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:	
Cross-Motions for Summary Judgment	

MEMORANDUM & ORDER

GORTON, J.

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

The two plaintiff classes are composed of direct purchaser plaintiffs ("DPPs") and end-payor plaintiffs ("EPPs"). DPPs, such as wholesalers and distributors, purchase generic drugs directly from drug manufacturers. EPPs are third-party payors, such as health plans and insurance companies, that indirectly purchase and/or provide reimbursement for generic drugs at the end of the distribution chain from retailers and other intermediaries. The DPPs and EPPs (collectively, "plaintiffs")

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

Pending before the Court are cross motions for summary judgment under Federal Rule of Civil Procedure 56. For the reasons that follow, both the defendants' and plaintiffs' motions will be denied.

I. Background

A. Factual Background

Both the Court and the parties are well acquainted with the facts, which are described in detail in the Report and Recommendation of United States Magistrate Judge M. Page Kelley on Ranbaxy's motion to dismiss the complaint of the plaintiffs 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). For purposes of completeness, however, the Court provides the following abbreviated summary of the background relevant to the pending motions.

In the early 2000s, Ranbaxy filed a series of applications with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and market generic versions of various pharmaceuticals. Under the Hatch-Waxman Act, Pub. L.

No. 98-417, 98 Stat. 1585 (1984), the first generic drug manufacturer to submit a substantially complete Abbreviated New Drug Application ("ANDA") is entitled to a 180-day period of exclusivity during which no other manufacturer is permitted to market a generic version of the subject drug. The FDA may, however, revoke the exclusivity period if the generic manufacturer fails to obtain tentative approval from the FDA within 30 months of submission, among other reasons. Tentative approval, which requires the manufacturer to demonstrate that its facilities comply with current good manufacturing practices, effectively means that the ANDA meets all the substantive requirements for final approval, but the FDA is barred from formally approving the application due to preexisting patents.

In 2004 and 2005, Ranbaxy submitted the first substantially complete ANDAs for the three brand drugs at issue here: Diovan, Nexium and Valcyte. Ranbaxy subsequently obtained tentative approval for each of those drugs in 2007 and 2008. Despite its early success, Ranbaxy failed to secure final approval for its generic version of Diovan until June, 2014 and did not bring that generic to market until July, 2014. Before defendants could secure final approval for its generic Nexium and Valcyte ANDAs, the FDA revoked its tentative approval for both drugs. Ranbaxy's generic versions of these two drugs were never brought to market.

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 Diovan, Nexium and Valcyte. Plaintiffs assert that but for defendants' allegedly anti-competitive conduct, generic versions of those three drugs would have entered the market and been available at lower prices much sooner. As a result, plaintiffs contend they paid artificially inflated prices for Diovan, Nexium and Valcyte during the Class Periods.

B. Relevant Procedural History

The five actions comprising this multidistrict litigation were centralized in this Court in February, 2019. In April, 2019, the Court consolidated for pretrial purposes all direct purchaser actions and all end-payor actions that were centralized in this District and assigned to this Court, thereby creating two putative class actions. Amended complaints were filed by the DPPs and EPPs later that month. The EPPs further amended their complaint in February, 2020 and March, 2021. The DPPs also amended their complaint in March, 2021. After oral argument, this Court certified two sets of classes, one for DPPs and EPPs, in May, 2021. Each set is composed of three

nationwide classes, one for each of the pharmaceuticals at issue.

Shortly thereafter, the parties filed cross motions for summary judgment. Parties have submitted oppositions to these motions, which have, in turn, engendered sur-replies. This Court heard oral argument on the motions in October, 2021.

II. Legal Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 50 (1st Cir. 1990)). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A fact is material if it "might affect the outcome of the suit under the governing law...." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

If the moving party satisfies its burden, the burden shifts to the nonmoving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and make all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). Summary judgment is appropriate if, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law. Celotex Corp., 477 U.S. at 322-23.

III. Analysis

A. Ranbaxy's Motion for Summary Judgment

Defendants contend that summary judgment is appropriate for a variety of reasons and, in the alternative, partial summary judgment on damages is required.

1. FDCA Preclusion

This Court has previously rejected Ranbaxy's contention that the authority to enforce violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") belongs exclusively to the FDA, recognizing that the issue is one of first impression in this Circuit. While Ranbaxy yet again asserts the relevance of Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001),

defendants have failed to provide any persuasive reason for the Court to reexamine its prior analysis, which concluded that the Buckman decision did not directly resolve the matter. See Arizona v. California, 460 U.S. 605, 618, supplemented by 466 U.S. 144 (1984) ("[W]hen a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case."). Neither party cites new case law addressing FDCA preclusion of federal antitrust claims involving fraud on the FDA and the Court has found none. See Naser Jewelers, Inc. v. City of Concord, N.H., 538 F.3d 17, 20 (1st Cir. 2008) ("Narrow exceptions to the doctrine exist if the initial ruling was made on an inadequate record or was designed to be preliminary; if there has been a material change in controlling law; if there is newly discovered evidence bearing on the question; and if it is appropriate to avoid manifest injustice." (citations omitted)).

Accordingly, the Court relies upon its prior reasoning and finds the plaintiffs' claims are not precluded by the FDCA.

2. RICO Predicate Offenses

Citing the recent decision in Kelly v. United States, 140 S. Ct. 1565 (2020), Ranbaxy urges this Court to reconsider its determination that the plaintiffs have provided evidence sufficient to allege the predicate offenses of mail and/or wire

fraud under RICO. As the Court has previously articulated, 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) (citation omitted). In other words, the thing obtained by fraud must be "property in the hands of the victim." Id. at 15. Defendants allege that plaintiffs have provided no cognizable property upon which to ground their RICO claims. Defendants seek to draw a distinction between Ranbaxy's regulatory interests and property rights.

The Court has already rejected this reasoning. In its order on defendants' motion to dismiss, the Court found the plaintiffs had sufficiently pled a predicate offense under RICO by asserting that Ranbaxy's fraud affected the interests of individuals and entities other than the government. Kelly, in which the Supreme Court distinguished between property sufficient for a fraud claim and "run-of-the-mine...regulatory power," even when such regulatory power causes foreseeable loss to third parties, does not change this calculus. 140 S. Ct. at 1573. Kelly is a straightforward application of the holding in

Cleveland, which this Court previously determined did not bar plaintiffs' claims. In both Kelly and Cleveland, a scheme to alter the government's regulatory choice did not implicate a property right.

Here, by contrast, the object of the scheme was not simply the government's regulatory choice but rather the property rights implicated by that choice. See In re JUUL Labs, Inc., Mktg., Sales Pracs., & Prod. Liab. Litig., 497 F. Supp. 3d 552, 615 (N.D. Cal. 2020) (finding Kelly did not foreclose plaintiffs' RICO claims where "the scheme was to secure the money and property of the end consumer"). As this Court has previously articulated, the victims of the alleged fraud need not be the parties upon whom the defendants' fraud was perpetrated. 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."). Nor is there a requirement in the mail or wire fraud statutes that the victim who is deprived of money or property be the party who was deceived by the defendants' scheme. See id.; accord. United States v. Valencia, No. CRIM. H-04-514-SS, 2006 WL 3716657, at *4 (S.D. Tex. Dec. 14, 2006), aff'd, 600 F.3d 389 (5th Cir. 2010); United States v. Howard, 619 F.3d 723, 727 (7th Cir. 2010).

Defendants suggest no other legal or factual deficiencies to undermine the Court's prior ruling.

3. Causation

Defendants assert that plaintiffs' theory of causation hinges on two premises: (1) Ranbaxy's alleged fraud induced the FDA to grant tentative approval for Diovan, Nexium and Valcyte before the expiration of the 30-month deadline to earn tentative approval for each drug, and (2) the FDA would have revoked Ranbaxy's period of exclusivity for generic Diovan if Ranbaxy had failed to obtain tentative approval within 30 months. Ranbaxy takes issue with both premises.

On the first issue, defendants argue that none of the tentative approvals was induced by fraud, as evidenced by the FDA's communications with Ranbaxy. More specifically, Ranbaxy points to a 2012 consent decree between the defendants and the FDA that established new practices and offices to ensure Ranbaxy's regulatory compliance, withdrew certain ANDAs and submitted other ANDAs to new audits. Diovan, Nexium and Valcyte were among those pharmaceuticals subject to new audits. After those audits, the FDA sent three letters to Ranbaxy informing it that those applications did not appear to contain any "untrue statements of material fact" or "data irregularities" and, based upon those findings, the FDA resumed consideration of whether

those ANDAs were eligible for final approval. Ranbaxy now asserts that those letters prove that the FDA's tentative approvals of Diovan, Nexium, and Valcyte were not induced by fraud and, thus, that plaintiffs cannot prove that the fraud alleged caused plaintiffs' injuries.

Ranbaxy further contends that the record disproves causation with respect to generic Diovan because, after Ranbaxy submitted its application but before the FDA granted Ranbaxy tentative approval, the FDA altered the requirements for approval of that application, thus invoking a statutory exception. The applicable provision, known as the "change-based exception", indicates that a first filer will forfeit its exclusionary period if it does not obtain tentative approval within 30 months,

> unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

21 U.S.C. § 355(j)(5)(D)(i)(IV). Ranbaxy contends that the exception applies because a change in the brand drug's USP monograph was one reason why Ranbaxy failed to obtain approval within 30 months of filing. Therefore, Ranbaxy explains, any alleged fraud was not the reason for the delay that resulted in the plaintiffs' alleged injury, i.e. the delay was inevitable and excusable.

"[A]n antitrust plaintiff must prove that he or she suffered damages from an antitrust violation and that there is a causal connection between the illegal practice and the injury." In re Intuniv Antitrust Litig., 496 F. Supp. 3d 639, 672 (D. Mass. 2020) (quoting In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 267 (D. Mass. 2014)). An antitrust violation may, however, still cause the plaintiffs' injury "even if there are additional independent causes of the injury." In re Nexium, 42 F. Supp. 3d at 267 (quoting In re Flonase Antitrust Litig., 798 F. Supp. 2d 619, 627–28 (E.D. Pa. 2011)). "Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, the burden shifts to the defendant to rebut this causal inference." In re Neurontin Mktg. and Sales Practices Litig., 712 F.3d 21, 45 (1st Cir. 2013) (internal quotation and citation omitted). "Defendants have a high bar to meet, because causation is generally a question best left for the jury." In re Loestrin 24 Fe Antitrust Litig., 433 F. Supp. 3d 274, 323 (2019) (citations omitted); see also Peckham v. Continental Cas. Ins. Co., 895 F.2d 830, 837 (1st Cir. 1990) ("Causation questions of this sort are normally grist for the jury's mill.")

Defendants have failed to rebut compellingly the plaintiffs' causal inferences on either of the issues addressed.

First, defendants' description of the subject letters as "no fraud" letters is misguided and inaccurately characterizes their significance. Plaintiffs have presented sufficient evidence to suggest that, in reaching the conclusion that the ANDAs

> [did] not appear to contain any untrue statements of material fact [nor] contain a pattern or practice of data irregularities affecting approval[,]

the FDA did not assess all the evidence now available to the Court. Moreover, as clearly articulated in the letters, the FDA's determinations of wrongdoing were constrained by the relevant consent decree and did not restrict the "FDA's ability to raise additional data integrity concerns regarding the review process" at a later time. These letters are not the conclusive exculpation that defendants confidently submit.

Even assuming, arguendo, that these letters are evidence that the FDA determined that defendants did not fraudulently secure tentative approval for the relevant drugs, that determination does not preclude the Court from making its own independent assessment. In the context of administrative decision-making, federal courts give the decisions of an administrative agency, such as the FDA, preclusive effect

> when an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate.

B & B Hardware, Inc. v. Hargis Indus., Inc., 575 U.S. 138, 148 (2015) (quoting Univ. of Tennessee v. Elliott, 478 U.S. 788, 798 (1986)). These conditions can, however, only be met "insofar as the proceeding resulting in the determination entailed the essential elements of adjudication." Restatement (Second) of Judgments § 83(2)(b) (1982); see Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 109–10, (1991) ("Although administrative estoppel is favored as a matter of general policy, its suitability may vary according to...the relative adequacy of agency procedures."). Here, the FDA process that resulted in the relevant letters did not include any sort of "adjudicative scheme...sufficient to trigger the doctrine of collateral estoppel." Rios-Pineiro v. United States, 713 F.3d 688, 692 (1st Cir. 2013). Compare Rios-Pineiro, 713 F.3d. at 692 (granting preclusive effect to agency decision where agency adjudication was alternative to Federal Court of Claims and procedures included limited discovery and examination of witnesses at hearing) with Johnson v. Vilsack, 833 F.3d 948, 957 (8th Cir. 2016) (declining to grant preclusive effect to agency decision that was based on selective information and parties had limited rights to present evidence or argument). For this reason, these letters carry no preclusive effect in the present litigation and cannot conclusively disprove causality.

Nor does the change-based exception undermine the plaintiffs' contention of causality. As an initial matter, while defendants argue that the FDA's tentative approval of generic Diovan in 2007 would have been delayed due to that change independent of any alleged fraud, they do not address causality in the context of Ranbaxy's initial, 2004 generic Diovan application. Ranbaxy was eligible for the tentative approval at issue only because it was the first filer in 2004 and plaintiffs contend that such initial eligibility was fraudulently based. Thus, to the extent the purported injuries stem from Ranbaxy, rather than from another manufacturer, securing the coveted first-filer status for generic Diovan, the monograph change did not break the "causal connection between the illegal practice and the injury." Sullivan v. Nat'l Football League, 34 F.3d 1091, 1103 (1st Cir. 1994), as amended on denial of reh'g (Oct. 26, 1994).

Moreover, as noted above, the possibility that plaintiffs' injuries resulted from multiple, independent causes does not exculpate the defendants. They have proffered insufficient evidence to rebut the inference that the alleged fraud, alone or in concert with the monograph change, caused plaintiffs' injuries with respect to generic Diovan. "Plaintiffs need not prove that the antitrust violation was the sole cause of their injury, but only that it was a material cause." In re Nexium

(Esomeprazole) Antitrust Litig., 42 F. Supp. 3d at 267 (D. Mass. 2014) (quoting Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1, 14 (1st Cir. 1979)); see also In re Nexium (Esomeprazole) Antitrust Litig., 309 F.R.D. 107, 141 (D. Mass. 2015), as amended (Aug. 7, 2015), aff'd, 842 F.3d 34 (1st Cir. 2016), and cases cited. The parties' experts present diverging perspectives with respect to the import of the change-based exception relative to the award of the exclusionary period to Ranbaxy. In light of that disagreement, "the evidence raises a genuine dispute of material fact on this causation theory." In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. CV 14-MD-02503, 2018 WL 563144, at *16 (D. Mass. Jan. 25, 2018).

4. Proof of Monopoly Power

Plaintiffs assert two claims under the Sherman Act: monopolization and attempted monopolization.

> To successfully prove a monopolization offense, a plaintiff must show that defendant (1) has monopoly power and (2) the defendant has engaged in impermissible exclusionary practices with the design or effect of protecting or enhancing its monopoly position.

Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 195 (1st Cir. 1996) (internal quotation and citation omitted). To prove attempted monopolization, a plaintiff must similarly prove predatory or anticompetitive conduct but need only demonstrate that there was "a dangerous probability of

achieving monopoly power" and "a specific intent to monopolize." Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993). With regard to both claims, "[m]onopoly power is the power to control prices or exclude competition." United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).

Plaintiffs may prove such power with two kinds of evidence: direct, such as super-competitive prices or restricted output, or circumstantial. See Coastal Fuels, 79 F.3d at 196–97 (citations omitted); accord. Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007). Some courts have, by implication, limited the circumstantial evidence that can support a claim of monopoly power to the defendant's market share in the relevant market. See Heerwagen v. Clear Channel Communications, 435 F.3d 219 (2d Cir. 2006) ("Indirect proof of market power, that is, proof that the defendant has a large percentage share of the relevant market, is a 'surrogate' for direct proof of market power."); Arani v. TriHealth Inc., 77 Fed. Appx. 823, 826 (6th Cir. 2003) ("The existence of monopoly power can be established by either: (1) presenting direct evidence of a defendant's exercise of control over prices or the actual exclusion of competitors; or (2) showing that a defendant has a high market share in a defined market."). Others, including the First Circuit Court of Appeals, have not done so. See Diaz Aviation Corp. v. Airport Aviation Servs.,

Inc., 716 F.3d 256, 265 (1st Cir. 2013) ("[M]onopoly power is *typically* proven by defining a relevant market and showing that the defendant has a dominant share of that market." (emphasis added)); Coastal Fuels, 79 F.3d at 197 ("Market power *may* be proved 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." (emphasis added)).

The Court therefore rejects defendants' assertions that the fact that Ranbaxy never sold Valcyte and Nexium, and thus never maintained a significant share of the relevant market, is dispositive of the Sherman Act claims. While an antitrust defendants' share of the relevant market is typically used as evidence of monopoly power, typicality is not necessary here. Within the highly regulated market for pharmaceuticals, plaintiffs have proffered sufficient evidence to create a genuine dispute of material fact as to whether Ranbaxy maintained monopoly power due to its first-filer status and the resulting exclusionary periods. This holistic assessment provides strong evidence that Ranbaxy maintained the "ability to lessen or destroy competition in the relevant market," the determining factor in assessing monopoly power. Sterling Merch., Inc. v. Nestle, S.A., 656 F.3d 112, 125 (1st Cir. 2011)

(internal quotation and citations omitted); see also Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc., 386 F.3d 485, 500–01 (2d Cir. 2004). "[A]fter full consideration of the relationship between market share and other relevant market characteristics," Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 98 (2nd Cir. 1998), the fact that Ranbaxy never sold Valcyte and Nexium is not dispositive. See F.T.C. v. Indiana Fed'n of Dentists, 476 U.S. 447, 460–61 (1986) ("the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition" (internal quotation and citation omitted)). These unique circumstances reveal that Ranbaxy's decision not to enter those markets is reflective, rather than dispositive, of the market power that the defendants allegedly wielded.

Defendants' argument that Ranbaxy did not have monopoly power in the Diovan market because of the presence of brand Diovan and the brand company's authorized generic ("AG") is equally unpersuasive. There is no dispute that the brand drug, the AG and Ranbaxy's generic version were, from a medical perspective, undifferentiated substitutes. Nor do plaintiffs contend that the entrance of generic Diovan into the market had no impact on the brand price. It is, however, undisputed that:

> Substitutability with other drugs shows a lack of market power only if it effectively limits the price to the competitive level or something slightly above, and if that is the case, then entry of new competitors should not have a substantial effect on average price.

In re Aggrenox Antitrust Litig., 199 F. Supp. 3d 662, 668 (D. Conn. 2016) (quotation and citations omitted). Here, plaintiffs have proffered compelling, though disputed, evidence that Ranbaxy charged super-competitive prices during their period of exclusivity for generic Diovan. That pricing data provides evidence that the medical substitutability of available alternatives was of limited import in this context.

Furthermore, contrary to defendants' assertion, courts have recognized the potential for monopoly power where the relevant market is limited to the generic version of the product and generic prices demonstrate a degree of independence from brand-name competition. See Geneva Pharms. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496 (2d Cir. 2004) (holding that, while "[i]t may seem paradoxical," the relevant product market was only the generic drug because "in examining the competitive pressures that affect the ability of a lone generic manufacturer to raise prices or reduce output, we are persuaded that competition among generics creates those restraints"); In re Lorazepam & Clorazepate Antitrust Litig., 467 F. Supp. 2d 74, 82 (D.D.C. 2006). Where there are disagreements "about the products that make up the market capable of constraining

[defendant's] profit margins and price to a competitive level," as here, summary judgment is inappropriate. In re Loestrin 24 Fe Antitrust Litig., 433 F. Supp. 3d at 299.

5. Standing to Recover "Brand-Brand" Damages

As this Court previously articulated, although it is true that "[c]ompetitors and consumers in the market where trade is allegedly restrained are presumptively the proper plaintiffs" in an antitrust action, Breiding v. Eversource Energy, 344 F. Supp. 3d 433, 452 (D. Mass. 2018) (quoting Serpa Corp. v. McWane, Inc., 199 F.3d 6, 10-11 (1st Cir. 1999)), it does not follow that consumers who are outside of that market necessarily lack standing. Rather, standing depends on whether the injury suffered "flows from that which makes defendants' acts unlawful." Serpa Corp., 199 F.3d at 10 (internal citation omitted).

Ranbaxy's contention that plaintiffs necessarily lack antitrust standing to recover for alleged brand-brand injury because their experts defined the relevant antitrust market as limited to ANDA-based generics is therefore unavailing. Brand-brand injuries are those stemming from transactions in which class members actually purchased brand drugs and would have also purchased brand drugs absent Ranbaxy's alleged wrongdoing.

Plaintiffs have provided evidence sufficient to create a genuine dispute as to whether Ranbaxy's activities caused brand purchasers to pay higher drug prices due to delayed generic entry. Plaintiffs' experts have proffered opinions that Ranbaxy's alleged delays allowed brand manufacturers to avoid the competitive pressure of generics for longer than would have otherwise been possible. As the defendants point out, plaintiffs' expert suggests that the cross-price elasticity of demand between brand and generic drugs is low. Low is not, however, the same as nonexistent. Other courts have countenanced recovery based upon similar theories. See In re Nexium (Esomeprazole) Antitrust Litig., 296 F.R.D. 47, 56 (D. Mass. 2013) (recognizing entry of generic drug would result in price decline of both brand and generic); Teva Pharms. USA, Inc. v. Abbott Lab'ys, 252 F.R.D. 213, 228 (D. Del. 2008) (considering brand-brand damages); In re Niaspan Antitrust Litig., 397 F. Supp. 3d 668, 690 (E.D. Pa. 2019) (same).

Thus, while brand-brand injuries rest upon transactions outside the generic markets in which Ranbaxy participated, its alleged anticompetitive behavior may still have caused damages to these plaintiffs. Plaintiffs have presented sufficient evidence of those damages to survive defendants' motion for summary judgment.

6. Partial Summary Judgment on Damages

Ranbaxy urges that the defendants are entitled to partial summary judgment based upon four alleged errors in the damages methodology used by plaintiffs. Those errors purportedly do not implicate a genuine dispute of material fact.

a. Damages for generic Nexium purchases

Three nationwide RICO classes of EPPs have been certified by this Court, one for each of the pharmaceuticals at issue. For Diovan and Valcyte, the classes include EPPs who purchased, paid or provided reimbursement for the relevant drug and/or AB-rated generic versions of the drug from the defendants during the relevant class period. In contrast, the Nexium class includes only those EPPs who purchased, paid or provided reimbursement for the AB-rated generic version of the drug, not the brand drug. As a result, plaintiffs' damages expert did not factor in brand rebates on purchases of Nexium in her calculation of damages, in contrast to her calculations for Diovan and Valcyte.

Claiming that neither plaintiffs nor their damages experts provides any justification for the inconsistency, defendants contend that the proffered calculations exaggerate the damages of Nexium EPPs because they do not account for rebates from brand manufacturers. At the hearing on the motion, defendants

proposed that the Nexium EPPs were actually better off as a result of Ranbaxy's alleged anti-competitive conduct because brand Nexium prices were lower than generic prices. Defendants argued that the delayed market entry of generic Nexium therefore saved class members money.

The problem with defendants' contention is that the class definition excludes EPPs who purchased brand Nexium and, thus, excludes EPPs who received the rebates at issue. Defendants' reliance on Los Angeles Mem'l Coliseum Comm'n v. Nat'l Football League, 791 F.2d 1356 (9th Cir. 1986), is misplaced. In that case, the Ninth Circuit Court of Appeals found that:

> plaintiff's gross recovery for the antitrust violation must be reduced by any benefits that plaintiff would not have received had there been no anticompetitive conduct by the defendant.

791 F.2d at 1366. In that case, however, plaintiffs were the parties who benefited from the supposed misconduct. Here, in contrast, the EPPs who benefited from the subject rebates are excluded from the relevant class. These rebates are, thus, simply irrelevant. To conclude otherwise would create an untenable disconnect between the plaintiffs' case for liability and their case for damages. See Comcast Corp. v. Behrend, 569 U.S. 27, 35 (2013) (citations omitted).

b. Manufacturers launching generic Diovan in September, 2012

Plaintiffs allege that, but for Ranbaxy's illegal and anticompetitive behavior, generic Diovan could have been marketed as early as September, 2012. Based on that timeline, plaintiffs' experts calculate the damages for two but-for scenarios, one in which three manufacturers would have launched generic Diovan between September, 2012 and April, 2013, and another in which at least five generic manufacturers would have launched the drug in September, 2012. Defendants take issue with the latter scenario, asserting that plaintiffs have not proffered evidence sufficient to conclude that five generic manufacturers would have been able to launch the pharmaceutical at that time.

"Expert testimony without...a factual foundation cannot defeat a motion for summary judgment." In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d. at 248 (citations omitted). Testimony, including the testimony of expert witnesses, can, however, be based on "probable and inferential as well as direct and positive proof." In re Asacol Antitrust Litig., 323 F.R.D. 451, 488 (D. Mass. 2017), rev'd and remanded, 907 F.3d 42 (1st Cir. 2018). "Any other rule would...be an inducement to make wrongdoing so effective and

complete in every case as to preclude any recovery, by rendering the measure of damages uncertain." Bigelow v. RKO Radio Pictures, 327 U.S. 251, 264 (1946).

Plaintiffs appropriately rely on such probable and inferential evidence, the only kind of evidence available given the counterfactual under consideration, and defendants do not substantively refute their logic. In fact, the defendants' own uncertainty regarding the precise number of market entrants in the but-for world highlights the genuine dispute as to this issue, which renders it unsuitable for resolution on a motion for summary judgment. Moreover, this is not a circumstance in which the plaintiffs' logic

> rest[s] solely on an expert's bottom line conclusion, without some underlying facts and reasons, or a logical inference process to support the expert's opinion.

In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d at 248. Rather, plaintiffs have supplied sufficient evidence regarding the interest of other generic manufacturers in producing generic Diovan before, during and after Ranbaxy's alleged anticompetitive behavior, to survive defendants' motion for summary judgment.

c. Brand-generic damages after actual generic entry date

Plaintiffs' damages calculations include brand-generic overcharges after generics entered the market. They allege that the conversion from the brand to generic product is not immediate and that Ranbaxy's anticompetitive practices delayed the conversion. The defendants take issue with this logic, suggesting that the plaintiffs cannot show that Ranbaxy's conduct prevented them from purchasing generics once they had come to market and, more specifically, that the difference in the generic volume between the actual world and but-for world was caused by Ranbaxy's alleged activity.

Defendants do not substantively address the plaintiffs' rebuttal that it can take several months, or more, for generic substitutes to penetrate the market fully and for brand prices to stabilize after generics are introduced. While plaintiffs were, of course, theoretically able to purchase generics once they became available, there is a genuine dispute of material fact as to whether Ranbaxy's alleged behavior resulted in artificially inflated drug prices even after there were generic options in the market. See, e.g., In re Nexium (Esomeprazole) Antitrust Litig., 296 F.R.D. 47, at 55-56 (D. Mass. 2013)

(noting that brand erosion after generic entry is generally accepted to increase over time).

d. Overcharges for indirect purchasers

Finally, defendants allege that, even among the DPPs, very few members of the plaintiff classes purchased the drugs at issue directly from Ranbaxy. Ranbaxy avers that, under precedent stemming from Hanover Shoe Inc. v. United Shoe Mach. Corp., 392 U.S. 481 (1968), those indirect purchasers can recover only based upon their net injuries, rather than from alleged overcharges at the time of purchase. Plaintiffs base their damages calculations upon those alleged overcharges which are higher than net injuries because plaintiffs passed along at least some of the super-competitive pricing to customers.

The proposition that indirect purchasers removed from an antitrust violator in a distribution chain may not seek damages against the alleged wrongdoer, see Illinois Brick Co. v. Illinois, 431 U.S. 720, 746-747 (1977), is, however, inapposite to the case at hand. Plaintiffs here do not seek damages based upon overcharges extracted by Ranbaxy directly but rather by other manufacturers that benefited from Ranbaxy's alleged malfeasance. In such circumstances, the distribution link between the defendants and plaintiffs is irrelevant because purchasers are "neither direct nor indirect purchasers." In re

Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 212 (S.D.N.Y. 2018); see also In re Loestrin 24 Fe Antitrust Litig., No. 1:13-MD-2472, 2019 WL 3214257, at *8-10 (D.R.I. July 2, 2019).

Moreover,

> [o]vercharges, the difference between the actual price and the presumed competitive price multiplied by the quantity purchased, provide what the Supreme Court has long recognized as the principal measure of damages for plaintiffs injured as customers, rather than as competitors.

In re Relafen Antitrust Litig., 218 F.R.D. 337, 344 (D. Mass. 2003) (quotations and citations omitted). Courts have countenanced such damages based upon overcharges when the injury stems alleged from delayed generic entry. See In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 296-297 (D. Mass. 2014), aff'd, 842 F.3d 34 (1st Cir. 2016) ("[T]his Court discerns no requirement that antitrust damages be demonstrated only by "lost profit" methodologies."); In re Solodyn, 2017 WL 4621777, at *10; In re Loestrin 24 Fe Antitrust Litig., 2019 WL 3214257, at *5 n.10. The cases cited by Ranbaxy for the proposition that antitrust plaintiffs may recover only to the extent of net injuries are unconvincing on this point because they concern competitors seeking lost profits, rather than overcharges.

B. Plaintiffs' Motion for Partial Summary Judgment

Plaintiffs seek partial summary judgment to preclude defendants from relitigating issues allegedly decided in prior litigation between Ranbaxy and the FDA ("the Burwell litigation"). See Ranbaxy Lab'ys, Ltd. v. Burwell, 82 F. Supp. 3d 159, 181 (D.D.C. 2015). In that litigation, Ranbaxy sought to invalidate the 2014 decisions of the FDA rescinding tentative approvals of the ANDAs for Ranbaxy's Nexium and Valcyte. After Ranbaxy unsuccessfully moved for a temporary restraining order, the FDA moved for summary judgment. In a thorough opinion, United States District Judge Beryl A. Howell of the District of Columbia granted the FDA's motion for summary judgment. Although Ranbaxy initially appealed that decision, it later withdrew its appeal before it was decided.

Issue preclusion, also known as collateral estoppel, "bars parties from relitigating issues of either fact or law that were adjudicated in an earlier proceeding." Vargas-Colon v. Fundacion Damas, Inc., 864 F.3dd 14, 25 (1st Cir. 2017) (citation omitted); see also Taylor v. Sturgell, 553 U.S. 880, 892 (2008). The doctrine may be used defensively, to prevent plaintiffs from asserting a previously litigated claim against the defendant, or offensively, to foreclose the defendant from re-litigating an issue that it previously lost. See Parklane Hosiery Co., Inc. v.

Shore, 439 U.S. 322, 326 n.4 (1979). Offensive use of issue preclusion does, however, raise concerns of fairness. See Enica v. Principi, 544 F.3d 328, 337 (1st Cir. 2008). Application is non-mutual where "the party asserting preclusion was not a party to the prior case." Brown v. Colegio de Abogados de Puerto Rico, 613 F.3d 44, 48 (1st Cir. 2010). Non-mutual offensive issue preclusion, the variety of preclusion plaintiffs seek to apply here, "historically spawned the greatest misgivings among jurists." Acevedo-Garcia v. Monroig, 351 F.3d 547, 573 (1st Cir. 2003). See generally Parklane Hosiery, 439 U.S. at 329–31 (1979). Despite these concerns, the Supreme Court has granted district courts broad discretion to apply non-mutual offensive issue preclusion. See id. at 331.

Federal common law provides the standard with which to assess the applicability of issue preclusion in this case because the prior litigation was adjudicated by a federal district court. See Negron-Fuentes v. UPS Supply Chain Solutions, 532 F.3d 1, 7 (1st Cir. 2008). Thus, "[i]ssue preclusion requires that (1) both proceedings involve[] the same issue of law or fact, (2) the parties actually litigated that issue [in the prior proceeding], (3) the prior court decided that issue in a final judgment, and (4) resolution of that issue was essential to judgment on the merits." Global NAPs, Inc. v. Verizon New Eng. Inc., 603 F.3d 71, 95 (1st Cir. 2010).

"Collateral estoppel is not limited to ultimate issues: necessary intermediate findings can now be used to preclude relitigation," Rodríguez-Garcia v. Miranda-Marin, 610 F.3d 756, 771 (1st Cir. 2010) (quoting Biggins v. Hazen Paper Co., 111 F.3d 205, 210 (1st Cir.1997) (emphasis original)); see also Restatement (Second) of Judgments § 27, cmt. j. Litigants are not, however, precluded from relitigating an issue if it came "under consideration only collaterally or incidentally." Norton v. Larney, 266 U.S. 511, 517 (1925); see also C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure § 4421 (2d ed. 2002). "Under modern preclusion doctrine, the central question is whether a party has had a full and fair opportunity for judicial resolution of the same issue." Manganella v. Evanston Ins. Co., 700 F.3d 585, 591 (1st Cir. 2012).

Plaintiffs seek to preclude Ranbaxy from contradicting or relitigating the following facts:

(1) By regulation and policy, the FDA conditions tentative approval on a finding of compliance with the current good manufacturing practices;

(2) The FDA did not alter that policy when it granted tentative approval to Ranbaxy's ANDAs;

(3) As of June 19, 2007 and based on information provided by Ranbaxy, the FDA's compliance staff believed that the compliance issues at Paonta Sahib had been resolved and therefore recommended tentative approval for two applications; for later applications, the FDA relied on earlier approvals to recommend tentative approval despite the compliance hold;

(4) The FDA's mistakes in granting tentative approval were caused in substantial part by Ranbaxy's malfeasance (including taking one year to turn over necessary audit reports, providing summaries that deceived the FDA into believing, as of June 19, 2007, that compliance issues at Paonta Sahib had been resolved, concealing the extent of Ranbaxy's non-compliance, and affirmatively interfering with the FDA's ability to recognize and rectify its mistakes);

(5) The Medicare Modernization Act provides a forfeiture mechanism with respect to exclusivity to prevent first applicants from "parking" their exclusivity rights, creating a bottleneck and stopping low-cost generic drugs from reaching the market; and

(6) The letters of August 10, 2012 and November 4, 2014, sent pursuant to the consent decree, allowed the FDA to resume consideration of whether Ranbaxy's ANDAs were eligible for approval but did not evaluate Ranbaxy's eligibility for tentative approval.

Prior to addressing the applicability of issue preclusion to each of these facts individually, however, defendants contend that issue preclusion is entirely unavailable to plaintiffs due to fundamental differences between the prior litigation and the instant case. More specifically, defendants argue that issue preclusion is inappropriate because: (1) Ranbaxy bore the burden of proof in the prior litigation, whereas plaintiffs bear the burden here, (2) the standard of review applied in the earlier case was more deferential to the FDA's view of the facts and law than the applicable standard of review here, and (3) Ranbaxy's procedural opportunities to develop the administrative record and take discovery in the prior litigation were severely limited.

Each of these objections and the precedent upon which they rely stem from

> the well-established principle that failure to carry a higher standard of proof on an issue does not preclude a subsequent attempt to satisfy a lower standard as to the same issue.

Fed. Practice and Procedure § 4422. Thus, Ranbaxy generally should not be foreclosed from relitigating an issue if it had the burden of proof in the prior litigation and that burden has shifted away from it in the subsequent litigation, see Medtronic, Inc. v. Mirowski Fam. Ventures, LLC, 571 U.S. 191, 200 (2014), the applicable standard of review is more demanding in the second action, see FPL Energy Maine Hydro LLC v. F.E.R.C., 551 F.3d 58, 64 (1st Cir. 2008), or defendants may benefit from substantial differences in the availability or admissibility of evidence, see Worcester v. Comm'r, 370 F.2d 713, 717 (1st Cir. 1966). See generally Fed. Practice and Procedure § 4422; Restatement (Second) of Judgments § 28(4). In each of these circumstances, courts have recognized that there are sufficient differences between the relevant cases that the defendant did not have previously "a full and fair opportunity for judicial resolution of the same issue." Rodríguez-García, 610 F.3d at 771 (quoting Fiumara v. Fireman's Fund Ins. Cos., 746 F.2d 87, 92 (1st Cir. 1984)).

The first two of these considerations weigh heavily in favor of Ranbaxy.

In the Burwell litigation, Ranbaxy bore the burden of proving that the rescission by the FDA of tentative approvals for its Nexium and Valcyte ANDAs was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," id. § 706(2)(C), or "without observance of procedure required by law," id. § 706(2)(D); see Otis Elevator Co. v. Sec'y of Labor, 762 F.3d 116, 120–21 (D.C. Cir. 2014). Here, in contrast, the plaintiffs bear the burden. Ranbaxy failed to satisfy its burden in the prior litigation but that does not require a finding that plaintiffs will satisfy their burden here. Thus, preclusion is unavailable in these circumstances because its application might inappropriately expand the holdings of the original court. See, e.g., Clarke v. Spencer, 585 F. Supp. 2d 196, 207 (D. Mass. 2008) ("[D]ifferences in burdens of proof also preclude application of collateral estoppel."), aff'd, 582 F.3d 135 (1st Cir. 2009).

The relevant standards of review in these cases are also readily distinguishable. The FDA in Burwell had to prove only there was a rational basis for its action and the Court deferred

to the FDA's view of the facts. In contrast, this Court is not required to defer to plaintiffs' facts, nor can they succeed by a showing of mere rationality. Rather, plaintiffs must demonstrate that their allegations are more likely true than not true. Correspondingly, Ranbaxy's burden in this case is much lower than in the Burwell litigation because it need demonstrate only that its contentions are as plausible as those of the plaintiffs. Preclusion is inappropriate in such circumstances. Cinelli v. City of Revere, 820 F.2d 474, 479-480 (1st Cir. 1987) (recognizing an exception to collateral estoppel where the party against whom preclusion is sought had a significantly heavier burden of persuasion the first time around).

Plaintiffs rely upon Bath Iron Works Corp. v. Dir., Office of Worker's Comp. Programs, 125 F.3d 18 (1997) for the proposition that shifting the burden of proof does not necessarily defeat the application of issue preclusion in a subsequent case. The Court agrees but notes that the decision in that case blends the analysis of applying issue preclusion in the context of different burdens of proof and standards of review. The Bath Iron Works decision is, however, markedly different from the case at hand. First, the party seeking issue preclusion in the second adjudication in Bath Iron Works was a party to the prior litigation, as was the defendant. Morever, issue preclusion was asserted defensively in Bath Iron Works.

To the contrary, plaintiffs here seek to apply non-mutual offensive issue preclusion. While neither of these elements is dispositive, both non-mutuality and the offensive application of issue preclusion is treated with greater caution than the variety of issue preclusion at issue in Bath Iron Works. See Acevedo-Garcia, 351 F.3d at 573.

Relatedly, the party in Bath Iron Works seeking to avoid issue preclusion bore the burden of proof in the second action. In essence, the plaintiff in the second case was seeking a second bite at the apple on his claim, which had already been decided. The situation here is different: Ranbaxy opposes issue preclusion but plaintiffs bear the burden of proof. It is also relevant to note that the example provided by the court in Bath Iron Works of circumstances in which collateral estoppel may be denied, i.e. "where the victor in the first case has a greater burden in the second," is just that, an example. 125 F.3d at 21. Plaintiffs inaccurately portray that example as dispositive.

The Court is also not convinced that Ranbaxy had a full and fair opportunity to litigate the facts upon which plaintiffs seek preclusion because the Burwell court made clear that, in assessing whether the FDA's rescission was arbitrary and capricious, it

> need not and ought not engage in lengthy fact finding, since generally speaking, district courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues, but operate instead as appellate courts resolving legal questions

Ranbaxy Lab'ys, Ltd. at 181 (D.D.C. 2015) (internal quotation and citations omitted). The Burwell court assessed the FDA's decision only "for a rational connection between the facts found and the choice made" and granted broad discretion to the facts as found by the FDA. Id. at 184 (citation omitted). Plaintiffs attempt to rebut the relevancy of that discretion by asserting that this Court would approach the FDA's determinations with the same deference as the Burwell court. However, due to that deference, a question remains as to whether the Burwell court actually decided the facts upon which the plaintiffs now seek preclusion, as required under the relevant standard to determine the application of issue preclusion described above.

More generally, the Court is unpersuaded that the issues upon which the plaintiffs seek issue preclusion are those addressed by the decision in Burwell. See Federal Practice and Procedure § 4422 (1981) ("As with all matters of issue preclusion, it remains important to make sure that the same issue is involved."); Galen Hosp. Alaska, Inc. v. Azar, 474 F. Supp. 3d 214, 227-228 (D.D.C. 2020). The plaintiffs seek to interpret each factual finding in the Burwell decision as an independent issue that was necessary to the ultimate conclusion

for the purpose of issue preclusion. In opposition, Ranbaxy would have this Court confine the import of that opinion to its holding that the rescission of Ranbaxy's ANDAs was not arbitrary and capricious.

Although the Court has not located relevant precedent regarding application of issue preclusion in the wake of a district court's analysis as to whether a determination of an administrative agency was "arbitrary and capricious," the decision of the Ninth Circuit Court of Appeals in Resolution Trust Corporation v. Keating, 186 F.3d 1110 (9th Cir. 1999), lends support to narrowly prescribing the impact of such a determination. There, the plaintiff sought to attach preclusive effect to the factual findings of a district court that had previously reviewed whether the rulings of the Federal Home Loan Board were arbitrary and capricious. The Appeals Court declined to ascribe preclusive effect to those findings, concluding that the only determination necessary to the outcome of the prior litigation concerned whether the agency's action was arbitrary and capricious and, thus, that it was only that determination that could support the application of issue preclusion. See id. at 1116. The Court reaches the same conclusion here.

ORDER

For the foregoing reasons,

1. the motion of defendants for summary judgment as to Direct Purchaser Plaintiffs (Docket No. 414) is **DENIED;**

2. the motion of defendants for summary judgment as to End Payor Plaintiffs (Docket No. 415) is **DENIED;** and

3. the motion of plaintiffs for partial summary judgment (Docket No. 417) is **DENIED.**

So ordered.

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

Dated November 22, 2021