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	Civil Action No. 15-cv-11828-NMG Class Action Oral Argument Requested

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

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I. INTRODUCTION

There is nothing "novel" about Magistrate Judge Kelley's application of federal law to the purchasers' complaint.[1] The report paves no new in-roads in preemption, fraud, or antitrust law.[2] Rather, it is Ranbaxy's record-setting violations of current good manufacturing practices (cGMP), its years-long deception on the topic, and its abuse of the regulatory system that make this case novel. Judge Kelley simply applied black-letter law to the unusual fact pattern and reached a predictable result.

If two federal statutes do not irreconcilably conflict, both are given full effect. The report concludes that RICO and the Sherman Act do not conflict with the FDCA, and so refuses to dismiss the purchasers' claims. There is no pre-emption analysis because pre-emption principles do not control the comparison of federal statutes.

A firm violates the antitrust laws if it wrongfully obtains the power to exclude competition. So the report permits antitrust claims to proceed where Ranbaxy obtained, through fraud, the power to exclude all generic competitors from two drug markets.

And causation and statute of limitations questions are fact-specific. So the report declines to resolve them on a motion to dismiss.

None of this is unprecedented. But Ranbaxy's misconduct was. For years, Ranbaxy hid cGMP issues from the FDA. When an FDA inspection raised cGMP concerns, Ranbaxy recruited its lawyers and auditors to mislead and stonewall the FDA. The team scrambled to obtain – through a barrage of false statements – tentative approval for its first-filed ANDAs, locking in the power to exclude competitors from the market. By the time the FDA discovered the true extent of Ranbaxy's non-compliance, Ranbaxy had created a regulatory morass that

[1] Defs.' Obj. to the Magistrate Judge's Report & Recommendation on Defs.' Mot. Dismiss ("Defs.' Obj.") at 1, ECF No. 58 (the report "allows every one of the Complaint's admittedly 'novel' claims go forward"); *but cf. Fay v. Noia*, 372 U.S. 391, 463 (1963) (Harlan, J., dissenting) ("novel" conclusion is not "necessarily incorrect or unwise").

[2] *See* Defs.' Obj. at 1.

took the FDA years to address. All the while, Ranbaxy's fraud kept affordable generic drugs off the market, forcing purchasers to spend hundreds of millions, if not billions, more for drugs.

Congress authorized the FDA to ensure public safety and the purity of drugs; it did not authorize the FDA to police the market or protect private parties' business interests. Instead, it enacted the antitrust laws and RICO to provide private remedies to those financially injured. The direct purchasers seek to vindicate those rights.

The magistrate judge thoughtfully addressed Ranbaxy's arguments, rejecting each. Ranbaxy's objection rehashes its unsuccessful arguments, complaining the report blazes new legal trails. But its arguments misstate the facts, mischaracterize the report, and contort governing law. The Court should adopt the report and recommendation in full.

II. BACKGROUND

The facts are set forth in the purchasers' complaint[3] and detailed in the report.[4] A few are repeated here only for context.

Meijer sues on behalf of all direct purchasers of Valcyte, Diovan, and generic versions of those drugs,[5] alleging Ranbaxy violated federal RICO and antitrust law by fraudulently procuring first-to-file ANDA status for those products, thereby unlawfully blocking bona fide generics from the marketplace. Ranbaxy knew for years that its Indian manufacturing facility did not comply with the FDA's cGMP.[6] Yet Ranbaxy continued to file ANDAs without regard for the likelihood they could be legitimately approved.[7] For many drugs, including generic

[3] Compl., ECF No. 1.

[4] Report & Recommendation on Defs.' Mot. Dismiss ("R&R"), ECF No. 52.

[5] Compl. ¶¶ 13, 276; *contra* Defs.' Obj. at 2, 22.

[6] Compl. ¶¶ 80-87; *see* Guilty Plea, Attachment A at 6-7, *United States v. Ranbaxy USA, Inc.*, No. 13-cr-238 (D. Md. May 13, 2013), ECF No. 7 ("Guilty Plea Statement of Facts") (admitting outside consultants' reports alerted Ranbaxy to cGMP issues at least as early as October 2003).

[7] Compl. ¶¶ 64-79.

Diovan and Valcyte, Ranbaxy secured first-to-file status.[8]

An FDA inspection in 2006 uncovered grave cGMP deficiencies.[9] Ranbaxy knew that its tentative approvals – and profits – were in jeopardy.[10] So it teamed up with its lawyers and auditors to misrepresent its cGMP status to the FDA in meetings, calls, and letters.[11]

It took the FDA nearly three years to uncover the truth.[12] Meanwhile, Ranbaxy secured tentative approvals – including for generic Valcyte and Diovan – to which it was not entitled.[13] And those tentative approvals gave it the power to exclude generic competitors from the market for six months after Ranbaxy decided to begin selling its products.[14] But in 2009, the FDA announced it was freezing all of Ranbaxy's pending ANDAs from the Paonta Sahib facility on the suspicion that some contained untrue statements of fact.[15] For the next five years, the FDA worked to untangle the mess created by Ranbaxy's fraud.[16] Meanwhile, the date on which generic Diovan should have become available – September 21, 2012 – came and went.[17] So too did the date for generic Valcyte – March 15, 2013.[18] But for Ranbaxy's fraudulent conduct and the remedial efforts it required, purchasers could have bought affordable generic versions of Diovan and Valcyte in 2012 and 2013, respectively.[19]

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[8] *Id.* ¶¶ 5-6, 11.

[9] *Id.* ¶¶ 88-91. Ranbaxy admitted as much. *See* Guilty Plea Statement of Facts at 4-6; Compl. ¶ 181.

[10] Compl. ¶ 92. Ranbaxy does not object to the finding that these allegations describe a RICO enterprise.

[11] *Id.* ¶¶ 93-122, 133-38, 148-58; *contra* Defs.' Obj. at 24-25 (seeking misstatements in the actual ANDAs).

[12] Compl. ¶¶ 158-59.

[13] *Id.* ¶¶ 123-32.

[14] *Id.* ¶¶ 55, 74-75, 78. Ranbaxy does not dispute that, with tentative approval, it gained exclusionary power.

[15] *Id.* ¶¶ 160-63.

[16] *Id.* ¶¶ 164-88.

[17] *Id.* ¶ 202.

[18] *Id.* ¶ 215.

[19] *Id.* ¶¶ 210, 223. On these dates, the purchasers' claims accrued. *Contra* Defs.' Obj. at 23-24.

The FDA did not grant approval for Ranbaxy's generic Diovan until June 2014.[20] And the FDA revoked Ranbaxy's generic Valcyte tentative approval later that year.[21] When Ranbaxy lost its Valcyte exclusivity, it sued.[22] In that suit, the FDA admitted for the first time – in a heavily redacted brief – that Ranbaxy had defrauded the agency during the tentative approval process in 2007 and 2008.[23]

III. STANDARD OF REVIEW

This Court reviews *de novo* any "properly objected-to" portion of a magistrate judge's report and recommendation.[24] But "it is improper for an objecting party to . . . submit[] papers to a district court which are nothing more than a rehashing of the same arguments and positions taken in the original papers submitted to the Magistrate Judge."[25] Conclusory arguments are also improper: an objecting party must "present[]" a "developed account" of its legal argument and an "explicit assessment of where the magistrate judge went wrong,"[26] and must not make arguments "at so high a level of generality, and in such an all-or-nothing manner, as to render" review of the recommendations "an exercise in guesswork."[27]

IV. ARGUMENT

Ranbaxy's objection to the report is nothing more than a do-over of the arguments it previously raised before the magistrate judge.[28] In essence, Ranbaxy treats the report process

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[20] Compl. ¶ 206.

[21] *Id.* ¶ 220.

[22] *Id.* ¶ 224.

[23] *Id.* ¶ 230. *Contra* Defs.' Obj. at 24 (suggesting the FDA publicized the fraud in 2009).

[24] Fed. R. Civ. P. 72(b)(3); *see also Lincoln Nat'l Life Ins. Co. v. Prodromidis*, 862 F. Supp. 10, 12 (D. Mass. 1994) (Gorton, J.) (This Court is "slow to reverse the thoughtfully reviewed, careful conclusions" of a magistrate judge.).

[25] *Gilday v. Spencer*, 677 F. Supp. 2d 354, 357 (D. Mass. 2009) (Gorton, J.) (citation omitted).

[26] *Maine Green Party v. Maine*, 173 F.3d 1, 4 n.5 (1st Cir. 1999).

[27] *Uncle Henry's Inc. v. Plaut Consulting Co., Inc.*, 399 F.3d 33, 42 (1st Cir. 2005).

[28] *Cf. Gilday*, 677 F. Supp. 2d at 357. Ranbaxy has not challenged the report's findings that: a "savings clause" inserted into the drug laws does not bar the purchasers' claims, R&R at 21-22; the purchasers alleged a pattern of

as a superfluous procedural exercise. However, the report analyzes the issues based on a correct view of the allegations and applicable federal statutes.

A. The purchasers' federal claims are not barred by the FDCA.

"When addressing the intersection of federal statutes, courts are not supposed to go out looking for trouble: they may not 'pick and choose among congressional enactments.'"[29] Instead, they "must employ a strong presumption that the statutes may both be given effect."[30]

In *POM Wonderful LLC v. Coca-Cola Co.*,[31] the Supreme Court instructed courts on how to apply this presumption. It applied standard statutory interpretation principles, cautioning that "the Court's pre-emption precedent does not govern [the] preclusion analysis in this case."[32] It asked whether anything in the text, structure, or purpose of the FDCA suggested a congressional intent to extinguish other federal remedies – in that case, the Lanham Act.[33] It found none.

Here, there is no evidence Congress intended the FDCA to eviscerate remedies under the Sherman Act or RICO.[34] The statutes have co-existed for decades, and Congress has never used the FDCA to bar any federal claims (though it has barred state-law medical device-related claims).[35] This is "powerful evidence" that Congress did not intend FDA oversight to be the

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racketeering activity and a substantive violation of RICO, *id.* at 48, 52; Parexel and Beardsley may have participated in the RICO enterprise, *id.* at 49-51; and Ranbaxy, Parexel, and Beardsley may have formed a conspiracy, *id.* at 51-53.

[29] *Lewis v. Epic Sys. Corp.*, 823 F.3d 1147, 1158 (7th Cir. 2016) (citation omitted).

[30] *Id.*

[31] 134 S. Ct. 2228 (2014).

[32] *Id.* at 2236 ("[T]his is a statutory interpretation case . . . . That does not change because the case involves multiple federal statutes.").

[33] *Id.* at 2237-40.

[34] *See* Pls.' Opp'n Mot. Dismiss ("Pls.' Opp'n MTD") at 4-5, ECF No. 25.

[35] *Wyeth v. Levine*, 555 U.S. 555, 574-75 (2009) ("[D]espite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs." (citation omitted)); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008) ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.").

exclusive means of policing violations of other federal laws, because "[p]re-emption of some state requirements does not suggest an intent to preclude federal claims."[36] And nothing in the structure or purpose of the laws suggests irreconcilable conflicts.[37] Rather, the laws complement each other;[38] allowing them to co-exist "takes advantage of synergies among multiple methods of regulation" "'provide[s] incentives' for manufacturers to behave well."[39] Permitting antitrust and RICO claims to proceed is "quite consistent" with Congress's purpose in "enact[ing] two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers."[40] Refusing to do so "would flout the congressional design."[41]

1. The report gives full effect to the FDCA, the Sherman Act, and RICO.

Applying *POM*, the report finds nothing in the text, purpose, or structure of the statutes suggesting the FDCA blocks Sherman Act or RICO claims.[42] It observes the FDCA does not expressly preclude federal claims;[43] although Congress could have "if it believed that Sherman Act [or RICO] claims could interfere with the FDCA."[44] Additionally, the report notes, the FDCA's purpose was to "ensur[e] public safety and purity" of drugs, "not polic[e]

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[36] *POM*, 134 S. Ct. at 2238 ("By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources.").

[37] *See* Pls.' Opp'n MTD at 5-6.

[38] *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) (noting the antitrust laws protect consumers "against conduct which unfairly tends to destroy competition"); Pub. L. No. 91-452, 84 Stat. 941 (1970) (noting RICO protects commerce from the ill effects of racketeering); *POM*, 134 S. Ct. at 2234 (noting the FDCA "is designed primarily to protect the health and safety of the public at large").

[39] *POM*, 134 S. Ct. at 2238-39 (quoting *Wyeth*, 555 U.S. at 579).

[40] *Id.* at 2239.

[41] *Lewis*, 823 F.3d at 1157 (quoting *POM*, 134 S. Ct. at 2238).

[42] R&R at 20-25.

[43] *Id.* at 20-21 ("Even assuming [the FDCA's medical-device pre-emption clause] could apply to drugs, this is not a preemption case. 'By taking care to mandate express pre-emption of some state laws, Congress [. . .] if anything indicated it did not intent the FDCA to preclude requirements arising from other sources.'" (citations omitted)); *see also id.* at 47 (noting RICO claims not precluded for the same reason).

[44] *Id.* at 21.

the markets for such items."[45]

The report found that the purchasers' claims depended on elements "above and beyond fraud on the agency," and were, therefore, "actionable."[46] Although "only the federal government is authorized to enforce the FDCA," and had already "investigated and punished Ranbaxy's conduct," the report concludes those penalties "do not address anticompetitive [or fraudulent] injury" the purchasers suffered.[47] So the purchasers' claims complement the FDA's actions, rather than "'usurp[ing] the agency's statutory right to . . . calibrate a 'measured response' to alleged fraud committed against it."[48]

2. Ranbaxy's objections ignore the Supreme Court's *POM* analysis and recycles arguments that a pre-emption case bars federal claims.

Ranbaxy devotes only a single footnote to *POM*. And even that misses the mark. Ranbaxy claims *POM* is factually distinguishable,[49] but Ranbaxy just ignores the Supreme Court's instructions for assessing the intersection of two federal statutes.

Instead, Ranbaxy recycles its unsuccessful argument[50] that *Buckman Co. v. Plaintiffs' Legal Committee*[51] bars federal claims, claiming *Buckman* "precludes private parties from pursuing claims based on allegations that an applicant defrauded the FDA."[52] Not so. *Buckman*

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[45] *Id.* at 22-23, 47.

[46] *Id.* at 26-27.

[47] *Id.* at 23, 26, 47.

[48] *Id.* at 23.

[49] Defs.' Obj. at 6 n.3. The report acknowledges that *POM* is "not directly on point," R&R at 19, yet recognizes the applicability of the Supreme Court's instructions. *Id.* at 20-21 (examining the text of the statutes), 22-23 (looking to the purpose and structure of the laws), 25 (asking whether the statutes can "comfortably coexist").

[50] *Accord Gilday*, 677 F. Supp. 2d at 357.

[51] 531 U.S. 341 (2001).

[52] Defs.' Obj. at 4-8. Ranbaxy claims that the purchasers levy "fraud-on-the-FDA" claims, based on a tally of the word "fraud" in the complaint. *Id.* at 4-5. But "fraud on the FDA" is a term of art referring to state-law claims where the *only* duty breached is a duty owed the FDA. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2006) (distinguishing "fraud-on-the-FDA" claims from "claims that sound in traditional state tort law" because *Buckman* focused on "the source and 'vintage' of the *duty* the drug maker is accused of breaching").

held "*state law* fraud-on-the-FDA claims conflict with, and are therefore impliedly *pre-empted* by, federal law."[53] "[T]his is not a pre-emption case," so *Buckman* "does not frame the inquiry."[54]

Ranbaxy ignores *Buckman*'s preemption foundations, calling the difference between *Buckman*'s state-law claims and the purchasers' federal claims "a distinction without a difference."[55] This stretches *Buckman* beyond its bounds. *Buckman* reflected the concern that "*state tort law*" involving medical devices would "skew[]" the "somewhat delicate balance of statutory objectives" created by Congress.[56] "*State-law fraud-on-the-FDA claims* inevitably conflict" with the FDA's authority, because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'"[57] The Court worried that "complying with the FDA's detailed regulatory regime *in the shadow of 50 States' tort regimes*" would impose on manufacturers additional "burdens *not contemplated by Congress* in enacting the FDCA[.]"[58]

Such concerns are irrelevant where Congress imposes both burdens. Congress enacted the Sherman Act and RICO, and has not exempted drug companies from those laws.[59] Other courts have rejected *Buckman*'s applicability to federal antitrust claims[60] and refused to dismiss RICO allegations like those here.[61] Ranbaxy continues to ignore these cases.

Ranbaxy claims the report's conclusion that the FDCA did not preclude federal claims

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[53] 531 U.S. at 348 (emphasis added). Ranbaxy later calls *Buckman* a "pre-emption analysis." Defs.' Obj. at 7 (quoting *Buckman*, 531 U.S. at 354-55 (Stevens, J., concurring)).

[54] *POM*, 134 S. Ct. at 2236.

[55] Defs.' Obj. at 5.

[56] *Buckman*, 531 U.S. at 348 (emphasis added); *see also id.* at 349 n.4 & 351 n.5 (citing medical device-specific sources to support its rationale).

[57] *Buckman*, 531 U.S. at 347, 350 (emphasis added).

[58] *Id.* (emphasis added).

[59] R&R at 21, 47.

[60] *United States ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 598-99 (E.D. Pa. 2014) (permitting allegations that defendants "presented fraudulent information to the government that secured Defendant a monopoly over the market" to proceed).

[61] *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993) (reversing dismissal).

was "demonstrably incorrect."[62] Not so. The FDCA has no express preclusion clause for drug claims.[63] Coca-Cola claimed, in *POM*, that, through 21 U.S.C. § 337(a), "[t]he FDCA expressly reserves enforcement to the United States and bars private causes of action."[64] But the Supreme Court *rejected* this argument, because "[t]he centralization of FDCA enforcement authority in the Federal Government does not indicate that Congress intended to foreclose private enforcement of other federal statutes."[65] Where a plaintiff "seeks to enforce" another federal statute, "not the FDCA or its regulations," § 337(a) is no barrier.[66] The purchasers seek to enforce the Sherman Act and RICO, not the FDCA.[67]

Ranbaxy cannot dispute that the FDA's penalties "do not address anticompetitive [or fraudulent] injury" suffered by the purchasers, nor that the "FDA's enabling statute does not entrust it with policing antitrust or RICO."[68] Boiled down, Ranbaxy's position is that, because it defrauded the FDA, purchasers cannot redress injuries under any theory tied to that fraud. But Congress provided private remedies in the antitrust and RICO laws, and has not limited those remedies in the FDCA.[69] It is "the duty of the courts . . . to regard each as effective."[70]

B. The complaint alleges market power under the Supreme Court's definition.

An antitrust plaintiff must show "detrimental effects" on competition[71] – usually by

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[62] Defs.' Obj. at 6; *see* 21 U.S.C. § 337(a) ("[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.").

[63] *Cf. Wyeth*, 555 U.S. at 574-75; *Riegel*, 552 U.S. at 327.

[64] Brief for Respondent at 4-5, *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), No. 12-761, 2014 WL 1260421, at *5-6.

[65] *POM*, 134 S. Ct. at 2239.

[66] *Id.*

[67] R&R at 26-27; *see* Pls.' Opp'n MTD at 7.

[68] R&R at 23, 47.

[69] *Id.* at 21, 22-23, 47.

[70] *Vimar Seguros y Reaseguros, S.A. v. M/V Sky Reefer*, 515 U.S. 528, 533 (1995) (citations omitted).

[71] *F.T.C. v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (citing 7 P. Areeda, Antitrust Law ¶ 1511 (1986)).

showing the monopolist has the "power to control prices *or* exclude competition."[72] While these two powers often go hand in hand, the test is disjunctive.[73]

Monopoly power "may be inferred from the predominant share of the market,"[74] but market share allegations are not essential.[75] To the contrary, an "exclusive focus on the market share percentages can produce a distorted picture of market power because 'the relative effect of percentage command of a market varies with the setting in which that factor is placed.'"[76] Monopoly power is a fact-intensive inquiry, and courts must "resolve antitrust claims on a case-by-case basis, focusing on the particular facts disclosed by the record."[77]

At bottom, though, "monopoly power" is, itself, just a "surrogate for detrimental effects" on the market.[78] Parties may "determine whether an arrangement has the potential for genuine adverse effects on competition"[79] by "defining the relevant market and considering evidence of the defendant's power within that market."[80] But this "is not always necessary."[81] Showing detrimental effects "obviate[s] the need for an inquiry" into market power.[82]

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[72] *United States v. E.I. DuPont de Nemours & Co.*, 351 U.S. 377, 391 (1956) (emphasis added); *United States v. Grinell Corp.*, 384 U.S. 563, 571 (1966).

[73] *Am. Tobacco Co. v. United States*, 328 U.S. 781, 811 (1946); *J.H. Westerbeke Corp. v. Onan Corp.*, 580 F. Supp. 1173, 1184 (D. Mass. 1984) ("the power *either* to set prices *or* to exclude competition in the relevant market.").

[74] *Grinnell*, 384 U.S. at 571.

[75] *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 783 n.2 (6th Cir. 2002) (monopoly power may be proven by "evidence of the control of prices," "the exclusion of competition," *or* "inferred from one firm's large percentage share of the relevant market."); *see also, e.g., J.H. Westerbeke*, 580 F. Supp. at 1188 (asking if defendant could raise prices or exclude competition *after* finding no predominant market share).

[76] *Broadway Delivery Corp. v. United Parcel Serv. of Am., Inc.*, 651 F.2d 122, 128 (2d Cir. 1981).

[77] *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 467 (1992).

[78] *Ind. Fed'n of Dentists*, 476 U.S. at 460-61 (quoting 7 P. Areeda, Antitrust Law ¶ 1511, p. 439 (1986)).

[79] *Id.* at 460.

[80] *Flegel v. Christian Hosp. Ne.-Nw.*, 4 F.3d 682, 688 (8th Cir. 1993) (citation omitted).

[81] *Id.*

[82] *Indiana Fed'n of Dentists*, 476 U.S. at 460.

1. The report acknowledges that this case presents an unusual set of facts, but applies the established definition of monopoly power.

The report acknowledges that the monopoly power inquiry here "is unusual because of the highly regulated market conditions."[83] Yet the report examines the complaint in light of those regulations, and finds it alleges that Ranbaxy's conduct had "detrimental effects" on the market.[84] The report analogized the Ranbaxy facts to a predatory pricing case, where a firm faces antitrust liability if it sells a product at unsustainably low prices to destroy competition in hopes of future monopoly profits, regardless of whether those profits are realized.[85] Here, Ranbaxy "reduced output and restricted competition in hopes of gaining future profits" by using its power to exclude generic versions of Valcyte and Diovan from the market while attempting to salvage its cGMP issues, even if it did not earn a profit during the exclusionary period.[86]

2. Ranbaxy mischaracterizes "monopoly power" and the report's rulings.

a. The report's standard is neither "new" nor "legally unprecedented."

The report invokes *Indiana Federation of Dentists v. FTC*'s holding that a monopoly power showing is obviated by "proof of actual detrimental effects" on competition.[87] Ignoring this proposition's Supreme Court pedigree, Ranbaxy calls it legally unprecedented.[88]

Ranbaxy claims that Judge Kelley held that "all allegedly anticompetitive conduct gives

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[83] R&R at 33.

[84] *Id.* at 34.

[85] *Id.*

[86] *Id.*

[87] *Id.* at 33 (citing *Indiana Fed'n of Dentists*, 476 U.S. at 460-61).

[88] Defs.' Obj. at 11. Other courts have applied *Indiana Federation of Dentists* in similar contexts. *See, e.g., Todd v. Exxon Corp.*, 275 F.3d 191, 206-07 (2d Cir. 2001); *Re/Max Int'l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1018 (6th Cir. 1999); *Great Western Directories, Inc. v. Sw. Bell Tele. Co.*, 63 F.3d 1378, 1384 (5th Cir. 1995); *Flegel*, 4 F.3d at 688; *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 202 (3d Cir. 1992); *Wilk v. Am. Med. Ass'n*, 895 F.2d 352, 360-61 (7th Cir. 1990); *R.C. Dick Geothermal Corp. v. Thermogenics, Inc.*, 890 F.2d 139, 164 (9th Cir. 1989); *Am. Steel Erectors, Inc. v. Local Union No. 7, Int'l Ass'n of Bridge, Structural, Ornamental & Reinforcing Iron Workers*, 932 F. Supp. 2d 240, 250 (D. Mass. 2013).

rise to a viable monopolization claim," and that her holding will "open the antitrust litigation floodgates" by eliminating the monopoly power requirement.[89] In other words, Ranbaxy argues the report eliminates the anticompetitive conduct requirement.

Ranbaxy treats detrimental *effects* as a synonym of anticompetitive *conduct*.[90] But monopoly power is a "surrogate for detrimental *effects*" on the market[91] – a synonym for anticompetitive *effects*. A plaintiff shows that a defendant's wrongful conduct had a detrimental effect on competition will have established *both* anticompetitive conduct *and* anticompetitive effect.[92]

b. Ranbaxy rewrites the monopoly power definition, adding new requirements and ignoring half the test.

Even if the purchasers need to allege the detrimental effects of Ranbaxy's conduct by alleging monopoly power, they have done so. Ranbaxy argues that it "cannot possibly have exercised" monopoly power because "[i]t never had the ability to raise prices *or earn any profits* . . . ."[93] But misstates the monopoly power test and ignores the allegations.

A firm usually will (but need not) earn profits as a monopolist.[94] Rather, as explained

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[89] Defs.' Obj. at 11-12.

[90] *But compare* Black's Law Dictionary 315 (8th ed. 1999) (defining "conduct" as "personal behavior") *with id.* at 554 (defining "effect" as "a result, outcome, or consequence").

[91] *Indiana Fed'n of Dentists*, 476 U.S. at 460-61 (emphasis added).

[92] *Cf. Newman v. Universal Pictures*, 813 F.2d 1519, 1522-23 (9th Cir. 1987) (rejecting argument that *per se* rule, which "presumes" anticompetitive effect from conduct, obviates antitrust injury requirement: the *per se* rule obviates a showing of "anticompetitive *effect*" but "does *not* excuse a plaintiff from showing that his injury was caused by the anticompetitive *acts*." (emphasis added)); *Zenith Radio Corp. v. Matsushita Elec. Indus. Co. Ltd.*, 513 F. Supp. 1100, 1253 n.235 (E.D. Pa. 1981) (party "ignored the fact that the anticompetitive *effect* . . . must have been the result of some anticompetitive *conduct*," and denying that "conduct can be inferred merely from proof of alleged consequences [i.e., effect] of that conduct") *aff'd in part sub nom. In re Japanese Elec. Prods. Antitrust Litig.*, 723 F.2d 238 (3d Cir. 1983), *rev'd on other grounds* 475 U.S. 574 (1986); *Fischer v. NWA, Inc.*, 883 F.2d 594, 600 (8th Cir. 1989) (discussing "anticompetitive conduct" and "anticompetitive effect" as distinct: the plaintiff's harm "was not caused by anticompetitive conduct *or* an anticompetitive effect of such conduct" (emphasis added)).

[93] Defs.' Obj. at 10-12 (emphasis added).

[94] *Cf. e.g., Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co., Inc.*, 549 U.S. 312, 318 (2007) (noting that, in predatory pricing cases, "the predator reduces the sale price of its product (its output) to below cost," – and *foregoes making a profit* – "hoping to drive competitors out of business" in the hopes that, "with competition vanquished," it could raise "output prices to a supracompetitive level").

above, monopoly power is defined by *either* the ability to raise prices *or* the power to exclude competition.[95] Here, Judge Kelley found – and Ranbaxy does not contest – that Ranbaxy acquired the ability to exclude generic competitors from the market.[96]

Ranbaxy tries to avoid the inconvenient half of the monopoly power definition, claiming the Supreme Court has declared that a wrongdoer has the power to "exclude competition" *only* if it "profits from that exclusion."[97] But *E.I. DuPont*, which Ranbaxy invokes, says no such thing.[98] Likewise, the treatise Ranbaxy cites does not define the "ability 'to exclude competition'" by "asking whether the defendant can price monopolistically without prompt erosion from rivals' entry or expansion";[99] it merely describes a *typical* antitrust inquiry.[100] Ranbaxy's other citations, too, describe only ordinary aspects of antitrust cases.[101]

But, as the report observes, "the situation here is far from ordinary."[102] The FDCA gives first filers, like Ranbaxy, the power to exclude other generics from the market, even before the first-filer itself enters the market.[103] Ranbaxy wrongfully acquired and maintained

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[95] *E.I. DuPont*, 351 U.S. at 391; *Grinell*, 384 U.S. at 571; *J.H. Westerbeke*, 580 F. Supp. at 1184.

[96] R&R at 31-32.

[97] Defs.' Obj. at 10 (citing *E.I. DuPont*, 351 U.S. at 394).

[98] 351 U.S. at 394 (beginning a section called "IV. The Relevant Market" by noting that "[w]hen a product is controlled by one interest, without substitutes available in the market, there is monopoly power").

[99] Defs.' Obj. at 10-11 (citing IIB Areeda & Hovenkamp, *Antitrust Law*, pp. 110-11 ¶ 501 (4th ed. 2014)).

[100] Areeda & Hovenkamp, *Antitrust Law*, pp. 110-11 ¶ 501. True, not all exclusions of competition yield monopoly power (i.e., a firm cannot have a monopoly by "forbidding everyone else from [] making a patented product" if "consumers have little use for it or can buy adequate substitutes from others"). *Id.* But this does not preclude the possibility of circumstances – like this case – where a defendant could exclude competition before entering the market. *Id.* ("[I]mpediments to rivals' entry or expansion . . . do not *necessarily* create or indicate any such power." (emphasis added)). Such a fact-specific inquiry is ill-suited for resolution on the pleadings.

[101] *Diaz Aviation Corp. v. Airport Aviation Servs., Inc.*, 716 F.3d 256, 265 (1st Cir. 2013), observed that, "absent direct proof of supracompetitive prices," a plaintiff will "*typically*" prove monopoly power through circumstantial evidence – "by defining the relevant market and showing that the defendant had a dominant marketshare." *Diaz* does not *compel* a plaintiff to follow this path. And *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 86 (D.D.C. 2006), explained that the monopoly power requirement is "*generally*" satisfied where, as in that case, a firm could "profitably raise prices substantially above the competitive level for a non-transitory period of time." It did not *require* parties to always prove the wrongdoer raised prices.

[102] R&R at 33.

[103] Compl. ¶¶ 54-55.

that power through fraud, and, in doing so, excluded generic competitors from the Diovan and Valcyte markets for years.[104] These allegations of anticompetitive conduct and effect state an antitrust claim. No further showing is needed.

In any event, the complaint alleges Ranbaxy *did* wrongfully acquire the power to raise prices: through fraud, it snagged the ability to offer its product at only a "modest discount" off the brand price, but still higher than the commodity price.[105] The fact that Ranbaxy may not have exercised that power with respect to Valcyte is immaterial. The Supreme Court has explained that "the material consideration in determining whether a monopoly exists is *not* that prices are raised" but rather "that power exists to raise prices . . . when it is desired to do so."[106] Not only that, Ranbaxy's fraud enabled the brand companies to keep the price of their products artificially high for longer than their patents allowed, causing purchasers to pay more than they should have.[107]

Furthermore, even if the ability to earn profits were a part of the monopoly power definition, the complaint alleges Ranbaxy acquired that ability. As the purchasers have explained, by locking in its first-to-file exclusivity, Ranbaxy acquired the ability to leverage its status into lucrative settlements with the brand company or other generic companies,[108] and to charge higher-than-commodity prices for the first six months it was on the market.[109] And Ranbaxy exercised these powers: first, with respect to generic Valcyte, Ranbaxy entered into a settlement with brand manufacturer Roche;[110] and second, with respect to generic Diovan,

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[104] *Id.* ¶¶ 12, 141, 155.

[105] *Id.* ¶ 29.

[106] *Am. Tobacco Co.*, 328 U.S. at 811.

[107] *See* Pls.' Opp'n MTD at 23.

[108] Compl. ¶¶ 66-67.

[109] *Id.* ¶¶ 28-29 (explaining that when only the first filer is in the market, the firm "prices its product below the brand product, but not as low as if it were facing competition from other generics").

[110] *Id.* ¶ 215.

Ranbaxy was able to charge higher-than-commodity prices, *even though* an authorized generic entered the market, until January 5, 2015.[111]

c. The report does not conflate different monopoly power standards.

Ranbaxy repackages another of its rejected arguments,[112] accusing Judge Kelley of "erroneous[ly]" finding that "market power" and "monopoly power" are "interchangeabl[e]."[113] This accusation is, to say the least, perplexing.[114]

They *are* interchangeable. As the report recognizes, "[m]onopoly power" is "*also* referred to as market power."[115] It is an "error" to hold the "belief or suspicion that market power and monopoly power are two different concepts when they are in fact, for antitrust purposes, qualitatively identical."[116] Courts, including the First Circuit, commonly oscillate between the terms.[117]

Ranbaxy relies on *Eastman Kodak*'s notion that "[m]onopoly power under § 2 requires . . . something greater than market power under § 1" to support its claim that

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[111] *Id.* ¶¶ 22, 24 (explaining an average cost-reduction once generic drugs commoditize is 85% off the brand price), 31 (noting the reduction when only two generics are on the market is about 50%), 208-09 (noting Ranbaxy and an authorized generic launched in the summer of 2014, and other generics did not enter until January 2015).

[112] *See* Defs.' Mot. Dismiss ("MTD") at 27, ECF No. 22 (arguing that, because the purchasers wrote "market power" instead of "monopoly power" at times in their complaint, they had failed to allege monopoly power).

[113] Defs. Obj. at 9 (alterations Ranbaxy's) (asserting that "market power" is somehow a lesser or different quantum of market control than monopoly power)

[114] Ranbaxy mischaracterizes Judge Kelley's wording: she wrote that the purchasers "argue[d] that they intended to use the terms interchangeably, and they are entitled to that inference." R&R at 32. If this Court prefers, the purchasers will amend their complaint to replace "market power" with "monopoly power."

[115] *Tops Markets, Inc. v. Quality Markets, Inc.*, 142 F.3d 90, 97-98 (2d Cir. 1998); *see also* R&R at 32.

[116] Thomas G. Krattenmaker et al., *Monopoly Power and Market Power in Antitrust Law*, 76 Georgetown L.J. 241, 241 (1987) (adopted by the Department of Justice at https://www.justice.gov/atr/monopoly-power-and-market-power-antitrust-law#fna).

[117] Courts, including the First Circuit, use both terms. *Cf. Coastal Fuels of P.R, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996) (requiring showing that defendant "had *monopoly power*," by showing "sufficient *market power*" to "raise price[s]" or "restrict[] output"); *Rebel Oil Co., Inc. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434-1438 (9th Cir. 1995) (considering sufficiency of circumstantial evidence of *market* power in a § 2 claim). Ranbaxy does not acknowledge *Coastal Fuels*, despite the purchasers' and Judge Kelley's reliance on that case.

"monopoly power" and "market power" are distinct.[118] This argument has been rejected before. In *IGT v. Alliance Gaming Corp.*,[119] IGT relied on the same *Eastman Kodak* quote "to support its conclusion that 'monopoly power' and 'market power' are entirely distinct terms."[120] But IGT, like Ranbaxy, did not "provide the relevant context for this statement": *Eastman Kodak* was discussing a difference in degree, not kind.[121] When plaintiffs rely on circumstantial evidence (i.e., market share) to establish monopoly power, a greater *percentage* is required under § 2.[122] But, where a lawsuit "does not involve a § 1 claim," the terminology is irrelevant, because, for § 2 claims, "market power" is "the same as 'monopoly power.'"[123] Here, any theoretical distinction between market power and monopoly power is irrelevant. The purchasers neither advance a § 1 claim, nor attempt to prove monopoly power by market share.[124]

d. The report applies the proper market definition.

Ranbaxy claims Judge Kelley "mis-defined the relevant markets" by "assum[ing] the relevant markets are generic Valcyte or generic Diovan *alone*," and ignoring the complaint's definitions.[125] Ranbaxy ignores the report's acknowledgement that "'the relevant markets are (a) *all* valsartan tablets – i.e., Diovan . . . *and* AB-rated bioequivalent valsartan tablets; and (b)

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[118] Defs.' Obj. at 9.

[119] No. 04-cv-1676, 2008 WL 7071468 (D. Nev. Oct. 21, 2008).

[120] *Id.* at *11.

[121] *Id.* (explaining that "the market share that an accused party must possess" in a § 1 tying claim "is less than the market share that the accused party must possess under § 2").

[122] *Id.*; *see also Eastman Kodak*, 504 U.S. at 481 (citing *Fortner Ents., Inc. v. U.S. Steel Corp.*, 394 U.S. 495, 501-02 (1969)) (percent of market share); *Fortner*, 394 U.S. at 501-02 (volume of the market controlled).

[123] *Id.* at *12 (addressing expert's choice of the term "market power" over "monopoly power" in his report).

[124] In any event, the purchasers sufficiently allege market share. Ranbaxy was the first filer in both the Diovan and Valcyte markets, Compl. ¶¶ 75, 78, and a first-filer generic controls 80% of the market, *id.* ¶ 24. *See Am. Tobacco Co*, 328 U.S. at 787 (control of more than two thirds of the market suffice). Ranbaxy's argument regarding Diovan, Defs.' Obj. at 12-13, fails for an additional reason. Low market share may be fatal *only* if "the defendant's share is less than 50% . . . *and* the record contains no significant evidence concerning the market structure to show that the defendant's share of that market gives it monopoly power." *Healthco Int'l, Inc. v. A-dec, Inc.*, No. 87-cv-235, 1989 WL 104064, at *7 (D. Mass. Apr. 17, 1989) (quoting *Broadway Delivery*, 651 F.2d at 128-29).

[125] Defs.' Obj. at 9-10 (citing R&R at 32).

all valganciclovir hydrochloride tablets – i.e., Valcyte . . . *and* AB-rated bioequivalent valganciclovir hydrochloride tablets.'"[126] But Ranbaxy ignores the report's observation that the complaint alleges that, through wrongful conduct, Ranbaxy "exclude[d] all ANDA generic competition" from *those* markets.[127] The complaint alleges different approaches to the market definition; the report does not err in acknowledging that.[128]

Ranbaxy does not specify what leads it to believe the report mis-defined the market, just pointing broadly to a page of the report;[129] but nowhere – on that page or elsewhere – does the report vary the purchasers' definitions. The report simply identifies the *type* of competitors Ranbaxy excluded from the markets.

C. Ranbaxy's fraudulent conduct caused generic delay and harmed the purchasers.

Both RICO and the Sherman Act require a showing of in-fact and proximate causation.[130] Proximate cause turns on a number of factors: whether the injury is covered by the governing law; the defendant's intent; the connection between the defendant's conduct and the plaintiff's injury; the directness of that connection; the definiteness of damages and their apportionment; and the lack of a more directly-harmed party.[131] Cause in-fact is more straightforward: courts need only ask whether the defendant's conduct was a substantial

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[126] R&R at 16 (emphasis added) (citing Compl. ¶ 256).

[127] R&R at 32.

[128] In any event, the complaint pleads an alternative, generic-only market for each drug. *See* Pls.' Opp'n MTD at 24-25 (citing Compl. ¶ 240). Courts have permitted such definitions before, *see, e.g.*, *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496-99 (2d Cir. 2004) (defining market as generic warfarin sodium); *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 81-82 (D.D.C. 2006) (defining market as generic versions of lorazepam and clorazepate); *cf. Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (Within the "outer boundaries" of a "broad market," "well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes."). This definition would undermine, rather than support, Ranbaxy's cause: in a generics-only market, Ranbaxy controlled a 100% market share for the period it unlawfully excluded competition.

[129] Defs.' Obj. at 9-10 (citing R&R at 32). As best the purchasers can tell, Ranbaxy may be referring to the summary of the purchasers' allegations beginning on page 31, and continuing to page 32.

[130] *See Holmes v. Sec. Inv. Protection Corp.*, 503 U.S. 258, 268 (1992) (RICO); *Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 534 (1983) (antitrust).

[131] *Assoc. Gen. Contractors*, 459 U.S. at 537-45.

contributing factor to the plaintiff's harm.[132]

Ultimately, causation is a fact-intensive inquiry ill-suited for resolution on a motion to dismiss.[133] At this stage in the proceedings, the allegations "need only show that the claim of causation is plausible."[134] A plaintiff need not rule out other potential causes of injury: such a requirement "exceeds the pleading requirements necessary to survive a motion to dismiss."[135]

1. The report correctly evaluates proximate cause.

The report surveys the factors relevant to proximate cause, and concludes the purchasers allege Ranbaxy's anticompetitive intent, injuries redressable by the antitrust laws and RICO, and a causal link between Ranbaxy's wrongful conduct and the injury.[136] Other factors, the report concludes, require fact-specific determinations unfit for a motion to dismiss.[137]

The report rejects Ranbaxy's arguments that (1) the FDA's intervening actions in response to Ranbaxy's fraud broke the causal chain, and (2) the purchasers' real complaint was with FDA's speed.[138] Intervening actions, the report notes, do not defeat proximate cause where they are the "foreseeable and natural result of the defendant's conduct."[139] The FDA's delay "was a natural and foreseeable consequence" of Ranbaxy's fraud because the FDA's pace

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[132] *See In re Neurontin Marketing & Sales Pracs. Litig.*, 712 F.3d 21, 34 (1st Cir. 2013).

[133] *Szulik v. State Street Bank & Trust Co.*, 935 F. Supp. 2d 240 (D. Mass. 2013) (Gorton, J.) ("[T]he question of causation raises issues of fact that cannot be resolved at this stage in the litigation."); *see also, e.g.*, *Loreley Financing (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 189 n.21 (2d Cir. 2015) ("[Q]uestions of causation are often complex, and where the issue is the chain of causation, that issue is not appropriate for resolution on a motion to dismiss." (citation omitted)); *Pub. Empl. Retirement Sys. of Miss. v. Amedisys, Inc.*, 769 F.3d 313, 325 (5th Cir. 2014) ("[T]he connection between [the defendant's misconduct] and the [resulting harm] . . . is a highly fact intensive inquiry that need not be reached at this point.").

[134] *Rodríguez-Reyes v. Molina-Rodríguez*, 711 F.3d 49, 56 (1st Cir. 2013).

[135] *Boston Cab Dispatch, Inc. v. Uber Techs., Inc.*, No. 13-cv-10769, 2015 WL 314131, at *4 (D. Mass. Jan. 26, 2015) (Gorton, J.).

[136] R&R at 34-36, 51-52.

[137] *Id.* at 36.

[138] *Id.* at 36.

[139] *Id.* at 37.

was "certainly affected by Ranbaxy's obfuscation."[140] "Ranbaxy had hidden the relevant information," so the "FDA could not review [tentative approval] any sooner" than it did.[141] The portion of the delay that is attributable to Ranbaxy, the report observes, "is a highly factual inquiry."[142] The report concludes the purchasers allege "sufficient facts" and "legitimate inferences," to raise "a factual question that cannot be resolved at this stage."[143]

2. Ranbaxy recycles meritless factual arguments about causation.

a. The purchasers allege cause-in-fact.

Ranbaxy claims the report "ignores 'but for' causation entirely."[144] Not so. It observes:

> Ranbaxy's compliance issues do not factor into the *but for analysis* – its deceit does. If not for the fraud, Ranbaxy would have told the FDA honestly about its abysmal manufacturing practices at some earlier point, and it still would not have been able to launch. Plaintiffs state that there was 'no realistic likelihood that the FDA would, absent Ranbaxy's fraud, grant tentative or final approval to [either the generic Valcyte or Diovan] ANDA.' Had Defendants admitted their compliance issues . . . they would likely have forfeited their TA and first-filer status earlier than they actually did.[145]

Elsewhere, the report notes that the complaint alleges "*but for* Ranbaxy's fraud, the FDA would have known earlier that [Ranbaxy's] compliance status was lacking, and would have been able to move more swiftly."[146]

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[140] *Id.*

[141] *Id.* Ranbaxy misrepresents the report, claiming it determined that "the FDA could not review the TA any sooner than 2014." Defs.' Obj. at 14 (internal quotations omitted). It constructs an elaborate argument about how this conclusion is "belied by the plaintiffs' own allegations." *Id.* But the report *never said* that the tentative approvals could not be reviewed "any sooner *than 2014*" – Ranbaxy added that date limitation. R&R at 37; *see also id.* at 14 (citing Compl. ¶¶ 217-18) (noting allegations that the FDA resumed Valcyte ANDA review in May 2012); *id.* at 13 (citing ECF No. 47-2) (referencing Ranbaxy's extra-record evidence that the FDA resumed Diovan review in July 2012).

[142] R&R at 37.

[143] *Id.* at 38.

[144] Defs.' Obj. at 13.

[145] R&R at 27 (citations omitted).

[146] *Id.* at 37 (emphasis added).

b. Ranbaxy's fact bound causation arguments have no bearing on a motion to dismiss.

Beyond this misrepresentation, Ranbaxy merely rehashes arguments that the report already explains are inappropriate at the Rule 12(b)(6) stage.[147] It is a factual question whether the FDA's review is a supervening cause or a "natural and foreseeable" result of Ranbaxy's fraud.[148] As Judge Kelley understood, the lawful exercise of the 180-day exclusivity "is not what Plaintiffs seek to challenge."[149] The wrongfully acquired exclusivity did not give Ranbaxy "free rein to come up with other varieties of anticompetitive behavior."[150]

c. Ranbaxy rehashes its meritless argument that it never needed tentative approval for its generic Diovan ANDA.

Ranbaxy spends nearly a third of its papers insisting that it never needed tentative approval for its Diovan ANDA.[151] Therefore, it claims, the purchasers could not show that fraud in obtaining tentative approval proximately caused the purchasers any harm.[152] Even if Ranbaxy's untimely assertion of this argument is overlooked, it fails on the merits.[153]

Within the FDCA's requirement that an ANDA applicant obtains timely tentative

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[147] Neither of these arguments is sufficiently developed to warrant serious consideration – or even say with certainty what Ranbaxy is arguing. *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived."). The purchasers have attempted link Ranbaxy's arguments to earlier submissions. Should Ranbaxy be offering an argument other than those raised to Judge Kelley, such argument is waived.

[148] Defs.' Obj. at 14; *accord* Def's Mem. MTD at 24-25 (arguing that the FDA's supervening regulatory actions prevent the purchasers from alleging causation).

[149] R&R at 24. *Contra* Defs.' Obj. at 14-15; Def. Mem. MTD at 16.

[150] R&R at 24. (analogizing to a "patent holder" that "still act[s] illegally to thwart competition").

[151] Defs.' Obj. at 15-21.

[152] *Id.* at 15.

[153] The length of Ranbaxy's argument is, perhaps, an artefact of the argument's provenance. This is the first time that Ranbaxy has set forth, in full, its argument. Ranbaxy did not raise it in the motion to dismiss, or even the reply. Instead, Ranbaxy first made the argument at oral argument, relying on extra-record material not qualified for judicial notice. *See* Pls.' Post-Hr'g Br. at 7 n.30. It briefly articulated its assertions in post-argument briefing. *See* Defs.' Post-Arg. Br. at 4-8. But Ranbaxy has waived this argument. *Akar v. Fed. Nat'l Mortg. Ass'n*, 845 F. Supp. 2d 381, 384 n.1 (D. Mass. 2012) (Gorton, J.) (When an argument is "not raised in [a] motion to dismiss, and thus not before the Magistrate Judge, the Court deems it to be waived."); *Solmetex, LLC v. Apavia LLC*, No. 15-cv-40144, 2016 WL 755613, at *2 n.2 (D. Mass. Feb. 25, 2016) (refusing to consider argument first raised at oral argument).

approval or forfeit its exclusivity is a provision that excuses untimely approval if it "is caused by a change in or a review of the requirements for [the ANDA's] approval."[154] Ranbaxy argues that, if the FDA changes its review requirements, this narrow exception relieves the ANDA applicant from *ever* needing *any* tentative approval, as opposed to simply excusing *a period of delay* associated with the need to respond to the regulatory change.[155] As Judge Kelly explained, however, Ranbaxy's interpretation is simply "implausible."[156]

Contrary to Ranbaxy's assertions, the FDA interprets this section to require it to determine whether a delay is justified by the timing and nature of the rule change, the extent of work needed by the sponsor to meet the change, and the back-and-forth between the agency and the applicant.[157] This review would be unnecessary if, as Ranbaxy claims, a change in approval requirements absolves an ANDA applicant of any responsibility for tentative approval. Another court has already agreed and found the statute excused only a *delay* in tentative approval, not the need for tentative approval itself.[158] Even Ranbaxy's own extra-record evidence, dredged up for the first time at oral argument, supports this view.[159]

Judge Kelley heeded the "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."[160] Ranbaxy castigates her for this analysis, and accuses her of ignoring the principles

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[154] 21 U.S.C. § 355(j)(5)(D)(i)(IV).

[155] Defs.' Obj. at 15-21.

[156] R&R at 47.

[157] *See* Pls.' Post-Hr'g Br. at 9-11 (collecting statements by the FDA).

[158] *Mylan Labs. Ltd. v. U.S. FDA*, 910 F. Supp. 2d 299, 311 (D.D.C. 2012) ("Congress . . . included in the statute an express exception to forfeiture for *delays* in tentative approval caused by changes in approval requirements beyond an ANDA applicant's control.").

[159] Mem. from Martin Shimer, Regulatory Support Branch, Office of Generic Drugs ("OGD"), on 180-Day Exclusivity for Valsartan Tablets 3 n.3 (Sept. 28, 2012) (submitted by Ranbaxy at oral argument as Ex. D) (the FDA interprets the statute to require first-filer to forfeit exclusivity if it failed to obtain timely tentative approval "unless the period is *extended*" by a change in approval requirements); *see also* Pls.' Post-Hr'g Br. at 7-8.

[160] *David v. Mich. Dep't of Treasure*, 489 U.S. 803, 809 (1989).

of statutory interpretation,[161] but there is no fault in her process.

Interpretation "depends upon reading the whole statutory text, considering the *purpose and context* of the statute."[162] While this process "begins with the language of the statute," the "plain meaning sometimes must yield if its application would bring about results that are either absurd or *antithetical to Congress's discernible intent*."[163] As the report notes, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which added § 355(j)(5)(D)(i)(IV) to the FDCA, was enacted to "reduc[e] delays in getting generic drugs to market."[164] To read that piece of legislation as completely obliterating a deadline in the event of even modest regulatory delay is antithetical to Congress's discernible intent.

D. Ranbaxy's remaining arguments are undeveloped and, in any event, meritless.

Ranbaxy crams four arguments into its last three and a half pages. It does not present a "developed account" of its legal argument or an "explicit assessment" of the magistrate judge's errors.[165] The arguments should be rejected outright,[166] but are easily exposed as meritless.

1. The purchasers have standing.

Ranbaxy's factual assertion – that the purchasers' assignor "only purchased brand Diovan and brand Valcyte," so "there is no plausible basis for concluding [it] would have bought [generic Diovan and Valcyte] had they become available sooner"[167] – is false.[168]

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[161] Defs.' Obj. at 19 (calling the statute "unambiguous" and claiming legislative history is, thus, irrelevant).

[162] *Dolan v. Postal Service*, 546 U.S. 481, 486 (2006).

[163] *In re Hill*, 562 F.3d 29, 32 (1st Cir. 2009); *see also Kasten v. Saint-Gobain Performance Plastics Corp.*, 563 U.S. 1, 7 (2011) (Where, as here, a provision "in isolation, may be open to competing interpretations . . . considering the provision in conjunction with the purpose and context" may show "that only one interpretation is possible.").

[164] R&R at 46-47 ("Where its *purpose* is so clear, 'the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress'" (emphasis added) (quoting *Chevron*, 467 U.S. at 842)).

[165] *Maine Green Party*, 173 F.3d at 4 n.5. This default is compounded by the same arguments' underdevelopment before the magistrate judge. *Curet-Velazquez v. ACEMLA de P.R., Inc.*, 656 F.3d 47, 54 (1st Cir. 2011) ("Arguments alluded to but not properly developed before a magistrate judge are deemed waived.").

[166] *Uncle Henry's*, 399 F.3d at 42.

[167] Defs.' Obj. at 22.

2. *Noerr-Pennington* does not bar this suit.

Noerr-Pennington provides limited protection from antitrust liability for legitimate petitioning.[169] But, where a petitioner files "objectively baseless" "sham" petitions, intent on abusing the governmental process, *Noerr-Pennington*'s limited immunity evaporates.[170] This is also true where a petitioner "[seeks] to bar [its] competitors from meaningful access to adjudicatory tribunals and so to usurp that decisionmaking process" by filing large volumes of petitions "with or without probable cause, and regardless of the merits of the cases."[171]

Ranbaxy claims that, because the report "concedes" that neither the Diovan nor Valcyte ANDAs were objectively baseless and instead found "other ANDAs, for other drugs" baseless, there was "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."[172]

There are many things wrong with this argument. First, the report does *not* "concede" there was nothing untruthful in the Diovan or Valcyte application process: it notes that Ranbaxy's petitioning was a sham "*[r]egardless* of whether the information in any individual ANDA was true or not."[173] Second, it does not find that *only* ANDAs for *other* drugs were shams.[174] And third, there *is* a legal basis for stripping immunity from Ranbaxy's Diovan and

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[168] Compl. ¶¶ 9, 11-12, 263-64, 266, 269 ("During the relevant period, Plaintiff and members of the direct purchaser class purchased substantial amounts of Diovan and Valcyte directly from their branded manufacturers *and/or purchased substantial amounts of generic versions of Diovan and Valcyte directly from Ranbaxy.*").

[169] *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

[170] *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus.* ("*PRE*"), 508 U.S. 49, 61 n.6 (1993).

[171] *Cal. Motor Transport Co. v. Trucking Unlimited.*, 404 U.S. 508, 511-12 (1972); *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015) (no immunity where defendant filed serial petitions "without regard to the[ir] merits" in order to harm competition, "even if some of those petitions have some merit").

[172] Defs.' Obj. at 23 (citing R&R at 31).

[173] R&R at 31.

[174] *Id.*

Valcyte petitioning as part of an overarching sham.[175]

3. **The fact-specific statute of limitations inquiry cannot be addressed now.**

The statute of limitations is a fact-intensive inquiry ill-suited for a motion to dismiss,[176] unless the claims' untimeliness is "definitively ascertainable from the allegations of the complaint" *and* "the facts so gleaned . . . conclusively establish the affirmative defense."[177] Ranbaxy contends that this is such a case, claiming the complaint alleges that "the FDA discovered and publicized Ranbaxy's fraud in February 2009."[178] But Ranbaxy misrepresents the purchasers' allegations: in 2009, the FDA disclosed Ranbaxy's compliance issues and fraudulent statements *in some (unspecified) ANDAs* in 2009. It did not disclose the fraud *during the tentative approval process*, or specifically identify affected ANDAs, until November 2014.[179]

In any event, a purchaser's cause of action first accrues each time it incurs an overcharge, not at the first inkling of anticompetitive conduct.[180] The complaint alleges that purchasers were first overcharged for Diovan on September 21, 2012;[181] and for Valcyte on March 13, 2013.[182] Both dates are less than four years before the purchasers' May 2015 complaint.[183] In any event, the report notes, the statute of limitations may be tolled, given

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[175] *California Motor Transport*, 404 U.S. at 511-12; *see also* R&R at 31 (invoking *Cal. Motor*).

[176] *Nat'l Assoc. of Gov't Workers v. Mulligan*, 854 F. Supp. 2d 126, 131 (D. Mass. 2012) (citation omitted).

[177] *In re Colonial Mortgage Bankers Corp.*, 324 F.3d 12, 16 (1st Cir. 2003).

[178] Defs.' Obj. at 24.

[179] Compl. ¶ 157-58, 230; *see also* Pls.' Opp'n MTD at 30.

[180] *Hanover Shoe v. United Shoe Mach. Corp.*, 392 U.S. 481, 489, 502 n.15 (1968) (citing *Chattanooga Foundry & Pipe Works v. City of Atlanta*, 203 U.S. 390, 396 (1906)); *see Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971); *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 190 (1997); *Rite Aid Corp. v. Am. Express Travel Related Serv. Co.*, 708 F. Supp. 2d 257, 263-64 (E.D.N.Y. 2010) ("A purchaser plaintiff's cause of action accrues when he or she actually pays an overcharge. By contrast, a competitor plaintiff's cause of action accrues at the time of the defendant's anticompetitive conduct." (citation omitted)).

[181] Compl. ¶¶ 208-10. Full generic competition did not occur until after January 5, 2015. *Id.* ¶ 209.

[182] *Id.* ¶¶ 216, 222-23.

[183] Even if the purchasers' damages began accruing earlier, as Ranbaxy suggests, the report observes that the continuing violation doctrine – which holds that "a new cause of action accrues to purchasers upon each overpriced

allegations that "the facts necessary for their complaint were not discoverable until the FDA's 2014 filing in the *Ranbaxy v. Burwell* case."[184]

4. Ranbaxy's final objection lacks particularity.

Ranbaxy accuses the purchasers of failing to plead their claims with particularity.[185] Ignoring the irony of this three-sentence argument, Ranbaxy is simply wrong.[186]

Ranbaxy appears to repackage its arguments about the lack of allegations of misstatements in the Diovan and Valcyte ANDAs themselves.[187] If so, it attacks a straw man. The purchasers' allegations do not rely on false statements *in the ANDAs* (filed in 2004 and 2005), but on false statements made (in 2007 and 2008) to get those ANDAs *tentatively approved*.

The complaint alleges Ranbaxy's fraud in "vivid detail":[188] that Ranbaxy, its lawyers, and its auditors misled the FDA about Ranbaxy's compliance issues.[189] Their misstatements led the FDA to tentatively approve first Ranbaxy's Flomax ANDA, and later the generic Diovan and Valcyte ANDAs.[190] Those wrongfully-obtained tentative approvals delayed availability of affordable generic drugs, and cost the purchasers billions of dollars.[191] These allegations are set forth with particularity.

V. CONCLUSION

This Court should adopt in full the report and recommendation.

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sale of the drug" may apply. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 746-47 (E.D. Pa. 2014); *see also* Pls.' Opp'n MTD at 30 n.163 (collecting cases).

[184] R&R at 39.

[185] Defs.' Obj. at 24-25.

[186] *Cf. Uncle Henry's*, 399 F.3d at 42 (disallowing conclusory objections).

[187] *See* MTD at 23 (claiming purchasers "did not identify any specific misrepresentations Ranbaxy made with respect to its applications" for generic Diovan and Valcyte).

[188] R&R at 28.

[189] Compl. ¶¶ 92-97.

[190] *Id.* ¶¶ 123-32, 139-45, 153-55.

[191] *Id.* ¶¶ 210, 223, 323.

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was served by filing it on the court's CM/ECF system and additionally via electronic mail to all counsel of record.

Dated: August 12, 2016

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