suit and, by virtue of a settlement agreement, Ranbaxy agreed to delay the marketing of generic Valcyte until March, 2013. Nearly one year after the passage of the agreed-upon launch date, Ranbaxy was still unable to secure final approval from the FDA. In November, 2014, the FDA rescinded the

TA for Ranbaxy's generic Valcyte ANDA and stripped Ranbaxy of first filer status. The FDA granted final approval to a competitor that same day and generic Valcyte entered the market shortly thereafter. Ranbaxy sued the FDA for revoking its TA but the FDA prevailed on summary judgment.

C. Procedural Background

The first case filed in this Court before centralization, Meijer I, was filed in 2015. In September, 2015, Ranbaxy moved to dismiss. This Court accepted and adopted the Report and Recommendation of Magistrate Judge Kelley ("R&R") denying defendant's motion to dismiss. The Court certified its order for interlocutory appeal, recognizing that defendant had raised a complex legal question of first impression. The First Circuit Court of Appeals declined to hear the interlocutory appeal. Meijer, Inc. v. Ranbaxy Inc., No. 17-8008 (1st Cir. Dec. 28, 2018).

Additional lawsuits were subsequently filed in the United States District Courts for the Eastern District of Pennsylvania, the Eastern District of New York and the District of Massachusetts. The United States Judicial Panel on Multidistrict Litigation determined the lawsuits involved common questions of fact and centralized the action in this Court for pretrial proceedings

(Docket No. 2). Upon centralization, the case was divided into two putative classes of direct purchasers and indirect purchasers. Each putative class filed an amended consolidated complaint (Docket Nos. 20, 22). Ranbaxy then moved to dismiss both complaints (Docket Nos. 63, 65).

II. Motions to Dismiss

A. Legal Standard

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In considering the merits of a motion to dismiss, the Court may only look to the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference in the complaint and matters of which judicial notice can be taken. Nollet v. Justices of Trial Court of Mass., 83 F. Supp. 2d 204, 208 (D. Mass. 2000), aff'd, 228 F.3d 1127 (1st Cir. 2000).

Furthermore, the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. Langadinos v. Am. Airlines, Inc., 199 F.3d 68, 69 (1st Cir. 2000). If the facts in the complaint are

sufficient to state a cause of action, a motion to dismiss the complaint must be denied. See Nollet, 83 F. Supp. 2d at 208.

Although a court must accept as true all the factual allegations in a complaint, that doctrine is not applicable to legal conclusions. Ashcroft v. Iqbal, 556 U.S. 662 (2009). Threadbare recitals of legal elements which are supported by mere conclusory statements do not suffice to state a cause of action. Id. Accordingly, a complaint does not state a claim of relief where the well-pled facts fail to warrant an inference of any more than the mere possibility of misconduct. Id. at 1950.

B. Application

Ranbaxy moves to dismiss both Consolidated Complaints on the grounds that: 1) Ranbaxy is entitled to Noerr-Pennington immunity; 2) plaintiffs cannot demonstrate proximate cause and 3) plaintiffs cannot establish a predicate offense under RICO. Although the motions overlap substantially, there are several arguments unique to each plaintiff group. With respect to the DPPs, the parties disagree over whether the Court should consider Ranbaxy's motion anew or treat it as a motion for reconsideration, given that the Court previously denied a motion to dismiss filed by Ranbaxy in Meijer I. Ranbaxy moves to dismiss the DPPs' complaint on the additional ground that the

federal antitrust claims of the DPPs are barred by the FDCA. With respect to the EPPs, Ranbaxy moves to dismiss on the grounds that 1) the FDCA preempts their state law claims; 2) their state law antitrust claims are unavailing; 3) their state law consumer protection claims lack merit; and 4) the statute of limitations bars several of their claims.

The Court will address arguments unique to the DPPs, unique to the EPPs and common to both plaintiff groups seriatim.

1. Arguments Unique to the DPPs

a. Effect of Meijer I

Preliminarily, the parties dispute whether the Court should even entertain defendants' motions to dismiss the claims of the DPPs. The DPPs submit that the Court should treat the motion as one for reconsideration because, by Ranbaxy's own admission, "the Court previously considered [its] argument[s] and was ultimately unpersuaded." Ranbaxy urges the Court to consider its arguments anew because additional plaintiffs and a third drug (Nexium) have altered the nature of the case.

This contest highlights an issue of substantial disagreement among federal courts: the nature of a consolidated complaint filed after MDL centralization. Several courts have referred to consolidated complaints as mere "procedural

device[s] used to promote judicial efficiency and economy" and have declined to give such complaints the "same effect as an ordinary complaint." See, e.g., In re Propulsid Prods. Liab. Litig., 208 F.R.D. 133, 141–42, 144 (E.D. La. 2002) (citing 9 Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 2382 (1971) and Diana E. Murphy, Unified and Consolidated Complaints in Multidistrict Litigation, 132 F.R.D. 597 (1991)). Other courts have entertained motions to dismiss consolidated complaints in the regular course. See, e.g., In re Zimmer Nexgen Knee Implant Prods. Liab. Litig., MDL No. 2272, 2012 WL 3582708 (N.D. Ill. Aug. 16, 2012); In re Trasylol Prods. Liab. Litig., No. 08–MD–1928, 2009 WL 577726 (S.D. Fla. Mar. 5, 2009).

Courts are more willing to consider a motion to dismiss a consolidated complaint if it challenges the sufficiency of factual allegations common to all plaintiffs. See, e.g., In re Katrina Canal Breaches Litig., 309 F. App'x 836 (5th Cir. 2009) (per curiam); In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig., No. MDL 05–01699 CRB, 2007 WL 2028408, at *9 (N.D. Cal. July 10, 2007).

This Court will follow that approach and will consider defendant's motion to dismiss insofar as it challenges issues

common to all DPPs. The Court will not apply the heightened motion for reconsideration standard but, with respect to any argument previously rejected by the Court in Meijer I, will provide only a cursory analysis to determine whether the law has substantially changed.

b. FDCA Preclusion of DPPs' Claims

Ranbaxy avers that, pursuant to Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), the authority to enforce violations of the FDCA belongs exclusively to the FDA. As a result, argues Ranbaxy, the FDCA precludes the DPPs' federal antitrust claims. This Court previously recognized that the issue is one of first impression in this Circuit. As far as this Court can discern, that has not changed. Indeed, Ranbaxy cites no new case law addressing FDCA preclusion of federal antitrust claims involving fraud on the FDA.

Furthermore, Ranbaxy fails to proffer any persuasive reason for this Court to reexamine its previous analysis of Buckman's application to federal antitrust claims. Accordingly, the Court incorporates the reasoning in Meijer I and holds the claims of the DPPs are not precluded by the FDCA.

2. Arguments Unique to the EPPs

a. FDCA preemption of the EPPs' Claims

Ranbaxy submits that whatever the merits of the Court's preclusion analysis in Meijer I with respect to the federal antitrust claims of the DPPs, it is inapplicable to the preemption analysis of the state law antitrust and consumer protection claims of the EPPs. To the extent that Ranbaxy alleges that the EPPs' federal RICO claim is precluded by the FDCA, the Court rejects that argument for the reasons articulated in Meijer I.

Ranbaxy avers that Buckman compels the Court to dismiss the EPPs' state law claims as preempted by the FDCA. In Buckman, the plaintiffs attempted to bring state law tort claims against a manufacturer and a federal regulatory consultant for injuries caused by orthopedic bone screws. 531 U.S. at 344. At summary judgment, the only remaining defendant was the federal regulatory consultant who had assisted the manufacturer in "navigating the federal regulatory process" in an allegedly fraudulent manner. Id. at 343. According to the plaintiffs, the consultant prepared a fraudulent FDA application on behalf of the bone screw manufacturer in an effort to secure FDA

approval for the bone screws. Id. at 354. The FDA did not, however, make an independent determination of fraud. Id. at 354.

The United States Supreme Court held that the FDCA preempted plaintiffs' state law tort claims. Id. at 343. The Court reasoned that the plaintiffs' claims did not rely on traditional state tort law independent of federal regulations. Id. at 350-53. Instead, the plaintiffs relied on the anti-fraud provisions of the FDCA in support of their claims. Id. at 343. In that sense, the suit was one for enforcement of the FDCA rather than for remediation of tortious conduct and thus inevitably conflicted with the FDA's responsibility to police fraud pursuant to the FDCA. Id. at 350.

Neither party proffers a citation that addresses the applicability of Buckman to state law antitrust and consumer protection claims. The First Circuit has, however, considered Buckman in similar circumstances. In Dumont v. Reily Foods Co., a customer brought a consumer protection claim alleging that a coffee creamer manufacturer mislabeled a product as containing hazelnut in violation of the FDCA. 934 F.3d 35, 41 (1st Cir. 2019).

The court applied Buckman and held that the claim was not preempted by the FDCA but declined to elucidate the standard governing FDCA preemption of consumer protection claims. Id. Instead, because the parties agreed on a standard, the court adopted it, in essence, without prejudice. Id. at 42.

Although Dumont fails to clarify the applicable standard, it is nonetheless instructive. On the one hand, the court dismissed so much of the complaint as attempted to hold the defendant liable for violating federal false labeling standards. Id. On the other hand, the court allowed to proceed a separate and independent consumer protection claim. Id. The court reasoned that

> the preemptive force [of the federal regulations] will restrict the factfinder to determining whether conduct that does violate the federal regulations is also deceptive under Massachusetts law by virtue of its nature rather than its federal illegality.

Id. at 43.

That reasoning is buttressed by the concurring opinion of Justice Stevens in Buckman in which he notes the absence of a determination by the FDA that the defendant in Buckman had committed fraud. Buckman, 531 U.S. at 354 (Stevens, J., concurring). Had the FDA found fraud, Justice Stevens

observed, the plaintiff would have been able to establish causation for his state law claims without second-guessing the FDA's decision making. Id. Under such circumstances, state law remedies "would not encroach upon, but rather would supplement and facilitate" federal enforcement. Id.

Here, the EPPs have alleged that the FDA found fraud. Indeed, the FDA went so far as to rescind tentative approval for Ranbaxy's generic Valcyte and generic Nexium ANDAs. Furthermore, the fraud found by the FDA and realleged by plaintiffs in the Consolidated Complaints is a necessary element in the causation analysis of the EPPs' claims but, as in Dumont and contrary to Buckman, their claims do not seek to remedy only FDCA noncompliance. The EPPs must establish that they were injured by conduct of Ranbaxy that is independently proscribed under state law by virtue of its nature rather than its federal proscription. Dumont, 934 F.3d at 43. As pled by the EPPs, such an indirect relationship between the state and federal claims does not warrant preemption. Id.

This Court's reluctance to broaden Buckman is consistent with the "legion of cases upholding parallel requirements to federal violations as actionable under

state law." See, e.g., In re Medtronic, Inc. Implantable Defibrillators Litig., 465 F. Supp. 2d 886 (D. Minn. 2006); Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). Other courts that have considered the application of Buckman to state consumer protection and antitrust claims have similarly held. See In re Lipitor Antitrust Litig., 336 F. Supp. 3d 395, 411 (D.N.J. 2018); In re DDAVP Indirect Purchaser Antitrust Litig., 903 F. Supp. 2d 198, 220-21 (S.D.N.Y. 2012).

Accordingly, the EPPs may utilize evidence of Ranbaxy's efforts to manipulate the regulatory process in order to prove their state law antitrust and consumer protection claims without converting them into preempted fraud-on-the-FDA claims.

b. State Antitrust Claims

i. Standing

Ranbaxy challenges the EPPs' standing to bring antitrust claims under the laws of Florida and Massachusetts. Both state statutes have, however, been interpreted as permitting claims by indirect purchasers. In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.,

No. 14-md-02503-DJC, 2015 WL 5458570, *16 (D. Mass. Sept. 16, 2015). Therefore, the EPPs have standing.

ii. Jurisdiction and Venue

Ranbaxy submits that the Arizona, Michigan and North Dakota claims of the EPPs must be dismissed for failure to bring those claims in the proper jurisdictions but Ranbaxy offers no support for its contention that the respective state statutes provide for exclusive state court jurisdiction. Absent an express congressional prohibition to the contrary, the Court declines to interpret the applicable laws as depriving federal courts of jurisdiction. See In re Remicade Antitrust Litig., 345 F. Supp. 3d 566, 590 (E.D. Pa. 2018) (allowing Arizona antitrust claim to proceed in federal court); Superior Consulting Co. v. Walling, 851 F. Supp. 839 (E.D. Mich. 1994) (allowing Michigan antitrust claim to proceed in federal court).

iii. State Action Doctrine

Ranbaxy contends that the Iowa and Minnesota claims of the EPPs fail because Ranbaxy is entitled to state action immunity, which permits anticompetitive conduct if authorized and supervised by government officials. FTC v.

Ticor Title Ins. Co.,504 U.S. 621, 627 (1992). This doctrine applies only to conduct "undertaken pursuant to a clearly articulated and affirmatively expressed state policy" that is "actively supervised" by government officials. Mueller v. Wellmark, Inc., 818 N.W. 2d 244, 258 (Iowa 2012). Ranbaxy provides no evidence whatsoever that its alleged anticompetitive activities were expressly approved or regulated as required by the state action doctrine. See Crippen v. City of Cedar Rapids, 618 N.W. 2d 562, 567 (Iowa 2000).

iv. Miscellaneous

Ranbaxy challenges the California claim of the EPPs because the applicable statute "bans combinations," but not single firm monopolies. Asahi Kasei Pharma Corp. v. CoTherix, Inc., 138 Cal. Rptr. 3d 620, 626 (Cal. Ct. App. 2012). The EPPs have adequately alleged, however, that Ranbaxy conspired with Beardsley and Parexel to mislead the FDA.

Ranbaxy's dispute with respect to the EPPs' Vermont antitrust claims will be analyzed below in tandem with its dispute with the EPPs' Vermont consumer protection claims because the arguments substantially overlap.

c. State Consumer Protection Claims

i. Notice and Demand

Ranbaxy urges dismissal of the California, Maine and West Virginia claims of the EPPs for failure to serve Ranbaxy with the required notice and demand prior to the filing of the respective suits. The EPPs concede that notice was not provided but maintain that Ranbaxy cannot convincingly argue that it had inadequate notice. The EPPs further maintain that any settlement demand would have been futile but, alternatively, ask for leave to amend to meet the statutory requirements.

The EPPs proffer no support for their contention that the required notice and demand was either unnecessary or futile. Indeed, the EPPs failed even to plead as much. Accordingly, the EPPs' consumer protection claims under the laws of California, Maine and West Virginia will be dismissed without prejudice. The EPPs may amend their consolidated complaint to meet the statutory requirements.

Contrary to Ranbaxy's assertions, dismissal with prejudice under California law is unnecessary. See Morgan v. AT&T Wireless Serv., Inc., 99 Cal.Rptr.3d 768, 789 (Cal. App. Ct. 2009) (explaining that dismissal with prejudice is

not required where it is not necessary to further the purpose of providing defendant with an opportunity to correct the alleged wrong before a lawsuit is filed).

ii. Standing

Ranbaxy asserts the EPPs lack standing under the consumer protection laws of Maine, Michigan, Missouri, Pennsylvania, North Carolina and Vermont because the EPPs did not purchase the goods at issue primarily for personal, familial or household purposes.

The EPPs explicitly exclude from their putative class any persons or entities who purchased branded or generic Diovan, Nexium or Valcyte for purposes of resale. The EPPs pay costs of individual consumers for prescription drugs used for personal, familial or household purposes.

Each challenged provision provides standing for entities that purchase goods on behalf of their members for the members' personal, familial or household use. Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC, 737 F. Supp. 2d 380, 421-22 (E.D. Pa. 2010) (allowing consumer protection suit under Pennsylvania and North Carolina statutes by health benefit plans that purchased goods for their members' personal use); Rathe

Salvage, Inc. v. R. Brown & Sons, Inc., 965 A.2d 355, 467 (Vt. 2008) (explaining Vermont statute was amended to ensure businesses were provided the same protections as individuals); Ports Petroleum Co. of Ohio v. Nixon, 37 S.W.3d 237, 240 (Mo. 2001) (explaining the Missouri statute is "unrestricted, all-encompassing and exceedingly broad"); Zine v. Chrysler Corp., 600 N.W.2d 384, 393 (Mich. Ct. App. 1999) (explaining the Michigan statute focuses on the use to which the goods would be put, not on the characterization of the plaintiff as a consumer). Ranbaxy cites no support for its suggestion that the Maine statute, which has not been examined in this context, should be otherwise construed.

iii. Conduct within the Scope of the Statute

The consumer protection statutes of Minnesota, Missouri, New Mexico, North Dakota and South Dakota relate only to conduct that occurs "in connection with the sale" of the goods at issue. Ranbaxy maintains that its alleged fraud was made in connection with the FDA approval process, not with respect to any sale of goods. Ranbaxy's argument fails all around. Sheet Metal Workers Local 441 Health & Welfare Plan, 737 F. Supp. 2d at 414 (applying the

Minnesota statute to misleading statements and deceptive acts made to the Patent and Trademark Office); Jackson v. Barton, 548 S.W.3d 263, 270 (Mo. 2018) (interpreting the Missouri statue to prohibit deceptive practices if there is a relationship between the sale and unlawful conduct by any person occurring before, during or after a sale); Lohman v. Daimler-Chrysler Corp., 166 P.3d 1091, 1097 (N.M. Ct. App. 2007) (affording the New Mexico statute broad scope "encompass[ing] misrepresentations which bear on downstream sales by and between third parties"); A & R Fugleberg Farms, Inc v. Triangle Ag, LLC, 2010 WL 1418870 (D.N.D. Apr. 7, 2010) (interpreting the North Dakota statute liberally to cover fraud and misrepresentation that induced individuals to enter into a contract); In re DDAVP Indirect Purchaser Antitrust Litig., 903 F. Supp. 2d at 229 (explaining the South Dakota statute applies to misrepresentations made to the Patent and Trademark Office because such representations, in turn, allow the defendant to manufacture and market their product).

iv. Facially inapplicable

The Michigan, Nevada and New Mexico statutes are, according to Ranbaxy, facially inapplicable because

Ranbaxy's conduct does not fall within the statutorily enumerated practices. With respect to Michigan and Nevada, federal courts have sustained causes of action under the state consumer protection statutes for similar allegedly anticompetitive conduct. FTC v. Mylan Labs., Inc., 62 F. Supp. 2d 25, 48 (D.D.C. 1999) (Michigan); Sergeants Benevolent Association Health & Welfare Fund v. Actavis, plc, No. 15 Civ. 6549 (CM), 2018 WL 7197233, *46-47 (S.D.N.Y. Dec. 26, 2018) (Nevada). The New Mexico statute is to be interpreted broadly in favor of consumer protection and applies to misrepresentations that are designed to enable manufacturers to sell goods. Lohman, 166 P.2d at 1097. Consequently, the challenged provisions are not facially inapplicable.

v. Reliance

Ranbaxy urges dismissal of the Pennsylvania, South Dakota and West Virginia consumer protection claims of the EPPs for failure to plead that the EPPs relied on defendant's fraud to their detriment.

To establish a cause of action under the Pennsylvania consumer protection statute, a plaintiff must demonstrate that he justifiably relied on the defendant's wrongful

conduct and that he suffered harm as a result. Yocca v. Pittsburg Steelers Sports, Inc., 854 A.2d 425, 438-39 (Pa. 2004). The South Dakota statute allows a party to establish third party reliance whereby a defendant makes a misrepresentation to a third party on which the plaintiff relies. Brookings Mun. Utilities, Inc. v. Amoco Chemical Co., 103 F. Supp. 2d 1169, 1178 (D.S.D. 2000).

The EPPs do not, however, identify any specific misrepresentations upon which they relied to their detriment. They allege that they purportedly bought branded and generic drugs at an artificially inflated price but they do not allege their decisions were made in reliance on Ranbaxy's conduct rather than out of necessity and a limited market. Accordingly, the EPPs have not established reliance as required by Pennsylvania and South Dakota law.

The Supreme Court of Appeals of West Virginia has interpreted the West Virginia consumer protection statute to cover both affirmative misrepresentations and omissions. White v. Wyeth, 705 S.E.2d 828, 837-38 (Va. 2010). Where an omission is the alleged violative conduct, a plaintiff may show proximate cause in the absence of any proof of reliance. Id. Plaintiffs have adequately alleged that

Ranbaxy's omissions proximately caused them ascertainable loss and may pursue their West Virginia consumer protection claim.

vi. Miscellaneous

Ranbaxy alleges that the Massachusetts claim of the EPPs fails because Ranbaxy's conduct did not "occur primarily within the commonwealth." M.G.L. c. 93A § 11. Plaintiffs have alleged, however, that at least some EPPs were injured by Ranbaxy's conduct in Massachusetts. Whether Ranbaxy can prove that the conduct did not occur primarily in Massachusetts is an issue ill-suited for disposition at this stage. See Workgroup Technology Corp. v. MGM Grand Hotel, LLC, 246 F. Supp. 2d 102, 118 (D. Mass 2003).

Ranbaxy submits that the EPPs' Minnesota claim fails because "the sole statutory remedy for deceptive trade practices" under the Minnesota consumer protection statute is injunctive relief which plaintiffs do not seek. Sup. Edge, Inc. v. Monsanto Co., 964 F. Supp. 2d 1017, 1041 (D. Minn. 2013). The EPPs do not contest the issue and the Court agrees with Ranbaxy.

Ranbaxy avers that the Nebraska claim of the EPPs fails because Ranbaxy's conduct is regulated under laws administered by a regulatory body or officer acting under statutory authority of the United States. Neb. Rev. Stat § 59-1617(1). As described above with respect to the EPPs' state antitrust claims, the state action doctrine does not bar such claims.

d. Statute of Limitations

Ranbaxy submits that the EPPs' RICO claim, antitrust claims under the laws of 18 states and consumer protection claims under the laws of nine states are all barred by a four-year statute of limitations. Specifically, Ranbaxy contends that when the FDA revoked Ranbaxy's approval for Valcyte and Nexium on November 4, 2014, the claims of the EPPs accrued. The EPPs' complaints were not, however, filed until November 6, 2018 and February 13, 2019, more than four years after that accrual and therefore after the expiration of each applicable statute of limitations.

The statute of limitations is a "fact-intensive" affirmative defense" and will be rejected unless shown "with certitude" at the motion to dismiss stage. See Nat'l Assoc. of Gov't Workers v. Mulligan, 854 F. Supp. 2d 126, 131 (D. Mass 2012). As explained in Meijer I, this case raises the issue of

a possible continuing violation which is ill-suited for resolution at this stage.

3. Arguments Common to Both Plaintiff Groups

a. Noerr-Pennington Immunity

Ranbaxy contends that it is entitled to Noerr-Pennington immunity which immunizes government petitioning activity even if anticompetitive effects result and even if the petitioner uses disingenuous tactics. See Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961) and United Marine Workers v. Pennington, 381 U.S. 657 (1965) ("the Noerr-Pennington doctrine"). There is an exception to the Noerr-Pennington doctrine for "sham petitioning", however, which holds that immunity is withheld if a defendant uses the petitioning process as a mere "anticompetitive tool without legitimately seeking a positive outcome." See, e.g., A.D. Bedell Wholesale Co., Inc. v. Phillip Morris Inc., 263 F.3d 239, 250 n.29 (3d Cir. 2001).

Ranbaxy submits one argument not rejected in Meijer I in support of its contention that the sham petitioning exception is inapplicable. It argues that the exception applies only when the alleged anticompetitive conduct is a

result of a defendant's use of governmental process as opposed to its use of the outcome of that process. See City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 381 (1991). The Supreme Court in Omni Outdoor Advertising, Inc. explained

> the purpose of delaying a competitor's entry into the market does not render lobbying activity a "sham," unless . . . the delay is sought to be achieved only by the lobbying process itself, and not by the governmental action that the lobbying seeks.

Id.

Ranbaxy submits that plaintiffs do not allege that it gained an anticompetitive advantage by merely seeking a TA for its ANDAs. Any alleged anticompetitive advantage, according to Ranbaxy, could have resulted only from the outcome of that process: the FDA's grant of the coveted exclusivity period. Ranbaxy provides no support, however, for its limitation of the governmental process at issue to include only the tentative approval stage as opposed to the entire ANDA approval process.

A grant of tentative approval, even as a first filer, is a mere step in the process of obtaining final approval and taking a generic drug to market. The grant of exclusivity is, to be sure, a consequential stage of the

ANDA approval process but it does not authorize a party to take a drug to market. 21 U.S.C. § 355(i)(5)(B)(iv). Here, plaintiffs adequately allege that Ranbaxy used a stage of the ANDA approval process to secure exclusivity while awaiting final approval to bar competition.

Drawing all reasonable inferences in favor of the plaintiffs, they have adequately alleged that the sham petitioning exception to the Noerr-Pennington doctrine applies.

b. Proximate Cause

Ranbaxy contends that plaintiffs have failed to allege proximate cause with respect to their antitrust and RICO claims because 1) the FDA's regulatory activity was an intervening factor and 2) no other manufacturer was in a position to secure final approval of a generic competitor during the relevant timeframe.

This Court already determined in Meijer I that Ranbaxy's obfuscation affected the FDA's pace in granting final approval to Ranbaxy and that plaintiffs have alleged sufficient facts and legitimate inferences to raise a factual question that is ill-suited for resolution at this

stage. Ranbaxy provides no reason for the Court to deviate from that holding.

c. RICO Predicate Offenses

Ranbaxy proffers one new argument with respect to plaintiffs' RICO claims: plaintiffs cannot demonstrate that Ranbaxy committed the alleged predicate acts of mail and/or wire fraud because Ranbaxy did not deprive the FDA of "property." See 18 U.S.C. § 1961(1).

Mail and wire fraud require proof of 1) a scheme or artifice to defraud, 2) knowing and willing participation in that scheme with the specific intent to defraud; and 3) the use of interstate mail or wire communications in furtherance of the scheme. Sanchez v. Triple-S Mgmt., Corp., 492 F.3d 1, 9-10 (1st Cir. 2007). Both statutes are "limited in scope to the protection of property rights." Cleveland v. United States, 531 U.S. 12, 18 (2000); Pasquantino v. United States, 544 U.S. 349, 355 & n.2 (2005). In other words, the thing obtained by fraud must be "property in the hands of the victim." Cleveland, 531 U.S. at 15.

The parties' primary disagreement involves the application of the holding in Cleveland. In that case, the

defendants were charged with engaging in a scheme that involved fraudulent applications to obtain video poker licenses in Louisiana. 531 U.S. at 15. The Supreme Court considered whether a government regulator conveys "property" under the mail fraud statute when it issues a license. Id. at 20. The Court acknowledged that the government had a substantial economic interest in the video poker industry but ultimately held that a license is not "property" in the hands of a government regulator. Id. The primary concern of the agency in issuing licenses is, according to the Court, regulatory and, for that reason, not actionable as mail fraud. Id.

The decision in Cleveland stands for the proposition that a government regulator does not own licenses; instead, it holds the regulatory power to issue licenses. Pasquantino, 544 U.S. at 357; see also United States v. Middendorf, No. 18-cr-36 (JPO), 2018 WL 3443117 (S.D.N.Y. July, 17, 2018) ("To borrow an analogy from physics, what is potential energy in the hands of the government becomes kinetic energy in the hands of a license-holder.").

Ranbaxy submits that a license to market drugs for a 180-day exclusivity period is virtually indistinguishable

from the license at issue in Cleveland and, therefore, cannot be considered "property" in the hands of the FDA.

This case is, however, distinguishable from Cleveland. In Cleveland, the citizens of the State of Louisiana and the State itself were the only alleged victims of the defendants' scheme to obtain a video poker license fraudulently. Cleveland, 531 U.S. at 15-17. For that reason, the only interests at stake were purely regulatory: the State's interest in "honest services" and in protecting its people from unregulated video poker operators. Id. at 372.

Here, in contrast, plaintiffs have alleged that Ranbaxy's fraud affected the interests of individuals and entities other than the government. Specifically, plaintiffs allege that Ranbaxy's conduct caused a delay in the availability of generic Diovan, Valcyte and Nexium which caused them to purchase those drugs at artificially inflated prices, an interest distinct from any regulatory interests of the FDA.

Ranbaxy asserts that its alleged fraud was directed solely at the FDA and, therefore, the FDA is necessarily its only "victim." Not so. Although the mail and wire

fraud statutes require a victim, the victim need not be the one who would be named in an indictment for mail or wire fraud. See United States v. Hatch, 926 F.2d 387, 392 (5th Cir. 1991) ("The focus of the mail fraud statute is upon the use of the mail to further a scheme to defraud, not upon any particular kind of victim."). More importantly, there is no requirement in the mail or wire fraud statutes that the victim who is deprived of money or property be the same party who was deceived by the defendant's scheme. See id.; accord. United States v. Valencia, No. 04-515, 2006 WL 3716657, at (S.D. Tex. Dec. 14, 2006), aff'd, 600 F.3d 389 (5th Cir. 2010); see also United States v. Howard, 619 F.3d 723, 727 (7th Cir. 2010)("[E]ven if an indictment names particular victims, the government need not prove intent to harm those named victims.").

Plaintiffs have alleged that Ranbaxy's fraud resulted in it securing an unfair and profitable market advantage which caused plaintiffs to pay higher prices for brand and generic Diovan, Valcyte and Nexium. Accordingly, they have sufficiently pled a predicate offense under RICO.

ORDER

For the forgoing reasons,

a. the motion of defendant Ranbaxy to dismiss (Docket No. 65) is, with respect to the complaint of the Direct Purchaser Plaintiffs, **DENIED**;

b. the motion of defendant Ranbaxy to dismiss (Docket No. 63) is, with respect to the consumer protection claims of the End-Payor Plaintiffs under the laws of: California, Maine, Minnesota, Pennsylvania, South Dakota and West Virginia, **ALLOWED**, but is otherwise **DENIED**; and

c. the motions of defendant Ranbaxy to dismiss the claims against Ranbaxy Laboratories Limited and Ranbaxy USA, Inc. (Docket Nos. 63, 65), are **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated November 27, 2019