UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MEIJER, INC. and MEIJER DISTRIBUTION, INC. on behalf of themselves and all others similarly situated,

Plaintiffs

v.

RANBAXY INC., RANBAXY LABORATORIES, LTD., RANBAXY U.S.A., INC. AND SUN PHARMACEUTICAL INDUSTRIES LTD.,

Defendants

Case No.: 15-cv-11828-NMG

DEFENDANTS' OBJECTIONS TO THE MAGISTRATE JUDGE'S
REPORT AND RECOMMENDATION ON DEFENDANTS' MOTION TO DISMISS

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Pursuant to Fed. R. Civ. P. 72(b) and the Court's Order dated June 20, 2016 (ECF No. 53), Defendants Ranbaxy, Inc. and Sun Pharmaceutical Industries Ltd. (collectively "Ranbaxy") respectfully submit the following objections to the Report and Recommendation on Defendants' Motion to Dismiss (ECF No. 52) entered on June 16, 2016 (the "Report").

INTRODUCTION

As the Report repeatedly acknowledges, no court has ever let a case like this one proceed. Yet it allows every one of the Complaint's admittedly "novel" claims go forward. Among the errors addressed below, the Report disregards Supreme Court precedent that expressly precludes private parties from pursuing claims which, as here, depend on an alleged fraud against the U.S. Food and Drug Administration ("FDA"). It conflates the antitrust concepts of "market power" and "monopoly power" while holding, for the first time in American history, that a defendant can be held liable under Section 2 of the Sherman Act when it never entered the alleged market or made a single penny from its allegedly anticompetitive conduct. And with respect to one of the two drugs at issue in this case, it adopts an interpretation of the Hatch-Waxman Act that conflicts with the statute's plain text and the FDA's consistent interpretation of it—***including the Agency's determination with respect to one of the Ranbaxy applications at issue in this very case***. For the reasons detailed both here and in Ranbaxy's earlier briefing on the motion to dismiss, Ranbaxy respectfully submits that the Complaint should be dismissed in its entirety pursuant to this Court's *de novo* review of the Report.[1]

ABBREVIATED FACTUAL AND REGULATORY BACKGROUND

In the interest of judicial economy, Ranbaxy hereby incorporates the detailed summary of (1) the relevant statutory and regulatory framework and (2) the Complaint's factual allegations, as set

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[1] In reviewing a report and recommendation under Fed. R. Civ. P. 72(b), the "district judge must determine *de novo* any part of the magistrate judge's disposition that has been properly objected to." Fed. R. Civ. P. 72(b)(3) (emphasis added). The following documents are part of the record: (1) the Complaint, motion papers, and briefing (ECF No. 1, 21-23, 25-27, 34-36, 43-45, 47, 48, 50, 51); (2) the argument transcript (Ex. A hereto), and (3) the Report (ECF No. 52).

forth in its Opening Brief in support of its Motion to Dismiss (ECF No. 22 at 1-10). The following brief summary, however, provides basic context for the issues addressed in these Objections.

Although the Complaint is replete with generalized allegations that Ranbaxy defrauded the FDA in connection with its effort to obtain approval for several different drugs, the Complaint specifically concerns only two products: (1) brand-name Diovan (valsartan) and its generic equivalents, and brand-name Valcyte (valganciclovir hydrochloride) and its generic equivalents. Complaint ¶¶ 285-295 (Count 1—Diovan); *id*. ¶ 296-306 (Count 2—Valcyte). Plaintiffs allege they are the assignees of direct purchasers of brand-name Diovan and brand-name Valcyte. *Id*. ¶ 13. Their Complaint's basic argument is that generic applicant Ranbaxy defrauded the FDA in connection with its efforts to secure approval for generic versions of both Diovan and Valcyte; that Ranbaxy's alleged misconduct against the FDA had the effect of preventing competing generic applicants from entering the market sooner; and that direct purchasers of Diovan and Valcyte therefore paid higher prices than they would have paid if (A) Ranbaxy had not defrauded the FDA and (B) the competing generic applicants had secured approval for their products and entered the market sooner than they did. *Id*. ¶ 2. Plaintiffs in turn allege that Ranbaxy's fraud on the FDA violated both Section 2 of the Sherman Act and the civil RICO statute. *Id*. ¶¶ 285-335.

More specifically, the Complaint alleges that Ranbaxy filed the first generic drug applications (or "ANDAs") seeking the FDA's approval for generic versions of the brand-name drugs Diovan and Valcyte in 2004 and 2005, respectively. Compl. ¶¶ 75, 78. Ranbaxy's first-to-file status matters, according to the Complaint, because the Hatch-Waxman Act grants the first ANDA-filer an opportunity to enter the market for a 180-day period during which no other generic can enter the market (except for a so-called "authorized generic" manufactured by the brand company). *Id*. ¶ 27-28. The first-filer's entitlement to this "180-day exclusivity period" is not absolute, however. In certain cases, the first filer can "forfeit" its eligibility for 180-day exclusivity, including where it

fails to obtain "tentative approval" (or "TA") for its ANDA within 30 months of filing "***unless*** the failure [to obtain TA within 30 months] 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) (emphasis added).[2]

Plaintiffs concede that their Complaint does not allege that Ranbaxy's generic Diovan and Valcyte ANDAs contained any untrue statements of material fact. Motion to Dismiss Hearing Tr. (Ex. A) at 50:25-51:6; ECF No. 23-1. Instead, they allege Ranbaxy knew that neither its generic Diovan nor its generic Valcyte ANDAs would qualify for TA within the 30-month deadline and that, to avoid the resulting forfeiture, Ranbaxy conspired with its outside counsel and a consultant to deceive the FDA into awarding TA anyway. Compl. ¶ 132. The Complaint further alleges that FDA awarded TA to Ranbaxy's generic Diovan and Valcyte ANDAs in reliance on Ranbaxy's fraudulent representations and thereby allowed Ranbaxy to maintain 180-day exclusivity—though it also expressly concedes that the Agency did not award Ranbaxy's Diovan ANDA TA within the 30-month deadline and instead allowed Ranbaxy to maintain its 180-day exclusivity for that product because Ranbaxy's failure to obtain TA within 30 months was due to a "'change in or a review of the requirements for approval of the application.'" Compl. ¶ 206 (quoting FDA decision).

The FDA subsequently granted final approval to Ranbaxy's Diovan ANDA on June 26, 2014, and Ranbaxy entered the market on July 7, 2014. *Id*. ¶ 203, 206, 208. Another company (Sandoz) launched an authorized generic version of Diovan the next day, so Ranbaxy competed with both the Diovan brand manufacturer (Novartis) and Sandoz during the first 180 days after launch, with additional generics entering the market thereafter. *Id*. ¶¶ 208-09. As a result, the Complaint never alleges that Ranbaxy ever achieved a dominant share of the alleged market for brand and

[2] TA means that an ANDA meets the statute's substantive requirements for final approval, but cannot receive a final approval that would permit the applicant to launch its product into the market because of a patent-based or regulatory exclusivity period held by another party. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA).

generic Diovan (or even that Ranbaxy ever captured more than 50 percent of the generic segment of that market). Ranbaxy never obtained final FDA approval for its generic Valcyte ANDA, and therefore never entered the alleged market for that drug or earned any profits from it. As a result, the Complaint likewise fails to allege that Ranbaxy ever achieved a dominant share of the alleged market for brand or generic Valcyte (or that Ranbaxy ever captured even a fraction of a percent of the generic segment of that market).

OBJECTIONS TO REPORT

I. THE REPORT ERRED IN DECLINING TO RECOMMEND DISMISSAL OF THE ENTIRE COMPLAINT PURSUANT TO *BUCKMAN.*

Though the Complaint nominally asserts claims under the Sherman Act and RICO, each of its claims depends on allegations that Ranbaxy defrauded the FDA into awarding TA to Ranbaxy's generic Diovan and Valcyte ANDAs. As set forth above, plaintiffs' theory is as follows: (1) Ranbaxy "needed to obtain [TA] … or its 180-day exclusivity would be forfeited," Compl. ¶ 139; (2) Ranbaxy was not eligible for TA, so it "resorted to conning the FDA into mistakenly granting [TA]," *id*.; (3) the FDA "rel[ied] on the misrepresentations made by Ranbaxy" when it awarded TA to these ANDAs, *id*. ¶ 141; (4) Ranbaxy's fraudulent scheme thereby "(wrongfully) preserved" its exclusivity, *id*.; and (5) plaintiffs were injured because "if Ranbaxy had not wrongfully acquired, maintained, or used [the resulting] 180-day exclusivity for [generic Valcyte and Diovan], there would have been no bottleneck for the entry of other generics, and … [plaintiffs] would have paid substantially less … than they did." *Id*. ¶ 210. Given the nature of plaintiffs' claims, it is no surprise that the Complaint uses some variation of the word "fraud" ***more than fifty times***.

Even if everything the plaintiffs say is true (and it is not), this fraud-on-the-FDA-dependent theory of liability is barred as a matter of law by the Supreme Court's holding that the Food, Drug and Cosmetic Act ("FDCA") precludes private parties from pursuing claims based on allegations that an applicant defrauded the FDA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

That is so because the FDCA's comprehensive regulatory scheme includes an array of provisions "aimed at detecting, deterring, and punishing false statements made during [the FDA's] approval processes." *Id.* at 349. As *Buckman* further observed:

> The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration [and the FDCA] leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [Act]: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

Id. at 349 & n.4 (internal notes and citations omitted). Private-party claims based on alleged fraud against the FDA thus conflict not only with the statute's explicit preclusion provision (21 U.S.C. § 337(a)); they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" by disrupting the federal government's ability to calibrate its response to suspected fraud. *Id*. at 350. And because such claims arise directly from actions taken during the FDCA's tightly-controlled approval process, allowing them to proceed would "result[] in additional burdens on the FDA's evaluation of an application." *Id*. at 351. Accordingly, private-party litigation predicated on alleged fraudulent conduct during the FDA approval process "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Id*. at 353.

The Report acknowledges *Buckman*'s holding that federal law bars private-party claims that (as here) are predicated on alleged fraud against the FDA, but attempts to distinguish *Buckman* on the ground that it involved state-law tort claims rather than federal claims that nominally arise under the Sherman Act and RICO. Report at 19-20 ("The balance between state and federal power is not at issue. For this reason, *Buckman*'s analysis does not directly resolve the matter."). But that is a distinction without a difference: Whether plaintiffs' fraud-on-the-FDA-dependent claims nominally arise under state or federal law, they conflict with the FDCA's explicit direction that "it is ***the Federal Government rather than private litigants*** who are authorized to file suit for noncompliance"

with the statute's truth-telling requirements, *Buckman*, 531 U.S. at 349 & n.4 (emphasis added; citing 21 U.S.C. § 337(a)); they disrupt the FDA's exclusive "responsibility to police fraud consistently with the Administration's judgment and objectives," *id*. at 350; and they threaten to interfere with the FDCA's approval process by imposing "additional burdens on the FDA's evaluation of an application." *Id*. at 351.

The Report nonetheless asserts that "'[w]hen addressing the interactions of federal statutes, courts are not supposed to go out looking for trouble." Report at 20 (emphasis omitted; quoting *Lewis v. Epic Sys. Corp.*, No. 15-2997, slip op. at 15 (7th Cir. May 26, 2016)). Instead, "courts look to harmonize statutory schemes rather than drumming up conflict." *Id*. at 22. But Ranbaxy's preclusion defense does not require the court to "drum up conflict." *Buckman* already held that private-party claims based on alleged fraud against the FDA "inevitably conflict" with both the FDCA's express preclusion clause, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)), and "the FDA's responsibility to police fraud consistently with the [Agency's] judgment and objectives." *Id*. at 350.[3]

The Report offers three responses to this straightforward point. *First*, it asserts that the "FDCA does not contain an express preemption or preclusion provision." Report at 20. But that is demonstrably incorrect. *Buckman* held that 21 U.S.C. § 337(a) plays precisely that role by "leav[ing] no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for" allegedly defrauding the FDA. 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).

Second, the Report asserts that plaintiffs' claims do not conflict with the FDCA because the purposes of the FDCA and the Sherman Act/RICO differ. Report at 23. But that equally could have been said of the personal-injury claims in *Buckman*. To paraphrase the Report, "The FDA's enabling

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[3] That likewise distinguishes the Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014). That case had nothing to do with an alleged fraud against the FDA; indeed, it did not involve any allegation that the defendant otherwise violated the FDCA. It therefore did not implicate the federal government's exclusive enforcement discretion to redress misconduct before the Agency. Here, by contrast, plaintiffs' claims necessarily depend on proof of such a fraud and thereby implicate the very conflict that *Buckman* recognized without dissent.

statute does not entrust it with policing [physical injuries to consumers]," and it "do[es] not address [physical] injury of the type that [the *Buckman*] plaintiffs allegedly suffered." *Cf. id*. In any event, the Report is wrong that plaintiffs' RICO and Sherman Act claims are compatible with the FDCA. As *Buckman* observed, the FDCA is full of "provisions aimed at detecting, deterring, and punishing false statements made during [its] approval processes," and it empowers the FDA alone to determine ***both*** whether to seek relief for an alleged fraud ***and*** the extent of any relief it seeks. 531 U.S. at 349 & n.4. Whether fraud-on-the-FDA-based private-party claims are brought under the FDCA, the Sherman Act, RICO, or state law, such actions invariably undermine the FDA's ability to exercise that exclusive authority. The Report's approach would allow private parties to pursue fraud-based claims even where the FDA chooses not to impose sanctions; it would allow private parties to seek compensatory damages even where the FDA determines no monetary penalty is appropriate; and it would allow private parties to seek billions of dollars in punitive damages even where the FDA determines that only a modest sanction is warranted. In short, private actions thus make it impossible for the FDA to calibrate the extent of the response to an alleged fraud.

Finally, the Report claims *Buckman* is distinguishable because the Complaint alleges the FDA already found that Ranbaxy engaged in fraud and "Justices Stevens and Thomas, in their concurrence to *Buckman*, note that the outcome of that case would have been different if the FDA had found fraud." Report at 27. But those two Justices expressly declined to join the majority opinion precisely because it would bar fraud-based claims even if the FDA agrees there was a fraud:

> If the FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme. ***Under the pre-emption analysis the Court offers today, however, parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process***.

Buckman, 531 U.S. at 354-55 (Stevens, J. concurring) (internal citations omitted; emphasis added). The concurrence itself thus refutes the Report's interpretation of *Buckman*. Because the Complaint necessarily depends on allegations that Ranbaxy defrauded the FDA, all of its claims are precluded under *Buckman* and Ranbaxy respectfully submits that the Report erred in failing to recommend dismissal of the Complaint in its entirety.

II. THE REPORT ERRED IN DECLINING TO RECOMMEND DISMISSAL OF PLAINTIFFS' ANTITRUST CLAIMS.

A. The Report Erroneously Concludes That Plaintiffs Adequately Alleged Monopoly Power.

It is axiomatic that ***monopoly power*** is an essential element of any claim under Section 2 of the Sherman Act. 15 U.S.C. § 2. The facts alleged, however, do not establish that Ranbaxy had monopoly power in either of the alleged markets: (1) Valcyte and its AB-rated equivalents (Count II), or (2) Diovan and its AB-rated equivalents (Count I). Compl. ¶ 256.[4] The Report's analysis of this issue errs in at least three respects. ***First***, it improperly conflates monopoly power and market power. ***Second***, it erroneously finds—as no court ever has—that Ranbaxy somehow had monopoly power in the alleged market for brand and generic Valcyte even though it concededly had a zero-percent market share and never sold the product or earned a single penny. ***Third***, it fails to make any monopoly power finding with respect to the alleged market for brand and generic Diovan, nor could it when the Complaint does not allege that Ranbaxy had a dominant share of the market or the ability to raise prices without losing sales. In sum, the Report accepts the unprecedented theory that Ranbaxy exercised monopoly power in the alleged markets even though Ranbaxy ***never*** held a dominant share in either alleged market. Ranbaxy respectfully submits that this was error, and plaintiffs' claims should be dismissed.

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[4] The Report inadvertently switches the drugs at issue in Counts I and II. Contrary to the headings on pages 19 and 39 of the Report, Count I of the Complaint concerns brand and generic Diovan (valsartan), while Count II concerns brand and generic Valcyte (valganciclovir hydrochloride). Throughout these objections, Ranbaxy refers to the counts by the number alleged in the Complaint, rather than the incorrect numerical identifiers in the Report.

1. The Report's Misinterpretation of "Market" and "Monopoly" Power

The Report concedes that the Complaint never alleges that Ranbaxy possessed monopoly power in either of the alleged markets, but instead alleges only that Ranbaxy possessed "market power." *See, e.g.* Compl. ¶ 240. Yet the Report dismisses this deficiency as "unavailing" based on the assertion that "market power" and "monopoly power" are "interchangeabl[e]." Report at 32. That is erroneous. For decades, the Supreme Court has expressly held otherwise: "Monopoly power under § 2 requires, of course, something greater than market power under § 1." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481 (1992). The First Circuit likewise has held that Section 2 does not bar all allegedly anticompetitive or exclusionary conduct, but instead applies only where such conduct is exercised during the defendant's "willful acquisition or maintenance" of "monopoly power." *Diaz Aviation Corp. v. Airport Aviation Servs., Inc.*, 716 F.3d 256, 265 (1st Cir. 2013) (requiring "market power" under Section 1 claim and "monopoly power" under Section 2).

The Report then compounds that error by mis-defining the relevant markets. Though the Report assumes the relevant markets are generic Valcyte or generic Diovan ***alone***, Report at 32, the Complaint alleges that the relevant markets consist of both the branded and generic versions of each product ***combined***. Specifically, the Complaint alleges the relevant markets as (1) "all valganciclovir hydrochloride tablets—*i.e.*, Valcyte … and AB-rated bioequivalent valganciclovir hydrochloride tablets"; and (2) "all valsartan tablets—*i.e.*, Diovan … and AB-rated bioequivalent valsartan tablets." Compl. ¶ 256. Yet the Report overlooks these allegations, asserting that Ranbaxy's "market power" existed by virtue of its alleged ability to exclude other generic companies from the market for generic versions of those products. Report at 32. As a result, the Report's legally irrelevant "market power" analysis is flawed even on its own terms; it fails entirely to account for the brand's dominant share of the actual markets alleged in the Complaint—a share that not only precludes the Report's finding of

market power, but forecloses any conceivable determination that Ranbaxy exercised "monopoly power" in either of the markets alleged in the Complaint.

2. The Report Erred In Finding That Ranbaxy Had Monopoly Power In The Alleged Market for Brand And Generic Valcyte (Count II)

The Report's conclusions regarding monopoly power with respect to Valcyte and its generic equivalents (Count II) are contrary to settled law. Ranbaxy never exercised monopoly power under any conceivable definition because it never entered that market; the FDA never approved Ranbaxy's generic Valcyte product, and Ranbaxy therefore has never sold a single generic Valcyte pill. Compl. ¶¶ 220, 232, 297. Given its conceded absence from the market, Ranbaxy cannot possibly have exercised either market power or monopoly power: It never had the ability to raise prices or earn any profits (let alone monopoly profits) in a market where it possessed ***a zero-percent share***.[5]

To its credit, the Report acknowledges that there is ***no precedent in antitrust history*** for the proposition that "a firm that has no sales or profits within a given market may possess monopoly power." Report at 33.[6] But it dismisses the fact that Ranbaxy never entered the alleged market on the ground that Ranbaxy's ability to "exclude" other generics from the market might be sufficient. Report at 34. That is incorrect. The Supreme Court long ago made clear that a Section 2 defendant's ability to "exclude competition" from the market constitutes monopoly power only if the defendant profits from that exclusion through its chokehold presence in the marketplace: "When a product is controlled by one interest, without substitutes available in the market, there is monopoly power." *United States v. E.I. DuPont de Nemours & Co.*, 351 U.S. 377, 394 (1956); IIB Areeda &

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[5] Because the plaintiffs allege Ranbaxy was "unlikely to ever be able to bring to market" such product, Compl. ¶ 259, plaintiffs cannot argue Ranbaxy had a "dangerous probability" of achieving monopoly power in that market.

[6] Plaintiffs cited *Anchor Wall* for the proposition that a party with no market share can still be deemed to have monopoly power under Section 2. ECF No. 34 at 3 (citing *Anchor Wall Sys, Inc. v. Rockwood Retaining Walls, Inc.*, 2007 WL 4465195 (D. Minn. Dec. 18, 2007)). But in *Anchor Wall*, the allegation was that the defendant's ***licensees*** possessed a dominant share (up to 80%) of the national market and that the defendant earned royalties on its licensees' sales. Here, by contrast, Ranbaxy never held any financial stake in the alleged market.

Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, pp. 110-111 ¶ 501 (4th ed. 2014) (ability "to exclude competition" is "asking whether the defendant can price monopolistically without prompt erosion from rivals' entry or expansion"). Coupled with the presence of branded Valcyte in the market, Ranbaxy's failure to sell a single generic Valcyte pill—much less charge supracompetitive prices—bars such claims. *See Diaz*, 716 F.3d at 265 ("[a]bsent direct proof of supracompetitive prices" charged by defendant, "monopoly power is typically proven by defining a relevant market and showing that the defendant had a dominant share of that market"); *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 86 (D.D.C. 2006) ("A firm is generally considered to have monopoly power if it can profitably raise prices substantially above the competitive level for a non-transitory period of time."). Because Ranbaxy never charged a penny and had a zero market share, it could not have exercised monopoly power as a matter of law.

The Report concedes that: (i) a firm is a "monopolist if it can profitably raise prices substantially above the competitive level" or if it has a "predominant share of the market," and (ii) that Ranbaxy never entered the market for brand and generic Valcyte at all, let alone charged such prices or had a predominant share of that market. Report at 32-33 (citation omitted). Yet the Report then proceeds to disregard *Diaz* and the very standard it just articulated and find monopoly power nonetheless.[7] Specifically, the Report announces a new and legally unprecedented standard for "monopoly power"—that it is only necessary to allege "detrimental effects on the market and financial harm to consumers." Report at 34. In so doing, the Report impermissibly conflates the standard for anti-competitive conduct with monopoly power, when in fact ***both*** are elements of a legally viable Section 2 claim. *See Diaz*, 716 F.3d at 265. To hold that all allegedly anti-competitive conduct gives rise to a viable monopolization claim, as the Report recommends here, would open the

[7] Tellingly, the primary case that the Report relies on for its new standard, *FTC v. Indiana Fed'n of Dentists,* 476 U.S. 447 (1986), is a Section 1 case, for which there is no monopoly power requirement.

antitrust litigation floodgates, and render meaningless the "monopoly power" requirement of Section 2 of the Sherman Act.[8] In all circumstances, therefore, Count II, should be dismissed.

3. The Report Erred In Finding That Ranbaxy Had Monopoly Power In The Alleged Market For Brand And Generic Diovan (Count I)

Count I, concerning the market for Diovan (valsartan) and its generic equivalents, fares no better. Indeed, although the Report at pages 39 to 46 separately addresses plaintiffs' antitrust claim regarding Diovan, it lacks ***any*** analysis of monopoly power in that market. The absence of any such analysis is both fatal to the Report's conclusion and unsurprising. After all, the Complaint does not allege that Ranbaxy ever controlled a predominant share of the alleged market for brand and generic Diovan or had the ability to exclude competition to the point that it could raise prices without losing sales. To the contrary, when Ranbaxy finally entered the market it had to ***lower*** prices to compete with both brand manufacturer Novartis (which from 2001 until July 2014 had an undisputed monopoly in this alleged market) and a competing version of generic Diovan marketed by Sandoz as an authorized generic. Compl. ¶¶ 208, 247. After the first 180 days, additional generic versions of Diovan entered the market, further reducing Ranbaxy's market share. *Id*. ¶ 209.

The Report seemingly thought Ranbaxy's eligibility for 180-day exclusivity was enough to confer market power (yet, again, not the monopoly power required under Section 2). But as the Complaint's concession that Novartis controlled the entire market during the period of Ranbaxy's allegedly fraudulent conduct makes clear, *id*., the first filer's eligibility for 180-day exclusivity does ***not*** allow it to achieve (much less maintain) monopoly power. Indeed, Novartis's undisputed control of the alleged market explains why the Complaint fails to allege that Ranbaxy ever had even 50% of

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[8] The predatory pricing case relied on in the Report, *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 231 (1st Cir. 1983), is also inapposite. In a predatory pricing case, the dominant firm cuts prices in the short-term in order to eliminate others from the market and charge monopoly prices later. Here, plaintiffs do not and cannot allege that Ranbaxy engaged in such conduct regarding Valcyte. Indeed, the Complaint alleges that Ranbaxy knew it would never be able to enter the market and charge monopoly prices for Valcyte. *See, e.g.* Compl. ¶ 259. Put another way, plaintiffs' own allegations fatally undermine their monopolization argument.

the Diovan market, let alone the 70% to 90% "dominant" market share that the First Circuit has recognized is necessary for monopoly power. *Town of Concord, Mass. v. Boston Edison Co.*, 915 F.2d 17, 30 (1st Cir. 1990); *see also Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 201 (3d Cir. 1992) (55% market share insufficient to support an inference of monopoly power); *Synthes, Inc. v. Emerge Med'l, Inc.*, No. 11-1566, 2012 WL 4473228, at *11 n.5 (E.D. Pa. Sept. 28, 2012) ("[I]t is well-established that 50% market share or just over is insufficient to establish monopoly power.").

Plaintiffs' real claim thus is not that ***Ranbaxy*** monopolized the alleged market for Diovan and its generic equivalents, but that the collateral effect of Ranbaxy's alleged fraud on the FDA was to prolong ***Novartis's*** monopoly power. *See, e.g.,* Compl. ¶ 259. Novartis, however, is not a defendant, and the Complaint does not allege that Ranbaxy conspired with Novartis. Plaintiffs' monopolization claims therefore fail as a matter of law. *See, e.g.*, *Diaz.,* 716 F.3d at 265; *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d at 86.

B. The Report Erroneously Concludes That Plaintiffs Adequately Pleaded Causation.[9]

Antitrust claims require a showing of both "but-for" and proximate causation. *Holmes v. Sec. Inv'r Prot. Corp*., 503 U.S. 258, 268 (1992) (citing *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 534 (1983)). This requirement limits the Sherman Act's reach: "[D]espite the broad wording of § 4 there is a point beyond which the wrongdoer should not be held liable." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 477 (1982) (additional citations omitted). Yet the Report ignores "but-for" causation entirely.

Moreover, an antitrust plaintiff must also prove "the causal connection between the alleged antitrust violation and harm to the plaintiff," "the nature of the plaintiff's alleged injury and whether the injury was of a type that Congress sought to redress with the antitrust laws ('antitrust injury')),"

[9] As the Report observes, the causation inquiries under the antitrust laws and RICO are governed by the same analysis. Report at 52. Accordingly, Defendants' causation arguments apply equally to both the Sherman Act and RICO claims, all of which should have been dismissed.

and "the directness with which the alleged market restraint caused the asserted injury." *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 14 (1st Cir. 2001) (internal quotations and citation omitted). As a matter of law, plaintiffs cannot show that Ranbaxy's conduct caused any antitrust injury to plaintiffs. *First*, courts have long recognized that where a competitor is excluded from the market because of a governmental regulatory scheme rather than the alleged anticompetitive conduct, there is no causation or antitrust injury. *Id.* at 15. In such a situation, "[a]ny injury suffered by [the plaintiff] is . . . unrelated to [the defendant's] allegedly exclusionary conduct, and [the plaintiff] lacks antitrust standing." *Id.*

Second, the Report's entire theory of causation is premised on the demonstrably false proposition that the FDA "could not review the TA any sooner" than 2014 because Ranbaxy had "hidden the relevant information." Report at 37. This assumption is contradicted by the Complaint itself, which specifically alleges that ***by February 2009***, FDA had: (i) discovered Ranbaxy's alleged fraud; and (ii) publicly announced that it had frozen all Ranbaxy ANDAs, including for generic Diovan and Valcyte, originating from the facility at issue. Compl. ¶¶ 161-62, 170. The Report's assumption that FDA "could not review" the TAs until 2014 is belied by plaintiffs' own allegations. Once that erroneous factual assumption is stripped away, plaintiff's entire causation case evaporates:

- Since Ranbaxy's alleged fraud was known to FDA by 2009 per the Complaint, there is no question that it was FDA's inaction, and not any conduct by Ranbaxy, that caused the delay until 2014 in the FDA's review of the Valcyte TA. Indeed, the Complaint does not identify a single allegedly fraudulent act by Ranbaxy that occurred after February 2009.

- For Diovan, the causation problem is even more fundamental, because when FDA did review the TA, it granted final approval. Compl. ¶ 206. Given this fact, plaintiffs cannot possibly show causation for Diovan either. The Complaint does not and cannot allege that FDA erred in granting final approval to Ranbaxy's generic Diovan ANDA or that an earlier review of that ANDA would have led to a different result.

Third, it is well-established that antitrust injury cannot be premised on the exclusion of competition when that competition was prevented by a legal or regulatory barrier. "[A] plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents

him from entering the market in any event." *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 268-69 (3d Cir. 1998) (internal quotations and citation omitted); *see also Sullivan v. Tagliabue*, 25 F.3d 43, 51-52 (1st Cir. 1994) (no causation where harm was due in part to independent regulatory rules of NFL and "an extended chain of independent events would have had to have occurred to give give credence to the Plaintiff's damages claim").

III. THE REPORT ERRED IN DECLINING TO RECOMMEND DISMISSAL OF PLAINTIFFS' DIOVAN-RELATED CLAIMS FOR LACK OF CAUSATION.

While the Report should have recommended that all claims be dismissed on causation grounds for the reasons discussed in the preceding section, plaintiffs' Diovan-related claims (whether arising under the Sherman Act or RICO) suffer from an additional causation flaw. That is so because plaintiffs' theory of liability depends not only on proving that Ranbaxy ***defrauded*** the FDA into awarding TA, but also on the legal proposition that Ranbaxy's ANDAs ***needed*** TA in order to remain eligible for exclusivity. *See* Compl. ¶ 192 ("Ranbaxy needed to secure tentative approval … in order to maintain first-to-file, 180-day exclusivity."). Without that proposition, plaintiffs' claims fail for lack of causation: If Ranbaxy would have remained eligible for 180-day exclusivity even ***without*** TA, it is irrelevant whether "Ranbaxy resorted to conning the FDA into mistakenly granting [TA]," *id*. ¶ 139, because plaintiffs would have suffered the precise same injuries they allege.

Plaintiffs attempt to plug this causal gap in their case by asserting that 21 U.S.C. § 355(j)(5)(D)(i)(IV) required Ranbaxy to obtain TA within 30 months of filing its generic Diovan ANDA or else forfeit its eligibility for exclusivity. *Id*. ¶ 62 ("[T]o preserve its 180-day exclusivity period a generic applicant must obtain at least [TA] within 30 months of the date the ANDA was filed."). But as Ranbaxy stressed—and as plaintiffs expressly conceded—the statutory provision plaintiffs invoke includes a crucial proviso called the "Change-Based Exception." Set off by the key word "unless," section 355(j)(5)(D)(i)(IV) provides that its requirement for securing TA does ***not*** apply where the FDA changes the requirements for approval after the first applicant's ANDA is filed:

> [T]he term "forfeiture event", with respect to an [ANDA], means the occurrence of any of the following … (IV) The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, ***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) (emphases added); *see also* Compl. ¶ 61 n.20 (conceding that an "exception to [the TA requirement] exists where 'the failure [to obtain tentative approval within 30 months] 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).") (first alteration added; second alteration in original).

That is precisely what happened here. As the Complaint again concedes, the FDA "notified Ranbaxy that the FDA had 'determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed,' and that Ranbaxy [therefore] was eligible for 180 days of exclusivity with respect to its generic Diovan product." Compl. ¶ 206 (quoting Letter from FDA to Ranbaxy (June 26, 2014)); *see also* FDA Memorandum re 180-Day Exclusivity for Generic Diovan at 6 (Sept. 28, 2012; ECF No. 43-4) ("FDA concludes that publication of the official USP drug substance monograph for valsartan with which Ranbaxy had to comply prior to approval constituted a change in the requirements for approval. FDA further concludes that Ranbaxy's effort to comply with this new requirement, and FDA's review of that effort, was a cause of Ranbaxy's failure to obtain [TA] by the 30-month forfeiture date."). Indeed, a subsequent generic Diovan applicant whose approval was blocked by Ranbaxy's exclusivity later challenged the FDA's determination that Ranbaxy retained its exclusivity despite failing to obtain TA, and the district court upheld FDA's determination based on the law's Change-Based Exception:

> Stripping Ranbaxy of exclusivity where, as FDA has determined, its failure to obtain tentative approval was caused by a change in approval requirements would contravene congressional intent as expressly stated in the [change-based] exception…. FDA has applied the tentative approval forfeiture provision and its

> [change-based] exception to the facts of this case as it sees them. Considering the purposes of not only the forfeiture provision … but also the [change-based] exception and the exclusivity incentive created by Congress, the Court will not set aside FDA's decision.

Mylan Labs. Ltd. v. FDA, 910 F. Supp. 2d 299, 311 (D.D.C. 2012).

Despite the FDA's judicially-affirmed determination that a post-filing change in the approval requirements exempted Ranbaxy's generic Diovan ANDA from statute's TA requirement, plaintiffs asserted that FDA's decision did not actually except Ranbaxy from the TA requirement at all. Instead, they argued that the TA requirement merely was ***tolled*** by this post-filing change in the approval requirements, and the Report agreed. Report at 45-46 ("In the absence of the FDA's clear opinion on the topic … [i]t makes sense to read the Change-Based Exception as an extension, not an obliteration, of the 30-month deadline."). The Report thus seemed to conclude that the statute's 30-month deadline was simply extended by some unspecified period of time—though neither plaintiffs nor the Report could identify the new TA deadline FDA supposedly applied or point to anything in the FDA's decision evaluating whether Ranbaxy met the alleged new deadline.

The determination in the Report that the "Change-Based Exception" merely tolls the 30-month TA requirement is contrary to the plain language of the statute, and is therefore legal error. For generations, it has been settled that when Congress uses the word "unless"—as it did in the establishing the Change-Based Exception to the TA requirement—the ordinary effect of that word is to ***except*** the statute's target from ***all*** requirements set forth in the clause subject to that proviso.

> The word unless has the force of except; its primary meaning is unloosened from, so what follows in the sentence after the word unless is excepted or unloosened from what went before it. For such a form of expression in a statute sometimes amounts to an affirmative enactment, and in fact *in proprio vigore* [by its own force], confers ***all*** that is excepted from a negative or restrictive provision.... Such a construction has long been established, in many fields, in many jurisdictions, and is well known to Congress.

WJIV-TV, Inc. v. FCC, 231 F.2d 725, 729 (D.C. Cir. 1956) (collecting cases; internal quotations and citations omitted; emphasis added); *see also Washburn & Moen Mfg. Co. v. Reliance Marine Ins.*

Co., 179 U.S. 1, 9 (1900) ("In 1764 Lord Mansfield in *Wilson v. Smith*, 3 Burr. 1550, held that the word 'unless' meant the same as 'except.'"). Accordingly, section 355(j)(5)(D)(i)(IV) obligates the first-filer to obtain TA in order to maintain eligibility for 180-day exclusivity, ***except*** when the Agency changes the requirements for approval after submission of the first applicant's ANDA. Once the Change-Based Exception kicks in, the first applicant is no longer obligated to obtain TA; the antecedent statutory forfeiture clause no longer applies.

The remainder of the statute's text removes any residual doubt. As the FDA recognized in its letter decision, Congress knew how to extend the statutory deadline when it wanted to. ECF No. 43-4 at 2-3 & n.4 (citing 21 U.S.C. § 355(q)(1)(G)). In direct contrast to the Change-Based Exception embedded within section 355(j)(5)(D)(i)(IV), the Petition-Based Extension expressly provides that "the 30-month period under [section 355(j)(5)(D)(i)(IV)] is ***deemed to be extended*** by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition" in those cases where "approval of the application was delayed because of a [citizen] petition." 21 U.S.C. § 355(q)(1)(G) (emphasis added). The fact that Congress did not authorize a similar extension of time in the Change-Based Exception thus speaks volumes: "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Bates v. United States*, 522 U.S. 23, 29–30 (1997) (internal quotation marks omitted); *see also Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 184 (1994) ("The fact that Congress chose to impose some forms of secondary liability, but not others, indicates a deliberate congressional choice with which the courts should not interfere."); *Touche Ross & Co. v. Redington*, 442 U.S. 560, 572 (1979) ("[W]hen Congress wished to provide a private damage remedy, it knew how to do so and did so expressly."). In short, the fact that Congress knew how to extend or toll the 30-month deadline in

certain circumstances not present here—and chose ***not*** extend or toll the 30-month deadline in the circumstances of this case—is fatal to the Magistrate's unprecedented interpretation of the statute.

Even so, the Report dismissed the critical distinction between these distinct textual provisions as irrelevant because the "entire statutory scheme shows a thirty-month deadline, with exceptions for short delays." Report at 45-46. This is incorrect. Only one statutory provision requires applicants to secure TA within 30 months, and its conceded "exception" is not limited to "short delays." The Change-Based Exception applies ***whenever*** FDA changes the approval requirements, and ***regardless*** of how long the resulting delay in generic competition might be. 21 U.S.C. § 355(j)(5)(D)(i)(IV). Only one other provision of the statute even references the 30-month deadline—the Petition-Related Extension—and, in contrast to the Change-Based Exception, it extends the 30-month period in circumstances that the Agency explicitly held ***inappicable*** here. ECF No. 43-4 at 2-3 & n.4 (citing 21 U.S.C. § 355(q)(1)(G) and observing that "no citizen petition was filed subject to 505(q) of the Act."). That is the relevant statutory "context," and it provides no support for rewriting the Change-Based Exception to mirror the Petition-Related Extension.

Unable to point to anything in the actual statute that supports her novel interpretation, the Report ultimately asserted that the statute's "legislative history teems with references to reducing delays in getting generic drugs to market." But resort to the law's legislative history is inappropriate when the law's plain text and context otherwise make its meaning clear. *See, e.g.*, *United States v. Woods*, 134 S. Ct. 557, 567 n.5 (2013) ("Whether or not legislative history is ever relevant, it need not be consulted when, as here, the statutory text is unambiguous."). And in any event, none of the statements that the Report quotes even references the Change-Based Exception—much less suggests it should be interpreted as extending the statutory deadline rather than eliminating it. It thus provides no support for the claim that Congress intended the Change-Based Exception to extend the statutory deadline. Instead, the best evidence of Congress's intent—the actual statutory language—makes

clear that the opposite is true. Because Ranbaxy therefore did not "need[] to secure tentative approval … in order to maintain first-to-file, 180-day exclusivity," Compl. ¶ 192, the Report erred in failing to recommend dismissal of plaintiffs' claims regarding generic Diovan for lack of causation.

Further, even assuming *arguendo* that there were any ambiguity in the FDCA on this point (which there is not), the FDA's interpretation of that statute is entitled to deference, and contrary to the Report's assertion (p. 45), the FDA has offered a "clear opinion" that Ranbaxy's interpretation is correct. In the FDA's words: when there is a "change in or review of the requirements for approval imposed after the application was filed, an application does not forfeit." ECF 43-4 at 7. The FDA further explained: "to avoid forfeiture, an applicant need ***only*** show that acceptability of one aspect of the ANDA (e.g., chemistry) was delayed due to a change in or review of the requirements for approval"—not that the applicant must ***also*** show that it subsequently obtained TA within a "grace period" while it met the new approval requirement. *Id.* at 2 (emphasis added). Indeed, the decision emphasized that "the 30-month timeframe is generally measured ***without regard to the length of time the ANDA was under review by the Agency***," *id*. (emphasis added), making the length of time it took the applicant to comply with the new approval requirement irrelevant.

Most importantly, the FDA's decision explained ***why*** the Agency does not interpret the Change-Based Exception as merely extending the TA requirement rather than eliminating it. As the decision noted, the plain language of a different statutory provision—the "Petition-Related Extension," which the FDA expressly held did ***not*** apply to Ranbaxy's generic Diovan ANDA—***does*** extend the deadline for obtaining TA in certain other circumstances:

> [N]ew subsection 505(q)(1)(G) of the Act … provides one exception [to the rule that the 30-month deadline is not extended]. This subsection provides that
>
> > If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a [citizen] petition, ***the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date***

> ***of final Agency action on the petition*** (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.
>
> Thus, pursuant to this provision, if tentative (or final) approval was delayed because of a petition such that the application was not ready to be approved at 30 months from the date of submission because of the time it took the Agency to respond to the petition, the 30-month-period-from-initial-submission deadline for obtaining a tentative (or final) approval will be extended by the amount of time during which the petition was under review.

Id. at 2-3 (emphasis added; quoting 21 U.S.C. § 355(q)(1)(G)). But as the Agency made clear, "no citizen petition was filed [in this case] subject to 505(q) of the Act," *id*. at 3 n.4, and so the TA deadline was ***not*** extended in this case. Given the FDA's explicit determination that the 30-month deadline was ***not*** extended here, the Report's assertion that the FDA did not provide a "clear opinion on the topic" is erroneous. *Cf*. Report at 45-46.

Finally, while the Court need not go further given the statute's plain text and clarity of the FDA's position on this matter, we note that the Court could eliminate any doubt by simply ***asking the FDA to file an amicus brief setting forth its interpretation of the statute.*** Such a request is appropriate given the Report's belief that there is an "absence of the FDA's clear opinion on" this dispositive matter, Report at 45, and the Department of Health and Human Services (which oversees the FDA) traditionally responds to such inquiries. *See, e.g.*, *Merrimon v. Unum Life Ins. Co. of Am.*, 758 F.3d 46, 55-56 (1st Cir. 2014) (deferring to agency's interpretation as expressed "in response to the Second Circuit's direct request," and citing *Conn. Office of Prot. & Advocacy for Persons with Disabilities v. Hartford Bd. of Educ.*, 464 F.3d 229, 239-40 (2d Cir. 2006) ("[W]e invited the United States Departments of Education ("DOE") and Health and Human Services ("HHS") to file amicus briefs in this case providing their interpretations of the relevant statutory provisions.")).

IV. THE REPORT CONTAINS NUMEROUS OTHER LEGAL ERRORS.

A. Plaintiffs' Claims All Fail For Lack Of Standing.

As set forth on pages 25-26 of Ranbaxy's opening brief (ECF No. 22), all of plaintiffs' claims fail for lack of standing. The Report, however, failed to address this argument at all. The gravamen of the Complaint is that generic forms of Diovan and Valcyte would have been available sooner in the absence of Ranbaxy's alleged fraud. Compl. ¶¶ 208, 222. But plaintiffs assert those claims as an assignee of Frank W. Kerr Co. ("Kerr"), which the Complaint alleges only purchased brand Diovan and brand Valcyte. *Id*. ¶ 13. Because Kerr never bought cheaper generic versions of these drugs once they were available, there is no plausible basis for concluding it would have bought them had they become available sooner. Accordingly, the named plaintiffs have not sufficiently alleged standing. *See Katz v. Pershing, LLC*, 672 F.3d 64, 71 (1st Cir. 2012) ("To satisfy the personal stake requirement, a plaintiff must establish each part of a familiar triad: injury, causation, and redressability."); *Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 768 (1st Cir. 2011) (named plaintiffs must have suffered their own injury).

B. Plaintiffs' Claims All Are Barred By The *Noerr-Pennington* Doctrine.

The Report errs in failing to recommend dismissal of the entire Complaint under the *Noerr-Pennington* doctrine, which protects the constitutional right to file "'petitions' before legislatures, administrative agencies, and courts." *Davric Me. Corp. v. Rancourt*, 216 F.3d 143, 147 (1st Cir. 2000). Although the doctrine originated as an antitrust defense, *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), it is now settled that *Noerr-Pennington* principles apply equally to RICO claims. *See Sosa v. DIRECTV, Inc.*, 437 F.3d 923, 931 (9th Cir. 2006); *Bath Petroleum Storage, Inc. v. Mkt. Hub Partners*, 229 F.3d 1135 (2d Cir. 2000) (Table); *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 826 (7th Cir. 1999); *see also Tomaiolo v. Mallinoff*, 281 F.3d 1, 11 n.9 (1st Cir. 2002) (noting that *Noerr-Pennington* "originated in the law of antitrust but … courts have extended it to other federal statutes

that provide causes of action so broad as potentially to chill the constitutionally protected right to petition the government").

The Report properly holds that Ranbaxy's alleged conduct is petitioning activity, but erroneously concludes that plaintiffs alleged sufficient facts to qualify for the "sham petitioning" exception. That exemption, however, requires more than allegedly false statements; the plaintiff must plausibly allege that the defendant's use of the governmental process was both "objectively baseless and intended only to burden a rival with the governmental decision-making process itself." *Davric*, 216 F.3d at 147. The Complaint not only fails to plead facts that suggest Ranbaxy engaged in sham petitioning with respect to their Diovan and Valcyte ANDAs, but its allegations expressly contradict such a claim. The Complaint acknowledges that the Diovan ANDA was not objectively baseless; quite the opposite, Ranbaxy obtained final approval to sell that drug and remains on the market today. Compl. ¶ 207. Further, the Complaint concedes that Ranbaxy legitimately sought to obtain approvals for both Valcyte and Diovan. *Id*. ¶ 183.

Indeed, the Report itself concedes that plaintiffs do not and cannot allege that either the Diovan or Valcyte ANDAs were objectively baseless. Report at 31. Instead, the Report erroneously applies the sham petitioning exception ***to these two ANDAs*** based on the allegation that Ranbaxy allegedly filed ***other ANDAs, for other drugs***, that supposedly were objectively baseless and for the alleged purpose of "clogging the administrative approval process." *Id*. But plaintiffs allege only that they purchased brand-name Diovan and brand-name Valcyte, and there is no legal basis for applying the sham petitioning exception to the only two products at issue in this case based on supposed sham petitioning for other drugs.

C. Plaintiffs' Claims All Are Time-Barred.

The Complaint likewise is barred by the four-year statute of limitations governing Sherman Act and RICO claims. 15 U.S.C. § 15b; *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*,

MDL No. 09-2067-NMG, 2015 WL 3751422, at *4 (D. Mass. June 15, 2015). Plaintiffs expressly allege that the FDA discovered and publicized Ranbaxy's fraud in February 2009. Compl. ¶¶ 161-163, 262(iii). Plaintiffs' claims thus accrued no later than February 2009—well over four years before plaintiffs filed this suit in May 2015.

The Report suggests that plaintiffs' claims may be saved by the "continuing violation" rule. Report at 39 (citing *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979)). But *Berkey Photo* merely held that the limitations period restarts each time the defendant "monopolist actually exercises its illicit power to extract an excessive price." *Id*. at 295. As discussed above, however, Ranbaxy never sold a single Valcyte pill and never had monopoly pricing power for Diovan either. Accordingly, the continuing violation exception is inapplicable as a matter of law.

The Report alternatively suggests that plaintiffs adequately "alleged that the facts necessary for their Complaint were not discoverable until the FDA's 2014 filing in the *Ranbaxy v. Burwell* case" concerning, among other things, the revocation of Ranbaxy's generic Valcyte TA. Report at 39. But the Complaint makes no such allegation; FDA's decision to rescind the Valcyte TA was not predicated on allegations of fraud; and *Burwell* had nothing to do with Diovan, for which TA was never revoked. Accordingly, there is simply no foundation for the Court's holding that plaintiffs could not have discovered their Diovan claims until the *Burwell* decision in 2014. Plaintiffs' claims should therefore be dismissed on statute of limitations grounds.

D. Plaintiffs Failed To Plead Their Claims With The Requisite Particularity.

Even assuming plaintiffs' fraud-on-the-FDA claims somehow are not barred by the foregoing grounds, plaintiffs have failed to plead those allegations with the particularity required by Rule 9(b). Plaintiffs' long-winded recitation of alleged fraudulent misconduct in Ranbaxy's business concerning *other* drugs cannot obfuscate the paucity of the Complaint's specific allegations about the only two

Ranbaxy drugs actually at issue in this case – generic Valcyte and generic Diovan. *See* ECF No. 22, at 22-23. This too requires dismissal of the Complaint.

CONCLUSION

For the foregoing reasons as well those advanced by Ranbaxy during oral argument and in Ranbaxy's prior memoranda (ECF No. 22, 36, 48, and 51), which are incorporated by reference here, Ranbaxy respectfully requests dismissal of the Complaint with prejudice.

REQUEST FOR ORAL ARGUMENT

Ranbaxy respectfully requests a hearing on its Objections to the Report.

Dated: July 25, 2016

Respectfully submitted,

/s/ Laurence A. Schoen

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CERTIFICATE OF SERVICE

I hereby certify that on the 25th day of July 2016, I filed and served the foregoing via the Court's CM/ECF system, which will serve notification of such filing by email to all counsel of record.

/s/ Laurence A. Schoen
Laurence A. Schoen