UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE LIPITOR ANTITRUST LITIGATION	MDL No. 2332
This Document Relates To: All Actions	Master Docket No.: 3:12-cv-2389 (PGS/JBD) **MEMORANDUM**

Pending before the Court are several motions—two Motions for Class Certification and a Motion for Summary Judgment. Herein, the Court addresses the Motion for Summary Judgment filed by Ranbaxy Inc., Ranbaxy Laboratories Limited, Ranbaxy Pharmaceuticals, Inc. (hereinafter, "Ranbaxy" or "Defendant").[1] (ECF No. 1183). Plaintiffs are direct purchasers, end payors, and optout retailers of brand and generic Lipitor, a cholesterol medication.

Defendant argues that Plaintiffs have failed to provide any evidence that FDA would have approved Ranbaxy's Lipitor ANDA any earlier—that is, on November

[1] This Motion was originally filed by both Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC (collectively, "Pfizer") and Ranbaxy. In August 2023, when oral argument was tentatively scheduled, DPPs and EPPs announced their tentative settlement with Pfizer. As such, Pfizer no longer participated in the motion practice surrounding this motion. Herein, the Court refers only to the remaining Defendant Ranbaxy although initial briefing was filed by both Pfizer and Ranbaxy.

29, 2011—had the November 30, 2011 launch date set forth in the disputed Settlement Agreement been different. For their part, Plaintiffs argue that there is extensive documentary evidence that Ranbaxy would have obtained FDA ANDA approval earlier than November 30, 2011 if the FDA had had a different launch date to target. They argue that had Pfizer not paid Ranbaxy to delay entry and the generic Lipitor launch date had been earlier than November 30, 2011, "it was more likely than not" that FDA would have approved Ranbaxy's [Lipitor] ANDA on an earlier date. (ECF No. 1217 at 3). A number of exhibits and two expert opinions—that of Plaintiffs' Expert Kurt Karst (ECF No. 1184-3 at Ex. 3 (hereinafter, "Karst Rep.")) and Defendant's Expert, Daniel Troy (ECF No. 1184-3 at Ex. 8 (hereinafter, "Troy Rep.")))—were submitted in support of this motion. Oral argument on the present motion, the Motion for Class Certification by the Direct-Purchaser Plaintiffs (ECF No. 1221), and the Motion for Class Certification by the End-Payor Purchaser Plaintiffs (ECF No. 1251) were heard on November 27 and 28, 2023. For the reasons below, the Court agrees with Defendant that no genuine issue of material fact exists. Summary judgment is therefore appropriate.

In ruling first on this Motion for Summary Judgment, the Court is acting in the interests of judicial efficiency given the fundamental inability of the Plaintiffs to show an integral element of their cause of action: causation. This is because, in order to have standing to sue, Plaintiffs must show that the harm they say they

experienced—class-wide overcharges due to the delayed entry of a generic Lipitor—was caused by the delay in the entry date of that generic Lipitor equivalent. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164 (3d Cir. 2017) ("In order to establish antitrust injury here, the Appellants must show that the harm they say they experienced—increased drug prices for Wellbutrin XL (and its generic equivalents)—was caused by the settlement they are complaining about." (internal citations omitted)). Plaintiffs contend that if FDA approval of Ranbaxy's Lipitor ANDA had occurred any earlier—even by one day—that it is sufficient to sustain their cause of action with respect to antitrust injury.

The elements of Plaintiffs' antitrust claims are injury, causation, and damages. *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2008). In order to sustain a cause of action, Plaintiffs must prove that they suffered an injury caused by Defendant's conduct. Here, a particular aspect of causation—whether FDA would have approved Ranbaxy's Lipitor ANDA earlier than it actually did in the real world had the disputed Settlement Agreement provided for a different, earlier entry date, thereby directly affecting the injury suffered by the prospective classes—is at the forefront. Plaintiffs here are unable to show that Ranbaxy would have obtained U.S. Food and Drug Administration (hereinafter, "FDA") approval for a generic Lipitor Abbreviated New Drug Application (hereinafter, "ANDA") before November 30, 2011 on November 29, 2011. Although Plaintiffs claim that

Pfizer, the manufacturer of brand-drug Lipitor, delayed competition per a disputed Settlement Agreement with Ranbaxy (manufacturer of generic Lipitor) which prevented the generic Lipitor equivalent to enter the market until November 30, 2011, the Court agrees with Defendant who contends that Plaintiffs have failed to create a genuine issue of material fact that it was more likely than not that FDA would have completed its review any sooner and approved Ranbaxy's generic drug manufacturer's ANDA earlier than November 30, 2011—even by one day—on November 29, 2011.

For the reasons below, summary judgment is **GRANTED**.

I.

The following facts are largely adopted from Defendant's Rule 56 Response (ECF No. 1235-1). Plaintiffs disputed many of Defendant's findings as "immaterial," sometimes arguing that a statement "implied" another conclusion that was not a fact. Unless otherwise noted, the Court disagreed with Plaintiffs' assessment and incorporated those findings as undisputed herein. Where the Court thought that an argument as to whether a fact was undisputed was colorable, the Court addressed such objections in a footnote.

I. Brand Lipitor for the Treatment of High Cholesterol and Reduction of Heart Risk

A class of drugs known as "statins" lowers cholesterol by slowing down the liver's production of cholesterol and increasing the liver's ability to remove

cholesterol that is already in the blood. (ECF No. 1235-1 at ¶ 1). Lipitor® is a statin containing the active pharmaceutical ingredient atorvastatin calcium. (ECF No. 1235-1 at ¶ 2).

Beginning in 1987, Pfizer secured several patents protecting Lipitor and the active ingredient, atorvastatin calcium. (ECF No. 1235-1 at ¶ 3). On June 17, 1996, Warner-Lambert—a wholly owned subsidiary of Pfizer, Inc.—submitted a New Drug Application (hereinafter, "NDA") seeking FDA approval to sell atorvastatin calcium. (ECF No. 1235-1 at ¶ 4). On December 17, 1996, FDA approved Warner-Lambert's NDA for atorvastatin calcium. (ECF No. 1235-1 at ¶ 5). Pfizer launched its atorvastatin calcium, Lipitor, in 1997. (ECF No. 1235-1 at ¶ 6). Atorvastatin calcium "can exist both in amorphous forms and in a significant number of different crystalline forms;" but "crystalline forms of atorvastatin, are more chemically stable than amorphous forms" and amorphous forms may exhibit "higher levels of impurities" and "be more susceptible to degradation" than crystalline versions. (ECF No. 1235-1 at ¶ 7). The active pharmaceutical ingredient in brand Lipitor is a crystalline form of atorvastatin calcium. (ECF No. 1235-1 at ¶ 8).

II. FDA's Review and Approval of Generic Drugs

FDA is charged with reviewing and approving ANDAs that seek approval to market generic versions of branded drugs. To ensure that a generic drug meets all statutory requirements for approval, FDA reviews the application to ensure that it

has all the necessary components and then performs a bioequivalence review, a chemistry/microbiology review, a labeling review, and a facility review (including a facility inspection). (ECF No. 1235-1 at ¶ 9).

FDA generally strives to review ANDAs efficiently to permit generic drugs to launch as early as possible, but its first priority is to ensure the safety and effectiveness of generic drugs. FDA will not "cut corners" to approve a product that it has not determined is safe and effective. (ECF No. 1235-1 at ¶10; *see also* ECF No. 1184-3 at T186:14–T187:3). Indeed, FDA does not always give ANDA approval for generic products by the earliest possible entry date. (ECF No. 1235-1 at ¶ 11). For example, FDA did not approve Ranbaxy's first-to-file ANDA for valsartan (generic Diovan®) until June 2014, despite that Ranbaxy was permitted to launch valsartan in 2012. (*Id.*). Similarly, Teva entered an agreement with Mylan and Pfizer that would have permitted Teva to launch an epinephrine auto-injector (generic EpiPen®) by June 22, 2015, but FDA did not approve Teva's ANDA until August 16, 2018. (*Id.*).[2]

[2] Plaintiffs dispute these facts as "immaterial[,]" stating that the statements are "not relevant to whether the FDA was likely to approve Ranbaxy's ANDA earlier than November 30, 2011 had Pfizer not paid Ranbaxy to delay its generic, the only issue that Defendants sought leave of Court to address in this motion." (*Id.*). In reply, Ranbaxy states that the fact is undisputed and that Plaintiffs' assertion is argumentative and does not comport with the Local Rules of the District of New Jersey. Because no genuine issue of material fact has been shown and because this information is helpful to evaluating the timeline and the regulatory history upon which FDA was working, the Court accepts the above included statements as fact.

III. Ranbaxy Filed the First ANDA for Generic Lipitor and Triggered a Patent Infringement Lawsuit

A. Ranbaxy's Lipitor ANDA

Manufacturers who file an ANDA seeking FDA approval to market a generic version of a brand product must include a "certification" in their ANDA based on the status of patents that cover the brand product; if FDA's "Orange Book" lists a patent or patents that cover the brand product, an ANDA applicant's patent certification must state: (1) that the patent has expired (hereinafter, a "Paragraph II Certification"); (2) that the applicant will not seek to launch a generic version of the brand product until all Orange Book listed patents expire (hereinafter, a "Paragraph III Certification"); or (3) that the relevant patents are "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[]" (hereinafter, a "Paragraph IV Certification"). (ECF No. 1235-1 at ¶ 12).

On August 19, 2002, Ranbaxy filed the first substantially complete ANDA that contained a Paragraph IV Certification; this ANDA sought approval to market a generic version of Lipitor (hereinafter, "Ranbaxy's Lipitor ANDA") and was, therefore, eligible for a 180-day period of marketing exclusivity (a period of time known as "first-filer exclusivity"). (ECF No. 1235-1 at ¶ 13).

Ranbaxy's Lipitor ANDA contained Paragraph IV Certifications alleging that Pfizer's U.S. Patent No. 4,681,893 (the "'893 patent") and U.S. Patent No. 5,273,995

(hereinafter, the "'995 patent") were either invalid or not infringed by Ranbaxy's generic atorvastatin calcium products. (ECF No. 1235-1 at ¶ 14).

Under the pre-2003 version of the Hatch-Waxman Act, FDA could not finally approve any subsequently-filed ANDA for atorvastatin calcium tablets until: (1) Ranbaxy's first-filer exclusivity lapsed; (2) Ranbaxy relinquished or selectively waived its first-filer exclusivity; (3) or FDA determined that Ranbaxy's application was not substantially complete when filed in 2002 and thus, Ranbaxy was not eligible for first-filer exclusivity in the first place. (ECF No. 1235-1 at ¶ 15).[3]

While FDA approved a "more chemically stable" crystalline form of brand Lipitor in 1996, Ranbaxy's 2002 ANDA sought approval for an amorphous form of atorvastatin calcium, which was "more susceptible to degradation." (ECF No. 1235-1 at ¶ 16). Ranbaxy's 2002 ANDA indicated that its "Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg and 80 mg [would] be manufactured at Ranbaxy Laboratories Limited's FDA registered and inspected Paonta Sahib, India facility" and the "manufacturer of the Atorvastatin Calcium drug substance used to produce the

[3] Plaintiffs dispute this finding in so much as it "implies that FDA had not determined in 2002 that Ranbaxy's generic Lipitor ANDA was substantially complete when filed in 2002." (*Id.*). In reply, Defendant states that the fact is undisputed and that Plaintiffs' assertion is argumentative. The Court agrees that no such implication is created by reciting the regulatory backdrop against which the parties were working. Because no genuine issue of material fact has been shown and because this information is helpful to evaluating the timeline and the regulatory history upon which FDA was working, the Court relies on this statement as fact.

ANDA batches of drug product [was] Ranbaxy Laboratories Limited, Toansa, India." (ECF No. 1235-1 at ¶ 17).

Between 2003 and 2008, FDA identified several deficiencies with Ranbaxy's amorphous atorvastatin calcium, including issues with the bioequivalence of the product to brand Lipitor, the stability and impurity of the generic product, and the product's labeling. (ECF No. 1235-1 at ¶ 18). Ranbaxy never received tentative or final approval of its ANDA for the amorphous form of atorvastatin calcium. (ECF No. 1235-1 at ¶ 19).

B. Pfizer Initiated Patent Litigation Against Ranbaxy

According to FDA:

> In order to challenge a patent in court, [a] generic applicant that submitted a paragraph IV certification must notify the brand product sponsor and any patent holder of the submission of the ANDA and patent challenge. If the brand product sponsor or patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, FDA approval to market the generic drug is generally postponed for 30 months unless the patent expires or is judged to be invalid or not infringed before that time. This 30-month postponement, commonly referred to as the "30-month stay," gives the brand product sponsor and patent holder a prescribed amount of time to assert patent rights in court before a generic competitor is approved and can market the drug.

(ECF No. 1235-1 at ¶ 20 (quoting Ex. 23, U.S. FOOD & DRUG ADMIN., Patent Certifications and Suitability Petitions, https://perma.cc/J9PD-S92Q (last visited May 20, 2024)).

Within forty-five days of receiving notice of Ranbaxy's Paragraph IV Certifications, Pfizer initiated a patent infringement lawsuit against Ranbaxy. Under the Hatch-Waxman Act, this triggered an automatic thirty-month stay of FDA's approval of Ranbaxy's Lipitor ANDA. (ECF No. 1235-1 at ¶ 21). In August 2006, the Federal Circuit Court held that Pfizer's '893 patent was valid and would be infringed by Ranbaxy's generic product and found that one claim in Pfizer's '995 patent was invalid due to a scrivener's error. (ECF No. 1235-1 at ¶ 22). In March 2008, Pfizer initiated a second patent infringement lawsuit against Ranbaxy, alleging that Ranbaxy infringed Pfizer's U.S. Patent No. 6,274,740 (hereinafter, the "'740 Patent") and U.S. Patent No. 6,087,511 (hereinafter, the "'511 Patent"), which cover the process of making Lipitor. (ECF No. 1235-1 at ¶ 23).

C. Pfizer and Ranbaxy Resolved Pending Patent Infringement Litigation

On June 17, 2008, Pfizer and Ranbaxy entered into a Settlement Agreement to resolve litigation between the two companies regarding some of Pfizer's Lipitor patents. (ECF No. 1235-1 at ¶ 24). The Settlement Agreement resolved, among other things, (i) patent litigation regarding some of Pfizer's patents for Lipitor, including litigation abroad; (ii) patent litigation regarding some of Pfizer's patents for brand drug Accupril®; and (iii) patent litigation in Ecuador regarding some of Pfizer's patents for brand drug Viagra®. (ECF No. 1235-1 at ¶ 25).

Through the Settlement Agreement, Pfizer provided Ranbaxy a license that permitted Ranbaxy to manufacture and launch a generic version of Lipitor containing the crystalline form of atorvastatin calcium on or after November 30, 2011, approximately five years prior to the expiration of Pfizer's latest-expiring Lipitor patent. (ECF No. 1235-1 at ¶ 26).[4]

In addition, the Settlement Agreement required Pfizer to transfer to Ranbaxy information regarding its manufacturing technology to "enable [Ranbaxy] to make the preferred crystalline" active pharmaceutical ingredient in Lipitor. (ECF No. 1235-1 at ¶ 27).

IV. While Ranbaxy's Lipitor ANDA Was Pending, the Company Faced Severe Regulatory Consequences for Violations of Current Good Manufacturing Practices

A. FDA Regulatory Programs to Ensure Compliance with Current Good Manufacturing Practices

"FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice [] regulations" (hereinafter, "cGMP" or "CGMP"). "The approval process for new and generic drug marketing applications includes a review of the manufacturer's

[4] Plaintiffs dispute this statement in so much that it "implies that Pfizer's patents would have prevented the launch of Ranbaxy's generic Lipitor until the patents expired." (*Id.*). Plaintiffs' argument is without merit; this is a statement laying out the earliest possible entry date of generic Lipitor under the disputed Settlement Agreement. The Court adopts this fact.

compliance with the CGMPs." (ECF No. 1235-1 at ¶ 28). FDA routinely "conducts inspections and assessments of regulated facilities to determine a firm's compliance with applicable laws and regulations." (ECF No. 1235-1 at ¶ 29). If, during an inspection, FDA investigators observe conditions at a manufacturing facility that they deem to be objectionable, the investigators list their observations on an FDA "Form 483." (ECF No. 1235-1 at ¶ 30).

"When FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer . . . often in the form of a Warning Letter." (ECF No. 1235-1 at ¶ 31). As detailed by FDA in its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" policy— commonly referred to as the "Application Integrity Policy" (hereinafter, the "AIP")—the AIP describes FDA's approach to "the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability." (ECF No. 1235-1 at ¶ 32).

As an aside, Paragraph 33 and Plaintiffs' response present a procedural concern that must be addressed. Plaintiffs dispute Paragraph 33 with a long recitation of facts and argument that do not comport with Local Rule 56.1 of the District Court of New Jersey. For its part, Ranbaxy claims that the statement in Paragraph 33 is undisputed.

For some unknown reason, Plaintiffs failed to submit a supplemental statement of disputed material facts where their Paragraph 33 response could have been more appropriately placed. Plaintiffs' response does not conform with the rules of this Court; it is rife with both legal arguments and conclusions of law. For instance, in one of the sentences in their response, Plaintiffs write: "Had Ranbaxy agreed to an earlier entry date with Pfizer, FDA would have targeted an earlier date to complete review of Ranbaxy's Lipitor." (ECF No. 1235-1 at 33, response o). This sentence is the heart of this motion for summary judgment and is wholly inappropriate in a Rule 56.1 statement as it neither disputes the statement originally set forth in Paragraph 33 nor does this statement raise a genuine issue of material fact.

Like other Courts in this District, the Court "will not go through the responses line by line to determine in each instance where Plaintiff[s] 'blur[] the line between fact and opinion'" to determine where nonconformity with Rule 56.1 exists. *Durkin v. Wabash Nat.*, No. 10-cv-2013, 2013 WL 1314744, at *6 (D.N.J. Mar. 28, 2013) (internal citations omitted). Instead, the Court adopts what it believes to be the key point of Paragraph 33: there is a regulatory process known as the AIP which enumerates FDA's review procedure. In the AIP, FDA responds to concerns about the reliability of data in the AIP applications. It is rarely invoked by FDA. (*See* Troy Rep. at ¶ 24; ECF No 1184-3 at Ex. 7 at Feb. 28, 2023 Karst Dep. at T57:2–4).

FDA's validity assessment to determine whether an application is affected by data-integrity issues "lead[s] to delays in [FDA's] review of pending applications." (ECF No. 1235-1 at ¶ 34).[5]

B. Between 2006 and 2008 FDA Discovered and Warned Ranbaxy of Several CGMP Violations at Ranbaxy's Paonta Sahib Facility

On February 20, 21, 22, 23, 24, and 25, 2006, FDA inspected Ranbaxy's Paonta Sahib facility. (ECF No. 1235-1 at ¶ 35). On February 25, 2006, FDA issued a Form 483 (hereinafter, the "February 25 Form 483") to Ranbaxy listing

[5] Plaintiffs dispute this assertion in so much that it "implies" that the FDA validity assessment led to delays in the ANDA review and that FDA "would not have begun reviewing Ranbaxy's Lipitor ANDA earlier absent the allegedly anticompetitive conduct . . . . ." To support this, Plaintiffs rely on their response to Paragraph 33. Again, Plaintiffs' response to Paragraph 33 is comprised of legal argumentation and conclusions of law. Further, it is unclear which items of evidence cited in Plaintiffs' Paragraph 33 response Plaintiffs believe support their purported dispute. *See Durkin*, 2013 WL 1314744, at *6 (stressing that arguments regarding the "force" and "legal relevancy" of a fact belong in a brief and should be disregarded in response to a New Jersey Local Rule 56.1 statement of fact); *see also James v. Vornlocker*, 19-cv-13690, 2022 WL 3927203, at *2 n.3 (finding that plaintiff "fail[ed] to create any disputed issue of material fact because her objections . . . advance legal conclusions masquerading as fact"); *Mays v. Toloza*, No. 13-cv-6108, 2021 U.S. Dist. LEXIS 164143, at *2 n.2 (deeming facts undisputed where plaintiff repeatedly cross-referenced its response to a previous paragraph covering "an array of topics" and the court was "unable to discern what in the record cause[d] Plaintiff to dispute a specific fact"). Looking at the statement itself and the Plaintiffs' response, there is a genuine dispute of material fact with relation to this fact. For this reason, the Court accepts Defendant's statements in Paragraph 34 as true.

eight "inspectional observations" related to "record retention, stability testing deficiencies, [and] inadequate laboratory staffing." (ECF No. 1235-1 at ¶ 36).[6]

On March 20, April 20, and May 25, 2006, Ranbaxy submitted responses to the inspectional observations set forth in the February 25 Form 483. (ECF No. 1235-1 at ¶ 37).[7] FDA considered Ranbaxy's "March 20, April 20, and May 25, 2006 responses to the FDA 483 Inspectional Observations issued at Paonta Sahib," but FDA "still [had] concerns regarding various observations." (ECF No. 1235-1 at ¶ 38).[8] Thus, on June 15, 2006, FDA issued a Warning Letter to Ranbaxy, directed to the company's Vice President of Manufacturing, Ramesh Parekh, which indicated that FDA's "inspection of [Ranbaxy's] pharmaceutical manufacturing facility in Paonta Sahib, India, during the period of February 20-25, 2006 . . . revealed significant deviations from U.S. Current Good Manufacturing Practice (CGMP) Regulations . . . in the manufacture of drug products." (ECF No. 1235-1 at ¶ 39).[9]

In its June 15, 2006 Warning Letter, FDA stated that "[u]ntil FDA has confirmed correction of the deficiencies observed during the most recent inspection

---

[6] Plaintiffs contend that this assertion is immaterial, and Defendant responds that Plaintiffs have failed to indicate their disagreement with Defendant's statement of fact. The Court believes that this information belongs in the brief as it provides context on the regulatory history and timeline under which FDA was working. As such, the Court admits this statement as fact.

[7] *See supra* note 6.

[8] *See supra* note 6.

[9] *See supra* note 6.

and compliance with CGMPs, [FDA] will recommend withholding approval of any new applications listing [Ranbaxy's] Paonta Sahib facility as the manufacturer of finished pharmaceutical drug products." (ECF No. 1235-1 at ¶ 40).[10]

The June 15, 2006 Warning Letter further indicated that Ranbaxy's "failure to correct the[] deficiencies may result in FDA denying entry of articles manufactured by [Ranbaxy] into the United States." (ECF No. 1235-1 at ¶ 41).[11] On August 29, 2006, Ranbaxy provided responses to FDA's Warning Letter dated June 15, 2006 and indicated that (1) Ranbaxy was "committed to addressing each issue identified in the Warning Letter and during the FDA['s February 2006] inspection;" (2) Ranbaxy was "undertaking a number of activities to improve [its] quality programs and to enhance [its] operational performance at the Paonta Sahib facility;" and (3) Ranbaxy had "retained Ron Tetzlaff and his colleagues at PAREXEL Consulting (PAREXEL) to verify that [its] stability laboratory program improvements [were] effective and systemic, and to verify the effectiveness of [Ranbaxy's] commitments made in response to the Warning Letter." (ECF No. 1235-1 at ¶ 42).[12] On November 29, 2006, Ranbaxy met with FDA to "update FDA

[10] *See supra* note 6.
[11] *See supra* note 6.
[12] *See supra* note 6.

on Ranbaxy's progress in resolving the Warning Letter issues, and to hear from FDA regarding any remaining concerns." (ECF No. 1235-1 at ¶ 43).[13]

On January 26, 27, 28, and 29, 2007, FDA re-inspected Ranbaxy's Paonta Sahib drug product facility and inspected the API facility for the first time. (ECF No. 1235-1 at ¶ 44).[14]

On February 1, 2007, FDA issued a second Form 483 (hereinafter, the "February 1 Form 483") detailing three inspectional observations made by FDA representatives during its January 2007 inspection of Ranbaxy's API facility and related to Ranbaxy's "[i]nadequate review of production & analytical records, [its] use of uncontrolled notebook in the warehouse, [and] batch records missing specific information." (ECF No. 1235-1 at ¶ 45).[15] On February 28, 2007, Ranbaxy submitted responses to the inspectional observations set forth in the February 1 Form 483. (ECF No. 1235-1 at ¶ 46).[16]

Thereafter, Ranbaxy and FDA communicated on a number of occasions regarding both FDA's inspectional observations and Ranbaxy's work to address FDA's concerns. This included communications: (1) on June 18, 2007 and September 14, 2007 when Ranbaxy submitted retroactive stability verification data

[13] *See supra* note 6.
[14] *See supra* note 6.
[15] *See supra* note 6.
[16] *See supra* note 6.

for various of its ANDAs; (2) on June 26, 2007, when Ranbaxy met with the Center for Drug Evaluation and Research's (hereinafter, "CDER") Office of Compliance to discuss Ranbaxy's and third-party consultant PAREXEL's retrospective stability verification projects; (3) on July 27, 2007, when Ranbaxy submitted protocols and final reports related to Ranbaxy's and PAREXEL's stability verification projects; (4) on October 9, 2007, when FDA indicated it had completed its review of "the Ranbaxy Stability Data Verification Project information" and provided a list of "questions and concerns that need clarification;" and (5) on October 25, 2007, when Ranbaxy provided responses to FDA's October 9, 2007 questions. (ECF No. 1235-1 at ¶ 47).[17]

On March 3, 4, 5, 6, and 7, 2008, FDA inspected Ranbaxy's Batamandi facility, which it deemed an "extension to the Paonta Sahib site." (ECF No. 1235-1 at ¶ 48).[18] On March 7, 2008, FDA issued a Form 483 (the "March 7 Form 483") to Ranbaxy listing seven inspectional observations regarding "discrepancies in batch production records (production operations conducted by employees who were apparently not present on the dates recorded), [and] inadequate [standard operating procedures] and laboratory controls." In April 2008, due to the various cGMP violations FDA discovered during its inspections of Ranbaxy's Paonta Sahib

[17] *See supra* note 6.
[18] *See supra* note 6.

facilities, Ranbaxy declared in federal court that it did not know and could not estimate "when the FDA will tentatively approve [its Lipitor ANDA] or whether [its ANDA] will ever be approved by the FDA." (ECF No. 1235-1 at ¶ 49).[19]

On May 1, 2008, Ranbaxy submitted responses to the inspectional observations set forth in the March 7 Form 483. (ECF No. 1235-1 at ¶ 50).[20] On September 16, 2008, FDA issued two Warning Letters to Ranbaxy indicating that inspections of Ranbaxy's Batamandi and Dewas manufacturing facilities revealed significant deviations from CGMP. (ECF No. 1235-1 at ¶ 51).[21]

FDA also issued an Import Alert that remains in effect today for generic drugs produced by Ranbaxy's Dewas and Paonta Sahib plants. Pursuant to that Import Alert: "U.S. officials may detain at the U.S. border, any active pharmaceutical ingredients . . . and both sterile and non-sterile finished drug products manufactured at these Ranbaxy facilities and offered for import into the United States." (ECF No. 1235-1 at ¶ 52).[22]

In its September 16 Warning Letter regarding Ranbaxy's Batamandi site, FDA noted that the Batamandi site was "under the same production and quality management as the existing Paonta Sahib site," the "Paonta Sahib site was involved

---

[19] *See supra* note 6.
[20] *See supra* note 6.
[21] *See supra* note 6.
[22] *See supra* note 6.

in various aspects of testing and production for the Batamandi site," FDA "consider[ed] the Batamandi (Unit II) facility to be a part of the existing Paonta Sahib facility," and "[a]s such, the violations observed during the March 2008 inspection are indications of continuing CGMP deficiencies in the quality systems at the Paonta Sahib facility including the failure of production and quality management to prevent such deficiencies." (ECF No. 1235-1 at ¶ 53).[23]

FDA further indicated that "[u]ntil FDA has confirmed correction of the deficiencies and compliance with CGMP, this office will continue to recommend disapproval of any new applications listing the Paonta Sahib facility as the manufacturing location for finished pharmaceutical drug products." (ECF No. 1235-1 at ¶ 54).[24] On November 13, 2008, Ranbaxy responded to FDA's September 16 Warning Letter. (ECF No. 1235-1 at ¶ 55).[25]

C. The United States Department of Justice Initiated an Investigation of Ranbaxy's CGMP Violations

In February 2007, the United States Department of Justice (hereinafter, "DOJ") executed search warrants at Ranbaxy's United States facilities and began an investigation concerning Ranbaxy's possible violations of federal laws, including: (1) potential violations of the Federal Food, Drug, and Cosmetic Act that the

[23] *See supra* note 6.
[24] *See supra* note 6.
[25] *See supra* note 4.

Government "ha[d] reason to believe" resulted in the introduction of "adulterated and misbranded products into interstate commerce;" (2) potential violations of the False Claims Act; and (3) "a pattern of systemic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information about stability and bioequivalence, failure to timely report the distribution of drugs that were out-of-specification ('OOS'), and attempts to conceal violations of current Good Manufacturing Practices ('cGMP') regulations from the FDA." (ECF No. 1235-1 at ¶ 56).[26]

The DOJ's investigation ended only after (1) Ranbaxy signed a consent decree that required Ranbaxy "to strengthen procedures and policies regarding data integrity and to comply with good manufacturing practices," and (2) Ranbaxy pleaded guilty "to felony charges relating to the manufacture and distribution of certain adulterated drugs made at two of Ranbaxy's manufacturing facilities in India" and "agreed to pay a criminal fine and forfeiture totaling $150 million and to settle civil claims under the False Claims Act and related State laws for $350 million." (ECF No. 1235-1 at ¶ 57).[27]

D. FDA Invoked its AIP Against Ranbaxy's Paonta Sahib Facility

[26] *See supra* note 6.
[27] *See supra* note 6.

On February 25, 2009, FDA announced that it invoked its AIP against Ranbaxy's Paonta Sahib facility. (ECF No. 1235-1 at ¶ 58). In a memorandum addressed to Ranbaxy's CEO and Managing Director, Malvinder Mohan Singh, FDA indicated that CDER:

> "ha[d] determined that Ranbaxy Laboratories Limited (Ranbaxy) submitted untrue statements of material fact in abbreviated and new drug applications filed with the Agency. These findings concern the submission of information, such as from stability test results in support of pending and approved drug applications, from the Ranbaxy Laboratories Limited site located at Paonta Sahib."

(ECF No. 1235-1 at ¶ 59). According to FDA, FDA's findings "indicate[d] a pattern and practice of submitting untrue statements of material fact and other wrongful conduct, which raise[d] significant questions regarding the reliability of the data and information contained in applications (pending and approved) that [Ranbaxy] has filed with the Agency and which contain data developed at the Ranbaxy Laboratories, Paonta Sahib site." (ECF No. 1235-1 at ¶ 60). As a result, and in accordance with FDA policy, FDA needed to "assess the validity of the data and information in all of Ranbaxy's affected applications which contain data developed at the Paonta Sahib site." (ECF No. 1235-1 at ¶ 61).

FDA's assessment of data and information validity took "priority over substantive scientific data review until questions of data integrity [were] resolved," and therefore, FDA notified Ranbaxy that it did "not intend ordinarily to conduct or to continue its normal substantive scientific review (including review of data and

labeling) of any such pending application or supplement, or of any new application or supplemental applications filed after the date of this letter, that contain data developed at the Paonta Sahib site, during a validity assessment of that application." (ECF No. 1235-1 at ¶ 62).[28]

Ranbaxy's atorvastatin calcium ANDA was among sixty-five applications impacted by FDA's invocation of the AIP. As a result of scientific review, Ranbaxy's Lipitor ANDA "was required to be delayed until FDA [was] satisfied that the data or information in the application [was] reliable." (ECF No. 1235-1 at ¶ 63).[29]

---

[28] Plaintiffs argue that this statement is disputed because it "implies that the scientific review of Ranbaxy's Lipitor ANDA was actually delayed until FDA completed a validity assessment was satisfied that the data or information in the ANDA was reliable . . . [and that] this statement . . . implies FDA would not have begun reviewing Ranbaxy's Lipitor ANDA earlier absent the allegedly anticompetitive conduct." Plaintiffs generally assert that this rationale was addressed in their Response to Paragraph 33. Defendant responds that the Plaintiffs failed to address why the fact was disputed, instead asserting a legal argument. Here, the Court agrees with Defendant's rationale; Plaintiffs have failed to explain why the facts here are in dispute, rather inserting legal argumentation in their Rule 56.1 response. Such a response is both improper and unhelpful. As such, the Court admits these facts as true.

[29] In a similar way to their response to Paragraph 62, Plaintiffs claim that this is disputed to the extent that the statement implies that the scientific review of Ranbaxy's Lipitor ANDA was actually delayed until the validity assessment was completed and that this statement implies that FDA would not have begun reviewing Ranbaxy's Lipitor ANDA earlier absent the allegedly anticompetitive conduct. Similarly, Plaintiffs incorporate by reference their response to Paragraph 33. For the reasons previously stated in the analysis of Paragraph 62, the Court deems this statement admitted. *See supra* note 28.

V. Ranbaxy Attempted to Resolve the Significant Violations of CGMP that Motivated Invocation of FDA's Application Integrity Policy

A. Ranbaxy Submitted a Corrective Action Operating Plan to FDA for Review

Once the AIP is invoked, an applicant is generally expected to develop a "corrective action operating plan," which is "the applicant's written operating plan that describes its commitment, procedures, actions, and controls to ensure data integrity." (ECF No. 1235-1 at ¶ 64).[30] Ranbaxy began planning its response to FDA's February 25, 2009 AIP letter immediately, beginning with an internal meeting on February 26, 2009. (ECF No. 1235-1 at ¶ 65).[31] On April 8, 2009, Ranbaxy met with FDA representatives to discuss FDA's February 25, 2009 letter "implementing the Application Integrity Policy (AIP) relative to product submissions containing data generated at Ranbaxy's Paonta Sahib, India manufacturing facility." (ECF No. 1235-1 at ¶ 66).[32] During the April 8, 2009 meeting, Ranbaxy "provide[d] FDA with updated information on the actions taken by Ranbaxy to address the issues mentioned in the AIP letter, and propose[d] elements for a Corrective Action Operating Plan (CAOP) going forward." (ECF No. 1235-1 at ¶ 67).[33]

---

[30] *See supra* note 6.
[31] *See supra* note 6.
[32] *See supra* note 6.
[33] *See supra* note 6.

According to minutes from the April 8, 2009 meeting, Joseph C. Famulare—then Deputy Office Director of FDA's Office of Compliance—stressed that FDA wanted "assurance from Ranbaxy that all data are accurate." Famulare noted that "the errors reported by Ranbaxy were not few in number," and he requested "a complete and comprehensive plan" to resolve Ranbaxy's cGMP violations, including a third-party assessment of Ranbaxy's raw data that could be sent directly to FDA (rather than through Ranbaxy). (ECF No. 1235-1 at ¶ 68).[34]

On May 18, 2009, Ranbaxy submitted a proposed Corrective Action Operating Plan ("May 18 CAOP") that Ranbaxy developed with third-party Quintiles Consulting (hereinafter, "Quintiles") and it "provide[d] for analysis of the cause and scope of data integrity issues; audit of approved and pending applications; and remediation of any errors detected." (ECF No. 1235-1 at ¶ 69).[35] The May 18 CAOP's purpose was to "(1) validate, through a series of audits, the reliability and integrity of data contained in applications submitted to FDA; (2) ensure quality of marketed products; and (3) prevent future instances of data errors and/or wrongful acts, and noncompliance with regulatory requirements for approved and pending applications—so as to help assure the credibility and accuracy of data contained therein." (ECF No. 1235-1 at ¶ 70).[36] The May 18 CAOP proposed to determine

[34] *See supra* note 6.
[35] *See supra* note 6.
[36] *See supra* note 6.

whether "the data contained in filed ANDA/NDA applications [was] authentic, and traceable to source documents; or otherwise reliable through audits, reviews, and assessments" by: (1) "[r]eview[ing] past events which may have caused compromised data to be included in applications made to FDA," (2) "[a]udit[ing] data contained in applications made to FDA; classify[ing] findings as minor, major or critical; identify[ing the] root cause of findings; and provid[ing] corrective actions to remediate past applications made to FDA–and prevent recurrence," (3) [a]ssess[ing] cGMP/Quality System compliance as it relates to the manufacturing of the product in the applications made to FDA, and develop[ing] corrective actions, as warranted." (ECF No. 1235-1 at ¶ 71).[37] The May 18 CAOP further indicated that third-party auditor Quintiles would audit applications implicated by the AIP "for authenticity of data, traceability, and stability performance" including by reviewing "bioequivalence, product formulations and manufacturing operations," classifying its findings as "Minor, Major, or Critical," developing, implementing, and verifying a corrective action plan, and reporting its findings directly to FDA. (ECF No. 1235-1 at ¶ 72).[38] On July 1, 2009, Quintiles submitted a Product Validity Evaluation Checklist addendum to the May 18 CAOP to FDA for its review. (ECF No. 1235-1 at ¶ 73).[39]

---

[37] *See supra* note 6.
[38] *See supra* note 6.
[39] *See supra* note 6.

B. FDA Provided Feedback Regarding Ranbaxy's Corrective Action Operating Plan

On July 31, 2009, FDA sent Ranbaxy a letter stating that it "concluded that [the May 18 CAOP] will require significant improvements to meet the expectations of the Application Integrity Policy" and noted that while the May 18 "CAOP provides a high-level overview of the operations that will be conducted as part of the plan," FDA expected "to review the protocols that will provide specific instructions and/or procedures to be followed by Quintiles;" FDA acknowledged in its letter that it had not completed its review of Quintiles' July 1, 2009 Product Validity Evaluation Checklist. (ECF No. 1235-1 at ¶ 74).[40]

On August 18, 2009, Ranbaxy met with FDA to discuss, among other things, FDA's feedback on the May 18 CAOP and the Product Evaluation Checklist. (ECF No. 1235-1 at ¶ 75).[41] Deborah Autor, the Director of CDER's Office of Compliance, opened the August 18 meeting "with an FDA presentation summarizing FDA's perspective regarding Ranbaxy's history of compliance, and FDA's residual concerns," noting, for instance, that FDA's current concerns included, (1) Ranbaxy's "[f]ailure to have an Appropriate Global Quality Culture," (2) Ranbaxy's "[l]ack of overall understanding of GMPs," (3) Ranbaxy's "[r]epeated violations of GMPs related to: (a) "lack of [standard operating procedures];" (b)

[40] *See supra* note 6.
[41] *See supra* note 6.

"[s]electing convenient data to report;" (c) [p]oor, inadequate or lack of investigations," (d) "[q]uestionable GMP practices regarding stability programs;" (e) "[q]uestionable data handling and reporting practices;" and (f) "[e]mployees not present at a site, appearing as performing an activity." (ECF No. 1235-1 at ¶ 76).[42] Ms. Autor's presentation included an "FDA Message" indicating that "Ranbaxy need[ed] to provide to FDA significant assurance of: 1) Sustainable CGMP conformance has been instituted, and; 2) Robust evaluation and comprehensive resolution of extant data integrity issues" adding that:

> The agency has invested an extraordinary amount of resources conducting reviews, inspections and evaluation of data submitted by Ranbaxy, in an attempt to work with Ranbaxy in achieving compliance. [Ranbaxy] has communicated its interest in being re-inspected by the agency without the needed changes in global quality philosophy, data integrity practices and CGMPs. We are not confident that all sites have a clear understanding of FDA requirements, including CGMPs.

(ECF No. 1235-1 at ¶ 77).[43] During the same August 18, 2009 meeting, FDA gave principle approval for Ranbaxy to commence initiation of the May 18 CAOP using the Product Evaluation Checklist submitted on July 1, 2009. (ECF No. 1235-1 at ¶ 78).[44]

C. Ranbaxy and its Third-Party Auditor Began an ANDA Validity Review Based on Ranbaxy's Corrective Action Operating Plan

---

[42] *See supra* note 6.
[43] *See supra* note 6.
[44] *See supra* note 6.

On September 30, 2009, Ranbaxy sent a letter to CDER's Deborah Autor reporting "significant progress" that Ranbaxy had made "in several critical areas," noting that Quintiles had "revised, and submitted to [FDA] the ANDA audit checklist consistent with [the] discussion on [August] 18th," had "used [the] checklist in completing a number of ANDA reviews," and "anticipate[d] submitting its first certifications to FDA soon." (ECF No. 1235-1 at ¶ 79).[45] On November 16, 2009, Quintiles completed a Ranbaxy Product Validity Evaluation Checklist Summary for Ranbaxy's Atorvastatin Calcium Tablets. (ECF No. 1235-1 at ¶ 80).[46] Quintiles summarized its findings and explained that its:

> review of raw data in comparison to data contained in ANDA # 76-477, Atorvastatin Calcium, has been completed while many results were verified as reported correctly in the ANDA, there were also deficiencies identified. These included analyst and documentation errors, documentation control issues and lack of an investigation regarding accelerated dissolution out of specification (OOS) result . . . . The Bioequivalence (BE) Study for Atorvastatin was evaluated in accordance with the approved assessment checklist and found to be deficient. Typical Fast/Fed clinical studies were conducted (in-vivo) and correlated to the first campaign in-vitro Comparative Dissolution testing. The most significant issue of this Side-by-Side (Ranbaxy/Innovator) dissolution testing is that the original dissolution data cannot be located. This is deemed to be a Critical finding and must be addressed. There are two Major findings that must be addressed.

---

[45] *See supra* note 6.

[46] *See supra* note 6.

(ECF No. 1235-1 at ¶ 81).[47] Quintiles proposed several recommended corrective actions, including that Ranbaxy repeat dissolution testing using new API and possibly a new clinical study. (ECF No. 1235-1 at ¶ 82).

D. FDA Clarified that Ranbaxy's Lipitor ANDA Validity Review Was Premature and Requested a Comprehensive Internal Review

On December 8, 2009, FDA formally responded to the May 18 CAOP indicating that FDA considered the current CAOP to be inadequate in several respects. (ECF No. 1235-1 at ¶ 83).[48] FDA advised that Quintiles "should finish its internal review of the underlying issues leading to FDA's invocation of the AIP prior to conducting validity assessments of the data contained in ANDAs subject to the AIP." (ECF No. 1235-1 at ¶ 84).[49] Following receipt of FDA's December 8, 2009 letter, Ranbaxy acknowledged that "the data upon which FDA makes critical public health decisions must be reliable" and that "any corrective or preventative actions [Ranbaxy] may take will be effective only if [it had] a clear understanding of the scope of wrongdoings and the underlying root cause(s)." (ECF No. 1235-1 at ¶ 85).[50] Thus, Ranbaxy agreed to have Quintiles conduct a detailed Internal Review "designed to determine the connection between original source data and the information ultimately submitted to the agency," including by interviewing

---

[47] *See supra* note 6.
[48] *See supra* note 6.
[49] *See supra* note 6.
[50] *See supra* note 6.

employees who were responsible for generating, reviewing, and approving data and corroborating objective evidence such as attendance documentation, operation records or eyewitness accounts to support any conclusions reached. (ECF No. 1235-1 at ¶ 86).[51] Pending the conclusion of Quintiles' internal review, Quintiles suspended its ongoing ANDA validity assessment and withdrew the ANDA validity assessments previously submitted to FDA. (ECF No. 1235-1 at ¶ 87).[52] Following a January 21, 2010 meeting between Ranbaxy and FDA, Quintiles submitted an internal review protocol to FDA for comment and FDA approved the proposed protocol on February 25, 2010. (ECF No. 1235-1 at ¶ 88).[53]

Quintiles initiated its internal review on February 26, 2010. (ECF No. 1235-1 at ¶ 89).[54] On April 30, 2010, Quintiles submitted an "Interim Report" to FDA and on June 2, 2010, Quintiles submitted an addendum to its April 30, 2010 report. (ECF No. 1235-1 at ¶ 90).[55] As part of its internal review, Quintiles interviewed over one hundred current and former Ranbaxy employees in the United States and India and conducted "extensive historical reviews of hardcopy and electronic records . . . ." (ECF No. 1235-1 at ¶ 91).[56] Ultimately, Quintiles concluded that "the major

---

[51] *See supra* note 6.
[52] *See supra* note 6.
[53] *See* supra note 6.
[54] *See* supra note 6.
[55] *See* supra note 6.
[56] *See* supra note 6.

findings at Paonta Sahib formulation site are sufficient to conclude that the ANDA submissions from this site are ***not supportable without remediation.***" (ECF No. 1235-1 at ¶ 92).[57] Quintiles indicated to FDA on May 28, 2010 and again on June 2, 2010 that it believed it "was at a point in the Internal Review where it may be appropriate to schedule a meeting between FDA, Quintiles and Ranbaxy to discuss where we are in the process, and agree on next steps." (ECF No. 1235-1 at ¶ 93).[58] On April 5, 2011, FDA met with Ranbaxy to "provide feedback on the Quintiles AIP Internal Review (IR) Report and discuss the next steps forward towards initiating the ANDA Validity Assessment." (ECF No. 1235-1 at ¶ 94).[59]

VI. While the AIP Was In Place, Ranbaxy Took Several Steps to Put Generic Atorvastatin on the Market As Soon As Possible

A. Ranbaxy Made Clear to FDA that Review of its Lipitor ANDA Was Top Priority and Requested that FDA Resume Scientific Review of Its ANDA on Multiple Occasions

On July 9, 2009, Ranbaxy provided a "priority list of the ANDAs referenced in the AIP" which "reflect[ed] the order of importance of the products both in terms of commercial importance and public health significance, *i.e.*, products that are of critical importance by virtue of either being the 1st generic drug product that can be available to consumers in the marketplace and/or providing a much needed

[57] *See* supra note 6.
[58] *See* supra note 6.
[59] *See* supra note 6.

additional source to the healthcare system." (ECF No. 1235-1 at ¶ 95). Ranbaxy's Atorvastatin Calcium Tablets were listed first on its July 9, 2009 priority ANDA list. (ECF No. 1235-1 at ¶ 96). On August 18, 2009, Ranbaxy met with FDA to discuss, among other things, the significance of timely availability of key generic drugs. (ECF No. 1235-1 at ¶ 97).

During its August 18, 2009 meeting with FDA, Ranbaxy provided an explanation of the benefits of several "first-to-file" products currently pending at Ranbaxy facilities, including Atorvastatin Calcium, "stress[ing] the importance of assuring the earliest availability of these products to the public" and asking that FDA "continu[e] their substantive scientific review" of these products. In addition, Ranbaxy told FDA that its planned launch date for generic Lipitor was November 30, 2011. (*See* ECF No. 1235-1 at ¶ 98).

In response, FDA asked Ranbaxy to provide an estimate of the total time for review of the relevant applications, indicating that "Ranbaxy should take corrective action based on the CAOP results," and noting that FDA would consider granting exceptions for first-to-file ANDAs "based on new information" that Ranbaxy submitted, and "corrective actions" taken by Ranbaxy. (ECF No. 1235-1 at ¶ 99). In a letter dated September 30, 2009, Ranbaxy responded to FDA's August 18, 2009 request for an "estimate of the total time for review of all applications" involving "important 'first to file' low cost generics" and indicated that "Quintiles now

estimates all reviews will be completed no sooner than April 2010." (ECF No. 1235-1 at ¶ 100). In light of Quintiles' timeline, Ranbaxy requested that, "recognizing the criticality of the timing of some of the 'first to file' applications," FDA "commence review of those key ANDAs as Quintiles certifies them, rather than delaying review until Quintiles has certified all affected applications." (ECF No. 1235-1 at ¶ 101). In its letter, Ranbaxy included a table of "time critical products," including atorvastatin, and indicated that Ranbaxy would submit "alternate data generated outside of the Paonta facility." (ECF No. 1235-1 at ¶ 102).

On March 3, 2011, Ranbaxy's counsel met with FDA. During this meeting, Ranbaxy stressed that, in their view, "there [was] no support in the statute, regulations, or the AIP itself for . . . withholding consideration of [Ranbaxy's Lipitor ANDA] where, [as in this case] there [was] no allegation or proof of fraud . . . ." According to the minutes from that meeting, the meeting concluded by Ranbaxy requesting "whether FDA would review the application" noting that an earlier request to that effect had been made and not yet answered that FDA commence review of Ranbaxy's Lipitor ANDA. (ECF No. 1235-1 at ¶ 103; ECF No. 1184-7 at 590).[60]

[60] Plaintiffs dispute this response on several grounds, including to the extent that the statement "implies" FDA would not have begun reviewing Ranbaxy' Lipitor ANDA earlier absent the allegedly anticompetitive conduct—incorporating by reference their response to Paragraph 33. The Court broadened the statement to provide a clear

B. Ranbaxy Submitted Major Amendments to its Lipitor ANDA

Following initial submission of an ANDA, applicants may submit amendments to their applications, either in response to FDA deficiency notices or with information not requested by FDA. ANDA amendments can be either minor (*i.e.*, "typically require less extensive assessment by FDA"), major (*i.e.*, "the content of the information or data provided will require extensive assessment"), or "telephone." (ECF No. 1235-1 at ¶ 104). Major Amendments may include, for example, "[m]anufacturing a new batch of drug product for any reason, "[p]erforming a new [bioequivalence] study," or "[d]eveloping new analytical procedures and providing full validation data," while Minor Amendments include, "[m]inor deficiencies in the drug master file," "[i]ncomplete dissolution data," or "[l]abeling deficiencies that have not been adequately addressed in response to an information request." (ECF No. 1235-1 at ¶ 105).

On December 4, 2009, Ranbaxy submitted a Major Amendment to its Lipitor ANDA (hereinafter, the "December 2009 Major Amendment"). (ECF No. 1235-1 at ¶ 106).[61] The December 2009 Major Amendment acknowledged that "Ranbaxy

---

picture of the factual events surrounding these statements. Accordingly, the Court adopts the above language.

[61] Plaintiffs dispute this response to the extent that the statement "implies that Ranbaxy could not have submitted this amendment earlier in time." This is a statement of fact and makes no such implication. Accordingly, the Court adopts the above language.

Laboratories Ltd., Paonta Sahib, India was proposed as a manufacturing site for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg [in] the original ANDA" and proposed a series of changes to the original application, including (1) a "[c]hange in the form of active pharmaceutical ingredient Atorvastatin Calcium from Amorphous to Crystalline[;]" (2) a "[c]hange in the manufacturer of Atorvastatin Calcium active pharmaceutical ingredient from M/s Ranbaxy Laboratories Ltd. to M/s Pfizer[;]" (3) a "[r]evision in drug substance specifications and testing methods" for the "Drug Substance[;]" (4) the "[a]ddition of a new manufacturing site Ohm Laboratories Inc., Terminal Road, New Brunswick, New Jersey for the manufacture of the Drug Product[;]" (5) the "[a]ddition of new analytical testing sites – Ohm Laboratories Inc.[;]" (6) "Qualitative and Quantitative changes in the Drug Product Formulation[;]" (7) a "[c]hange in the manufacturing process of the Drug Product[;]" (8) a "[r]evision in drug product specifications and testing methods" for the "Drug Product[;]" and (9) a "[c]hange in container closure system." (ECF No. 1235-1 at ¶ 107).[62] Ranbaxy's December 2009 Major Amendment was supported by new bioequivalence studies. (ECF No. 1235-1 at ¶ 108).[63] Notably, Ranbaxy was able to change the form of active pharmaceutical ingredient in its atorvastatin calcium tablets from amorphous to crystalline by relying on the license Pfizer provided to

[62] *See supra* note 61.
[63] *See supra* note 61.

Ranbaxy in the Settlement Agreement, which enabled Ranbaxy to manufacture and launch a crystalline form of atorvastatin calcium tablets and thereby avoid resolution of the various ANDA deficiencies that had delayed tentative approval of Ranbaxy's Lipitor ANDA between August 19, 2002 and February 25, 2009. (ECF No. 1235-1 at ¶ 109).[64] On November 12, 2010, Ranbaxy submitted another major amendment to its Lipitor ANDA (the "November 2010 Major Amendment"). (ECF No. 1235-1 at ¶ 110).[65] The November 2010 Major Amendment proposed two further changes to Ranbaxy's Lipitor ANDA, including (1) an "[a]dditional source of API – Ranbaxy Laboratories Limited's DMF 24139 for Atorvastatin Calcium, USP (crystalline)" manufactured by Ranbaxy's Toansa, India facility and (2) "[m]inor changes in the manufacturing process of the drug product manufactured using the proposed Ranbaxy API." (ECF No. 1235-1 at ¶ 111).[66]

C. Ranbaxy Entered into an Agreement with Teva Pharmaceuticals USA to Allow for Potential Launch of Generic Lipitor Prior to November 30, 2011

On December 7, 2010, Ranbaxy entered an agreement with Teva Pharmaceuticals USA (hereinafter,

"Teva") "to market finished generic atorvastatin calcium tablet products for the prescription drug marketplace that are AB Rated" to brand Lipitor products (the

[64] *See supra* note 6.
[65] *See supra* note 61.
[66] *See supra* note 61.

"Atorvastatin Agreement"). (ECF No. 1235-1 at ¶ 112).[67] Ranbaxy "believe[d] it [was] eligible for First to File Exclusivity rights for the Product," but in order to make generic atorvastatin calcium tablets more quickly available to consumers in the United States, Ranbaxy agreed—under certain conditions—to either "selectively waive or relinquish its First to File Exclusivity rights," and permit Teva to launch generic atorvastatin calcium tablets pursuant to Teva's own ANDA (hereinafter, "Teva Lipitor ANDA"). (ECF No. 1235-1 at ¶ 113).[68] Under the terms of the Atorvastatin Agreement, Teva agreed to use commercially reasonable efforts to manufacture initial commercial launch quantities of its generic atorvastatin calcium tablets by no later than June 28, 2011. (ECF No. 1235-1 at ¶ 114).[69] In order to launch its generic atorvastatin calcium tablets pursuant to the Atorvastatin Agreement, Teva was required to provide Ranbaxy with written notice by November 30, 2011 that Teva had initial launch quantities of generic Atorvastatin Calcium Tablets ready for commercial sale in the United States, that Teva had obtained tentative approval for the Teva Lipitor ANDA or had received written confirmation from FDA that the Teva Lipitor ANDA was eligible for final approval, and requesting that Ranbaxy effectuate a selective waiver or relinquishment of its first-

[67] *See supra* note 6.
[68] *See supra* note 6.
[69] *See supra* note 6.

to-file exclusivity rights. (ECF No. 1235-1 at ¶ 115).[70] On December 15, 2010, Teva consented to the disclosure of the Atorvastatin Agreement to FDA. (ECF No. 1235-1 at ¶ 116).[71] On February 3, 2011, Ranbaxy's counsel notified FDA that it had "entered into an agreement with Teva which was intended to expedite the launch of generic atorvastatin" and summarized the critical aspects of the Atorvastatin Agreement, stating that "the agreement envisions that Ranbaxy will continue to seek approval of its own ANDA with the intent to commercialize the product," and "the agreement between Teva and Ranbaxy provides that Ranbaxy is required to either relinquish its exclusivity or, if Ranbaxy's [Lipitor] ANDA has been approved, to selectively waive its exclusivity in favor of Teva, provided that Teva's application is in position to obtain final FDA approval, and Teva has manufactured sufficient inventory for launch by June 30, 2011." (ECF No. 1235-1 at ¶ 117).[72] Ranbaxy stressed in its February 3 letter that "[a]s a result of the Teva/Ranbaxy arrangement, Ranbaxy's exclusivity would not be a bottle neck for approval of other pending atorvastatin applications, and at least one generic version of atorvastatin should be on the market in advance of the anticipated November 30, 2011 launch date." (ECF No. 1235-1 at ¶ 118).[73]

---

[70] *See supra* note 6.
[71] *See supra* note 6.
[72] *See supra* note 6.
[73] *See supra* note 6.

VII. FDA Faced Significant Pressure from Generic Manufacturers of Atorvastatin to Reassess Whether Ranbaxy's Lipitor ANDA Was Substantially Complete When Originally Filed in 2002

A. Apotex, Mylan, and Teva Argued that Ranbaxy's 180-Day First-Filer Exclusivity Should Be Extinguished Under the AIP and In Response FDA Expedited Review of Various Lipitor ANDAs

Prior to the December 8, 2003 enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (hereinafter, "MMA"), 180-day exclusivity was to be awarded to the first applicant to file a substantially complete ANDA with a Paragraph IV Certification. (ECF No. 1235-1 at ¶ 119). The amendments passed in the MMA established that a first-filer's 180-day exclusivity period can be forfeited under certain circumstances, thus, permitting the sponsors of later-filed ANDAs to obtain final FDA approval. (ECF No. 1235-1 at ¶ 120). Because Ranbaxy submitted its Lipitor ANDA in 2002, the MMA's forfeiture provisions did not apply to it and Ranbaxy's first-filer exclusivity could be lost only if Ranbaxy was "not actively pursuing approval of its [Lipitor ANDA]" or if FDA found that Ranbaxy's Lipitor ANDA "was not substantially complete when received in 2002, and therefore did not qualify for the exclusivity under 21 C.F.R. § 314.107(c)(2)." (ECF No. 1235-1 at ¶ 121).

Recognizing that, but for Ranbaxy's eligibility for 180-day exclusivity, their subsequently-filed atorvastatin calcium ANDAs might be eligible for approval prior to November 30, 2011, Apotex Inc, Mylan Inc., and Teva Pharmaceuticals USA

each wrote FDA arguing that "the agency should declare Ranbaxy ineligible for 180-day exclusivity (in short, because of the AIP)." (ECF No. 1235-1 at ¶ 122).[74] Mylan Inc. additionally filed a lawsuit against FDA "arguing that since Ranbaxy's ANDA 076477 originated from the Paonta Sahib site, it should be rejected, and that any applicable 180-day exclusivity period is extinguished." (ECF No. 1235-1 at ¶ 123).[75] Given the "unusual facts surrounding" Ranbaxy's Lipitor ANDA, including the invocation of FDA's AIP while the ANDA was pending and the various challenges FDA received to Ranbaxy's eligibility for first-filer exclusivity, FDA decided to reassess whether Ranbaxy's Lipitor ANDA was substantially complete when filed. (ECF No. 1235-1 at 124).[76] Nevertheless, so that FDA would "be prepared to take an action no matter what the outcome of the Ranbaxy 180-day eligibility decision," FDA granted expedited review status to the Teva Lipitor ANDA, Mylan's ANDA 91-226, Apotex's ANDA 90-548, and Sandoz Inc.'s ANDA 77-575 "based upon

---

[74] *See supra* note 6.

[75] *See supra* note 6.

[76] Here, Plaintiffs dispute this statement of fact to the extent that the statement "implies that FDA would not have re-examined the substantial completeness of Ranbaxy's Lipitor ANDA earlier in time had there been a need, *i.e.*, an earlier Ranbaxy agreed upon entry date for FDA to target." No such implication is created by this statement of fact. Because this information is helpful to evaluating the timeline and the regulatory history under which FDA was working, the Court relies upon this statement as fact.

their stated ability to be approved on or about June 28, 2011." (ECF No. 1235-1 at ¶ 125).[77]

B. FDA Re-Examined Ranbaxy's Lipitor ANDA and Determined that It Was Substantially Complete When Filed

On July 29, 2011, Martin Shimer—Branch Chief of the Office of Generic Drug's Regulatory Support Branch—issued a memorandum documenting FDA's re-examination of Ranbaxy's eligibility for first-filer exclusivity. (ECF No. 1235-1 at ¶ 126).[78] The memorandum explained that under 21 C.F.R. § 314.107(c)(3) "exclusivity can be lost if the eligible applicant is 'not actively pursuing approval of its abbreviated application;'" but any lull in the review of Ranbaxy's Lipitor ANDA was "a function of the AIP status of the ANDA, rather than a result of Ranbaxy's failure to pursue approval," and therefore, "this regulation (which has never been applied in practice) does not appear to be an appropriate basis on which to deny Ranbaxy eligibility for exclusivity." (ECF No. 1235-1 at ¶ 127).[79] FDA thus focused its re-examination on the "second basis for finding Ranbaxy ineligible for

---

[77] *See supra* note 6.

[78] Here, the Plaintiffs dispute this statement of fact to the extent that it "implies FDA could not and would not have issued approval to Ranbaxy's ANDA earlier than November 30, 2011 and/or re-examined the substantial completeness of Ranbaxy's Lipitor ANDA earlier in time had there been a need, *i.e.*, an earlier Ranbaxy agreed upon entry date for FDA to target." (*Id.*). No such implication is created by this statement. As such, because this information is helpful to evaluating the timeline and the regulatory history under which FDA was working, the Court relies upon this statement as fact.

[79] *See* discussion at *supra* notes 6 and 78.

180-day exclusivity" and assessed whether Ranbaxy's Lipitor ANDA was substantially complete when it was submitted in 2002. (ECF No. 1235-1 at ¶ 128).[80]

The Office of Generic Drugs "re-reviewed Ranbaxy's original 2002 ANDA submission to verify that it contained the items required for the ANDA to be considered substantially complete," including by: (1) "compar[ing] the information recorded on the ANDA Checklist for Completeness and Acceptability as an Application . . . with the contents of the ANDA[;]" (2) "confirm[ing] that Ranbaxy's original submission contained all required information described in the checklist, including a signed and completed application form, a basis for submission description of the reference listed drug (RLD), patent certification, comparison between the proposed generic drug and RLD (*i.e.*, conditions of use, active ingredient(s), route of administration, dosage form, strength), labeling, bioavailability/bioequivalence information, components and composition statements, raw materials controls, description of manufacturing facility, outside firms including contract testing laboratories, manufacturing and processing instructions, in-process controls, container information, controls for the finished dosage form, stability information for finished dosage form, samples, environmental impact analysis statement, and Generic Drug Enforcement Act information[;]" and (3) "in light of the concerns about data reliability raised by the issues that formed

[80] *See supra* note 78.

the basis for the AIP . . . look[ing] at documents contained in Ranbaxy's original submission in greater depth than is usual for a substantial completeness and filing assessment," – *e.g.*, "compar[ing] the lot numbers recorded on various documents to ensure consistency throughout the submission," and "review[ing] the dates recorded on documents such as batch records, certificates of analysis, methods, method validations, and stability data to ensure that the processes were performed in the correct order." (ECF No. 1235-1 at ¶ 129).[81] In addition, CDER's Office of Compliance "also reviewed sections of ANDA 076477 . . . as well as a number of other documents" in order to "determine whether there was any evidence specific to ANDA 076477 to indicate that this application was affected by the same systemic concerns that were the basis for the AIP." (ECF No. 1235-1 at ¶ 130).[82] Following the re-examination, FDA's Office of Generic Drugs and Office of Compliance concluded that, when filed, Ranbaxy's Atorvastatin ANDA "was sufficiently complete to permit a substantive review, and that there is no evidence of fraud to support a conclusion that this determination is not justified." Thus, FDA concluded that Ranbaxy retained its first-filer status and was entitled to the 180-day exclusivity period. (ECF No. 1235-1 at ¶ 131).[83]

VIII. FDA Granted Ranbaxy an Exception to the AIP and Permitted the Office of Generic Drugs to Resume its Review of Ranbaxy's Lipitor ANDA

[81] *See supra* note 78.
[82] *See supra* note 78.
[83] *See supra* note 78.

On May 11, 2011, FDA's Office of Compliance issued a memorandum "address[ing] the question of whether OGD should proceed with the review of Ranbaxy['s Lipitor] ANDA, as amended" (hereinafter, the "AIP Exception Memo"). (ECF No. 1235-1 at ¶ 132).[84] The AIP Exception Memo acknowledged submission of the December 2009 Major Amendment and the November 2010 Major Amendment, and indicated (1) that "[p]ursuant to the AIP, neither of these amendments has been reviewed" and (2) the "amendments to the Ranbaxy application necessitate, in essence, a new full review of the main elements of the ANDA, including the CMC information, bioequivalence studies, and labeling." (ECF No. 1235-1 at ¶ 133).[85]

In addition to its "new full review" of Ranbaxy's Lipitor ANDA, FDA needed "to ensure data reliability of the new Ranbaxy submissions from Ohm Laboratories" and "determine that they are free of the concerns which gave rise to the AIP;" this assessment would require FDA to answer at least the following questions: (1) "Have data from Paonta Sahib or other facilities with significant cGMP or data reliability concerns been included in the Ohm Laboratories submission?" (2) "Have data 'migrated' from earlier submissions into the amendments?" and (3) "Does the application adequately address known areas of concern, including dissolution,

[84] *See supra* note 78.
[85] *See supra* note 78.

stability, other analytical data, and exhibit batch production records?" (ECF No. 1235-1 at ¶ 134).[86]

The Office of Compliance determined that review of Ranbaxy's Lipitor ANDA would be appropriate and recommended that review proceed because, "among other things: (1) the initial findings of the third-party auditor conducting the internal review at Paonta Sahib indicate that the practices at issue arose during a time period after 2002; (2) this and other evidence currently available to FDA suggests that the pattern of activity discussed in the AIP letter would not have affected the originally filed 2002 ANDA (*e.g.*, untrue statements identified by FDA occurred subsequent to the original ANDA filing); (3) the ANDA, as amended, purportedly does not contain data from the Paonta Sahib facility; (4) at this time, FDA is not aware of evidence that the application for which Ranbaxy is seeking approval (*i.e.*, as amended in 2009 and 2010) contains unreliable data or information; (5) review may be necessary to avoid a situation in which the statutory 180-day exclusivity blocks approval of any ANDA for atorvastatin; and (6) the overall circumstances are such that the agency believes it will be able to determine whether the data and information in the application as amended are reliable and whether the ANDA meets the requirements for approval." (ECF No. 1235-1 at ¶ 135).[87]

---

[86] *See supra* note 78.
[87] *See supra* note 78.

FDA acknowledged in the AIP Exception Memo that "November 30, 2011, is the earliest date Ranbaxy could market its atorvastatin calcium product under its 2008 settlement with Pfizer," but stressed that "[i]f the data are found to be unreliable, or the application otherwise does not meet the requirements for approval, FDA would not approve the ANDA" and that "[t]o be approved, any ANDA for atorvastatin must meet the requirements under section 505(j) of the FD&C Act and applicable regulations." (ECF No. 1235-1 at ¶ 136).[88] FDA proposed that, if Ranbaxy was granted an AIP exception, an expedited review of Ranbaxy's Lipitor ANDA commence immediately, but noted that while it "anticipated that FDA's review of [Ranbaxy's Lipitor ANDA could] be completed by" November 30, 2011, "[p]rompt review of the ANDA does not, of course, guarantee that the application will be ready for final approval by November 30, 2011." (ECF No. 1235-1 at ¶ 137).[89] FDA granted Ranbaxy an exception to the AIP on May 16, 2011. (ECF No. 1235-1 at ¶ 138).[90]

IX. FDA Proceeded to Complete its Review of Ranbaxy's Lipitor ANDA by November 30, 2011

FDA completed its "new full review" of Ranbaxy's Lipitor ANDA "both for reliability and approvability" between May 16, 2011 and November 30, 2011—in

[88] *See supra* note 78.
[89] *See supra* note 78.
[90] *See supra* note 78.

just over six months' time. (ECF No. 1235-1 at ¶ 139).[91] Between 2010 and 2011, FDA's median review time to review an ANDA from start to finish was 27.85 months and 29.52 months, respectively.[92] (ECF No. 1235-1 at ¶ 140).

FDA's decision to proceed with its review of Ranbaxy's Lipitor ANDA "set off flurry of activity at [the Office of Generic Drugs]—and at Ranbaxy." (ECF No. 1235-1 at ¶ 143).[93] Following the May 16, 2011 AIP exception, FDA and Ranbaxy's activity related to the Ranbaxy Lipitor ANDA review included the following items:

i. *June 2, 2011*: Ranbaxy submitted a Gratuitous Labeling Amendment.
ii. *June 3, 2011*: Ranbaxy submitted a Patent Amendment.
iii. *June 7, 2011*: Ranbaxy submitted a Gratuitous Chemistry, Manufacturing, and Controls Amendment.
iv. *June 14, 2011*: Ranbaxy re-submitted its June 3, 2011 Patent Amendment to a corrected address.
v. *June 14, 2011*: FDA notified Ranbaxy of several minor quality deficiencies and requested all available long-term stability data from Ranbaxy.
vi. *June 20, 2011*: FDA notified Ranbaxy of bioequivalence deficiencies and requested that Ranbaxy conduct additional dissolution testing.
vii. *July 18, 2011*: Ranbaxy submitted a Bioequivalence Amendment in response to FDA's June 20 deficiency notice.
viii. *July 27, 2011*: Ranbaxy responded to FDA's June 14 quality deficiency letter.
ix. *July 28, 2011*: Ranbaxy submitted a Patent Amendment.
x. *July 29, 2011*: FDA completed its Labeling review and determined that Ranbaxy's submissions were acceptable.

[91] *See supra* note 78.
[92] *See supra* note 6.
[93] *See supra* note 78.

xi. *August 16, 2011*: FDA notified Ranbaxy of additional bioequivalence deficiencies and requested that Ranbaxy repeat dissolution testing.

xii. *August 24, 2011*: FDA and Ranbaxy met telephonically regarding FDA's August 16 bioequivalence deficiency notice.

xiii. *August 26, 2011*: Ranbaxy submitted a Bioequivalence Amendment in response to FDA's August 16 deficiency notice.

xiv. *September 1, 2011*: Ranbaxy submitted a Gratuitous Amendment in further response to FDA's June 14 quality deficiency letter.

xv. *September 22, 2011*: FDA's Division of Bioequivalence submitted a request for a for-cause inspection of Ranbaxy's Ohm Laboratories dissolution testing site, citing a "history of questionable dissolution data submitted for" Ranbaxy's Lipitor ANDA.

xvi. S*eptember 28-October 3, 2011*: FDA's Office of Manufacturing and Product Quality conducted the requested inspection of Ranbaxy's Ohm Laboratories dissolution testing cite.

xvii. *October 3, 2011*: FDA requested that Ranbaxy submit a Telephone Amendment to address minor chemistry deficiencies.

xviii. *October 5, 2011*: Ranbaxy submitted a Telephone Amendment in response to FDA's October 3 request.

xix. *October 21, 2011*: FDA completed its Quality (Chemistry) Review and determined that Ranbaxy's submissions were acceptable.

xx. *October 25, 2011*: FDA's Division of Bioequivalence received the Office of Manufacturing and Product Quality's Inspection Report and found it acceptable.

xxi. *October 25, 2011*: FDA completed its Bioequivalence Review and determined that Ranbaxy's submissions were acceptable.

xxii. *November 21-25, 2011*: FDA conducted a pre-approval inspection of Ranbaxy's Toansa manufacturing facility.

xxiii. *November 25, 2011*: FDA issued a Form 483 (hereinafter, the "November 25 Form 483") to Ranbaxy listing inspectional observations made by FDA representatives during its November 21–25, 2011 inspection of Ranbaxy's Toansa API facility.

xxiv. *November 29, 2011*: Ranbaxy responded to FDA's November 25 Form 483.

xxv. *November 30, 2011*: FDA entered an overall recommendation of "Acceptable" in the Establishment Evaluation System for Ranbaxy's Toansa facility.

xxvi. *November 30, 2011*: FDA approved Ranbaxy's Lipitor ANDA. (ECF No. 1235-1 at ¶ 144).[94]

It was the Office of Generic Drug's "prompt review of Ranbaxy's [Lipitor ANDA]" and "Ranbaxy's prompt[] respon[ses] to OGD" deficiency communications that "led to sign-off (i.e., acceptable status) of the application's labeling discipline review on July 29, 2011, the quality (chemistry) discipline review on October 21, 2011, the bioequivalence discipline review on October 25, 2011, and the facility discipline reviews on October 25, 2011 . . . and on November 30, 2011." (ECF No. 1235-1 at ¶ 145).[95]

On October 26, 2011, Ranbaxy requested that FDA complete its review and approve Ranbaxy's Lipitor ANDA two weeks in advance of Ranbaxy's November 30, 2011 licensed entry date. (ECF No. 1235-1 at ¶ 146).[96] However, FDA was

---

[94] Plaintiffs dispute this statement to the extent that it "implies" that Ranbaxy received FDA's request on September 29, 2011 rather than October 3. 2011 as described in subpart xviii. (ECF No. 1235-1 at ¶ 144). Additionally, Plaintiffs incorporate their response to Paragraph 33 by reference and dispute the statements in paragraph 144 to the extent that it "implies FDA would not have begun work on Ranbaxy's Lipitor ANDA earlier had there been a need, *i.e.*, an earlier Ranbaxy agreed-upon entry date for FDA to target." (*Id.*). This timeline creates no such implication. The Court accepts this timeline into the factual record.

[95] *See supra* note 94.

[96] Plaintiffs dispute this statement of fact to the extent that it "implies FDA was targeting a date two weeks in advance of Ranbaxy's November 30, 2011 licensed entry date to complete review of Ranbaxy's Lipitor ANDA." No such implication is created by this statement. As such, because this information is helpful to evaluating the timeline, regulatory history, and back-and-forth between Ranbaxy and FDA. The Court relies upon this statement as fact.

unable to accommodate Ranbaxy's request for early approval. Instead, correspondence demonstrates that FDA scheduled its inspection of Ranbaxy's Toansa facility on November 14, 2011 and conducted the inspection between November 21 and 25, 2011. (ECF No. 1235-1 at ¶ 147).[97]

On November 25, 2011, FDA issued the November 25 Form 483 to Ranbaxy listing inspectional observations made by FDA representatives during its November 21-25, 2011 inspection of Ranbaxy's Toansa API facility. (ECF No. 1235-1 at ¶ 148).[98] On November 29, 2011, FDA "acknowledged the significance of tomorrow [November 30, 2011], which [was] the widely anticipated launch date of generic atorvastatin." But it informed Ranbaxy that "it did not appear that resolution of the Toansa inspection results could be reached by tomorrow because multiple parties are involved, and [FDA] did not venture to guess when resolution would be reached." When Ranbaxy asked "whether, if they were to submit . . . an amendment [removing the Toansa site] immediately, the ANDA could be approved tomorrow,"

---

[97] Plaintiffs dispute this statement. They state that "November 14, 2011 is the date FDA notified Ranbaxy of the Toansa inspection, not necessarily the date FDA scheduled the Toansa inspection." After its review of the evidence provided, the Court disagrees, and the Court adopts the above language. (*See* ECF No. 1184-10 at 919).

[98] Plaintiffs dispute this response to the extent that the statement "implies that FDA would not have conducted the Toansa inspection earlier had there been a need, *i.e.*, an earlier Ranbaxy agreed-upon entry date for FDA to target." This is a statement of fact and makes no such implication. Accordingly, the Court adopts the above language.

FDA responded that "it was possible, but [FDA] could not guarantee it," even one day before Ranbaxy's licensed entry date. (ECF No. 1235-1 at ¶ 149).[99] Ranbaxy submitted a response to the November 25 Form 483 on November 29, 2011. (ECF No. 1235-1 at ¶ 150).[100] On November 30, 2011, FDA documented that it had completed its validity assessment, and it concluded that its "review of Ranbaxy's [Lipitor] ANDA. . . and inspection of facilities referenced in the ANDA does not reveal irregularities that would cause [FDA] to question the reliability of the ANDA." (ECF No. 1235-1 at ¶ 151).[101] In the end, FDA approved Ranbaxy's Lipitor ANDA on November 30, 2011. (ECF No. 1235-1 at ¶ 152).

X. FDA's Expedited Review of Alternative Lipitor ANDAs Did Not Result in the Earlier Launch of Generic Atorvastatin Calcium Tablets

FDA conducted its review of Apotex, Mylan, Teva, and Sandoz's respective ANDAs for atorvastatin calcium tablets, reasoning that if FDA were to determine that Ranbaxy's Lipitor ANDA was not "substantially complete" at the time of its submission, it would be in "the public interest to have completed [the] scientific reviews of any atorvastatin ANDA that otherwise could be approved and marketed to the American public as early as June 28, 2011." (ECF No. 1235-1 at ¶ 153).[102]

---

[99] *See supra* note 98.
[100] *See supra* note 98.
[101] *See supra* note 98.
[102] *See supra* note 6.

Nevertheless, no generic manufacturer was able to obtain tentative or final approval by June 28, 2011, despite FDA's review. (ECF No. 1235-1 at 154).[103] Indeed, Teva—which had the contractual right to launch its own generic atorvastatin calcium product before November 30, 2011, irrespective of whether Ranbaxy was entitled to first-filer exclusivity—could not obtain tentative FDA approval until December 1, 2011. (ECF No. 1235-1 at 155).[104] This approval process was mired by problems which started on January 31, 2011, FDA sent Teva a letter captioned "Warning Letter" (hereinafter, "The January 31, 2011 Warning Letter") indicating that FDA had "identified significant violations of Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals" at Teva's Jerusalem manufacturing facility. (ECF No. 1235-1 at ¶ 156).[105] This January 31, 2011 Warning Letter indicated that "[u]ntil all corrections have been completed and FDA has confirmed corrections of the violations and [Teva's] compliance with CGMP, FDA may withhold approval of any new applications or supplements listing [Teva] as a drug product manufacturer." (ECF No. 1235-1 at ¶ 157).[106] FDA re-inspected Teva's Jerusalem facility on June 19, 2011. (ECF No. 1235-1 at ¶ 158).[107] According to an email communication between Teva and Ranbaxy, Teva received a

[103] *See supra* note 6.
[104] *See supra* note 6.
[105] *See supra* note 6.
[106] *See supra* note 6.
[107] *See supra* note 6.

"close-out letter from FDA" on September 9, 2011; as stated in this email, this close-out letter formally notified the company that Teva had "addressed the issues raised by the FDA in a warning letter received on January 31, 2011." (ECF No. 1235-1 at ¶ 159).[108] During and after the period in which FDA imposed the January 31, 2011 Warning Letter, Teva was in frequent contact with FDA to respond to deficiencies in the Teva Lipitor ANDA. (ECF No. 1235-1 at ¶ 160).[109] On November 16, 2011, FDA requested a Telephone Amendment from Teva to resolve certain minor deficiencies in the Teva Lipitor ANDA, including a request that Teva revise the expiration dating of Teva's atorvastatin calcium product to 18 months; Teva indicated that it would comply with FDA's request on November 17, 2011. (ECF No. 1235-1 at ¶ 161).[110] On November 29, 2011, FDA indicated to Teva that the Teva Lipitor ANDA approval package was being finalized, but FDA "could not commit to tentative approval" by November 30, 2011. (ECF No. 1235-1 at ¶ 162).[111] On November 29, 2011, Teva moved for a preliminary injunction and temporary restraining order that would force Ranbaxy to selectively waive its first-filer exclusivity pursuant to the Atorvastatin Agreement. (ECF No. 1235-1 at ¶ 163).[112]

---

[108] *See supra* note 6.
[109] *See supra* note 6.
[110] *See supra* note 6.
[111] *See supra* note 6.
[112] *See supra* note 6.

In a brief filed in the United States District Court for the Southern District of New York on November 30, 2011, Ranbaxy argued that Teva had failed to perform its obligations under the Atorvastatin Agreement because (1) FDA had not tentatively approved the Teva Lipitor ANDA, and (2) Teva did not have initial commercial launch quantities ready for commercial sale, in part because Teva had not re-labeled 10 million bottles of atorvastatin calcium in accordance with FDA's November 16, 2011 request in time for launch. (ECF No. 1235-1 at ¶ 164).[113]

On November 30, 2011, the Teva and Ranbaxy lawsuit was settled. (ECF No. 1235-1 at ¶ 165).[114]

II.

A motion for summary judgment should be granted only if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). "A factual dispute is 'genuine' if the 'evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Razak v. Uber Techs., Inc.*, 951 F.3d 137, 144 (3d Cir. 2020) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "A factual dispute is 'material' if it 'might affect the outcome of the suit under the governing law.'" *Id.*

[113] *See supra* note 6.
[114] *See supra* note 6.

"The Court must view the facts and evidence presented on the motion in the light most favorable to the nonmoving party." *Id.* (quoting *Anderson*, 477 U.S. at 255). Moreover, summary judgment "is inappropriate when the evidence is susceptible of different interpretations or inferences by the trier of fact." *Hunt v. Cromartie*, 526 U.S. 541, 553 (1999). Thus, the judge's function "is not himself to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial." *Anderson,* 477 U.S. at 249. As such, "the court must ask whether, on the summary judgment record, reasonable jurors could find facts that demonstrated, by a preponderance of the evidence, that the nonmoving party is entitled to a verdict." *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 860 (3d Cir. 1990).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it . . . must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." *Wasserman v. Bressman*, 327 F.3d 229, 238 (3d Cir. 2003) (internal marks omitted). Where the moving party bears the burden of proof, the evidence presented in support of summary judgment must be "credible." *Id.* at 237. "Once a moving party with the burden of proof makes such an affirmative showing, it is entitled to summary judgment unless the

non-moving party comes forward with probative evidence that would demonstrate the existence of a triable issue of fact." *Id.* at 238.

The nonmoving party "must do more than simply show that there is some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Summary judgment may be granted if the nonmoving party's "evidence is merely colorable or is not significantly probative." *Anderson*, 477 U.S. at 249–50.

III.

a. Antitrust Causation

At their core, the elements of the Plaintiffs' claims are (1) violation of the antitrust laws; (2) individual injury resulting from that violation, and (3) measurable damages. *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2008) (internal citations omitted). The second element is known as the "causation" requirement. *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 626 (E.D. Pa. 2011) (citing *Callahan v. A.E.V., Inc.*, 182 F.3d 237, 250 (3d Cir.1999)). Accordingly, an antitrust plaintiff must show that it suffered an antitrust injury that was sufficiently linked to the complained-of conduct.

Antitrust injury "involves a causation requirement in order to define the class of potential plaintiffs eligible to bring suit—those 'injured . . . by anything forbidden in the antitrust laws.'" *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998

F.2d 391, 395 (7th Cir. 1993) (citations omitted). This causation requirement "requires a plaintiff to show that the defendant's antitrust violation was a 'material cause' of the plaintiff's injury." *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) (internal citations omitted). "On occasion . . . an independent cause fully accounts for the plaintiff's alleged injury and breaks the causal connection between the alleged antitrust violation and the plaintiff's injury." *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F.Supp.2d 751, 756 (E.D. Pa. 2003).

b. Causation as Applied

The causation question presented within this motion is whether FDA would have approved Ranbaxy's Lipitor ANDA even a day before it actually did on November 30, 2011 (the earliest date that Ranbaxy was permitted to release its generic Lipitor under the disputed Settlement Agreement). The resolution to this question lies in the answer to two, parallel sub-questions: (1) whether FDA would have granted an AIP exception before May 16, 2011 absent the disputed Settlement Agreement and (2) whether Ranbaxy would have obtained final FDA approval earlier than November 30, 2011 absent the disputed Settlement Agreement. For the reasons below, there is no genuine issue of material fact as to these two sub-questions. Summary judgment is therefore appropriate.

i. Evidence that FDA Would Have Granted an AIP Exception Before May 16, 2011 Absent the Disputed Settlement Agreement

This first question relates to a regulatory mandate encountered by Ranbaxy in its journey to ANDA approval: the AIP and the subsequent AIP exception. In the first instance, the Court disagrees with Plaintiffs' position that the evaluation of the AIP process and its effect only goes to question of the impact of the length of any delay in Ranbaxy Lipitor ANDA's approval (*See* ECF No. 1217 at 38)—the AIP and Ranbaxy's ability to obtain the AIP exception are central to deciding when and whether the Ranbaxy Lipitor ANDA would be approved and how all plaintiffs in this matter were affected. Thus, to decide whether Ranbaxy's Lipitor ANDA could have been reviewed and approved earlier by FDA, the Court must assess the AIP process given that absent the AIP exception, any FDA review of Ranbaxy's Lipitor ANDA would have been impossible. For the reasons below, there is no evidence to suggest that the AIP exception would have been granted any earlier. Arguments to the contrary are pure speculation.

The AIP is a process invoked "[w]hen FDA finds that a manufacturer has significantly violated FDA regulations . . . ." (ECF No. 1235-1 at ¶ 31). Manufacturers are often alerted in the form of a warning letter. Thereafter, a manufacturer's ANDA review is required to be delayed "until FDA is satisfied that the data or information in the application is reliable." (*Id.*). Here, FDA invoked its AIP against Ranbaxy on February 25, 2009. About two years later on May 16, 2011—after a series of back-and-forth between Ranbaxy and FDA—FDA granted

an exception to its AIP policy; this allowed a review of the Ranbaxy's generic Lipitor ANDA to proceed in spite of the AIP.

The Court first addresses the numerous communications between Ranbaxy and FDA—a significant factual history that cuts against Plaintiffs' argument. Over the period of two years between when the AIP was imposed and when the AIP exception was granted, Ranbaxy and FDA communicated often; these communications were largely efforts by Ranbaxy to secure an AIP exception in the first place—an event that was by no means guaranteed. These correspondences are summarized below:

- **February 25, 2009:** FDA invokes the AIP against Ranbaxy's Paonta Sahib site.
- **April 8, 2009:** Ranbaxy meets with FDA to discuss the AIP.
- **May 18, 2009:** Ranbaxy submits the May 18 CAOP.
- **July 9, 2009**: Ranbaxy provides a "priority list of the ANDAs referenced in AIP" which includes Ranbaxy's generic Lipitor ANDA. Ranbaxy's Lipitor ANDA was listed first on that list.
- **July 31, 2009**: FDA rejects the May 18 CAOP.
- **August 18, 2009:** Ranbaxy meets with FDA to discuss May 18 CAOP and the Product Evaluation Checklist. FDA gives principle approval of May 18 CAOP incorporating changes added by Quintiles. During this meeting, Ranbaxy informs FDA that it intends to launch generic Lipitor on November 30, 2011.
- **September 30, 2009:** Ranbaxy advises FDA that Quintiles reporting "significant progress" that Ranbaxy had made "in several critical areas," noting that Quintiles had "revised, and submitted to [FDA] the ANDA audit checklist consistent with [the] discussion on [August] 18th," had "used [the] checklist in completing a number of ANDA reviews," and "anticipate[d] submitting its first certifications to FDA soon."
- **December 4, 2009:** Ranbaxy submits the December 2009 Major Amendment to its Lipitor ANDA, changing: (1) the manufacturer of the atorvastatin

calcium in its formulation from its Paonta Sahib facility to a facility operated by Pfizer; (2) adding Ohm Laboratories as a manufacturing site; and (3) changing the form of its atorvastatin calcium from amorphous to crystalline.

- **December 8, 2009:** FDA formally responds to May 18 CAOP.
- **November 12, 2010:** Ranbaxy submits the November 2010 Major Amendment to its Lipitor ANDA to add another source for its atorvastatin calcium through a Ranbaxy facility in Toansa, Punjab, India as well as "[m]inor changes" in the drug product manufacturing process.
- **March 3, 2011:** Ranbaxy's counsel meets with FDA. They stress that, in their view, "there [was] no support in the statute, regulations, or the AIP itself for . . . withholding consideration of [Ranbaxy's Lipitor ANDA] where, [as in this case] there [was] no allegation or proof of fraud . . . ." Additionally, Ranbaxy requested that FDA commence review of Lipitor generic ANDA.
- **May 11, 2011**: FDA issues the AIP Exception Memo, which considers whether Ranbaxy should be given an AIP Exception to allow review of ANDA to commence. The AIP Exception Memo concludes that FDA, having "considered the complicated circumstances related to Ranbaxy's atorvastatin ANDA . . . concluded that they support review of the ANDA."
- **May 16, 2011:** FDA grants Ranbaxy an AIP exception.

In addition to showing the frequency and complexity of the interactions between the parties, this factual timeline demonstrates three main points. First, it highlights the major amendments that occurred on two occasions during this back-and-forth. In 2009 and 2010, Ranbaxy submitted major amendments to its ANDA. These major amendments required that FDA—when and if the Ranbaxy Lipitor ANDA was excepted from the AIP—restart its entire review of the Ranbaxy Lipitor ANDA. As FDA stated in its AIP Exception Memo: "The amendments to the Ranbaxy application necessitate, in essence, *a new full review* of the main elements of the ANDA, including the CMC information, bioequivalence studies, and labeling." (ECF No. 1235-1 at ¶ 133 (emphasis added)). This included a detailed examination

of the data reliability of the new Ranbaxy submissions from Ohm Laboratories to determine that those submissions were "free of the concerns which gave rise to the AIP." (ECF No. 1184-5 at 211). While FDA gave no timeline on how long such a review would take, FDA stated that it "anticipate[d]" that it could complete the ANDA review by that November 30, 2011; at the point of the AIP Exception Memo's issuance, that date was approximately seven months away. (*Id.* at 213). It is noteworthy that the AIP Exception Memo used the word "anticipated," *not* guaranteed or promised. The Court reads this language in the AIP Exception Memo as an abstract discussion, looking to events that had not yet occurred.

Second, this back-and-forth across a period of two years highlights the fact that, although FDA's knowledge of the November 30, 2011 launch date never changed, FDA took more than two years to grant an AIP exception to Ranbaxy in the first place. There is no evidence that FDA would have reviewed this application any faster should the earliest possible launch date under the disputed Settlement Agreement even one day earlier on November 29, 2011. Similarly, while FDA might have written in that same AIP Exception Memo that it "anticipated" completion by such a date, there is no evidence to show that the review could have or would have been completed any faster. There has been no testimony by FDA on this point or any other party to suggest that FDA was dragging its feet. Plaintiffs point only to FDA's awareness of the November 30, 2011 and the fact that FDA

wrote that it "anticipate[d]" that its review could be completed by that date as evidence supporting that the process would be. FDA's awareness of the earliest launch date and language to that effect is insufficient to raise a genuine issue of material fact.[115]

Third, the Court notes that the AIP mechanism itself raises separate issues with Plaintiffs' argument. Specifically, the AIP's unusual nature and the fact that it required a "restart" of application review upon its lifting render Plaintiffs' arguments that FDA would have approved Ranbaxy's Lipitor ANDA earlier than November 30, 2011 on November 29, 2011 difficult to accept as anything beyond speculation. The first point—the unusual nature of the AIP—is agreed to by the experts in this case. As stated by Daniel Troy, former FDA Chief Counsel from 2001 and 2004:

> The AIP is an exceptional and rarely used program, intended for only the most severe cases of non-compliance. In fact, only four firms out of 11 on the current AIP list (last revised in December 2021) have been added to the list by the Center for Drug Evaluation and Research ("CDER"), the division of FDA responsible for generic drug applications, and there are only 19 firms listed on FDA's website that have ever been subject to the AIP.

(Troy Rep. at ¶ 24). For his part, Plaintiffs' expert Kurt Karst—in response to the question at his deposition "do you agree that the invocation of the AIP is an unusual step for the FDA"—responded: "Yes, I do agree with that." (ECF No 1184 at Feb. 28, 2023 Karst Dep. at T57:2–4). The highly unusual nature of the AIP creates a

[115] *See* discussion at *infra* at 74.

problem for the Court in assessing Plaintiffs' arguments about what FDA "would have done" where Plaintiffs are unable to offer information other than speculation on this point. The actual implications of the AIP create difficulties in forecasting what FDA would have done since the Ranbaxy Lipitor ANDA approval process "restarted" upon the lifting of the AIP given the major amendments that had been submitted. Indeed, once an AIP exception was granted, FDA conducted a "new full review" of the ANDA, defined as reviewing the main elements of the Ranbaxy Lipitor ANDA from scratch. (Troy Rep. at ¶ 27).

These points bring to bear a greater, main point: regulatory requirements in this case obstruct Plaintiffs' argument that FDA would have moved quicker had the earliest entry date been November 29, 2011. Indeed, Plaintiffs largely fail to address these significant regulatory requirements that Ranbaxy encountered. Plaintiffs contend that the evidence shows that FDA made an exception to the AIP to review "Ranbaxy's Lipitor ANDA *before* 'it was able to confirm the data and information in Ranbaxy's [Lipitor] ANDA as amended were reliable.'" (ECF No. 1217 at 39) (emphasis in the original). Further, Plaintiffs argue that FDA's "completion of the validity assessment after granting the AIP exception necessarily means that FDA began its substantive review of Ranbaxy's Lipitor ANDA before confirming the reliability of data information in Ranbaxy's ANDA[,]" apparently arguing that had the November 30, 2011 date been different by one day, FDA could have started this

same review earlier and granted the exception earlier. (*See id.* at 40). These arguments fail to address the main problem facing the Court: what evidence is there that FDA would have tried to and could have achieved an altered timeline had it had a different entry-date to target? Arguments about when the review began do not address this argument—they are speculative. In terms of evidence with respect to FDA's speed of review or incentives to review, the Court possesses only this factual timeline and speculation as to how FDA's awareness of November 30, 2011 motivated the approval process. Plaintiffs' argument is uncompelling, and there is little evidence to support it. What evidence there is, the Court finds to support a reading of FDA's diligence and concern with drug review—a concern that would not be altered based upon a drug entry date.

This conclusion is supported when looking at the problems encountered by another generic manufacturer on its road for Lipitor ANDA approval: Teva. As previously mentioned, Ranbaxy and Teva agreed that Teva could launch its generic Lipitor prior to November 30, 2011 "if Teva received FDA tentative approval (or FDA indicated the ANDA was otherwise approvable except for Ranbaxy's exclusivity), and manufactured certain quantities for sale." (ECF No. 1184 at 34). FDA was aware that Teva was permitted earlier market entry.

Notwithstanding its awareness of earlier possible entry for one of the "largest blockbuster drug ever,"[116] FDA did not approve Teva's generic ANDA prior to November 30, 2011. Instead, FDA issued a warning letter to Teva regarding its Jerusalem facility on January 31, 2011. FDA re-inspected Teva's Jerusalem facility on June 19, 2011, and according to an email communication between Teva and Ranbaxy, Teva received a "close-out letter from FDA" on September 9, 2011. According to the email communication, the close-out letter formally notified the company that Teva had "addressed the issues raised by FDA in a warning letter received on January 31, 2011." On November 16, 2011, FDA requested a Telephone Amendment from Teva to resolve certain minor deficiencies in the Teva Lipitor ANDA, including a request that Teva revise the expiration dating of Teva's atorvastatin calcium product to 18 months; Teva indicated that it would comply with FDA's request on November 17, 2011. On November 29, 2011, FDA indicated to Teva that the Teva Lipitor ANDA approval package was being finalized, but FDA "could not commit to tentative approval" by November 30, 2011. Teva did not receive the approval prior to November 30, 2011. This timeline demonstrates to the Court that FDA's awareness of the availability of an earlier entry date when handling the same "blockbuster" drug made no difference in FDA's approval timeline where there were regulatory mandates in place. Further, it again highlights FDA's

[116] ECF No. 1184-5 at 340.

commitment to ensuring the safety of drugs on the market for consumers. In addressing Teva's Lipitor ANDA, Plaintiffs largely gloss over these facts, merely stating in a footnote:

> Because there is evidence that FDA would have approved Ranbaxy's [Lipitor] ANDA as amended earlier had Pfizer not paid Ranbaxy to delay, the Court need not reach the question of whether Teva's generic would have also been approved earlier or if there were other ways that FDA could have approved Ranbaxy's ANDA.

(ECF No. 1217 at 6 n.1). While the Court need not address the speed at which the Teva Lipitor ANDA was approved in formulating its decision, the Court believes that the Teva Lipitor ANDA approval timeline sheds light onto regulatory mandates encountered by manufacturers and how FDA does not alter its regulatory review processes merely because there is an earlier entry date allowed for these manufacturers.

The Court's decision is also supported by Third Circuit precedent. In *In re Wellbutrin*, the Third Circuit examined *inter alia* the district court's granting summary judgment to defendant, GlaskoSmithKline ("GSK"). *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143 (3d Cir. 2017). The Court briefly recites the underlying facts of *In re Wellbutrin*, which are similar to those of the case presently before the Court. In 1985, GSK obtained FDA approval for bupropion hydrochloride, a drug which became branded as "Wellbutrin." *Id.* at 145. Over the years, several companies tried to develop an extended-release

formulation of bupropion hydrochloride ("Wellbutrin XL"), with at least two companies—Biovail and Andrx Pharmaceuticals, LLC—creating these formulations and obtaining patents covering extended-release formulations of the drug. *Id.* Since GSK never developed an extended-release formulation of bupropion hydrochloride (and it wished to access an extended-release formulation), GSK obtained an exclusive license to some of Biovail's patents. *Id.* In August 2002, GSK filed an NDA for the new formulation, which was approved the following year. *Id.*

Between September 2004 and May 2005, four generic manufacturers—Anchen, Abrika, Impax, and Watson—filed ANDAs seeking approval to market generic versions of Wellbutrin XL. *Id.* Each of the four filed a paragraph IV certification. *Id.* Anchen was the first to file its ANDA, and, as a result, was entitled to the 180-day exclusivity period. *Id.*

Biovail filed patent infringement suits against all four generic companies. *Id.* On December 21, 2005, Andrx filed suit against GSK, alleging that Wellbutrin XL, in 150 mg dosages, violated Andrx's '708 patent. *Id.* at 146. Andrx also filed suit against Anchen for infringing the same patent with a generic version of Wellbutrin XL. *Id.* In both cases, Andrx sought damages and an injunction against the sale of infringing products. *Id.* In February 2007, all the parties involved in the Wellbutrin-related patent litigation (except for Abrika) entered into a settlement. *Id.* Pursuant to the terms of the agreements, Anchen waited until May 2008 to launch its 150 mg

generic version of Wellbutrin XL, and GSK waited 180 days to launch authorized generic versions of both 150 mg and 300 mg Wellbutrin XL. *Id.* at 145–46; 160.

In examining a series of disputed settlement agreements, the Third Circuit evaluated whether the District Court had correctly granted summary judgment on the question of whether the increased drug prices were caused by the disputed settlement agreements. The Third Circuit determined that *In re Wellbutrin* plaintiffs had no antitrust standing which is proven by a plaintiff showing that the "'injury [is] of the type that antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful.'" *Id.* (citing *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 233 (3d Cir. 2013)). The Third Circuit reasoned that to establish antitrust injury, *In re Wellbutrin* plaintiffs needed to show that the harm they experienced—the increased drug prices for Wellbutrin XL and its generic equivalents—was caused by the disputed settlement. *Id.* at 164–65. The *In re Wellbutrin* plaintiffs sought to meet their burden by "pointing to evidence showing that, in the absence of the agreements, [a generic] would have launched . . . no later than the middle of 2007." The Third Circuit noted:

> At first glance, that argument seems appealing. Indeed, the District Court found that there was at least a question of fact as to whether Anchen would have launched the drug in June 2007. The problem with the argument however, is that it does not take into account [a] blocking patent, the '708 patent. It is not enough for the Appellants to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal. After all, if the launch were stopped because it was illegal, then the Appellants injury (if it could still be called that)

> would be caused not by the settlement but by the patent laws prohibiting the launch. After all, if the launch were stopped because it was illegal, then the Appellants' injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch . . . . That a regulatory or legislative bar can break the chain of causation in an antitrust case is beyond fair dispute.

Id. The Third Circuit noted that the *In re Wellbutrin* plaintiffs attempted to circumvent this legality hurdle with two arguments: a license-based argument and litigation-based argument.

The Third Circuit concluded that the record supported neither argument. With respect to arguments that Anchen would have been able to receive a license to distribute a generic (the license-based argument), the Third Circuit stated that plaintiffs needed to:

> produce evidence from which a reasonable jury could conclude that it [was] more likely than not that Anchen *would* have obtained a license. Evidence showing that Anchen *may* have been able to obtain a license does not meet that standard. A plaintiff cannot satisfy the summary judgment burden based on speculation alone.

Id. at 167. Additionally, the Third Circuit disagreed with *In re Wellbutrin* plaintiffs' argument that because Anchen was negotiating a license agreement with Andrx in the days preceding the disputed settlement agreements and had agreed on all but one of the terms, that a reasonable jury could infer that the two companies would have reached an agreement. The Third Circuit rejected this argument, stating:

> [T]his argument is completely speculative. It is certainly possible that Anchen and Andrx would have reached an agreement, but it is also

> certainly possible that negotiations would have stalled and failed. Many a contract has foundered on a single deal-breaker point. Without more specific or concrete evidence, the jury in this case would be left within anything on which it could rely to reach a conclusion one way or another.

Id.

In terms of the litigation-based argument, or the scenario premised upon the idea that Anchen would have prevailed in the underlying patent litigation between Anchen and Andrx, the Court examined plaintiffs' arguments that the size of the reverse payment was a surrogate for the patent's weakness and approximations by defendant's expert regarding the chances of prevailing on different issues in that litigation. The Third Circuit pointed out that neither *In re Wellbutrin* plaintiffs nor GSK identified any other evidence in the record that spoke to the possibility of the resolution of the Anchen-Andrx litigation. As such, "no reasonable jury could conclude that Anchen would have been more likely than not to prevail." *Id.* at 168. The Third Circuit concluded that summary judgment was appropriate.

Like in *In re: Wellbutrin*, Plaintiffs here must show that an earlier launch of the Ranbaxy's generic Lipitor would have been legal. There is nothing in the record aside from speculation that the regulatory requirements presented by FDA's AIP would have permitted an entry date for Ranbaxy's generic Lipitor on November 29, 2011 or that FDA would have altered its regulatory processes to expedite the AIP process had the earliest launch date been November 29, 2011. Like in *In re*

Wellbutrin, "a regulatory or legislative bar [has] brok[en] the chain of causation in [this] antitrust case . . . ." *Id.* at 164–65. Similar to *In re Wellbutrin*, here, there was a regulatory requirement that actually precluded earlier entry of Ranbaxy's Lipitor ANDA—a barrier that was independent of the disputed agreement. These regulatory requirements interrupted the causal link between the alleged injury and any damages complained-of injury by Plaintiffs, and the Court does not see how any factfinder could find otherwise.

Here, the AIP Exception Memo setting forth the decision to grant the AIP exception discusses how FDA "anticipated" its review of the Ranbaxy Lipitor ANDA *could* be completed by the November 30, 2011 date, not that this review *would* be completed by that date. Further, FDA disclaimed this prospective timeline by saying: "Prompt review of the ANDA does not, of course, guarantee that the application will be ready for final approval by November 30, 2011. To be approved, any ANDA for atorvastatin must meet the requirements under section 505(j) of the FD&C Act and applicable regulations." This language is insufficient to create a genuine issue of material fact as to an earlier launch date. Instead, the language shows that while FDA may have been targeting a date, FDA approval was limited by its AIP and was uncertain on the approval timeline. Particularly where Ranbaxy submitted major amendments to its ANDA—which included a change to the actual form of the atorvastatin calcium and a change to the facilities where the product

would be produced—that required a new full review of the Ranbaxy Lipitor ANDA upon a resumption of the review process, it is difficult to see how a reasonable jury could have found the FDA AIP's exception timeline to be different on the information before the Court.

As speculative arguments often go, Plaintiffs' argumentation also works against them. In an alternate world, it is just as likely that the AIP process could have taken longer to complete, or FDA could have refused to grant the AIP exception—thereby resulting in further interruptions in Ranbaxy's Lipitor ANDA review and delaying review even longer than it did in the actual world. The Court struggles to see how it can accept that FDA's mere awareness of a date evidenced—evidenced by FDA documents and language that FDA "targeted" a date—creates a genuine issue of material fact as to the ability of FDA approval to occur even a day earlier. There is no genuine issue of material fact before the Court as to whether the AIP exception could have been granted earlier. Absent the granting of this AIP exception, review of Ranbaxy's Lipitor ANDA could not have occurred.

The Court proceeds to the next sub-question.

ii. Evidence that Ranbaxy Would Have Obtained Final FDA ANDA Approval Earlier had the November 30, 2011 Launch Date been Different

Even assuming that there was a genuine issue of material fact surrounding FDA's ability to grant an earlier AIP exception, there is no evidence that Ranbaxy

would have received approval of its ANDA earlier than it did had the launch date of Ranbaxy's generic Lipitor been November 29, 2011 instead of November 30, 2011. The principal issue with evaluating the question of an earlier ANDA approval is that it requires the Court to guess what FDA would have done had the launch date for generic Lipitor been different. Guesswork does not create a genuine issue of material fact, and no reasonable jury could find for Plaintiffs. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986) ("The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff."). Summary judgment is therefore appropriate.

Plaintiffs rely almost exclusively upon FDA's awareness of the November 30, 2011 date to demonstrate that FDA would have approved Ranbaxy's Lipitor ANDA earlier. Plaintiffs use this awareness in an attempt to demonstrate that it motivated FDA's approval process and decision-making timeline. It is undisputed that FDA knew of the November 30, 2011 date as the earliest date that Ranbaxy could have launched its generic Lipitor under the Settlement Agreement. Indeed, there is extensive documentation on this point. The question before the Court is better phrased as follows: how did FDA's awareness of the November 30, 2011 launch date affect FDA's review and what evidence exists that there could have been earlier

FDA approval of Ranbaxy's Lipitor ANDA if the disputed Settlement Agreement had provided for a different date of entry?

The Court finds two documents helpful in evaluating these questions: the AIP Exception Memo and a note regarding a phone call with Ranbaxy and FDA on October 26, 2011 (hereinafter, the "October 2011 Cumulative Monthly Report"). In the AIP Exception Memo from the Director of the Office of Compliance to the Director for the Center for Drug Evaluation and Research regarding "Proposal to Review Ranbaxy's Atrovastatin ANDA," FDA states:

> November 30, 2011, the earliest date Ranbaxy can market its atorvastatin product under its 2008 settlement with Pfizer, is about 7 months away. We anticipate that FDA's review of this ANDA can be completed by that date. If this application is granted an exception from the AIP's restriction on review. OGD proposes that expedited review of this ANDA both for reliability and approvability commence immediately. Prompt review of the ANDA does not, of course, guarantee that the application will be ready for final approval by November 30, 2011. To be approved, any ANDA for atorvastatin must meet the requirements under section 505(j) of the FD&C Act and applicable regulations.

(ECF No. 1184-5 at 213). Further discussion between FDA and Ranbaxy that November 30, 2011 was the earliest possible launch date is detailed in the October 2011 Cumulative Monthly Report. This appears to be an internal call note drafted by Sameer Manan of Ranbaxy. In it, Manan details a phone call between Manan and Bob West of FDA on October 26, 2011. The note reads:

> FDA Telephone Contact- Sameer Manan with Bob West. Sameer called Bob to check on the status of the ANDA and inform him that we

> received the EIR from the NJDO, wherein they have given an approval recommendation for the product. Bob said he has the approved clearance from compliance and they are looking at the end of the month for approval. Sameer questioned him 'end of October, or November' and he said, "no, November 30th, isn't that the day you are targeting too?" I explained that we have a settlement agreement which permits us to launch on Nov 30th, but nothing is in the way of preventing the Agency from approving us before that date. He agreed, but said they were working and targeting the Nov 30th date. He said it isn't written in stone, but at this point they were targeting Nov 30th. He asked if there was a benefit to getting the approval sooner and I explained that yes. If we received approval at least 2 weeks ahead of that date, it would enable us to talk to our customers and get the product where it had to be to ensure a smooth launch on the 30th. He said he couldn't promise anything, but again that they are working towards the Nov 30th date. I thanked him and told him I will check back in 2 weeks.

(ECF No. at 1184-10 at 210).

Both of these documents are instructive on several points. Both excerpts demonstrate FDA's knowledge of the November 30, 2011 date as the earliest possible launch date—a fact that is beyond dispute. However, the documents demonstrate other important facts. The AIP Exception Memo, for example, reiterates the fact that approval of the Ranbaxy Lipitor ANDA was conditioned upon an AIP exception being granted. Indeed, the AIP Exception Memo's sense of urgency surrounding the Ranbaxy Lipitor ANDA launch date is tempered by this fact. Specifically, the AIP Exception Memo reads:

> November 30, 2011, the earliest date Ranbaxy can market its atorvastatin product under its 2008 settlement with Pfizer, is about 7 months away. We anticipate that FDA's review of this ANDA can be completed by that date. *If this application is granted an exception from the AIP's restriction on review.*

(ECF No. 1184-5 at 213 (emphasis added)). Thus, Ranbaxy's Lipitor ANDA approval was always conditional upon an AIP exception or complete removal of the AIP. In every alternate world, it always would be conditional upon these facts—*even if Ranbaxy's Lipitor ANDA launch date were earlier*. Ranbaxy's Lipitor ANDA approval was wholly predicated upon the AIP exception being granted or the AIP being removed. As such, Ranbaxy's Lipitor ANDA approval was based upon an event completely separate of the date put forward by the disputed Settlement Agreement. As previously discussed, there has been no substantive showing that the November 30, 2011 date had any bearing upon the AIP period and the exception Ranbaxy was eventually granted.

Next (and perhaps most importantly), both of these documents highlight the fact that the November 30, 2011 date was merely a target for FDA. Even had that "target" been earlier, there is no evidence to suggest that FDA's review process would have been faster. The AIP Exception Memo itself disclaims: "Prompt review of the ANDA does not, of course, guarantee that the application will be ready for final approval by November 30, 2011." Similarly, the October 2011 Cumulative Monthly Report entry notes that: "[Bob West] said he couldn't promise anything, but again that they are working towards the Nov 30th date. I thanked him and told him I will check back in 2 weeks." Pointing to these statements as evidence that—had the launch date under the disputed Settlement Agreement been November 29,

2011—FDA would have worked faster and approved the date more quickly is insufficient. Accordingly, the Court does not find that arguing that the earliest launch date being a target and showing the Court evidence that FDA was targeting such a date leads to the conclusion that FDA would have reviewed the Ranbaxy Lipitor ANDA any faster.

The argument's speculative nature is highlighted by Plaintiffs' argumentation at oral argument. Plaintiffs argued that the occurrence of FDA approval in itself on the earliest possible entry date under the disputed Settlement Agreement is evidence that FDA would have targeted and achieved an earlier date had the earliest launch date been November 29, 2011 because it would be wildly coincidental if this approval had occurred on this date for any other reason. (Nov. 27, 2023 Tr. at T36:4–10). Plaintiffs stated that it is "very reasonable . . . very easy to conclude that if FDA was aware of an earlier agreed upon entry date, they would have done what they did in the real world, martial their resources to target an earlier date, and either meet the specific earlier date or the earliest date right after that date." (*Id.* at T36:4–10). In a colorful analogy, Plaintiffs stated that Defendant would have the Court believe that the Ranbaxy Lipitor ANDA was approved on November 30, 2011 in a "sheer cosmic coincidence . . . That it was just somehow a quirk of the universe that such a thing could happen." (*Id.* at T36:13–18). This argumentation further highlights to the Court the speculative nature of Plaintiffs' argumentation; unable to

point to any information aside from documents showing that FDA was "targeting" November 30, 2011, Plaintiffs rely on the actual approval date as proof of that FDA could have moved faster. Such arguments are appeals to "metaphysical doubt[s] as to material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). As previously noted, the date of approval in itself is not proof that FDA would have approved the Ranbaxy's Lipitor ANDA any faster.

Language from FDA itself is particularly helpful in evaluating this point. In the AIP Exception Memo, FDA explained:

> It is acknowledged that the circumstances here do not fit squarely under OGD's MaPP 52.40.3, which among other things describes circumstances under which an ANDA will be given expedited review. However, the circumstances here (e.g., the existence and complexity of the questions related to Ranbaxy AIP and ANDA reliability and the highly uncertain date upon which ANDAs may be eligible for final approval, the review issues posed by the applications, and the size of the market demand for this drug product) are of such an unusual nature that they could not have been anticipated. Review of these applications on an expedited basis, is, however, consistent with OGD's long-term goal of reviewing pending ANDAs in such a manner that, by the time patent and exclusivity barriers to approval have expired, appropriate reviews will have been completed. With first generic ANDAs that have been found scientifically approvable, OGD has a long history of approving these as promptly as permitted under statutory provisions pertaining to patents, patent litigation, and exclusivity. Prompt review of ANDAs does not, of course, guarantee that any application will be ready for final approval as of a specific date.

(ECF No. 1184-9 at 190 n.1). FDA acknowledges in its memorandum the unusual circumstances surrounding the Ranbaxy Lipitor ANDA. FDA recognizes that the

"circumstances here (e.g., the existence and complexity of the questions related to Ranbaxy AIP and ANDA reliability and the highly uncertain date upon which ANDAs may be eligible for final approval, the review issues posed by the applications, and the size of the market demand for this drug product) *are of such an unusual nature that they could not have been anticipated.*" (*Id.* (emphasis added)). FDA further explains: "With first generic ANDAs that have been found scientifically approvable, OGD has a long history of approving these as promptly as permitted under statutory provisions pertaining to patents, patent litigation, and exclusivity. Prompt review of ANDAs does not, of course, guarantee that any application will be ready for final approval as of a specific date." (*Id.*). The Court notes that first, FDA acknowledged that the elements of the Ranbaxy Lipitor ANDA process were so unusual "they could not have been anticipated." Additionally, FDA stated that, while OGD has a "long history of approving" ANDAs "as promptly as permitted under statutory provisions . . . . [p]rompt review of ANDAs, does not, of course, guarantee that any application will be ready for final approval as of a specific date." Again, FDA was *targeting* a date. A target date does not equal a guarantee or even raise the likelihood that, more likely than not, FDA would have approved Ranbaxy's Lipitor ANDA any faster for a reasonable jury. Even if that target date had been earlier, the Plaintiffs have failed to show that FDA would have reviewed the ANDA application on a different timeline given the incredibly unusual

circumstances of this case. The Court is unmoved by the argument that the approval on November 30, 2011 is proof itself; particularly considering the facts from FDA putting forth the unusual nature of the Ranbaxy Lipitor ANDA, the likelihood of the purported "cosmic coincidence" appears high. The Court fundamentally disagrees with Plaintiffs that a target date is sufficient to raise a genuine issue of material fact as to whether FDA would have moved faster on the Ranbaxy Lipitor ANDA.

This conclusion is additionally supported when evaluating FDA ANDA review of other "blockbuster" drugs. Specifically, other ANDAs for other blockbuster drugs were not approved by FDA by the earliest launch dates. These dates support the Court's conclusion that even if FDA "targets" a date, this does not necessarily mean that FDA is able to, can deliver by that date, or whether "targeting" has any effect at all on FDA review. Indeed, if FDA approval is not ready by a certain date—despite an earlier launch date's availability—FDA does not approve it. Take the EpiPen, a medication used to treat anaphylaxis, for example. In April 2012, Teva entered into a settlement agreement with Mylan and a Pfizer subsidiary "that would allow Teva to launch a generic version of the blockbuster drug, epinephrine auto-injector ("EpiPen") by June 22, 2015 or earlier under certain circumstances. However, even with this date, Teva's generic version of the EpiPen was not approved until August 16, 2018. (ECF No. 1235-1 at ¶ 11; Troy Rep. at ¶ 145). Another example is the generic version of Diovan, a blood pressure

medication. In 2007, Ranbaxy and Novartis reached a settlement in which Ranbaxy "agreed that it would not market generic Diovan until the expiration of the U.S. patent in 2012 or until the patent claims were declared invalid, whichever came first, and no later than September 2012." (Troy Rep. at ¶ 142). FDA did not approve Ranbaxy's ANDA for generic Diovan until June 2014.

These examples hammer home the fact that FDA is not glued to meeting earliest possible entry dates and will not achieve an earlier entry-date merely to achieve a target date put forth by pharmaceutical manufacturers. Overall, this evidence (or the lack thereof) shows that there is no genuine issue of material fact, and summary judgment is appropriate in this case.

IV.

For the reasons set forth above, there is no genuine issue of material fact as to whether FDA would have approved Ranbaxy's Lipitor ANDA earlier than November 30, 2011 on November 29, 2011. Indeed, the evidence presented to the Court is that FDA *may* have been able to do so.

Plaintiffs' evidence showing that FDA "*may* have been able" to approve Ranbaxy's Lipitor ANDA on November 29, 2011 does not meet the summary judgment standard. *See In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 167 (3d Cir. 2017). Accordingly, no genuine dispute of material fact as to this question exists.

Summary Judgment is granted.

6/6/24

PETER G. SHERIDAN, U.S.D.J.