UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

v. CIVIL ACTION NO. 15-11828-NMG

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

REPORT AND RECOMMENDATION ON
DEFENDANTS' MOTION TO DISMISS (#21)

KELLEY, U.S.M.J.

In this action Plaintiffs seek redress for Defendants' alleged anticompetitive and racketeering behavior prior to the market entry of two generic drugs. The case presents an issue of apparent first impression: whether Sherman Act claims brought by purchasers of a product may be predicated on an underlying fraud on the Food and Drug Administration.[1] Both parties rely primarily on Supreme Court precedent that, while instructive, is not precisely on point. *See*

[1] At oral argument, Defendants' counsel stated: "… I would submit, Your Honor, that the reason there isn't a lot of precedent is I don't believe anyone has ever tried to take a case of fraud on the FDA and package it as an antitrust case." (#45, Transcript of Motion Hearing, March 31, 2016, at 26:13-26:17.) Plaintiffs' counsel admitted that this type of case "hasn't been brought before, but these facts are pretty rare… The FDA hasn't had to come down on a manufacturer like this ever before… with respect to good manufacturing practices… the kind of misconduct that would happen here hasn't happened before." (#45 at 42:10-42:18.)

Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001) (defendants), *and POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014) (plaintiffs).

Defendants filed a Motion to Dismiss (##21, 22, 23), Plaintiffs opposed (##25, 26), and Defendants replied (##31, 36). For the reasons set forth below, I recommend that Defendants' Motion to Dismiss be ALLOWED as to all counts against Ranbaxy Laboratories Limited and Ranbaxy USA, Inc., and DENIED as to all counts against Ranbaxy, Inc. and Sun Pharmaceutical Industries Limited.

I. **Facts**

A. Background and Statutory Scheme

Some background is necessary to understand the issues in this case, so a summary of the relevant statutory and regulatory provisions follows. The Food and Drug Administration ("FDA") is the federal agency responsible for regulating and approving prescription drugs under the Food, Drug and Cosmetic Act ("FDCA"). (#1, Complaint, ¶33; *see generally* 21 U.S.C. § 301 *et seq.*) All pharmaceutical products must be approved by the FDA before being sold in interstate commerce in the United States. Title 21 U.S.C. § 355. Obtaining FDA approval for a new drug is an onerous process. (#1 ¶¶34, 39; *and see* 21 U.S.C. § 355 *et seq.*) To ease this burden, in 1984 legislation known as the Hatch-Waxman Act created a fast-track process for pharmaceutical companies to obtain FDA approval to produce generic versions of approved drugs. (#1 ¶¶39-42; Pub. L. No. 98-417, 98 Stat. 1585 (1984).) Under this scheme, a prospective generic drug manufacturer initiates the approval process by filing an Abbreviated New Drug Application ("ANDA") with the FDA. (#1 ¶¶43-55; 21 U.S.C. § 355(j).) The ANDA process was

further refined by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003). (#1 ¶60.)

B. ANDA Approval Process

Currently, there are three "milestones" in the ANDA approval process: receipt, tentative approval, and final approval. (#26-3[2] at 12[3]; *Ranbaxy Labs., Ltd. v. Burwell*, 82 F. Supp. 3d 159, 166 (2015).) The District Court for the District of Columbia has summarized the process succinctly:

> … [An] ANDA typically passes through three distinct phases of FDA review on the generic drug's way to the marketplace. A generic drug manufacturer must first perfect an application before that application is reviewed on the merits. If the ANDA could be approved, except for the presence of blocking patents or other periods of exclusivity, the ANDA may be tentatively approved, which approval does not allow the marketing of the drug but may serve to preserve eligibility for a 180-day generic marketing exclusivity period by eliminating a potential forfeiture event. After any patent impediments are removed, the ANDA may be granted final approval, at which point the drug may be marketed in interstate commerce.

Ranbaxy Labs., Ltd., 82 F. Supp. 3d at 170. Each of these steps is described in more detail below.

1. Receipt and Patent Certification

When a new ANDA is submitted, the FDA must determine whether it contains all the information required by statute. (#1 ¶44; #26-3 at 12; 21 U.S.C. § 355(j)(2)(a).) If so, the application is deemed "received." *Id.* "'Receipt' is a term of art… [meaning] 'that FDA has made a threshold determination that the [ANDA] is sufficiently complete to permit a substantive review.'" (#26-3 at 13 (quoting 21 C.F.R. § 314.101(b)(1)).) In its ANDA, the prospective

[2] FDA Memorandum In Opposition to Ranbaxy's Motion for a Preliminary Injunction & In Support of Summary Judgment, *Ranbaxy Labs, Ltd. v. Burwell*, No. 14-cv-1923-BAH (D.D.C. Dec. 22. 2014), ECF No. 55-1.

[3] All page numbers cited are those assigned by ECF.

manufacturer (the "prospect") must make detailed representations as to bioequivalence, demonstrate its ability to manufacture a safe, stable product, and show compliance with current good manufacturing practices ("cGMP"), among other things. (#1 ¶¶46-48; #26-3 at 12-13 (citing 21 C.F.R. §§ 314.50(d)(1), 314.94(a)(9)(i)).) The FDCA also lists circumstances under which an ANDA must be rejected. (#26-3 at 12 (citing 21 U.S.C. § 355(j)(4)).)

Usually the entity responsible for research and development (the "innovator") holds a patent on the drug it discovered; therefore, the prospect must claim in its ANDA one of four statutory exemptions to the patent. (#1 ¶51; 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).) Paragraph IV of Hatch-Waxman, relevant here, allows the prospect to assert either that the innovator's patent is invalid or that it will not be infringed by the prospect's generic drug. (#1 ¶51(d); 21 U.S.C. § 355(j)(2)(A)(vii)(IV).) An ANDA filing under Paragraph IV is *per se* an act of patent infringement, and triggers a 45-day window for the innovator to file suit against the prospect. (#1 ¶52; 35 U.S.C. § 271(e)(2).) In exchange for assuming this risk of litigation, the first prospect to file a successful Paragraph IV ANDA is rewarded with 180 days of exclusive rights to market and sell the generic version of the drug. (#1 ¶54; 21 U.S.C. §355(j)(5)(B)(iv).) During this exclusivity period, the first filer competes only with the brand manufacturer and any generic version of the drug authorized by the brand manufacturer and marketed under the authority of its original FDA approval. (#1 ¶55 n.13.) In doing so, the ANDA process effectively delays market competition to create an economic incentive for generics to challenge the patent.

The initial 180-day exclusivity period is the most profitable time for a new generic, because the first ANDA filer "typically captures an overwhelming majority of unit sales while offering only a relatively modest discount off the price of the brand." (#1 ¶¶28-29.) After

multiple generic manufacturers launch their products, the price settles at market levels. (#1 ¶30.) Therefore, the exclusivity period is "whoppingly lucrative" for prospective generic manufacturers. (#45 at 35:11, *and see F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (exclusivity period "possibly 'worth several hundred million dollars'" (quoting Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L.Rev. 1553, 1579 (2006))).)

2. Tentative Approval and Exclusivity Eligibility

If the ANDA meets all the FDA's substantive requirements for approval yet faces pending technical obstacles due to a patent, another manufacturer's exclusivity, or a change of the applicable rules, the FDA may grant tentative approval ("TA"). (#1 ¶¶56-57; 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.107(b)(3)(v).) By statute, the FDA "shall approve" an ANDA unless a listed exception applies. (#26-3 at 13 (citing 21 U.S.C. § 355(j)(4) and 21 C.F.R. § 314.127).) "[I]n the FDA's view, the requirements for tentative and final approval are identical, except that tentative approval does not require a showing that the ANDA will not infringe upon any valid patent. Thus, the FDA must withhold tentative approval for the same reasons it must withhold final approval, including a lack of CGMP compliance." *Ranbaxy Labs., Ltd.*, 82 F. Supp. 3d at 189. Even after the technical hurdle is resolved, TA is not a green light for entering the market. If enough time has elapsed, the FDA may still require further investigation before issuing a final approval letter. (#1 ¶58; #26-3 at 14 (quoting *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19 (D.D.C. 2004) ("Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform.") (additional citations omitted)).)

Merely winning the race to file a "received" ANDA does not ensure that a prospect will get the exclusivity period. The MMA sought to motivate prospects to get to market sooner by imposing a deadline on the first filer. (#26-3 at 15.) Under this amendment, the exclusivity period is generally forfeited if the first filer fails to obtain TA within 30 months of its ANDA filing date. (#1 ¶61; 21 U.S.C. § 355(j)(5)(D)(i)(IV); *and see* 21 U.S.C. § 355(j)(5)(D)(iii) ("If all first applicants forfeit the 180-day exclusivity period under clause (ii) — *** (II) no applicant shall be eligible for a 180-day exclusivity period").) "Congress enacted the forfeiture provisions to 'ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.'" 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer) (quoted in *Hi-Tech Pharmacal Co., Inc. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008), and #26-3 at 15).

However, there are two relevant exceptions to the forfeiture provisions. First, if the FDA causes the delay itself by "a change in or a review of the requirements for approval of the application," the exclusivity period is not forfeited even if the first filer cannot obtain TA within 30 months.[4] (#1 ¶61 n.20; #26-2[5] at 15 (quoting 21 U.S.C. § 355(j)(5)(D)(i)(IV)).) Second, the exclusivity period is tolled while the FDA examines a citizen petition concerning the ANDA. (#1 ¶19 n.20; 21 U.S.C. §355(j)(5)(D)(IV).) In sum, the first filer "must demonstrate within 30 months that its application would be approved but for any blocking patents, exclusivities, or stays" in order to get exclusivity. (#26-3 at 40.) In the event that all first filers "forfeit the

[4] Defendants have argued that in this circumstance "there is no deadline to obtain [TA] or else forfeit exclusivity" (#48 at 9-12); Plaintiffs assert that the deadline is merely tolled. (#47 at 10-16.) Discussion of this issue is below at page 44.

[5] FDA Memorandum in Opposition to Ranbaxy's Motion for a Temporary Restraining Order, *Ranbaxy Labs, Ltd. v. Burwell*, No. 14-cv-1923-BAH (D.D.C. Nov. 18, 2014), ECF No. 23.

exclusivity right in one of the ways specified by statute, no other generic can obtain it." *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2229, 186 L. Ed. 2d 343 (2013) (citing 21 U.S.C. § 355(j)(5)(D)).

3. Final Approval

Once the patent issues are resolved, and when the FDA is satisfied that a tentatively approved prospect has met its manufacturing requirements, the FDA grants final approval for the prospect to manufacture and sell its generic drug product. (#1 ¶63; 21 U.S.C. § 355(j)(4) (final approval "shall" be granted unless one of eleven enumerated conditions applies).) As described above, if time has elapsed since the TA, the FDA may investigate to ensure that the information in the ANDA is still current and correct. (#1 ¶58; #26-3 at 14; 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB).) If a prospect has secured the right to the exclusivity period, other generics may enter only after the 180 days have passed. From the consumer's perspective, the entry of additional generic drugs onto the market profoundly affects pricing. A brand manufacturer who holds a patent can charge "supra-competitive prices" for its drug, and the price drops only slightly during the exclusivity period. (#1 ¶25.) Once multiple generic versions of the drug are released, the price drops drastically and generic sales overtake the lion's share of the market. (#1 ¶24.) Generic drugs save consumers an estimated $8 to $10 billion per year. (#1 ¶32.)

C. Parties

Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively "Meijer"), named plaintiffs, are Michigan corporations. (#1 ¶13.) They are assignees of the claims of Frank W. Kerr Co., who purchased Valcyte (valganciclovir hydrochloride) and Diovan (valsartan)[6] from

[6] For simplicity, the generic versions of these drugs are referred to here as "generic Valcyte" and "generic Diovan."

the brand manufacturer and resold it to Meijer. *Id.* The named plaintiffs are seeking class certification on behalf of "all direct purchasers of drugs for which generic entry was delayed in substantial part by Ranbaxy's wrongful acquisition and maintenance of 180-day exclusivities." (#1 ¶4.) Specifically, these include direct purchasers of Valcyte at least between March 15, 2013, and November 20, 2014; and direct purchasers of Diovan at least between September 21, 2012, and July 7, 2014. (#1 ¶9.)

Defendant Ranbaxy Inc. is a Delaware corporation headquartered in New Jersey. (#1 ¶15.) Sun Pharmaceutical Industries Limited ("Sun Pharma") is a public limited company incorporated and headquartered in India. (#1 ¶18.) The complaint names two defendants who are no longer in existence: Defendant Ranbaxy USA, Inc., was a Florida corporation until its dissolution on October 24, 2014 (#1 ¶16), and Defendant Ranbaxy Laboratories Limited ("Ranbaxy Labs") was, until March 2015, a corporation organized and headquartered in India. (#1 ¶14.) Sun Pharma merged with Ranbaxy Labs and assumed its liabilities on or about March 25, 2015. (#1 ¶¶236-39.) Defendants have requested that Ranbaxy USA, Inc. and Ranbaxy Labs be dismissed (#22 at 8 n.1), and Plaintiffs have not opposed. Sun Pharma and Ranbaxy Inc. have assumed all liabilities of the two dismissed defendants, and so the case can go forward with them. Collectively, these defendants are referred to as "Ranbaxy."

D. Defendants' Alleged Conduct

Plaintiffs allege that Defendants hastily submitted multiple ANDAs with incorrect or fraudulent information, thereby wrongfully locking in the exclusivity periods and deterring other potential generic drug manufacturers from entering the market, in violation of the Sherman Act, 15 U.S.C. § 2. (#1 ¶11.) They further allege that Defendants enlisted the help of a law firm and a

regulatory consultant to prolong their deceit of the FDA, in violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq*. (#1 ¶12.) The facts, as alleged in the complaint, are as follows.[7]

Beginning in the late 1990s or early 2000s, Ranbaxy filed numerous ANDAs with the FDA. (#1 ¶65.) In each instance it sought to acquire first-filer status, and thus take advantage of the 180-day exclusivity period, by either manufacturing the drug or using its market power to leverage a settlement with the brand company. (#1 ¶¶66-67.) Ranbaxy achieved its high volume of ANDA filings by including false, fraudulent, and forged data, including fabricated product test results and deceptively inaccurate information about its manufacturing processes. (#1 ¶69.) Among Ranbaxy's many filings were an ANDA for generic Diovan on December 24, 2004, followed by an ANDA for generic Valcyte in 2005. (#1 ¶¶75, 78.)

During this time, Ranbaxy became one of the top 10 generic drug makers in the United States, and India's largest generic pharmaceutical company. (#1 ¶¶72-73.) However, its growth came at the cost of ethical business practices. (*See* #1 ¶¶4-8, 80-86.) In 2006, at the request of a whistleblower, the FDA inspected Ranbaxy's facility in Paonta Sahib, India, and found "serious and systematic" issues of noncompliance with cGMP. (#1 ¶¶87-91; #47-2[8] at 5.) On June 16, 2006, it put a hold on all Ranbaxy ANDAs originating from that facility, including the generic Diovan and Valcyte ANDAs. (#1 ¶91; #47-2 at 5.)

[7] Plaintiffs' complaint includes significant detail about Ranbaxy's serious ongoing problems. While relevant to paint a picture of Ranbaxy's corporate culture and manufacturing practices, these allegations do not pertain directly to Plaintiffs' claims regarding generic Valcyte and Diovan, and so they are omitted or summarized here. (*See generally* #1 ¶¶4-8, 80-86; #26-2 at 17-25; #26-4 at 15-37.)

[8] Exhibit 2 to Plaintiffs' Posthearing Memorandum, "Regulatory Background."

In response, Ranbaxy Labs hired law firm Buc & Beardsley LLP ("Beardsley") and auditor Parexel Consulting LLC ("Parexel"). (#1 ¶94.) Parexel and Beardsley signed an agreement under which Parexel's audit results were not given directly to the FDA. *Id.* Rather, Beardsley and Ranbaxy controlled the information given to the FDA. (#1 ¶95.) Beardsley reviewed all of Parexel's results, and designated them as privileged attorney work product. *Id.* This collaboration operated to discourage competition on the merits, and promote Ranbaxy's scheme of "filing, maintaining, and pursuing ANDAs for drugs that it knew it was unlikely to ever be able to bring to market." (#1 ¶259.) Without the collaboration, Ranbaxy would not have been able to obtain exclusivity for generic Diovan and Valcyte; Ranbaxy would not have received TA for those two drugs; and another, more qualified generic applicant would have brought the products to market sooner. (#1 ¶262.)

After Ranbaxy provided incomplete information regarding stability sample tests, the FDA issued a warning letter on June 15, 2006. (#1 ¶98.) This began a series of meetings and correspondence in which the FDA expressed its concerns, and Ranbaxy attempted to allay them without disclosing Parexel's full audit results. (#1 ¶¶99-113; #47-2 at 5.) The FDA was not satisfied with Ranbaxy's evasion, and on February 14, 2007, federal agents executed search warrants at Ranbaxy's New Jersey facility. (#1 ¶115.) In April 2007, the whistleblower who alerted the FDA of the issues at Paonta Sahib filed a False Claims Act complaint against Ranbaxy. (#1 ¶121.) In June 2007, Ranbaxy mailed letters to the FDA falsely assuring it that the compliance issues were resolved. (#1 ¶¶126-32; #47-2 at 5-6.) In reliance on these letters, the FDA granted three more TAs to Ranbaxy ANDAs, including the generic Diovan ANDA on October 25, 2007, and the generic Valcyte ANDA on June 20, 2008. (#1 ¶¶141, 155.)

The FDA's compliance suspicions continued. On July 3, 2008, the government enforced a subpoena to obtain the Parexel audits it had been seeking since 2006. (#1 ¶156.) Upon receiving the audits, the FDA realized that Ranbaxy's troubles ran deeper than it had realized. (#1 ¶¶158-159.) It issued additional warning letters, eventually blocking 30 of Ranbaxy's products from import into the United States. (#1 ¶160.) On February 25, 2009, the FDA instituted its Application Integrity Policy to investigate questionable data in Ranbaxy's Paonta Sahib ANDAs. (#1 ¶161; #47-2 at 6.) It froze scientific review of all Ranbaxy's ANDAs from Paonta Sahib, and began reviewing the data and information for validity. (#1 ¶¶162-63.) During this time, Ranbaxy had to institute multiple recalls of its products. (#1 ¶¶135, 165.)

The FDA initially proposed that Ranbaxy forfeit its exclusivity for 16 drugs, including generic Valcyte and generic Diovan. (#1 ¶168.) This would mean huge economic losses for Ranbaxy, so it negotiated a compromise. (#1 ¶170.) On January 25, 2012, Ranbaxy entered into a consent decree with the FDA, requiring it (among other things) to withdraw several ANDAs. For five remaining ("excepted") ANDAs, Ranbaxy was ordered to submit data showing that "(1) each excepted ANDA had been substantially complete at the time of submission and (2) the ANDA, as submitted, did not contain a 'pattern or practice of data irregularities affecting approval.'" (#1 ¶¶171-72, 178; #47-2 at 7 (citing Consent Decree ¶XIV.B, *United States v. Ranbaxy Labs., Ltd.*, No. 12-cv-250 (D. Md., filed Jan. 25, 2012)).) Ranbaxy's generic Diovan and Valcyte ANDAs were among these "excepted" ANDAs. (#1 ¶170.) Ranbaxy had to undergo audits and submit additional information "sufficient to demonstrate [to the FDA] that the applications were, in fact, substantially complete at the time of submission." (#1 ¶178.) If the excepted ANDAs passed the audit, Ranbaxy would retain first-filer status. (#1 ¶170.)

In 2013, Ranbaxy entered a civil settlement and criminal plea agreement with the federal government in which Ranbaxy admitted that some of its ANDAs contained false statements and that it had been aware of "substantial cGMP compliance problems since at least October 2003." (#1 ¶¶180, 187; #47-2 at 7.) It was fined $350 million in the civil case for "selling adulterated drugs and making false statements to the FDA"; it also paid a criminal fine of $130 million, with a forfeiture penalty of $20 million. (#1 ¶¶180-81; #47-2 at 7-8.) After these settlements, FDA inspections continued to reveal problems at Ranbaxy's facilities in Gloversville, New York; Mohali, India; and Toansa, India. (#1 ¶¶189-191.) On the date this litigation commenced, Ranbaxy remained out of compliance at Paonta Sahib. (#1 ¶6.)

1. Diovan (valsartan)

Valsartan, branded Diovan, is "an angiotension II receptor antagonist… approved by the FDA for the treatment of hypertension and heart failure, as well as to reduce cardiovascular mortality in patients with problems of the left ventricle of the heart following myocardial infarction." (#1 ¶247.) It was the only drug approved to treat "hypertension, high-risk heart attack survivors, and patients with heart failure," and therefore is not reasonably interchangeable with other drugs. *Id.* Ranbaxy filed an ANDA for generic Diovan in 2004 with certifications under Paragraphs III and IV, which made it eligible for first-filer status. (#1 ¶¶75, 194 n.31.) In 2007, it amended its ANDA to include an additional Paragraph IV certification, triggering the innovator's right to enforce the newly challenged patent. (#1 ¶195.) On August 9, 2007, the innovator filed suit. (#1 ¶196.) In September 2007, Ranbaxy amended its ANDA and the innovator's patent litigation settled. (#1 ¶¶197-98.) By the terms of the settlement, Ranbaxy agreed to delay the launch of its generic Diovan until September 21, 2012. *Id.*

Based upon information from its consent decree audits, the FDA concluded in May 2012 that Ranbaxy's generic Diovan ANDA "was substantially complete at the time it was filed." (#47-2 at 7; #43-2,[9] Exhibit B.) On July 6, 2012, the FDA wrote that the generic Diovan ANDA "'did not appear to contain any untrue statements of material fact' or 'a pattern or practice of data irregularities affecting approval,'" and announced its intent to resume reviewing the ANDA. (#47-2 at 7.)

Other ANDA filers had received TAs by this time, but the FDA refused to grant them final approval because of Ranbaxy's first-filer status. (#1 ¶202.) Ranbaxy could not bring Paonta Sahib into compliance, so it moved generic Diovan manufacturing to its New Brunswick, New Jersey plant. (#1 ¶¶204-05; #47-2 at 8.) On June 26, 2014, Ranbaxy's generic Diovan ANDA received final FDA approval. (#1 ¶206.) The FDA determined that, although TA had been delayed beyond the 30-month statutory deadline, Ranbaxy was still entitled to the exclusivity period because the delay was caused by a change to the USP monograph.[10] (*Id.*; #47-2 at 8.) Ranbaxy launched generic Diovan on July 7, 2014, and the next day the innovator launched an authorized generic version. (#1 ¶208.) On January 5, 2015, after the exclusivity period, the FDA approved other generic manufacturers whose products launched immediately. (#1 ¶209.)

[9] July 6, 2012 Letter from FDA to Ranbaxy Labs., Ltd.

[10] "A monograph is a written document, or standard, that describes an item (e.g., a finished drug, a drug ingredient, or food chemical)… [including] the name of a substance; its definition; package, storage, and labeling requirements; and information on tests needed to ensure the substance is of the appropriate strength, quality, and purity." U.S. Pharmacopeial Convention, *USP Fact Sheet, USP Standards: Monographs,* available at: http://www.usp.org/sites/default/files/usp_pdf/EN/regulator/monograph_backgrounder_dec_2011.pdf (last visited April 26, 2016).

As described above, Ranbaxy allegedly engaged in a scheme to keep generic competitors out of the market. (#1 ¶286.) Because of this, Plaintiffs and class members paid the innovator's higher price for Diovan, rather than being able to purchase lower-priced generic equivalents. (#1 ¶289.) During the period between the agreed-upon launch date and Ranbaxy's actual launch, the price of Diovan was higher than it would have been in the absence of Ranbaxy's acts. (#1 ¶290.)

2. Valcyte (valganciclovir hydrochloride)

"Valganciclovir hydrochloride is an orally administered antiviral medication, approved by the FDA for the treatment of cytomegalovirus ("CMV") retinitis in AIDS patients and for the prevention of CMV disease in organ transplant recipients." (#1 ¶248.) In December 2005, Ranbaxy filed its ANDA, including a Paragraph IV certification. (#1 ¶¶78, 212.) On April 28, 2006, the innovator sued Ranbaxy for patent infringement. (#1 ¶213.) During the pendency of that case, the FDA granted Ranbaxy's generic Valcyte TA in 2008. (#1 ¶214.) In August 2010, the patent suit settled, and Ranbaxy agreed to delay launching its generic Valcyte until March 15, 2013. (#1 ¶215.) The FDA classified the generic Valcyte ANDA as excepted. (#1 ¶217.) After review, the FDA issued a letter on May 15, 2012, notifying Ranbaxy of its intent to begin or resume reviewing the generic Valcyte ANDA. (#1 ¶¶217-218.)

The agreed-upon launch date passed without a market entry; Ranbaxy was still ensnared in compliance issues that prevented final FDA approval for generic Valcyte. (#1 ¶218.) In early 2014, two citizen petitions were submitted to the FDA arguing that Ranbaxy should not have exclusivity for generic Valcyte. (#1 ¶¶219-220; #47-2 at 8-9.) In response, the FDA realized its TA for Ranbaxy's generic Valcyte ANDA had been a mistake, because Ranbaxy had not been in compliance with the cGMP requirements at the time it was granted. (#1 ¶220; #47-2 at 9.) On

November 4, 2014, the FDA rescinded the TA and determined that Ranbaxy had forfeited exclusivity for generic Valcyte. (#1 ¶220; #47-2 at 10.) On the same day, Ranbaxy's competitor Endo Pharmaceuticals and another applicant received final approval and shortly afterward launched their generic products. (#1 ¶¶221-22.) If either Ranbaxy's compliance status had been appropriate or its application with exclusivity eligibility had not been pending, these competitors would have entered the market sooner. (#1 ¶223.)

On November 14, 2014, Ranbaxy sued the FDA for revoking its TA for generic Valcyte and one other drug, arguing that it did not need to be cGMP compliant as of the ANDA filing date. (#1 ¶¶224-28.) The FDA disagreed, noting that its TAs had been erroneously granted in reliance on Ranbaxy's misleading representations, and that the statute did not allow it to grant TA unless cGMP compliance was in place. (#1 ¶230; #26-4 at 15.) In February 2015, the court granted summary judgment to the FDA. (#1 ¶¶232-35.)[11]

As described above, Ranbaxy allegedly engaged in a scheme to keep generic competitors out of the market. (#1 ¶299.) Because of this, Plaintiffs and class members paid the innovator's higher price for Valcyte, rather than being able to purchase lower-priced generic equivalents. (#1 ¶300.) During the period between the agreed-upon launch date and the competitors' launch, the price of Valcyte was higher than it would have been in the absence of Ranbaxy's acts. (#1 ¶301.)

3. Market power

Exclusivity allows the first filer to wield power over the market in at least three ways. (#1 ¶241.) First, it controls when the first generic drug enters the market, because it could delay its

[11] Ranbaxy appealed this ruling; however, the parties subsequently filed a joint stipulation to dismiss the case voluntarily. (Joint Stipulation, *Ranbaxy et al. v. Burwell et al*., No. 15-5063 (D.C. Cir. Oct. 6, 2015), Doc. No. 1576632.)

own entry and therefore delay the exclusivity period. (#1 ¶242.) Second, it has the (lawful) "ability to capture an overwhelming majority of the market in a very short span of time" during the exclusivity period itself. (#1 ¶243.) Finally, it sets the price of its product during the exclusivity period. (#1 ¶244.) Purchasing decisions of prescription drugs are made by doctors, not end consumers of drugs. (#1 ¶251.) Doctors are usually not aware of, and not sensitive to, price differences. (#1 ¶250.)

There are no functionally similar medicines for Valcyte and Diovan, so there are no other drugs to compete with generic versions of these drugs. (#1 ¶252.) Plaintiffs have alleged that "the relevant markets are (a) all valsartan tablets – i.e., Diovan (in all its forms and dosage strengths) and AB-rated bioequivalent valsartan tablets; and (b) all valganciclovir hydrochloride tablets – i.e., Valcyte (in all its forms and dosage strengths) and AB-rated bioequivalent valganciclovir hydrochloride tablets." (#1 ¶256.)

E. Case History

On May 12, 2015, Plaintiffs filed their complaint charging the captioned defendants with violations of the Sherman Act, 15 U.S.C. § 2, and the RICO Act, 18 U.S.C. §§ 1962 and 1964. (#1 ¶19.) They allege a private right of action under the Clayton Act, 15 U.S.C. §15(a). *Id.* On July 23, 2015, the parties filed a Joint Stipulation Regarding Service of Complaint, which was formalized in an order the next day. (##12, 13.) On September 25, 2015, Defendants Ranbaxy Inc. and Sun Pharmaceuticals Industries Ltd. moved under Fed. R. Civ. P. 12(b)(6) to dismiss Plaintiffs' complaint with prejudice. (##21, 22, 23.) Plaintiffs opposed on October 26, 2015 (#25), and Defendants replied, with leave of court, on December 2 and 8, 2015. (##31, 36.) On March 31, 2016, oral arguments on the motion were held before the undersigned. (##42, 45.)

Pursuant to the Court's order, all parties filed exhibits on April 1, 2016 (##41, 43, 44) and post-hearing memoranda on April 11, 2016. (##47, 48.) Plaintiffs filed a supplemental authority on May 27, 2016 (#50) and Defendants filed a response on May 31, 2016. (#51.)

II. Motion to Dismiss Standard

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The court "must take the allegations in the complaint as true and must make all reasonable inferences in favor of the plaintiffs." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). This "highly deferential" standard of review "does not mean, however, that a court must (or should) accept every allegation made by the complainant, no matter how conclusory or generalized." *United States v. AVX Corp.*, 962 F.2d 108, 115 (1st Cir. 1992). Dismissal for failure to state a claim is appropriate when the pleadings fail to set forth "'factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory.'" *Berner v. Delahanty*, 129 F.3d 20, 25 (1st Cir. 1997) (quoting *Gooley v. Mobil Oil Corp.*, 851 F.2d 513, 515 (1st Cir. 1988)).

"[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. A court's assessment of the pleadings is "context-specific," requiring "the reviewing court to draw on its judicial experience and common sense." *Id.* at 679; *accord Maldonado v. Fontanes*, 568 F.3d 263, 268 (1st Cir. 2009). "[W]here the well-pleaded facts do not permit the court to infer more

than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – 'that the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)); *accord Maldonado*, 568 F.3d at 268.

In antitrust cases, "dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746 (1976); *Podiatrist Ass'n, Inc. v. La Cruz Azul de Puerto Rico, Inc.*, 332 F.3d 6, 13 (1st Cir. 2003). "The district court should not grant [a motion to dismiss] unless it appears to a certainty that the plaintiff would be unable to recover under any set of facts." *Roma Const. Co. v. aRusso*, 96 F.3d 566, 569 (1st Cir. 1996) (citing *Hosp. Bldg. Co.*, 425 U.S. at 746.)

On a motion to dismiss, the court may consider documents beyond the complaint only if such documents were "expressly incorporated" into the complaint; are undisputedly authentic; are "central to plaintiffs' claim[s]"; or are "sufficiently referred to in the complaint." *Watterson*, 987 F.2d at 3; *accord Graf v. Hospitality Mut. Ins. Co.*, 754 F.3d 74, 76 (1st Cir. 2014) (quoting *Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33-34 (1st Cir. 2001)). Here, the following documents are referenced sufficiently in the complaint: #23-1/#43-2 (letter from the FDA to Ranbaxy dated July 6, 2012); #23-2/#43-3 (letter from the FDA to Ranbaxy dated August 10, 2012); #43-5 (undated Diovan TA letter); #26-2, #26-3, and #26-5 (FDA court filings); Memorandum of Decision in *Ranbaxy Labs, Ltd. v. Burwell* (#26-4); and Consent Decree in *United States v. Ranbaxy Labs., Ltd.*, No. 12-cv-250 (D. Md., filed Jan. 25, 2012). Defendants' FDA memorandum of September 28, 2012 (#43-4) will not be considered for purposes of this motion, as Plaintiffs have objected to it (#47 at 11, n.30) and it is not necessary for the decision. *See infra* at 45.

III. Legal Analysis

A. Count I: Violation of the Sherman Act, 15 U.S.C. §2, with regard to generic Valcyte.

1. Sherman Act claims are not precluded by the FDCA under the preemption analysis in *Buckman*.

Section 2 of the Sherman Act makes it illegal to "monopolize, or attempt [or conspire] to monopolize ... any part of the trade or commerce among the several States." Title 15 U.S.C. § 2. Plaintiffs assert that, through deceiving the FDA, Defendants have obtained and wielded monopoly power in the U.S. market for generic Valcyte. This case raises the novel issue of whether such claims are precluded by the FDCA. Both parties rely on Supreme Court cases that are not directly on point. Because there is nothing in these two federal statutes expressly prohibiting this type of suit, and because the statutes' purposes are complementary, the claims are not precluded.

Defendants argue that pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the FDA alone possesses the authority to enforce claims predicated upon violations of the FDCA. (#22 at 11.) In *Buckman*, injured individuals attempted to bring state law tort claims against a consultant for injuries caused by orthopedic bone screws. 531 U.S. at 344. They alleged that the consultant had deceived the FDA to obtain its approval, although the agency had not made a determination of fraud. *Id.* at 354. The Supreme Court found that plaintiffs' state law claims were preempted by the FDCA, which contains "various provisions aimed at detecting, deterring, and punishing false statements made during… approval processes." *Id.* at 343, 349. It reasoned that states do not typically police fraud against federal agencies, and therefore no presumption against preemption applied. *Id.* at 347. Here, the question is one of preclusion rather

than preemption: both statutes concerned are federal. The balance between state and federal powers is not at issue. For this reason, *Buckman*'s analysis does not directly resolve the matter.

Plaintiffs primarily rely upon *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014). In *POM*, the Supreme Court allowed Lanham Act claims for a misleading juice label subject to FDA regulations. *Id.* at 2233. The Court analyzed the overlap of the Lanham Act and FDCA – both federal statutes – as a matter of statutory interpretation, not preclusion. *Id.* at 2236. Finding that the statutes could be harmonized, the Court noted: "When two statutes complement each other, it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statute to preclude the operation of the other." *Id.* at 2238. Regarding a similar intersection of two statutes, the Seventh Circuit observed: "When addressing the interactions of federal statutes, courts are not supposed to go out *looking* for trouble: they may not 'pick and choose among congressional enactments.' … Rather, they must employ a strong presumption that the statutes may both be given effect." *Lewis v. Epic Systems Corp.*, No. 15-2997, *slip op.* at 15 (7th Cir. May 26, 2016) (quoting *Morton v. Mancari*, 417 U.S. 535, 551 (1974)). Here, the court must conduct the same analysis for the Sherman Act and the FDCA. The relevant inquiries are 1) whether there is any conflict between the two statutes and, if not, 2) whether Plaintiffs have appropriately alleged violations of the Sherman Act (and not simply the FDCA). *See Lewis*, No. 15-2997, at 13.

2. Nothing in the FDCA blocks Sherman Act claims.

i. The FDCA does not contain an express preemption or preclusion provision.

The FDCA contains an express preemption clause for state-law claims concerning medical devices, but not for prescription drugs. (#25 at 18 (citing *Wyeth v. Levine*, 555 U.S. 555,

574-75 (2009), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008).) Even assuming this 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 intend the FDCA to preclude requirements arising from other sources.'" (#25 at 18, n.33 (quoting *POM*, 134 S. Ct. at 2231).) Congress has had ample opportunity to act if it believed that Sherman Act claims could interfere with the FDCA. *See POM*, 134 S. Ct. at 2237 (lack of Congressional action is "powerful evidence that Congress did not intend FDA oversight to be the exclusive means" of addressing an issue) (citing *Wyeth*, 555 U.S. at 575). Therefore, Defendants cannot rely upon the FDCA's narrow medical device preemption clause to bar Plaintiffs' Sherman Act claims with regard to drugs.

ii. The "savings clause" does not extend to this type of claim.

The savings clause cited by Defendants does not block this suit. In full, the text of this clause reads:

> Any action taken by the Assistant Attorney General or the [Federal Trade] Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

MMA, Pub. L. No. 108-173, § 1117, 117 Stat. 2066, 2463 (Dec. 8, 2003).[12] In context, this clause is in a section of the MMA called "Subtitle B: Federal Trade Commission Review." It provides that a settlement agreement between an innovator and a generic, or between two

[12] This text was enacted as part of the MMA as a statutory note, yet appears nowhere in the FDCA itself. *See* 21 U.S.C. § 355 *et seq*. Since neither party has questioned whether the clause applies to the FDCA, the Court will treat it as though it had been codified.

generics, must be submitted to the Federal Trade Commission and the Department of Justice for review prior to marketing the drug at issue. *See id*. The plain meaning of this clause is to *allow* broad-ranging claims within this context. Defendants ask the Court to read it as preempting other types of suits that may relate to the entire FDCA, an interpretation that is far too broad.

> Courts lean on the side of enforcing antitrust laws, absent clear direction to the contrary.
>
> The antitrust laws represent a 'fundamental national economic policy'… 'Implied antitrust immunity is not favored, and can be justified only by a convincing showing of clear repugnancy between the antitrust laws and the regulatory system'… Repeal is to be regarded as implied only if necessary to make the [subsequent law] work, and even then only to the minimum extent necessary.

Nat'l Gerimedical Hosp. & Gerontology Ctr. v. Blue Cross of Kansas City, 452 U.S. 378, 388-89 (1981) (internal citations omitted). Where there is no showing of "plain repugnancy," antitrust claims should go forward. *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 350-51 (1963). As in *POM* and *Lewis*, courts look to harmonize statutory schemes rather than drumming up conflict. *POM*, 134 S. Ct. at 2237; *Lewis*, No. 15-2997 at 13. This case also deals with a matter of significant public importance: the public availability of affordably priced generic pharmaceutical products. These considerations weigh in favor of reading the savings clause narrowly.

iii. The FDA's regulatory authority does not include the Sherman Act.

The FDA "is tasked with promoting public health through, among other things, the regulation and approval of prescription drugs." (#22 at 3, *and see POM*, 134 S. Ct. at 2234 ("The FDCA statutory regime is designed primarily to protect the health and safety of the public at large").) Its purview is ensuring the safety and purity of items consumed by the American public, not policing the markets for such items. *See* 21 U.S.C. § 301 *et seq*. Defendants are correct that

the FDA has exclusive authority to punish and deter fraud upon itself (#22 at 5), but this does not extend to anticompetitive behavior.

It is true that the government has already investigated and punished Ranbaxy's conduct. However, the remedies imposed go only toward fraud on the FDA. They do not address anticompetitive injury of the type that Plaintiffs allegedly suffered. The FDA's enabling statute does not entrust it with policing antitrust or RICO; therefore, Plaintiffs' claims do not "usurp the agency's statutory right to… calibrate a 'measured response' to alleged fraud committed against it." (#22 at 22.) "[T]he question of whether or not particular acts of regulatory gaming harm competition is and should be an antitrust question, not merely one that involves interpreting statutes or agency regulations." Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 67 Tex. L. Rev. 685, 688 (2009); *and see Actavis*, 133 S. Ct. at 2230-31 ("[I]t would be incongruous to determine antitrust legality by measuring [a] settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.") Therefore, allowing antitrust actions to go forward in the FDCA context is appropriate.

In contrast, courts have foreclosed private action where antitrust is within the agency's wheelhouse. *See Nat'l Gerimedical Hosp.*, 452 U.S. at 389 ("Intent to repeal the antitrust laws is much clearer when a regulatory agency has been empowered to authorize or require the type of conduct under antitrust challenge"). For example, regarding the Federal Communications Commission, the Supreme Court found that "the agency was acting as an 'effective steward of the antitrust function,' and any private antitrust claims would be counterproductive…" (#22 at 24 (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 413

(2004).) In *Trinko*, regulations required telephone service providers to share their networks with competitors, a framework which "significantly diminishe[d] the likelihood of major antitrust harm." *Trinko*, 540 U.S. at 412. Defendants also cite several cases concerning the Securities and Exchange Commission, which has the duty to regulate and maintain securities markets – a mission much more closely tied to antitrust policing than that of the FDA. *See Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 279 (2007) ("securities law and antitrust law are clearly incompatible"); *Gordon v. N.Y. Exch., Inc.*, 422 U.S. 659, 685-86 (1975) ("To permit operation of the antitrust laws with respect to commission rates… would unduly interfere, in our view, with the operation of the Securities Exchange Act"). (#22 at 25; *and see* #25 at 21.) Because the FDA does not regulate competition in the pharmaceutical market, its powers are not infringed upon by this claim.

iv. The lawful exclusivity period is not at issue here.

Defendants correctly point out that Congress authorized a limited term of competition in the 180-day exclusivity period. (#22 at 23.) This is not what Plaintiffs seek to challenge. Just because the law provides for the 180-day exclusivity does not grant manufacturers free rein to come up with other varieties of anticompetitive behavior. As an analogous example, patent holders have a "lawful right to exclude others from the market" for a certain period, but a patent holder may still act illegally to thwart competition. *Actavis*, 133 S. Ct. at 2230.

There is evidence that Congress did not view the legitimate exclusivity period as foreclosing other types of anticompetitive conduct. Senator Hatch's comments in the debate leading up to passage of the MMA reflect a wish to deter abuse:

> Perhaps no single provision of the [Hatch-Waxman Act] has caused so much controversy as the 180-day marketing exclusivity rule… The 180-day exclusivity

> provision appears to have led to strategic conduct that has delayed and not fostered the competitive process. … The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws and the Hatch-Waxman Act by delaying generic entry for a substantial period.

148 Cong. Rec. S7347-48 (July 25, 2002). For these reasons, Plaintiffs may challenge anticompetitive conduct that is distinct from the exclusivity period itself.

v. The Sherman Act is regularly enforced in the pharmaceutical context.

As evidence that these statutes can comfortably coexist, the Federal Trade Commission ("FTC") often enforces provisions of the antitrust laws within the pharmaceutical industry. *See, e.g., Actavis*, 133 S. Ct. 2223. In fact, Congress specifically provided in the FDCA for FTC oversight of agreements between brand and generic manufacturers. *See* 21 U.S.C. § 355(j)(5)(D)(i)(V). It is difficult to understand how this could be possible if these statutes were incompatible.

Further, there is no authority reserving this arena for the FTC. In determining whether a private plaintiff may bring suit, "[t]he central inquiry remains whether Congress intended to create, either expressly or by implication, a private cause of action." *Touche Ross & Co. v. Redington*, 442 U.S. 560, 575-76 (1979). Here, Congress has unambiguously provided a private right of action in the Clayton Act: "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor…" 15 U.S.C. § 15(a). Defendants have not pointed to any authority, nor does there appear to be any, to show that this provision does not apply within this particular context.

3. Plaintiffs have alleged all elements of a Sherman Act violation.

i. Plaintiffs seek to remedy violations of the Sherman Act, not violations of the FDCA.

Plaintiffs have alleged violations of the Sherman Act, predicated in part upon actual findings of fraud by the FDA. (#1 ¶¶180-181, 187; #47-2 at 7-8.) The elements of § 2 of the Sherman Act are "(1) possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Diaz Aviation Corp. v. Airport Aviation Servs., Inc.*, 716 F.3d 256, 265 (1st Cir. 2013) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)). However, Defendants argue that Plaintiffs' "*real* claim is that Ranbaxy committed fraud against the FDA." (#22 at 11; emphasis in original.) The Court agrees that only the federal government is authorized to enforce the FDCA. (*Id.* (citing *Buckman*, 531 U.S. at 349 n.4, and 21 U.S.C. § 337(a)); #31 at 5.) Therefore, it is necessary to examine the underpinnings of Plaintiffs' claims.

To determine whether a cause of action is rooted in fraud on an agency or some other legal theory, courts look to the elements of the asserted claim. If the claim requires the plaintiff to establish elements of a tort above and beyond fraud on the agency, "thus regulating the interaction between the defendant and plaintiff," it is actionable; if it concerns solely the "defendant's interaction with a federal agency," it is not. *Tigert v. Ranbaxy Pharm., Inc.*, Civ. No. 12-00154, 2012 WL 6595806, at *4 (D.N.J. Dec. 18, 2012) (quoting *Yocham v. Novartis Pharm. Corp.*, 736 F. Supp. 2d 875, 887 (D.N.J. 2010)). This is in line with *Walker Process*, where the court allowed a Sherman Act claim for a patent procured by fraud on the USPTO and required the plaintiff to prove other elements of its § 2 claims. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). Because Plaintiffs still must establish the

elements of a Sherman Act violation concerning Defendants' influence on the market and its resulting effects on consumers, their claim may proceed.

Ranbaxy's fraud will be a necessary logical step in Plaintiffs' proof. Defendants assume that, but for the fraud, Ranbaxy's compliance status would have been up to speed: "[I]f there weren't fraud against the government, all that would have happened is we would have gotten our ANDA. We would have gotten our exclusivity… and we would have been able to launch at any point during [the patent] window with our exclusivity." (#45 at 9:4-9:11.) However, 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." (#1 ¶294.) Had Defendants admitted their compliance issues with regard to generic Valcyte, they would likely have forfeited their TA and first-filer status earlier than they actually did. (#1 ¶262.) By continuing to pursue their meritless regulatory goal, Defendants allegedly delayed the launch of competitors' products.

ii. Unlike in *Buckman*, here Plaintiffs have alleged that the FDA made a determination that Defendants committed fraud.

Aside from the state law preemption question, *Buckman* can be distinguished from the instant case because, Plaintiffs aver, the FDA has responded to Ranbaxy's fraud by rescinding TA. 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:

> [A]n essential link in the chain of causation that respondent must prove in order to prevail is that, but for petitioner's fraud, the allegedly defective orthopedic bone screws would not have reached the market. The fact that the [FDA] has done

> nothing to remove the devices from the market, even though it is aware of the basis for the fraud allegations, convinces me that this essential element of the claim cannot be proved. … This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the [application] process and had then [acted upon it]… Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decisionmaking or overburdening its personnel…
>
> 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.

531 U.S. at 353-54, *and see* #22 at 9.

Here, Plaintiffs have alleged Ranbaxy's fraud in vivid detail. The complaint describes the FDA's investigation and sanctioning of Ranbaxy for serious compliance failures and misleading statements or evasions. (#1 ¶¶87-89, 98, 92-162, 170, 180-81.) Ranbaxy entered a consent decree with the FDA and paid civil and criminal penalties. (#1 ¶¶180-81, 203.) Unsurprisingly, Defendants do not accept this characterization of Ranbaxy's actions, and dispute the facts. They point to a letter from the FDA to Ranbaxy dated August 10, 2012, which states that the generic Valcyte ANDA "does not appear to contain any untrue statements of material fact… nor does it appear to contain a pattern or practice of data irregularities affecting approval." However, this letter does not negate Plaintiffs' allegations at this stage. Plaintiffs 1) are not challenging the FDA's assessment of the validity of this ANDA (#45 at 50:25-51:6), and 2) have alleged that the FDA's further investigation in 2014, *after* the letter cited by Defendants, resulted in the determination that the 2008 generic Valcyte TA was a mistake. (#1 ¶¶155, 220, 230-31; #25 at 14-15.)

Defendants further argue that the complaint lacks specific allegations of wrongdoing with regard to the generic Valcyte ANDA. Plaintiffs alleged that Ranbaxy submitted misleading information to the FDA, and this "informed… [the FDA's] responses to several later ANDAs, including those for generic Diovan and Valcyte." (#1 ¶132; #22 at 30.) They stated that the FDA granted the generic Valcyte TA in error, in reliance upon Ranbaxy's false statements. (#1 ¶¶155; #25 at 14.)[13] This describes a causal chain of events that is logically plausible. *See, e.g., Iqbal,* 556 U.S. at 663 ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.") A finer level of detail will be available only after discovery.

iii. Plaintiffs have adequately alleged a sham exception to the *Noerr-Pennington* doctrine.

The *Noerr-Pennington* doctrine is an exception to antitrust law that shields efforts to petition the government or to influence public officials, even if anticompetitive effects result. *Noerr-Pennington* immunizes petitioning activity regardless of the petitioner's intent and purpose, and even if the petitioner uses disingenuous tactics or causes collateral damage to competitors in the process. *See Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965) (the "*Noerr-Pennington* doctrine"). Here, Plaintiffs have alleged that "Ranbaxy's anticompetitive conduct is not entitled to qualified *Noerr-Pennington* immunity" (#1 ¶291) because of the sham exception, as detailed below. (#1 ¶293.) Neither party has challenged the idea that Ranbaxy's ANDAs could be considered "petitioning."

[13] Plaintiffs have included details and sources that could make it possible for them to prove this allegation without unduly intruding into the FDA's decision-making process or burdening the agency.

An exception to *Noerr-Pennington* immunity exists in cases of "sham petitioning." To prove this, a plaintiff must show that the petitioner's efforts were "objectively baseless" to the extent that "no reasonable litigant could expect success on the merits," and that the petitioner's true intent was to harm the plaintiff through abuse of the governmental process. *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993). In *California Motor Transport Company v. Trucking Unlimited*, a trucking company effectively prevented its competitor from having meaningful access to tribunals through a pattern of repetitive claims. 404 U.S. 508 (1972). In aggregate, that company's overuse of legitimate government processes violated the antitrust laws. *Id.* at 511-512.

Defendants are not entitled to assert immunity based on fraudulent misrepresentations. Defendants rely on *Davric Maine Corporation v. Rancourt*, in which the court declined to find a sham exception. 216 F.3d 143, 148 (1st Cir. 2000). In that case, defendants' efforts to petition the government were partly successful and therefore not objectively baseless; they sought to benefit from the outcomes of government action, not the processes themselves. *Id.* The *Davric* court found that "[e]ven *false* statements presented to support [petitions before legislatures, administrative agencies, and courts] are protected." *Id*. at 147 (emphasis in original). Notably, *Davric* did not involve allegations of fraud. (#25 at 26.) However, the Supreme Court distinguished the import of statements by the forum in which they are made. "Misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process." *Cal. Motor Transp*., 404 U.S. at 513, *and see In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y., 2002) (no *Noerr-Pennington* immunity where defendant fraudulently listed a patent in the FDA's "Orange Book").

Here, Plaintiffs have alleged facts to show sham petitioning. Defendants petitioned the FDA by submitting ANDAs, and they sought the legitimate outcome of FDA approval and first-filer status. However, the complaint alleges that Defendants submitted large volumes of ANDAs in hopes of blocking their competitors: "Ranbaxy recklessly stuffed the generic drug approval queues with grossly inadequate applications, deceived the FDA into granting tentative approvals to lock in statutory exclusivities to which Ranbaxy was not entitled, and brandished these undeserved exclusivities to exclude others while its own applications floundered…" (#1 ¶2.) Regardless of whether the information on any individual ANDA was true or not, Plaintiffs allege that Ranbaxy was incapable of producing the drugs, were all their ANDAs actually to be approved: "Ranbaxy [filed ANDAs] with little regard for whether it would be able to promptly bring the generic drug to market..." (#1 ¶5.) As in *California Motor Transport*, simply because some of the efforts were successful does not negate the overarching sham of clogging the administrative approval process. *See* 404 U.S. at 512. Plaintiffs allege that Ranbaxy intended to burden competitors by obtaining undeserved exclusivities to block the entry of other generics. (#1 ¶6.) Therefore, Plaintiffs have effectively alleged a sham exception to protected petitioning activity.

iv. Plaintiffs have alleged monopoly power, despite highly regulated market conditions and unusual facts.

Showing a violation of § 2 of the Sherman Act requires "(1) that the defendant possesses 'monopoly power in the relevant market,' and (2) that the defendant has acquired or maintained that power by improper means." *Town of Concord, Mass. v. Boston Edison Co.*, 915 F.2d 17, 21 (1st Cir. 1990) (citing *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966), and *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 230 (1st Cir. 1983)). Here, Plaintiffs have

alleged that Ranbaxy wrongfully obtained the right to the legal exclusivity for generic Valcyte, thereby acquiring market power. (#25 at 35.) It excluded all other generic competitors from the date it acquired first filer status until the date it lost the status. (#25 at 36.) Although Ranbaxy was not selling drugs during the alleged class period and therefore could not have a disproportionate market share in the traditional sense, it was able to exclude all ANDA generic competition while it was attempting to secure final approval. (#25 at 38-39.)

Defendants have argued that the complaint is insufficient because 1) it only alleges market power, not monopoly power and 2) Defendants did not actually sell products in the market and thus could not have monopoly power. (#22 at 34-36.) The first argument is unavailing. "Monopoly power, *also referred to as market power*, … is 'the power to control prices or exclude competition.'" *Tops Mkts., Inc. v. Quality Mkts., Inc*., 142 F.3d 90, 97-98 (2d Cir. 1998) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956)) (emphasis added), *and see Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996). Plaintiffs argue that they intended to use the terms interchangeably, and they are entitled to that inference. (#25 at 38.) The second argument is more involved.

Monopoly power "may be proven directly by evidence of the control of prices or the exclusion of competition…" *Tops Markets*, 142 F.3d at 98, or it may "be inferred from the structure and composition of the relevant market." *Broadcom Corp. v. Qualcomm Inc*., 501 F.3d 297, 307 (3d Cir. 2007) (citing *United States v. Microsoft Corp*., 253 F.3d 34, 51 (D.C. Cir. 2001) (*en banc*); additional citations omitted.) "A firm is a monopolist if it can profitably raise prices substantially above the competitive level… Where evidence indicates that a firm has in

fact profitably ['cut back the market's total output and raise[d] price'], the existence of monopoly power is clear." *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (*en banc*), *and see Coastal Fuels*, 79 F.3d at 196-97. Market power "ordinarily may be inferred from the predominant share of the market." *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966). However, the situation here is far from ordinary.

The parties agree there is no directly relevant precedent for alleging monopoly power where the product never actually reached the market and earned no profits. Instead, Ranbaxy possessed the mere *possibility* of profit if they were able to maintain the right to the exclusivity period and launch generic Valcyte. Plaintiffs have alleged that Ranbaxy's Indian stock prices rose due in part to their high volume of ANDA filings (#1 ¶70), but this is too remote of an effect to qualify as a "profit." It appears to be a question of first impression whether a firm that has no sales or profits within a given market may possess monopoly power.

Although Defendants may not have generated profit in the traditional sense, this case is unusual because of the highly regulated market conditions. The "purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition," and therefore "'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" *F.T.C. v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (quoting 7 P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)). In the "predatory pricing" context, firms may violate § 2 of the Sherman Act by selling at unsustainably low prices in hopes of driving out competition and profiting in the future. *See, e.g., Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 231 (1st Cir. 1983) (citing Phillip Areeda & Donald F. Turner,

Predatory Pricing and Related Practices Under Section 2 of the Sherman Act, 88 Harv. L. Rev. 697 (1975)). Within the highly regulated market for generic Valcyte, on the allegations in the complaint Ranbaxy reduced output and restricted competition in hopes of gaining future profits. Ranbaxy allegedly had the power to exclude competitors while its ANDA was pending, because of its first-filer status. By alleging actual detrimental effects on the market and financial harm to consumers, Plaintiffs have successfully pled that Defendants wielded monopoly power.

v. Plaintiffs have alleged anticompetitive conduct.

In addition to monopoly power, Section 2 requires "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Grinnell*, 384 U.S. at 570-571. Here, the complaint states that Ranbaxy acquired and maintained power, in the form of the right to the exclusionary period, through a scheme of deception and delay rather than lawful competitive means. (*See, e.g.*, #1 ¶¶6-7.) Therefore, Plaintiffs have adequately alleged improper anticompetitive conduct.

vi. Plaintiffs have alleged proximate cause, where the FDA and Ranbaxy shared culpability for delay.

Antitrust claims, like RICO 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: "An antitrust violation may be expected to cause ripples of harm to flow through the Nation's economy; but 'despite the broad wording of § 4 there is a point beyond which the wrongdoer should not be held liable.'" *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters* ("*AGC*"), 459 U.S. 519, 534 (1983)

(quoting *Blue Shield of Va., Inc. v. McCready*, 457 U.S. 465, 477 (1982) (additional citations omitted)). Proximate cause presents a multi-pronged inquiry into the following factors: 1) a specific intent on the part of the defendant to cause harm, 2) a causal connection between the defendant's conduct and the plaintiff's injury, 3) an injury of the sort covered by antitrust laws, 4) the relative directness or indirectness of the injury, 5) the possibility of apportioning damages, 6) the definiteness of damages, and 7) the possibility of less remote claimants. *Id*. at 537-45; *and see In re Neurontin Mktg. & Sales Practices Litig.* ("*Neurontin II*"), 712 F.3d 21, 35 (1st Cir. 2013), *cert. denied sub nom. Pfizer Inc. v. Kaiser Found. Health Plan, Inc.*, 134 S. Ct. 786 (2013). Here, some factors cut each way.

The following factors are in Plaintiffs' favor. Plaintiffs have asserted that Defendants had the specific intent to act anticompetitively, therefore harming Plaintiffs as a class. The alleged injury is that Plaintiffs paid higher prices than they would have absent Defendants' anticompetitive conduct: precisely the type of grievance contemplated by Sherman Act § 2. *AGC*, 459 U.S. at 538 ("the Sherman Act was enacted to assure customers the benefits of price competition"). It does not matter that Ranbaxy supposedly misrepresented facts to the FDA and not to Plaintiffs. Defendants cite to *Anza v. Ideal Steel Supply Corporation*, a RICO case, in which the defendants committed fraud on the State of New York, causing it to lose tax revenue. 547 U.S. 451, 458 (2006). Although the proximate cause inquiry in RICO cases relies on similar factors, in *Anza* the plaintiff's harm was caused by "a set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State)." *Id.* In that case, the claims did not require the Court to assess antitrust causation. *Id.* at 459 ("[Plaintiff's] lost sales could have resulted from factors other than [Defendant's] alleged acts of fraud… it would

require a complex assessment to establish what portion of [Plaintiff's] lost sales were the product of [Defendant's] decreased prices.") Because this is an antitrust claim, this analysis is already done, and the alleged violation and harm are causally linked.

Other factors are less clear. There is certainly a logical connection: as alleged, Defendants' acts caused the FDA to waste time on meritless applications, which prevented potential generic competitors from entering, which in turn caused Plaintiffs to pay more. Yet there are two unknown factors that give pause: competitors' readiness to produce generic Valcyte, and the FDA's approval of those competitors. But for Defendants' misrepresentations, the FDA would still have had to grant final approval to a competitor, who must have been able to come to market. Although the FDA made an independent judgment, its decision-making was impacted by Ranbaxy's conduct. *See Neurontin II*, 712 F.3d at 39 (doctors were not an intervening cause of injury because the defendant knew they would rely upon its misrepresentations). As with the prescribing physicians in *Neurontin II*, the FDA does not pay for the drugs it approves and it did not suffer financial loss. Therefore, the FDA's actions do not break the causal chain. Plaintiffs have alleged that other generics would have come to market if not for Ranbaxy, and Plaintiffs carry the burden of proof.[14] *See id.*

Defendants argue that the FDA's regulatory activity is an intervening factor, so there can be no proximate cause. (#22 at 31.) Further, they say that Plaintiffs' problem is with the FDA's speed in regulating, not anything Ranbaxy did or failed to do. (#31 at 10-11.) However, the

[14] Plaintiffs acknowledge that they lack access to the relevant information at this stage of the case. "It is unknown at this time the extent to which, if at all, Ranbaxy's wrongfully acquired tentative approval for its generic Valcyte ANDA played into the agreement to delay entry from August of 2010 to March of 2013. It is also unknown what impact a forfeiture of Ranbaxy's first-to-file exclusivity would have had on the efforts of other generic ANDA filers seeking to bring generic Valcyte to market." (#1 ¶216.)

proximate cause requirement is satisfied where the injury is a foreseeable and natural result of the defendant's conduct. (#25 at 31, citing *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639, 657-58 (2008), *and see Anza*, 547 U.S. at 461 ("When a court evaluates… proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries").) On these facts, the FDA's pace was certainly affected by Ranbaxy's obfuscation, and the delay was a natural and foreseeable consequence. The FDA could not review the TA any sooner, because Ranbaxy had hidden the relevant information. (*See, e.g.*, #1 ¶6.) Again, but for Ranbaxy's fraud, the FDA would have known earlier that its compliance status was lacking, and would have been able to act more swiftly.

Although the amount that Plaintiffs overpaid is relatively straightforward and ascertainable, it is unclear how to apportion the liability. What portion of the delay was due to Ranbaxy's conduct, as opposed to the FDA's regulatory process or the readiness of competing manufacturers? This is a highly factual inquiry, requiring conditional assumptions about what might have happened had Ranbaxy acted differently years ago. Additionally, there exists the possibility of multiple recoveries. Competitors could also seek damages for antitrust and RICO injuries. The government has already fined Ranbaxy for the same conduct, although not in the antitrust or RICO context and not to the immediate benefit of Plaintiffs.

Also relevant to directness is whether there exists "an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement," and if so, whether denying a remedy to that class would allow a "significant antitrust violation" to go unpunished. *AGC*, 459 U.S. at 542. In general, both consumers and competitors may bring suit for antitrust injury. *Serpa Corp. v. McWane, Inc.*, 199 F.3d 6, 11 (1st

Cir. 1999) (quoting *SAS of Puerto Rico, Inc. v. Puerto Rico Tel. Co.*, 48 F.3d 39, 44 (1st Cir. 1995) ("[T]he presumptively 'proper' plaintiff is a customer who obtains services in the threatened market or a competitor who seeks to serve that market")). Here, Plaintiffs are identifiable, as purchasers of higher-priced brand Valcyte, with sufficient self-interest in their alleged financial losses.

But it is difficult to say who was more "immediately" harmed by Ranbaxy's conduct. In the scenario Plaintiffs have alleged, competitors missed out on the profits they would have earned by entering the market sooner. The competitors are also much better positioned to prove the hypotheticals necessary to a finding that Ranbaxy was culpable.[15] Competitors are armed with information about when they would have been likely to launch, and how long the FDA approval process has taken in other cases.

On balance, Plaintiffs have alleged sufficient facts to survive this motion to dismiss. Plaintiffs' allegations fall into "the realm of legitimate inference," such that probable cause becomes a factual question that cannot be resolved at this stage. 65A C.J.S. Negligence § 981. *See AGC*, 459 U.S. at 531 (noting that "Congress intended the [Sherman] Act to be construed in the light of its common-law background"), *and Boston Cab Dispatch, Inc. v. Uber Techs., Inc.*, No. 13-10769-NMG, 2015 WL 314131, at *8 (D. Mass. Jan. 26, 2015) (finding, where plaintiffs had adequately pled causation, that it was "more appropriate to address such arguments at the summary judgment stage" rather than on a motion to dismiss).

[15] Defendants note that "plaintiffs do not (and cannot) allege that any other generic had tentative approval for generic Valcyte as of the start of the alleged damages period, when plaintiffs claim generic entry would have occurred." (#22 at 32.) Assuming *arguendo* that this is true, it does not mean that Plaintiffs cannot prove that some other generic manufacturer obtained TA and would therefore have been eligible to launch before the *end* of the alleged damages period.

4. The statute of limitations cannot be determined at this stage of litigation.

Defendants have alleged that Plaintiffs are beyond the applicable statute of limitations. Plaintiffs have noted that this is "a fact-intensive affirmative defense disfavored in the Rule 12 context, and must be rejected unless shown 'with certitude.'" (#25 at 42 (citing Fed. R. Civ. P. 8(c) and *Nat'l Assoc. of Gov't Workers v. Mulligan*, 854 F. Supp. 2d 126, 131 (D. Mass. 2012)).) As described in the discussion of monopoly power above, this is not a typical market scenario, and so the inquiry into the possibility of a "continuing violation" is not a simple one. *See Hanover Shoe v. United Shoe Mach. Corp.*, 392 U.S. 481, 489, 502 n.15 (1968), *and Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 295 (2d Cir. 1979). Additionally, Plaintiffs have alleged that the facts necessary for their complaint were not discoverable until the FDA's 2014 filing in the *Ranbaxy v. Burwell* case. (#25 at 43.) For these reasons, the case should not be dismissed as untimely at this stage.

B. Count II: Violation of the Sherman Act, 15 U.S.C. §2, with regard to generic Diovan.

The primary difference between counts I and II is that, unlike generic Valcyte, Defendants actually produced and sold generic Diovan with the FDA's approval. (#1 ¶208.) There is no allegation that the FDA made a fraud determination with respect to Ranbaxy's generic Diovan ANDA; rather, it allowed Ranbaxy to keep the right to the exclusivity period and launch the product. Plaintiffs' counsel acknowledge that "we don't have it in [the complaint] anywhere, the FDA going back and taking a look at the tentative approval and itself revoking or rescinding the tentative approval" of generic Diovan. (#45 at 47:16-19, *and see* #22 at 16

("Plaintiffs do not allege that the FDA relied on false representations in granting the approval or that such approval should be rescinded.")[16]

1. Based on subsequent courts' interpretations of *Buckman*, Plaintiffs may provide proof of fraud on the FDA even without the agency's own finding.

It is a question of apparent first impression in this Circuit whether Plaintiffs may provide proof of fraud absent the FDA's edict on the topic. Other courts have reached conflicting conclusions, relying on interpretations of *Buckman*. *See, e.g., Lofton v. McNeil Consumer & Specialty Pharm.*, 682 F. Supp. 2d 662 (N.D. Tex. 2010), *aff'd,* 672 F.3d 372, 373 (5th Cir. 2012); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008); *and Tigert v. Ranbaxy Pharm., Inc.*, No. 12-00154, 2012 WL 6595806 (D.N.J. Dec. 18, 2012). All these cases concerned state tort law claims. At issue were Michigan and Texas statutes which presumptively limit drug manufacturers' tort liability if the FDA has approved the product at issue. Both statutes allow that presumption to be rebutted when the defendant has withheld information from, or misrepresented facts to, the FDA. In these cases, the question was whether the plaintiffs could provide evidence of frauds the FDA had not found.

In *Desiano*, the Second Circuit distinguished the circumstances of *Buckman* from a state tort claim for failure to warn on three grounds. 467 F.3d at 92-98. First, the statute did not

[16] Although Defendants assert that the FDA did not find fraud for generic Valcyte either, and rescinded TA merely because of a mistake, Plaintiffs are entitled to an inference in their favor on this factual question. *Cooperman v. Individual, Inc.*, 171 F.3d 43, 46 (1st Cir. 1999) (on a motion to dismiss, court must "accept as true all well-pleaded allegations and give plaintiffs the benefit of all reasonable inferences.") Regardless, under the analysis that follows, Count I should be allowed to proceed even absent the FDA's conclusive decision of fraud.

attempt to police fraud against the FDA; rather, it arose from Michigan's authority to "regulate and restrict" the operation of state tort law. *Id.* at 94. Second, the claims "sound[ed] in preexisting common law," not in violations of the FDCA. *Id.* To determine this, the court looked to the "source and 'vintage' of the duty" allegedly breached, and examined whether there were "freestanding allegations" of wrongdoing apart from the fraud. *Id.* at 94-95. Third, it noted that, within the statutory scheme, fraud was an affirmative defense rather than an element of the claim. *Id.* at 96.

Applying the *Desiano* factors to this case, antitrust claims do not seek to remedy fraud against the FDA (as addressed in detail above). Next, these claims sound in antitrust, not violations of the FDCA. In *Buckman*, the lone duty at issue was defendants' duty to be honest with the FDA. Here, Defendants have a duty not to act in anticompetitive ways that harm the market, a duty that reaches more broadly than mere honesty because of the additional elements of the Sherman Act claim. Fraud is necessary, but not sufficient, to impose liability because Plaintiffs have alleged an overarching scheme involving multiple ANDAs. Their allegations of anticompetitive behavior go beyond Ranbaxy's disclosures to the FDA, and are therefore freestanding. In contrast, *Desiano* and *Tigert* note that *Buckman*'s claim relied on fraud alone: "The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeons who used these devices did anything wrong. There's no claim here of medical malpractice." *Desiano*, 467 F.3d at 95 (quoting Oral Argument Transcript, *Buckman*, 531 U.S. at 346–347 (2000) (No. 98–1768)).

Although the *Desiano* court focused on fraud as an affirmative defense, it specifically left room for proof of fraud as an element of a claim. Overall, it held that claims will not unduly burden the FDA "where proof of fraud against the FDA is permitted but not conclusive":

> So long as a court or jury is *allowed to consider* evidence of fraud against the FDA in an ordinary common law tort suit, and so long as juries are likely to react to such evidence, there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* [*v. Wyeth–Ayerst Labs.*] Courts. Requiring such evidence when a plaintiff seeks to counter a statutory defense from liability would not significantly alter that incentive. Only when proof of fraud is by itself *sufficient* to impose liability—and indeed is the sole basis of liability (as it was in *Buckman*)—does the incentive to flood the FDA appreciably escalate.

Id. at 97 (emphasis in original).

The Fifth Circuit disagreed with *Desiano* on this point, and found the Texas law preempted by the FDCA "unless the FDA itself has found fraud." *Lofton*, 672 F.3d at 380, *accord Garcia v. Wyeth–Ayerst Labs.* 385 F.3d 961 (6th Cir. 2004). The *Lofton* court reasoned that, to prove a fraud the FDA had not identified, plaintiffs would "necessarily re-tread[] the FDA's administrative ground both to conduct discovery and to persuade a jury." *Lofton*, 672 F.3d at 380. Further, it noted that imposing liability would "intrude[] on the competency of the FDA and its relationship with regulated entities," and could cause manufacturers to "flood the FDA with [unnecessary] information," in anticipation of potential future lawsuits. *Id.* However, this rationale was based on a violation of the Supremacy Clause, which is not at issue here because both statutes are federal. *See id.*

Although none of these cases is directly on point and the law remains unclear, *Desiano*'s rationale is more persuasive. Plaintiffs seek to prove fraud only to the extent it is necessary for their antitrust claims, rather than solely reinforcing the FDA's powers. This case does not ask the

agency to do anything, and therefore the traditional concerns about judicial deference are not implicated. *Cf. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (whether agency must change its interpretation of statutes); *Heckler v. Chaney*, 470 U.S. 821 (1985) (whether agency could be compelled to act). As discussed above, antitrust enforcement does not fall within the FDA's enabling statute, so proof of this element does not intrude upon its authority.

There is little concern that manufacturers will begin flooding the FDA with information. The information required for an ANDA is spelled out in the statute. *See* 21 U.S.C. § 355(j)(2)(A) ("An abbreviated application for a new drug shall contain…"). The *Desiano* court did not find that this type of suit would "significantly alter" the manufacturers' submissions to the agency. 467 F.3d at 97. Finally, on the facts of this case, providing additional incentive for manufacturers to make full and honest disclosures to the FDA may actually be desirable.

Further, concerns about burdening the FDA are unfounded. Plaintiffs allege that "the FDA has said that the circumstances of the generic Diovan tentative approval, in terms of it being obtained through misrepresentation and duping in the FDA… is identical to all the other tentative approvals that they say [] should not have issued." (#45 at 48:8-12.) On the factual allegations in the complaint, Plaintiffs may be able to prove misrepresentations without intruding on the FDA's authority. (*See, e.g.*, #1 ¶4 ("employees often forged test results, changed data, and retroactively created documentation. They performed stability tests… on the same day, instead of at 3-, 6-, and 9-month intervals as required by regulations. And they performed bioequivalence and stability tests on research-and-development batches of drugs [in violation of regulations]…").) As much as Defendants argue otherwise, these facts concern *Ranbaxy's*

conduct in comparison with *Ranbaxy's* own representations and the applicable regulations, not information about the FDA's internal decision-making processes. At this point in the litigation, it is inappropriate to dismiss this claim. "[O]nce a claim for relief has been stated, a plaintiff 'receives the benefit of imagination, so long as the hypotheses are consistent with the complaint.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007) (quoting *Sanjuan v. Am. Bd. of Psychiatry & Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994), *as amended on denial of reh'g* (Jan. 11, 1995)). Because Plaintiffs may be able to prove Ranbaxy's fraud on the FDA with respect to generic Diovan, this count should not be dismissed.

2. The statutory deadline for obtaining TA is tolled, but does not disappear, when the monograph changes.

Defendants also raise a question of statutory interpretation. They assert that the 30-month deadline for obtaining TA is removed, and not merely tolled, because the monograph for generic Diovan changed during the pendency of their ANDA. (#48 at 9.) The relevant statutory provision states that exclusivity is forfeited when a first-filer "fails to obtain tentative approval of the application within 30 months after the [filing date], *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) (emphasis added). It does not mention an extension or tolling of the deadline. In contrast, 21 U.S.C. § 355(q)(1)(G) does: "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 [citizen] petition and ending on the date of final Agency action on the petition."

In other words, Defendants argue that "[w]here this Change-Based Exception applies, there is no deadline to obtain TA or else forfeit exclusivity; when FDA changes the rules of the

game after the first applicant submits its ANDA, no TA is required to preserve exclusivity." *Id.* They say the Change-Based Exception eliminates the deadline "*even if there are other contributing causes* to the failure to obtain TA." *Id.* at 10 (emphasis in original.) For generic Diovan, because the Change-Based Exception was one reason among several for delaying launch beyond 30 months, Defendants say that they cannot be held liable for fraud on any set of facts. Plaintiffs strenuously oppose this notion, arguing that "[t]he statutory scheme only excuses periods of delay; it does not jettison the timely approval requirement entirely." (#47 at 11.) They note that the FDA has evaluated delays in other cases, and that there is ample legislative history showing an intent to speed up generic availability, not put it on hold indefinitely. (*Id.* at 13-16.) The deadline is relevant for Plaintiffs' claim that Defendants did not obtain TA for generic Diovan soon enough.

Defendants rely on the statutory text and a September 28, 2007 memorandum from the FDA. (#48 at 9-10.) Plaintiffs point to the word "delay" in the same FDA memorandum as conclusive evidence of their opposing view. (#47 at 11-13.) They also cite other FDA decisions in which the agency determined that a "delay" past the 30-month deadline was excused due to the Change-Based Exception. (*Id*. at 13-15.) However, neither party has been able to point to an affirmative statement by the FDA that the Change-Based Exception either tolls or removes the deadline.

In the absence of the FDA's clear opinion on the topic, the Court must examine the question. Statutory interpretation involves dueling canons of construction. Although the text of the two provisions is different, to interpret the statute as Defendants suggest would be to ignore its context and ample evidence of Congressional intent. The entire statutory scheme shows a

thirty-month deadline, with exceptions for short delays. *See Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989) ("It is a 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.") It makes sense to read the Change-Based Exception as an extension, not an obliteration, of the 30-month deadline.

As well, the legislative history teems with references to reducing delays in getting generic drugs to market. Where its purpose is so clear, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43. In 2003, Congress enacted the forfeiture provisions as part of the MMA. During debate, senator after senator referenced the goal of faster generic market entry. *See, e.g.*, 149 Cong. Rec. S8686-03 (June 26, 2003) (statement of Sen. Leahy that "the unfortunate loophole exploited by a few is that secret deals can be made that allow the manufacturer of the generic drug to claim the 180-day grace period to block other generic drugs from entering the market," and statement of Sen. Feingold hailing amendment that "will bring more competition to the prescription drug market by preventing pharmaceutical companies from blocking generic drugs from entering the market"; *and* 149 Cong. Rec. S15533-02 (Nov. 22, 2003) (statement of Sen. Collins referring to "closing loopholes in our patent laws that some of the large brand name pharmaceutical companies have exploited in order to delay consumers access to lower priced generic drugs"; statement of Sen. Stabenow that the proposed legislation did not go far enough "to be able to allow more generic drugs on the market to increase competition"; statement of Sen. Bond that reform "ensures generic drugs, less expensive than brand-name pharmaceuticals, are moved to market much faster"; and statement of Sen. Hatch praising provision that "limits drug manufacturers to one

and only one 30-month automatic stay"). Senator Hatch summarized the purpose thus: "The Hatch-Waxman reforms on generic system drugs get less expensive drugs to the market faster, providing everyone with less expensive drugs." 149 Cong. Rec. S15533-02 (Nov. 22, 2003).

In this context, it is implausible that Congress intended that a monograph change could allow a prospective generic drug to be put on hold indefinitely, regardless of any subsequent events. It is more in line with the rest of the statutory scheme and legislative history to adopt Plaintiffs' view: that the deadline is tolled for the time it takes a prospect to comply with the change. With this interpretation Plaintiffs may be able to prove fraud as an element of their claim, and show that Defendants would not have been able to obtain TA in time to save their exclusivity. Therefore, this claim should not be dismissed.

C. Count III: Violation of RICO, 18 U.S.C. §1962(c), against Ranbaxy Labs, Ranbaxy Inc., and Sun Pharma.

The preclusion analysis above for Sherman Act claims also applies to RICO claims predicated on fraud on the FDA, for the same reasons. Both RICO and the FDCA are federal statutes, and there is no reason in the statutory text or court precedent to prevent this claim from proceeding. Therefore, the analysis of Count III begins with the question of whether Plaintiffs have alleged facts to support the elements of RICO.

In order to recover, Plaintiffs must establish four elements: "1) conduct; 2) of an enterprise; 3) through a pattern; 4) of racketeering activity." *In re Neurontin Mktg., Sales Practices & Products* ("*Neurontin I*"), 433 F. Supp. 2d 172, 177 (D. Mass. 2006) (citing *Libertad v. Welch*, 53 F.3d 428, 441 (1st Cir.1995), and *Sedima, S.P.R.L. v. Imrex, Co., Inc.*, 473 U.S. 479, 496 (1985)); 18 U.S.C. § 1962(c). They must also show "that the alleged activity has

caused injury to the plaintiff's 'business or property.'" *Zareas v. Bared-San Martin*, 209 F. App'x 1, 2 (1st Cir. 2006) (quoting *Sedima*, 473 U.S. at 496-97).

1. Plaintiffs have asserted RICO "conduct" by Defendants.

To "conduct or participate… in the conduct of such enterprise's affairs" requires that the person exercise "some part in directing the enterprise's affairs," that is, some part in the operation or management of the enterprise. *Aetna Cas. Sur. Co. v. P & B Autobody*, 43 F.3d 1546, 1559 (1st Cir. 1994) (citing *Reves v. Ernst & Young*, 507 U.S. 170, 179 (1993)). Defendants argue that the purported enterprise did not comprise distinct members because Ranbaxy Labs and Ranbaxy Inc. were effectively the same entity. (#22 at 37.) Further, they assert that Beardsley and Parexel were merely agents of Ranbaxy and did not "conduct" the activity alleged. *Id.* Each of these relationships will be examined in turn.

i. Ranbaxy Inc. and Ranbaxy Labs are not distinct.

The complaint does not allege separate activities by Ranbaxy Inc. and Ranbaxy Labs. Plaintiffs note that "district courts must 'look to the allegations in the complaint to determine whether the parent's activities are sufficiently distinct from those of the subsidiary at the time that the alleged RICO violations occurred.'" (#25 at 31 n.102 (citing *Bessette v. Avco Fin. Servs.*, 230 F.3d 439, 449 (1st Cir. 2000).) However, the complaint often refers to the defendants collectively as "Ranbaxy," and Ranbaxy Inc. and Ranbaxy Labs are always mentioned together in the RICO counts. (#1 ¶¶308-10, 317-19, 321, 330, 334.) The complaint makes no factual distinction between the actions of Ranbaxy Inc., Ranbaxy Labs, Ranbaxy USA, Inc., and Sun Pharma, so they cannot be separate "persons" within the meaning of RICO. These entities will be referred to simply as "Ranbaxy" for the purpose of analyzing the other relationships.

ii. Parexel may be more than an agent of Ranbaxy.

Defendants claim that Parexel was merely an agent of Ranbaxy (#22 at 31), while Plaintiffs argue that Parexel had its own role. (#25 at 30-31.) The complaint appears contradictory. Plaintiffs assert that Ranbaxy "dictated the information to be provided by its consultant." (#25 at 29-30 (citing #1 ¶¶95-96, 101).) Yet Parexel's audits themselves are not alleged to be false or misleading; on the contrary, it appears that the audits were straightforward about Ranbaxy's compliance problems. (*See, e.g.*, #1 ¶¶182e ("the stability verification and Parexel's audit showed that discrepancies and irregularities in the stability data did impact then-pending ANDAs"); ¶182h ("Parexel's audits… upon information and belief, showed that false data was submitted in conjunction with ANDAs"), *and* ¶313 (referencing "the damning conclusions of Parexel's audit reports").) This indicates that Parexel's acts were independent, but *in opposition to* the purported enterprise's goal of hiding Ranbaxy's compliance failures from the FDA.

However, Parexel's alleged intentional falsehoods during a meeting with FDA officials are enough to attach liability. Plaintiffs cite to *Neurontin I*, a case in which a drug manufacturer and two marketing firms formed a RICO enterprise. 433 F. Supp. 2d at 183, *and see* #25 at 29. The marketing firms in *Neurontin I* actively promoted false information about the off-label uses of the drug Neurontin by hosting events, recruiting doctors to speak, and drafting articles purportedly written by physicians. *Id.* at 178. Similarly, Plaintiffs state that Parexel intended to deceive the FDA (#1 ¶183), agreed to "give Ranbaxy's responses to the FDA a patina of legitimacy," and "[knew] that the information transmitted to the FDA regarding its audits would be materially misleading… [and] agreed to allow its findings to be funneled through Beardsley."

(#1 ¶315.) They allege specific false statements by Ron Tetzlaff, Parexel's corporate vice president, at a November 29, 2006 meeting with the FDA. (#1 ¶¶105-06, 108-112, 182c.) If proven, these assertions would show that Parexel promoted false information about Ranbaxy's compliance status, in furtherance of the scheme.

iii. Beardsley may be more than an agent of Ranbaxy.

The final allegations concern Beardsley, the law firm. The parties agree that attorneys can be part of a RICO enterprise. (#25 at 30 (citing *Handeen v. Lemaire*, 112 F.3d 1339, 1348-49 (8th Cir. 1997)); #31 at 13.) However, attorneys, like other professionals, must still fall within the statutory requirements to be subjected to RICO liability. "Furnishing a client with ordinary professional assistance, even when the client happens to be a RICO enterprise, will not normally rise to the level of participation sufficient to satisfy the Supreme Court's pronouncements in [*Reves*, 507 U.S. at 172]." *Handeen v. Lemaire*, 112 F.3d 1339, 1348 (8th Cir. 1997). In *Handeen*, an attorney not only represented a client in a fraudulent bankruptcy filing but took a lead role in devising various means of expanding upon the fraud. *Id.* at 1350. In contrast, in *Reves*, there was no liability for a financial auditor who did not operate or manage the RICO enterprise, even where the auditor withheld relevant information in its audit results. 507 U.S. at 186.

In order to show a RICO enterprise here, Plaintiffs will have to prove that Beardsley acted independently of Ranbaxy, in ways that go beyond ordinary legal practice. The complaint describes Ranbaxy "directing the actions of Beardsley and Parexel, and controlling what Beardsley and Parexel told the FDA, or did not tell the FDA" (#1 ¶317a), "directing Beardsley and Parexel to refuse to provide to the FDA – copies of audits performed by Parexel at the

Paonta Sahib facility, because those audits would have belied Ranbaxy's misrepresentations" (#1 ¶315f), and "directing Beardsley and Parexel to refuse to provide [Parexel's audit results] to the FDA" (#1 ¶317f). But it also contains allegations of independent action, asserting that Beardsley intentionally made false statements with the purpose of deceiving the FDA.[17] (*See, e.g.,* #1 ¶¶137, 182d, 182g-h, 182j, 183.) Further, it alleges that "Beardsley transmitted some of those statements via mail or wire… [and] aided Ranbaxy's fraudulent endeavors through multiple communications with the FDA and assertions of attorney-client privilege and attorney work product…" (#1 ¶314.) These allegations could support some set of facts that, if proven, would satisfy the requirements of RICO.

iv. The complaint sufficiently alleges that Ranbaxy, Parexel, and Beardsley formed a RICO enterprise.

By statute, an "'enterprise' includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." Title 18 U.S.C. § 1961. The term is to be "construed expansively." *United States v. Cianci*, 378 F.3d 71, 79 (1st Cir. 2004) (citing *United States v. Turkette*, 452 U.S. 576, 586–87 (1981)). The enterprise requires a common purpose, as distinguished from the pattern of acts that constitute the racketeering activity. *United States v. Turkette*, 452 U.S. 576, 583 (1981). Here, the enterprise consisted of Ranbaxy, Beardsley, and Parexel, who created an "association-in-fact" although they did not form a single legal entity. (#1 ¶310.) These participants allegedly

[17] The complaint contains other statements of Beardsley that do not appear to be false or improper. (*See, e.g.,* #1 ¶118 ("[On a conference call with the FDA on April 5, 2007] Beardsley acknowledge[d] that Ranbaxy had not yet addressed all of the concerns raised in the 2006 warning letter"); #1 ¶145 ("Beardsley informed the FDA that Ranbaxy needed "to think through the implications for the criminal case of providing the audits"); #1 ¶182b ("as Beardsley would admit the following year, Ranbaxy had *not* addressed all issues described in the Warning Letter").)

joined forces "to aid in protecting and profiting from Ranbaxy's first-to-file status associated with a number of Ranbaxy ANDAs – including the ANDAs for generic Diovan and Valcyte – by misleading, through affirmative statements and omissions, the FDA regarding the compliance status of Ranbaxy's Paonta Sahib facility, the truthfulness of the data contained within the ANDAs, and the completeness of the ANDAs." (#1 ¶¶12, 311, 319.) This common goal is distinct from the alleged mail and wire fraud.

2. Plaintiffs have included detailed fraud allegations to establish a pattern of racketeering activity, and a resulting injury.

A "pattern of racketeering activity" consists of "a series of criminal acts" as enumerated in the RICO statute. 18 U.S.C. § 1961(1); *Turkette*, 452 U.S. at 583. Plaintiffs must plead predicate acts of mail and wire fraud with particularity. (#22 at 28 (citing *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991).) Here, they have met that burden. The complaint mentions specific details about alleged misrepresentations made to the FDA, including dates and individuals involved. (#25 at 33 (citing #1 ¶¶89, 182-83).) It also includes "travel in interstate and foreign commerce in aid of racketeering enterprises in violation of 18 U.S.C. § 1952." (#1 ¶312.) Although these statements do not mention the generic Valcyte or Diovan ANDAs specifically, their substance concerns Ranbaxy's cGMP compliance status at pertinent times and is therefore relevant to those ANDAs. *See id.* Plaintiffs have alleged that they were forced to pay higher prices for brand Valcyte, a financial injury resulting from Defendants' conduct.

3. Plaintiffs have alleged proximate cause.

This provision of RICO is modeled on the civil action provision of the Clayton Act, and the proximate cause requirements of the two statutes are similar. *Holmes*, 503 U.S. at 267. Therefore, the analysis above governs. As above, although this is a close call and the outcome

will depend heavily on the facts to be unearthed in discovery, Plaintiffs have set out a plausible logical connection.

D. Count IV: Violation of RICO, 18 U.S.C. §1962(d), against Ranbaxy Labs, Ranbaxy Inc., and Sun Pharma.

This count alleges a conspiracy to commit the offense described in Count IV. *See* 18 U.S.C. § 1962(d). Based on the analysis above, Plaintiffs have properly alleged a conspiracy between Ranbaxy, Parexel, and Beardsley. In *Rosenthal*, the Fifth Circuit held that conspiracy covers any person who "adopt[s] the goal of furthering or facilitating the criminal endeavor." 805 F.3d 523, 532 (5th Cir. 2015) (internal citations omitted), *and see Salinas*, 522 U.S. at 63-64 ("A conspiracy may exist even if a conspirator does not agree to commit or facilitate each and every part of the substantive offense"). "Because the core of a RICO civil conspiracy is an agreement to commit predicate acts, the complaint must allege such an agreement." *Dep't of Econ. Dev. v. Arthur Andersen & Co. (U.S.A.),* 924 F. Supp. 449, 472 (S.D.N.Y. 1996) (quoting *Morin v. Trupin*, 832 F. Supp. 93, 99 (S.D.N.Y.1993)). The complaint mentions multiple formal agreements for the purpose of hiding Ranbaxy's compliance issues from the FDA: Ranbaxy Labs' engagement of Beardsley (#1 ¶94); an agreement between Ranbaxy, Beardsley and Parexel (#1 ¶¶94-95); and an agreement between Parexel and Ranbaxy (#1 ¶113). These facts are sufficient to allege a conspiracy.

IV. Conclusion

For the reasons stated above, I RECOMMEND that the Defendants' Motion to Dismiss (#21) be ALLOWED as to all counts against Ranbaxy Laboratories Limited and Ranbaxy USA, Inc., and DENIED as to all counts against Ranbaxy, Inc. and Sun Pharmaceutical Industries Limited.[18]

/s/ M. Page Kelley
M. Page Kelley
June 16, 2016. United States Magistrate Judge

[18] The parties are advised that any party who objects to this Report and Recommendation must file specific written objections with the Clerk of this Court within 14 days of the party's receipt of this Report and Recommendation. The written objections must specifically identify the portion of the recommendations to which objection is made and the basis for such objections. The parties are further advised that the United States Court of Appeals for this Circuit has repeatedly indicated that failure to comply with Rule 72(b), Fed. R. Civ. P., shall preclude further appellate review. *See Keating v. Secretary of Health and Human Services*, 848 F.2d 271 (1st Cir. 1988); *United States v. Emiliano Valencia-Copete*, 792 F.2d 4 (1st Cir. 1986); *Scott v. Schweiker*, 702 F.2d 13, 14 (1st Cir. 1983); *United States v. Vega*, 678 F.2d 376, 378-379 (1st Cir. 1982); *Park Motor Mart, Inc. v. Ford Motor Co.*, 616 F.2d 603(1st Cir. 1980); *see also Thomas v. Arn*, 474 U.S. 140 (1985).