NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE LIPITOR ANTITRUST LITIGATION	MDL No. 2332
	Master Docket No. 3:12-cv-2389 (PGS)
This Document Relates to: All Direct Purchaser Class Actions	MEMORANDUM AND ORDER

SHERIDAN, U.S.D.J.

This matter is before the Court on the Direct Purchaser Class Plaintiffs' motion for leave to amend the consolidated class action complaint (ECF No. 435) and a motion to dismiss all Direct Purchaser Complaints brought by Pfizer, Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Co., and Warner-Lambert Company, LLC. (ECF No. 246).

INTRODUCTION

This matter arises out of Defendant Pfizer's[1] sale of a pharmaceutical product under the brand name Lipitor, and out of the sale by Ranbaxy[2] of a generic version of Lipitor. The Judicial Panel on Multidistrict Litigation transferred several related actions to this Court for coordinated

[1] This opinion refers to four Defendants collectively or alternatively as "Pfizer": Pfizer Inc., Pfizer Manufacturing Ireland, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC. Pfizer Inc. is a Delaware corporation that sold branded Lipitor. Pfizer Manufacturing Ireland ("Pfizer Ireland"), formerly known as Pfizer Ireland Pharmaceuticals, formerly known as Warner Lambert Export, Ltd., is a partnership organized and existing under the laws of Ireland, and is a wholly-owned indirect subsidiary of Pfizer, Inc; Pfizer Ireland was the exclusive licensee of the '995 patent, which is the patent at issue in this litigation. Warner-Lambert Company is a corporation formerly organized under Delaware law which co-promoted Lipitor with Pfizer and later became a wholly-owned subsidiary of Pfizer by merger in 2000; in 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC.

[2] This opinion refers to Defendants Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., and Ranbaxy Laboratories, Ltd, collectively or alternatively as "Ranbaxy."

and consolidated pretrial proceedings, pursuant to 28 U.S.C. § 1407. Presently pending before the Court are several motions to dismiss the Plaintiffs' various Complaints. This opinion addresses two motions: the Motion to Dismiss the Direct Purchaser Plaintiffs'[3] Claims (Dkt. No. 246) filed by Pfizer pursuant to Fed. R. Civ. P. 12(b)(6), and the Motion for Leave to Amend the Consolidated Class Action Complaint (Dkt. Entry No. 435) filed by the Direct Purchaser Class Plaintiffs. The Court has considered the briefs of the parties, and oral argument held on July 24, 2013.

BACKGROUND

On motions to dismiss, the Court accepts as true the plaintiff's material allegations and construes them in the light most favorable to the plaintiff. *Baldwin v. Univ. of Pittsburgh Med. Ctr.*, 636 F.3d 69, 73-4 (3d Cir. 2011) (citing *Alston v. Countrywide Fin. Corp.*, 585 F.3d 753, 758 (3d Cir. 2009)). A court may also properly look at public records, including judicial proceedings, the relevant patents and the patents' prosecution histories. *See, e.g., Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d. 244, 256 n.5 (3d Cir. 2006) (citing *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999)); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d

[3] At the time the motion to dismiss was filed, three groups of Direct Purchaser Plaintiffs asserted claims in three operative complaints: (1) "Direct Class Plaintiffs": a purported class of direct purchasers identified in Consolidated Amended Class Action Complaint and Jury Demand, No. 3:12-cv-02389-PGS-DEA (Sept. 10, 2012) ("Compl."), (2) "Opt-Out *Walgreen* Plaintiffs": identified in Complaint and Demand for Jury Trial, *Walgreen Co. et al. v. Pfizer Inc. et al.*, No. 3:12-cv-04115-PGS-DEA (July 5, 2012) ("*Walgreen* Compl."); and (3) "Opt-Out *Meijer* Plaintiffs": identified in Complaint and Demand for Jury Trial, *Meijer, Inc. et al. v. Pfizer Inc. et al.*, No. 3:12-cv-04537-PGS-DEA (July 19, 2012) ("*Meijer* Compl."). While the motion was pending, an additional group of Direct Purchasers brought suit, and stipulated with Defendants that they would be subject to the decision on this pending motion. *See Rite Aid Corp. et al. v. Pfizer Inc. et al.*, No. 3:12-cv-07561-PGS-DEA (Dkt. Nos. 1 & 9). The facts alleged in all of the Complaints are substantially similar; this decision primarily refers to the Direct Class Plaintiffs' Complaint, although the Court has reviewed and considered all of them.

Cir. 1993). Thus, the following facts are taken from the various Direct Purchaser Complaints and from related public records.

This matter arises from actions brought by purchasers of a pharmaceutical product sold by Pfizer under the brand name Lipitor. Plaintiffs assert that Pfizer violated federal antitrust laws by using patents for or related to Lipitor to block generic competition for the product, and by paying Ranbaxy to settle infringement litigation and stay off the market until an agreed-upon entry date.

Lipitor belongs to a class of drugs called statins, which lower cholesterol by inhibiting a liver enzyme called 3-hydroxy 3-methylglutrayl-coenzyme A reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate of the metabolic production of cholesterol; inhibiting HMG-CoA reductase inhibits the production of cholesterol. High cholesterol is thought to be associated with coronary heart disease and atherosclerosis. The active ingredient in Lipitor is called atorvastatin calcium.

Pfizer has obtained the following seven patents covering different aspects of the Lipitor product: U.S. Patent No. 4,681,893 (the "'893 patent"); U.S. Patent No. 5,273,995 (the "'995 patent," reissued in part as U.S. Reissue Patent No. 40,667 (the "RE '667 patent'")); U.S. Patent No. 6,126,971 (the "'971 patent"); U.S. Patent No. 5,686,104 (the "'104 patent"); U.S. Patent No. 6,087,511 (the "'511 patent"); U.S. Patent No. 6,274,740 (the "'740 patent"); and U.S. Patent No. 5,969,156 (the "'156 patent"). *See, e.g.*, Compl. ¶¶ 3, 7-8, 88-89, 179-80, 186-87, 193-95, 323, 326.

Plaintiffs' claims are largely based on allegations concerning the prosecution history of one particular Lipitor Patent – the '995 patent – as well as its relationship to the '893 patent. Compl. ¶¶ 197-281; *Walgreen* Compl. ¶¶ 160-215; *Meijer* Compl. ¶¶ 156-211. The prosecution

of the '995 patent was preceded by the issuance of the '893 patent – the original Lipitor patent – to Pfizer in 1987. Compl. ¶ 70. Plaintiffs' claims involve an allegation that Pfizer fraudulently obtained the '995 patent after the issuance of the '893 patent by avoiding the prior art contained in the '893 patent.

The '995 patent issued on December 28, 1993. *Id.* ¶ 159. Three years later, on December 17, 1996, the FDA approved atorvastatin calcium – "Lipitor" – for the treatment of hypercholesterolemia and mixed dislipidemia. *Id.* ¶ 178. Pfizer listed both the '893 and '995 patents and three other patents (the '971 and '104 patents, covering certain formulations of atorvastatin calcium, and the '156 patent, for its crystalline form) in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book").[4] *Id.* ¶¶ 179, 192-196. Pfizer also held two patents claiming the process for making Lipitor (the '511 and '740 patents). *Id.* ¶ 195.

The '893 patent expired on March 24, 2010. The '995 patent expired on June 28, 2011. *Id.* Compl. ¶ 180. The remaining patents listed in the Orange Book have not yet expired. Compl. ¶ 322.

[4] The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399 (2006), requires a company seeking to market a new drug to file information for any patents covering the drug for which a claim for infringement could reasonably be asserted, which the FDA lists in the Orange Book. Under Hatch-Waxman, manufacturers seeking to market a generic form of an innovator drug before the last expiring Orange Book-listed patent must file a "Paragraph IV Certification" with its ANDA, certifying that its product will not infringe any listed patent and/or that the patent is invalid or unenforceable. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This constitutes an artificial act of infringement, after which the innovator has 45 days to sue, which lawsuit would trigger a 30-month stay of final FDA approval of the ANDA. See id. § 355(j)(5)(B). This allows the generic manufacturer to litigate patent validity and infringement to avoid facing an "at risk" product launch and exposure to substantial damages. The first generic to file an ANDA containing a Paragraph IV Certification is eligible for 180 days of generic marketing exclusivity, during which the FDA may not approve any later-filed ANDAs. See id. § 355(j)(5)(B)(iv).

A. Scientific Background

Isomers are chemical compounds that have the same molecular formula (*i.e.*, the same type and number of atoms), but different structural formulas (*i.e.*, different arrangements of those atoms in space). *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495, 502 (D.Del. 2005), *aff'd in part*, 457 F.3d 1284 (Fed. Cir. 2006). Enantiomers are isomers that are mirror images of each other with respect to how their atoms are arranged in space.[5] The two enantiomers in any given enantiomeric pair can be distinguished from one another, and the percentage of each particular enantiomer in a mixture can be ascertained. A mixture with equal amounts of two opposite enantiomers present is called a racemic mixture or racemate.

Pairs of enantiomers share many chemical and physical properties, such as identical melting points, solubility, and colors. However, other properties, such as biological properties, may differ. Enzymes, including HMG-CoA reductase, typically display a preference for interacting with one enantiomer over the other. It is common for one enantiomer (the "active" enantiomer) of an enantiomeric pair to have all or most of the biological activity when interacting with an enzyme, while the other enantiomer (the "inactive" enantiomer) has little or no biological activity.

The active ingredient in Lipitor is atorvastatin calcium. Compl. ¶ 178. Atorvastatin is the active enantiomer in the compound, referred to as the "r-trans" enantiomer. Its corresponding inactive enantiomer is referred to as the "s-trans" enantiomer. Because of the structural makeup of atorvastatin, these are two of its four possible enantiomers. Atorvastatin calcium is the particular salt form of the active enantiomer used in Lipitor. *Id.*

[5] The Complaint provides by way of an analogy and illustration the image of a person's left hand and right hand, which are also non-superimposable mirror images of each other.

B. Prosecution of the '995 Patent

Pfizer filed a patent application in 1986 for a large group of compounds and pharmaceutical compositions useful in lowering cholesterol. This application led to the issuance of the '893 patent on July 21, 1987. Complaint ¶ 88. Pfizer claimed that the disclosed compounds were useful to lower cholesterol "by virtue of their ability to inhibit the biosynthesis of cholesterol through inhibition" of the HMG-CoA reductase enzyme. The class of compounds covered by the '893 patent is referred to therein as Structural Formula I. Included among the many compounds within the Structural Formula I family was the racemic compound comprised of atorvastatin and its corresponding inactive enantiomer and "pharmaceutically acceptable salt[s]" thereof. *Id.* ¶¶76-77, 87, 89, 184.

Exactly two years after issuance of the '893 patent, on July 21, 1989, Pfizer submitted a patent application seeking additional patent protection for just the isolated active enantiomer of atorvastatin, which as stated above is one of the compounds disclosed by the '893 patent. The new patent application claimed atorvastatin calcium, *i.e.*, the active R-trans isomer of atorvastatin in calcium salt form – which is the active ingredient in Lipitor. *Id.* ¶¶ 110-11. The specification disclosed that the R-trans isomer displays "unexpected and surprising inhibition of cholesterol biosynthesis." *Id.* ¶ 110.

Plaintiffs allege that this patent application was a direct result of prodding by senior management at Pfizer. After the '893 patent issued, Pfizer internally designated atorvastatin as a "lead compound" for further investigation. *Id.* ¶ 90. Shortly thereafter, senior management at Pfizer asked Roth, the '893 patent inventor, if there was anything about the active enantiomer that would entitle it to an additional period of patent protection. *Id.* ¶ 92-93. Having worked with atorvastatin for years, Roth wasn't aware of any surprising characteristics which would

warrant further patent protection. *Id.* So Don Maxwell, the vice president of discovery research, told Roth to go through the old lab books to see if there was some data that showed something surprising. Roth was instructed to provide any surprising data to Pfizer's patent attorney. *Id.*

Plaintiffs claim that in developing Lipitor, Pfizer used several tests[6] to assess and compare the inherent differences among the compounds that would eventually be covered by the '893 patent. The tests measured the ability of the compounds to decrease the production of cholesterol. *Id.* ¶¶ 112, n.9, 127, 130. Plaintiffs claim that the tests, as well as internal Pfizer research memos confirmed that the R-trans enantiomer was about twice as active as the racemate (*i.e.*, the compound with equal parts s-trans and r-trans enantiomers). *Id.* ¶¶ 114, 123, 125, 127, 129, 130, 132, 167. Plaintiffs claim that this was a result that was expected both based on the state of the knowledge in the field, as well as by Pfizer's own research in studying statins. Plaintiffs allege that despite what the research showed, during the prosecution of that patent application Pfizer represented on at least three different occasions that atorvastatin had unexpected properties. *Id.* ¶¶ 110-111, 143-145, 154-155. Pfizer is alleged to have falsely claimed that activity of the enantiomer was "surprising" and "unexpected," and quantitatively that it was at least ten times more active than the racemate. To support these assertions, Pfizer allegedly submitted only a sub-set of the most favorable, but allegedly flawed, testing data and internal research.

The patent specification twice stated that Pfizer "unexpectedly found" that the active enantiomer "provides surprising inhibition" of cholesterol. *Id.* ¶110 (quoting specification as saying "[i]t is now unexpectedly found that the enantiomer . . . provides surprising inhibition of

[6] The Complaints list the in vitro COR and CSI assays and the in vivo AICS screen as the primary tests. *Id.* ¶¶ 127, 130.

the biosynthesis of cholesterol," and "an ordinarily skilled artisan may not predict the unexpected and surprising inhibition of cholesterol biosynthesis of the present invention in view of [prior] disclosures"). The specification also presented a short table (the "CSI table") reporting data showing the active enantiomer (denoted "[R-(R*R*)] isomer") was ten-times more active than the racemate in inhibiting the synthesis of cholesterol. *Id.*

However, Plaintiffs allege that the CSI table "was both affirmatively false and intentionally presented in a misleading manner." *Id.* ¶ 114. The CSI table falsely represents the data Pfizer obtained through its tests. *Id.* ¶¶ 114-124. The very fact that the CSI table does not disclose certain relevant data, or the source of the data that was disclosed, would have misled the patent examiner into concluding that Pfizer had confirmed the data by a number of repeat assays and that the chart fairly depicted all appropriate, relevant data. *Id.* ¶ 115. However, Plaintiffs allege that in fact the table actually contained only limited data "cherry-picked" from multiple flawed tests conducted over several years using different formulations of varying atorvastatin salts. *Id.* ¶ 116. For example, the data for the active and inactive enantiomer were taken from a single run of the same experiment. *Id.* ¶ 117. In contrast, the data collected for the racemate is an "average" of five separate runs. *Id.* Plaintiffs allege that such "averaging" is not standard protocol in the field. Also in contravention of established protocol in the field, Pfizer left out values from at least ten test runs when it reported an "average" for the racemate. Complaint ¶121, Fig. 7. Figure 7 in the Complaint is a chart showing the source of the data presented in the CSI Table. If the results of certain test runs had been included in the calculation rather than excluded, there would only have been a twofold increase and no unexpected or surprising result. Likewise if the results of certain included test runs had been omitted, results would show only a twofold increase. *Id.* ¶ 122.

During the '995 patent prosecution, Pfizer conceded early on that atorvastatin was *prima facie* obvious in that any person skilled in the art would have known that the racemic compounds disclosed in the '893 patent could be "split" into their individual "right" and "left" enantiomers, and that one of those enantiomers would be about twice as active as the racemate. *Id.* ¶¶ 102-104, 140-142. Pfizer argued that the *prima facie* obvious objection could be overcome because the invention – atorvastatin – possessed a surprising quality. Roth submitted a declaration claiming that the active enantiomer possessed "surprising and unexpected activity" and that the data "indicated activity *at least ten-fold more* than that of the racemate." *Id.* ¶¶ 143-144.

The data on which Roth relied in support of the statements in his declaration derived from the results of a CSI assay comparing the inhibition activity of cholesterol synthesis of various compounds. *Id.* ¶¶ 112, 139. Pfizer and Roth later identified the source of the particular CSI assay relied upon in the Roth Declaration as the CSI 118 test. *Id.* ¶ 145. CSI 118 was the only test that compared the active enantiomer, the inactive enantiomer, and the racemate in the same salt form in a head-to-head test. Plaintiffs claim that CSI 118 was "deeply flawed": Pfizer's lab notebooks reported that the compounds did not dissolve completely before the test was conducted; Pfizer did not determine the concentrations of its test solutions before conducting the test; and Pfizer never re-ran the screen to confirm its outcome. *Id.* ¶¶ 146-148. CSI 118 reported activity of the active enantiomer in calcium salt form that was twenty-five times greater than the reported activity of the active enantiomer in sodium salt form. *Id.* ¶ 149. Plaintiffs allege that this difference was an indicator that the screen's outcome was wrong. *Id.* Despite knowledge of the allegedly flawed nature of CSI 118, Pfizer and Roth knowingly used the CSI 118 data to support their claim that the active enantiomer has ten times greater inhibition of cholesterol synthesis than the racemate, and claimed this as a "surprising level of activity"

which, in turn, supported patentability. *Id.* ¶¶ 151-152.

The PTO Examiner initially rejected all clams in the application for the '995 patent as anticipated by, or, in other words, not novel in view of, the '893 patent. Compl. ¶ 153. Pfizer appealed and argued that the patent examiner's objections went to obviousness and Pfizer had already submitted evidence to overcome the objection. Pfizer again claimed the active enantiomer was "surprisingly active" and stated three times that it had "greater than 10 times" the activity of the racemate. *Id.* ¶ 154 (quoting appeal brief as saying "[t]he R isomer as claimed appears to be . . . more than *10 times more active* than the mixture," "the present invention describes the particular R isomer *which is found to have greater than 10 times the activity* of the . . . racemic mixture," "the compound of the present invention… has greater than 10 times the activity than the reference compound," and "the R isomer is the most desired and the most surprisingly active isomer of the two possibilities if one is to select from the trans compounds").

The Board reversed, overturning the anticipation rejection and holding that the '893 patent only described the trans racemate, which contained the R-trans and the S-trans isomer in a mixture, but did not disclose which isomer (S or R) was preferred, nor did it explain how one skilled in the art might make a pure optical isomer separately. *Ex parte Roth*, No. 92-2941, at 3-4 (B.P.A.I. Oct. 19, 1993) ("Novelty of an optically pure isomer is not negated by the prior art disclosure of its racemate."). The Board suggested that the Examiner consider a rejection for obviousness because the product was known to be racemic and methods of separating the racemic mixture into its enantiomers were known to those skilled in the art. *Id.* ¶ 157-158. But no such rejection occurred, and the '995 patent issued on December 28, 1993. Compl. ¶ 159. Plaintiffs allege that the patent could not have issued unless the examiner found a basis for overcoming an obviousness rejection and that the only allegedly surprising or unexpected

characteristic Pfizer had identified that could possibly overcome an obviousness rejection was the alleged "unexpected" ten-fold difference in activity between the active enantiomer and the racemate. Compl. ¶¶ 160-163.

C. '995 Patent Infringement Litigation

1. U.S. Litigation

On August 19, 2002, Ranbaxy filed the first Abbreviated New Drug Application ("ANDA") to market generic Lipitor. Complaint ¶ 197. Other generic companies followed with ANDAs of their own beginning in 2005. As the first generic to file, Ranbaxy was entitled to six months as the only generic competitor on the market. *Id.* ¶ 198. Ranbaxy's 180 days would not begin to run until either Ranbaxy began marketing its generic Lipitor or a court determined all Orange Book-listed Lipitor patents to be invalid and/or not infringed, whichever came first. *Id.* ¶198.

In or around February of 2003, Ranbaxy sent two Paragraph IV certifications to Pfizer, asserting that the sale, marketing, or use of Ranbaxy's generic atorvastatin calcium product would not infringe any valid Lipitor patents listed in the Orange Book. *Id.* ¶ 199. In response, Pfizer sued Ranbaxy in the District of Delaware alleging that Ranbaxy's ANDA product would infringe the '893 and '995 patents (but not the other Lipitor patents). *Id.* ¶ 200.[7] Because Pfizer

[7] In total, Pfizer sued eleven generic applicants that filed Lipitor ANDAs containing Paragraph IV Certifications. Compl. ¶¶ 200, 300, 336, 340, 347; *see Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 1:03-cv-00209-JJF, ECF No. 1 (D. Del. Feb. 21, 2003); *Pfizer Inc. v. Cobalt Pharm., Inc.*, No. 1:07-00790-JJF, ECF No. 1 (D. Del. Dec. 6, 2007); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, No. 1:07-cv-00360-JJF, ECF No. 1 (D. Del. June 7, 2007); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, No. 08-237-JJF, ECF No. 1 (D. Del. Apr. 25, 2008); *Pfizer Inc. v. Apotex Inc.*, No. 1:08-cv-07231, ECF No. 1 (N.D. Ill. Dec. 17, 2008); *Pfizer Inc. v. Mylan Inc.*, No. 1:09-cv-00441-LPS, ECF No. 1 (D. Del. June 15, 2009); *Pfizer Inc. v. Kremers Urban, LLC*, No. 1:09-cv-00924-LPS, ECF No. 1 (D. Del. Dec. 3, 2009); *Pfizer Inc. v. Dr. Reddy's Labs. Ltd.*, No. 1:09-cv-00943-LPS, ECF No. 1 (D. Del. Dec. 8, 2009); *Pfizer Inc. v. Actavis Grp. hf.*, No. 1:10-cv-00675-LPS, ECF No. 1 (D. Del. Aug. 11, 2010); *Pfizer Inc. v. Aurobindo Pharma Ltd.*, No. 1:11-cv-00569-LPS, ECF No. 1 (D. Del. June 27, 2011); *Pfizer Inc. v. MSP Singapore Co. LLP*, No. 1:11-cv-00713-LPS, ECF No. 1 (D. Del. Aug. 15, 2011); *Pfizer Inc. v. Macleods Pharm. LTD*, No. 1:11-cv-05662-PKS, ECF No. 1 (S.D.N.Y. Aug. 15, 2011).

filed its complaint within 45 days, it triggered an automatic two-and-a-half year stay of FDA approval of Ranbaxy's ANDA. *Id.* ¶ 198.

From 2003 to 2006, the infringement litigation progressed through discovery, a trial (in 2004), a district court decision (in 2005), and an eventual appeal and decision by the Federal Circuit (in 2006). *Id.* ¶ 201. Pfizer maintained that the patent specification did not represent a claim of ten-fold increase in activity but that the data showed that the active enantiomer had surprising activity. Based on the record then before it, the district court found the '893 and '995 patents valid, enforceable, and infringed. Complaint ¶¶ 208-209; *Pfizer*, 405 F. Supp. 2d at 517, 521. The court also specifically rejected Ranbaxy's claims of inequitable conduct in procuring the '995 patent, claims that are asserted by way of antitrust theories here in this litigation:

> As for the data submission issue, the Court is not persuaded that [Pfizer] manipulated or 'cherry picked' data with deceitful motives to achieve a deceitful result. [Pfizer] had ample data to support the claims it made to the PTO, and it provided the PTO with the data it believed was scientifically sound. The Court is not persuaded that the instances of non-disclosure cited by Ranbaxy are sufficient to demonstrate an intent to deceive the PTO. Pfizer has advanced reasonable and credible grounds for the non-production of certain data that weigh against a conclusion that Pfizer scientists and employees were intentionally deceiving the PTO.

Pfizer, 405 F. Supp. 2d at 525. The court entered judgment in favor of Pfizer and against Ranbaxy on Ranbaxy's counterclaim of inequitable conduct. *Id.* at 525-26.

On November 2, 2006, the Federal Circuit reversed the district court's ruling on the '995 patent on a technicality, determining that claim 6 – the sole claim that Pfizer claimed Ranbaxy's ANDA product infringed – was invalid for, effectively, a scrivener's error. *Pfizer Inc. v. Ranbaxy Labs.*, 457 F.3d 1284, 1291-1292 (Fed. Cir. 2006). The Federal Circuit declined to

address the district court's other determinations regarding the '995 patent, such as the court's determination that there was no inequitable conduct before the PTO. *Id*.

In late 2006, the district court amended its final judgment order to enjoin the effective date of any approval of Ranbaxy's ANDA for generic Lipitor until March 24, 2010 (the expiry of the '893 patent) and to remove from its final judgment order any prohibition of effective FDA approval of Ranbaxy's ANDA based on the '995 patent. *Id.* ¶ 216. The district court's final judgment order, as amended, was sent to the FDA. *Id.*

2. International Litigation

Pfizer also filed several patent infringement lawsuits in other countries involving counterparts to the '995 patent. *Id.* ¶23, n.7. According to the Complaint, the factual record developed in the foreign lawsuits is the basis for many of the allegations of fraud on the PTO in the instant complaints. *Id.* at 23 n.7.[8] The foreign counterparts to the '995 patent were identical to it in all meaningful respects, including the language in the patent specification addressing surprising and unexpected activity and the table showing a tenfold increase in the activity of the active enantiomer as compared to the racemate. Direct Purchaser Plaintiffs allege that these "lawsuits in foreign jurisdictions reveal [Pfizer's] abuses before the PTO . . . [and that] courts in Australia and Canada have concluded that counterparts to the '995 patent were obtained as a result of these material misrepresentations." *See* Compl. ¶ 13. Plaintiffs add that "these decisions post-date a decision to the contrary in the District of Delaware [i.e., Judge Farnam's

[8] "Many of the facts recounted in [Section E of the DP Complaint, which is titled "1989-1993: Warner-Lambert obtains a follow-on enantiomer patent by fraud,"] have come to light during international patent litigation." *Id.* (citing *Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC* (Appeal) (2008 FCAFC 82 (May 28, 2008); *Pfizer Canada Inc. v. Ranbaxy Labs. Ltd*., 2007 FC 91 (January 25, 2007); *Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC*, 2006 FCA 1787 (December 20, 2006); *Pfizer Canada Inc. v. Novopharm Ltd*., 2006 FC 1471 (Dec. 17, 2006).

decision] . . . [and are] based on a more comprehensive factual record and analysis [than Judge Farnam's decision]." *Id.* at 3 n.1.

While the district court in the Ranbaxy litigation was considering its decision, Pfizer sued generic manufacturers Ranbaxy and Novopharm in Canada. *Pfizer Canada Inc. v. Novopharm Ltd*., 2006 FC 1471 (Dec. 7, 2006) (*available at* http://decisions.fct-cf.gc.ca/en/2006/2006fc1471/2006fc1471.html); *Pfizer Canada Inc. v. Ranbaxy Labs. Ltd.*, 2007 FC 91 (January 25, 2007) (available at *www.patenthawk.com/rulings/T-507-05.pdf*). Shortly after the Federal Circuit invalidated the '995 patent, the patent's Canadian counterpart (the '546 patent) was ruled invalid by the Canadian trial court in the Canadian Ranbaxy litigation, due to the falsity of the data purportedly supporting the claim of ten-fold surprising activity. *Pfizer Canada Inc. v. Ranbaxy Labs. Ltd.*, 2007 FC 91 (January 25, 2007), ¶ 124. Even though the Canadian decision was based on the falsity of the data supporting claims in the patent specification, the Canadian court found only that the specification of the Canadian equivalent of the '995 patent did not "correctly and fully" describe the claimed invention, but made no finding that Pfizer committed fraud or otherwise acted with intent to deceive. *Id.*, ¶¶ 83, 123-124. On appeal, the Canadian Federal Court of Appeals unanimously reversed the trial court decision, holding that the specification sufficiently identified the claimed invention, advantages of the invention, and methods for producing the patented compounds. *Pfizer Canada Inc. v. Ranbaxy Labs. Ltd.*, 2008 FCA 108 (March 20, 2008), ¶¶52-64 (available at http://reports.fja.gc.ca/eng/2009/2008fca108.html). The Canadian Federal Court of Appeals concluded that Pfizer's enantiomer patent was fully valid and enforceable. *Id.* at ¶ 84.

Pfizer had also sued Ranbaxy in Australia. On December 20, 2006, the federal court of Australia revoked the Australian counterpart to the '995 patent. *Ranbaxy Australia Pty Ltd. v. Warner-Lambert Comp.*, [2006] FCA 1787 (*available at* http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2006/2006fca1787). The court found that the counterpart to the '995 patent was invalid under the Australian doctrine of "false suggestion," which unlike *Walker Process* fraud, contains no requirement of a deliberate intent by the patentee to deceive the patent office. *Ranbaxy Australia Pty Ltd. v. Warner-Lambert Comp.*, [2006] FCA 1787 (available at http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2006/2006fca1787). An Australian appellate court upheld the decision. *Ranbaxy Australia Pty Ltd. v. Warner Lambert Corp. LLC*, [2008] FCAFC 82 (May 28, 2008) (available at http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2008/2008fcafc0082). While, the Australian appellate court specifically said that it "did not go so far as to conclude" that Pfizer intended to deceive the Australian patent office, the appellate court did uphold the trial court's findings which included that, essentially, the scientific data available to Pfizer at the time of the patent application did not support a claim of surprising difference in activity between the active enantiomer and the racemate, and that there were no reasonable grounds for Pfizer to make many representations it had made in the specification. *Id.* ¶ 139; *see Ranbaxy Australia Pty Ltd. v. Warner-Lambert Comp.*, [2006] FCA 1787, ¶ 276.

D. '995 Patent Reissue Proceedings.

In January of 2007, Pfizer initiated reexamination proceedings by filing Reissue Patent Application No. 11/653,830 ("the reissue application") to rectify the error identified by the Federal Circuit in claim 6 of the '995 patent. Compl. ¶¶ 219-20. During reissue proceedings,

Ranbaxy filed multiple protests to prevent reissue of the '995 patent, asserting arguments it raised in the Delaware litigation which were never addressed on appeal, including that the '995 patent was anticipated by and obvious in view of the '893 patent, as well as that the '995 patent had been procured through deception. Compl. ¶¶ 224, 237; *see also* Ranbaxy Mem. In Supp. Of Ranbaxy Defs.' Motion To Dismiss Direct Purchaser Pls.' Compl., Master Docket No. 3:12-cv-2389 (PGS/DEA) (Dkt. Entry No. 244), at 7-8, 11-12 (Nov. 16, 2012) ("Ranbaxy Mem."). Pfizer disclosed to the PTO relevant materials from the '995 patent litigation as well as from the patent proceedings in Australia and Canada involving foreign counterparts of the '995 patent. *See* Supplemental Commc'n, at 21 (June 7, 2007), Declaration of Brendan G. Woodard, dated November 16, 2012 (Dkt. Entry No. 246-2) ("Woodard Decl."), Ex. 1 (description of each patent).Woodard Decl., Ex. 7; Second Info. Disclosure Statement, at 2-3 (June 7, 2007), *id.*, Ex. 8. Pfizer expressly informed the PTO that the Australian decision addressed the issue of whether the foreign counterpart to the '995 patent "was obtained by false suggestion or misrepresentation" under Australian law. Supplemental Commc'n, at 29.

In its application, Pfizer stated that it was "not at this point in the reissue rely[ing] for patentability on any comparisons based on CSI," and explained that it had "learned of significant errors in the COR results which neither Pfizer nor the parties adverse to it had discovered before." Compl. ¶ 223. Pfizer did not submit "corrected biological data" because, it explained, it was "not currently relying on the biological data for patentability" (which would include CSI, COR, and AICS data). *Id.* ¶ 226. Instead of relying on the biological data to show a surprising level of activity, Pfizer relied upon evidence of Lipitor's commercial success as objective indicia of non-obviousness supporting patentability. Compl. ¶¶ 228, 233.

In April 2008, Pfizer and Ranbaxy entered into a settlement agreement (discussed in more detail below), under which the Plaintiffs allege that Ranbaxy either expressly or impliedly agreed to discontinue its protests to the pending reissuance proceedings. *Id.* ¶ 238. The PTO then reissued the '995 patent as the '667 reissue on April 6, 2009, despite Pfizer's disavowal of reliance on biological data and its disclosure of findings in the Australian and Canadian proceedings. *Id.* ¶ 241. The PTO based its ruling to grant the re-issuance of the '995 patent on Pfizer's arguments that the commercial success of Lipitor shows that the '995 patent could not have been obvious. *Id.* Because the PTO determined reissue based on commercial success, it did not look at the biological data during the reissuance and thus it never explicitly considered or decided whether Pfizer's claims about the active enantiomer's activity were true.

E. Pfizer's FDA Petition

As the 30-month stay of approval triggered by Pfizer's U.S. suit against Ranbaxy neared its end in August 2005, Pfizer filed a petition with the FDA, which Direct Purchaser Plaintiffs allege was a sham filed in the hopes of further delaying the approval of Ranbaxy's atorvastatin calcium product. *Id.* ¶¶244-246. Any person can submit an unsolicited petition on any topic to FDA. *AstraZeneca Pharmaceuticals, LP v. FDA*, 850 F. Supp.2d 230, 235 (D.D.C. 2012) (citing 21 CFR §§ 10.25(a), 10.30); *In re Prograf Antitrust Litig.*, 2012 WL 293850, No. 11-md-2242, *2 (D. Mass. Feb. 1, 2012). Petitions constitute a formal demand on FDA to take, or refrain from taking, a particular action, and require a response. *Biovail Corp. v. FDA*, 448 F. Supp.2d 154, 159-60 (D.D.C. 2006) (FDA has 180 days from receipt of petition to approve, reject or issue tentative response indicating why decision cannot be made); *see also* 21 CFR 10.30(e)(2)(i)-(iii). In its petition, Pfizer urged the FDA to view ANDA applicants for generic Lipitor using amorphous atorvastatin calcium with "considerable skepticism," arguing that amorphous forms

of atorvastatin "may be susceptible to higher levels of impurities than are found in Lipitor and that may degrade more quickly and thus have inferior stability compared to Lipitor." *Id.* ¶ 268.

Salts of atorvastatin are, like salts of many compounds, polymorphic, meaning they can take either amorphous or crystalline forms. Complaint ¶ 249. The FDA generally views different polymorphs of a drug substance as the same active ingredient when evaluating ANDAs. *Id.* ¶¶ 250-258. The FDA reinforced this position over the years, and plaintiffs allege that Pfizer was aware of this. Complaint ¶¶ 251-258, 260, 261. In addition, plaintiffs allege that Pfizer knew from its own research that the amorphous version of atorvastatin presented fewer concerns for patient safety than did the crystalline form. *Id.* ¶ 266. Eventually, on the very first date on which Ranbaxy could enter the market, the FDA rejected Pfizer's petition, citing its long-standing policies for handling polymorphs. *Id.* ¶¶ 277-281. However, the version of generic Lipitor for which Ranbaxy obtained final approval is the crystalline form of atorvastatin calcium covered by the '156 patent *See* Ranbaxy Atorvastatin Label, at 10 (Rev.04/2012), Woodard Decl., Ex. 16.

F. The Settlement Agreement With Ranbaxy

Finally, Plaintiffs allege that Pfizer filed baseless infringement litigation over process patents, which failed to meet basic Article III requirements, as a vehicle to effectuate an anticompetitive agreement with Ranbaxy behind the pretext of a litigation settlement. On March 24, 2008, Pfizer sued Ranbaxy alleging infringement of the '740 and '511 patents, which covered a particular process for making amorphous atorvastatin calcium that begins with the crystalline form. *Id.* ¶¶ 298-300. Plaintiffs allege that Pfizer's purpose in entering into the lawsuit was not to win this new lawsuit, but to create a pretext for an anticompetitive agreement it would label as a "settlement" of litigation.

At the time of suit in March 2008, Ranbaxy was already enjoined from entering the market until March 24, 2010 when the '893 patent was set to expire, due to Judge Farnan's decision. *Id.* ¶¶ 216, 301. Because the '740 and '511 patents are process patents, which by definition cannot be listed in the Orange Book, in order to keep Ranbaxy off the market past March 24, 2010, Pfizer would need to satisfy the traditional grounds for obtaining a declaratory judgment under patent law – demonstrating the existence of a justiciable case or controversy, and obtaining an injunction including proving a likelihood of success on the merits. Compl. ¶ 295. Plaintiffs allege that Pfizer could not meet this standard, Pfizer knew it could not meet the standard – Judge Farnam had previously ruled that the mere threat of litigation over the process patents could not support jurisdiction prior to actual generic market entry –, and that in fact the Complaint contained only conclusory allegations concerning infringement. *Id.* ¶¶ 209, 302-303. Ranbaxy moved to dismiss, pointing out that "any harm to Pfizer from alleged infringement of the [process patents is] much less imminent now than [when Judge Farnam] found no imminent threat of harm or injury." *Id.* ¶ 301.

On June 17, 2008, before the court could rule on Ranbaxy's motion to dismiss, Pfizer and Ranbaxy entered into a "settlement" agreement – what Plaintiffs call the "Delay Agreement." *Id.* ¶¶ 311, 312, 320-322. The agreement was submitted to the Federal Trade Commission and Department of Justice pursuant to 21 U.S.C. § 355 (2010). Plaintiffs allege that the agreement constituted a reverse payment agreement, and that as a result of it, the direct purchasers and members of the class were deprived of the price-reducing benefits of timely generic competition. *Id.* ¶¶ 286-96, 312-22, 324, 327.

The agreement settled global patent proceedings regarding Lipitor including all U.S. patent litigation (although at that time, the only pending litigation concerning United States sales

of Lipitor was the process patent action being settled). Compl. ¶¶ 312, 316; Ranbaxy Press Release (June 18, 2008), Woodard Decl., Ex. 9; Pfizer Press Release (Form 8-K) (June 18, 2008), *id.*, Ex. 10. Ranbaxy agreed not to compete with Pfizer, to keep its generic product off the market until November 30, 2011, not to waive or relinquish its first-to-file 180 day marketing exclusivity, and to drop its challenge to the '995 reissuance proceeding. *Id.* ¶¶238, 315-316, 324, 325. Plaintiffs allege that in return, Pfizer agreed to forgive outstanding money judgments Pfizer had obtained against Ranbaxy (unrelated to generic Lipitor) and to give Ranbaxy the right to market generic Lipitor in at least eleven international markets. Complaint ¶316, 324. The Settlement also resolved U.S. litigation between Pfizer and Ranbaxy pertaining to Ranbaxy's generic Caduet, Pfizer's combination of atorvastatin and amlodipine. Woodard Decl., Ex. 9. Pfizer also agreed to dismiss its action in the District of New Jersey regarding Ranbaxy's launch at risk of a generic version of Pfizer's product Accupril. Compl. ¶¶ 316-17; Woodard Decl., Exs. 9-10.

Plaintiffs allege that if it were not for the settlement, Ranbaxy's generic Lipitor product could have entered the market as early as March 24, 2010, when the '893 patent expired. *Id.* ¶ 298; *see* ¶¶ 316-317. Plaintiffs also allege that the settlement agreement's provision whereby Ranbaxy agreed not to waive its 180 day marketing exclusivity effectively blocked any other ANDA filer from entering the market, until six months after the agreed upon entry date, which was November 30, 2011. *See generally* Complaint ¶¶330-350. Other generic competitors could only come to market by obtaining a judgment of invalidity or non-infringement with respect to all the patents listed in the Orange Book (thus triggering Ranbaxy's 180 days), or by convincing the FDA to revoke Ranbaxy's 180 day exclusivity. *Id.* ¶¶ 330-335. Plaintiffs allege that Pfizer and Ranbaxy were able to delay other generics from the market (such as Apotex, Mylan, and

Actavis) by delaying other litigation efforts, avoiding court battles over some patents, and settling cases prior to any judgment on the merits. *See id.* ¶ 335.

After the settlement, subsequent ANDA filers could still have triggered Ranbaxy's 180-day exclusivity period and marketed generic Lipitor "by obtaining court decisions that all of the unexpired patents Pfizer listed in the FDA 'Orange Book' claiming Lipitor were invalid or not infringed." Compl. ¶ 331. Eleven subsequent ANDA filers challenged the Lipitor patents and all filers subsequently settled. *See, e.g.*, Compl. ¶ 336-50; End-Payors' Compl. ¶¶ 333-47.

G. Approval of Ranbaxy's ANDA

Years after Pfizer and Ranbaxy entered into the settlement agreement, Ranbaxy's ANDA was approved by the FDA on November 30, 2011, the day Ranbaxy's license to the unexpired Lipitor patents began. *See* FDA Approval Letter of Ranbaxy ANDA (Nov. 30, 2011), Woodard Decl., Ex. 15. The 30-month stay of FDA approval of Ranbaxy's ANDA had expired back in August 2005. Compl. ¶¶ 244-45.

In 2008, the FDA accused Ranbaxy of data integrity and good manufacturing practices issues at its Paonta Sahib, Batamandi and Dewas, India facilities. Consent Decree, *U.S. v. Ranbaxy Laboratories, Ltd.*, No. 1:12-cv-00250-JFM, ECF No. 2, ¶¶ III, IX (D. Md. Jan. 25, 2012), Woodard Decl., Ex. 12. In September 2008, the FDA then banned Ranbaxy from importing generic drugs due to compliance issues in the Paonta Sahib and Dewas facilities, and in February 2009, the FDA halted review of all drug applications from the Paonta Sahib site, accusing Ranbaxy of falsifying data and test results. *Id.* ¶¶ XVII, XXVII, XLIX (LI.); Letters from FDA to Ranbaxy, dated September 16, 2008, Woodard Decl. Ex. 13. Ranbaxy's ANDA identified Paonta Sahib as a manufacturing site for atorvastatin. *See* Answer, *Mylan Pharm., Inc. v. FDA*, No. 1:11-cv-00566, ECF No. 14, ¶¶ 46-47 (D.D.C. Mar. 30, 2011), Woodard Decl., Ex.

14. The Complaint alleges on information and belief that despite this apparent obstacle to FDA approval, in 2009 Ranbaxy had moved its manufacturing site for atorvastatin from India to Ranbaxy‘s wholly-owned subsidiary, Ohm Laboratories in New Jersey, and that when Ranbaxy ultimately received FDA approval to market generic Lipitor in the U.S. it was from the New Jersey facility. Compl. ¶ 363. The Complaint alleges that Ranbaxy would have moved forward with the site transfer even earlier absent Ranbaxy’s anticompetitive conduct.

H. The Instant Complaints

To summarize, the Direct Purchaser Complaints allege that Pfizer obtained the follow-on enantiomer patent – the '995 patent – by fraud in order to extend Lipitor's patent protection 15 months beyond the expiration date of the '893 patent. Pfizer did so by fabricating lab results, falsely claiming that the atorvastatin enantiomer “surprisingly” inhibited cholesterol ten times more powerfully than its related racemic mixture. Plaintiffs allege that after fraudulently procuring the '995 patent, Pfizer listed it in the Orange Book with the ’893 patent that already covered Lipitor to impose regulatory hurdles and enable it to later bring litigation to stall generic competition, even though Pfizer allegedly knew the patent could not reasonably be asserted against generic competitors. In addition, through its citizen petition, Pfizer urged imposition of additional and unwarranted FDA review of amorphous forms of atorvastatin produced by generics even though Pfizer knew there was no reason to justify the heightened scrutiny. Plaintiffs also allege that Pfizer's infringement litigation over the ‘740 and ‘511 process patents, was baseless, and was only filed to provide a vehicle for what Plaintiffs allege is an anticompetitive agreement. Plaintiffs allege that the agreement was a “reverse payment” arrangement in which Pfizer paid Ranbaxy to stay off the market until the end of November 2011, and under which Ranbaxy agreed to maintain its 180 day marketing exclusivity. Plaintiffs

allege that the agreement, combined with Pfizer's efforts to avoid judicial determinations on its Lipitor patents, delayed other generic competitors from entering the market for atorvastatin calcium and deprived Plaintiffs of the benefits of competition.

The direct purchasers Plaintiffs allege that all of the above amounted to Pfizer, first acting alone and later with Ranbaxy, engaging in a comprehensive anticompetitive scheme to delay generic competition in the market for Lipitor. The complaint asserts violation of sections 1 & 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2. Plaintiffs allege that but for the defendants' conduct, Ranbaxy would have entered the market sooner, as early as March 24, 2010, and Plaintiffs allege that as a direct result, direct purchasers suffered antitrust injury by paying substantial overcharges on their purchases of atorvastatin calcium.

The Direct Purchaser Class Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a) and (b)(3), as representatives of a Direct Purchaser Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for or will pay for Lipitor and/or generic equivalents directly from any of the defendants at any time during the period March 24, 2010 through and until the anticompetitive effects of defendants' conduct cease (the "Class Period").

Compl. ¶ 399.

I. The Motions to Amend

On August 7, 2013, after briefing, supplemental briefing, and oral argument on the motions to dismiss, Direct Purchaser Class Plaintiffs filed a Motion for Leave to Amend the Consolidated Amended Class Action Complaint (Dkt. Entry No. 435). The Direct Purchaser Class Plaintiffs seek to amend their Complaint to clarify their reverse payment allegations in light of the recent Supreme Court decision in *FTC v. Actavis, Inc.* *See* 133 S. Ct. 2223 (2013).

Other Direct Purchaser Plaintiffs have also filed notices requesting leave to amend their complaints should the Court grant the motions to dismiss their complaints (Dkt. Entry Nos. 439, 440).

DISCUSSON

I. Legal Standard on Motion to Dismiss

To give a defendant fair notice, and permit early dismissal if the complained-of conduct does not provide adequate grounds for the cause of action alleged, a complaint must allege, in more than legal boilerplate, those facts about the defendant's conduct giving rise to liability. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007); Fed.R.Civ.P. 8(a) and 11(b)(3). These factual allegations must present a plausible basis for relief (i.e., something more than the mere possibility of legal misconduct, and more than mere conclusory allegations). *See Ashcroft v. Iqbal*, 556 U.S. 662, 681, 129 S. Ct. 1937, 1951, 173 L. Ed. 2d 868 (2009).

"In its review of a motion to dismiss pursuant to Rule 12(b)(6), the Court must "accept all factual allegations as true and construe the complaint in the light most favorable to the plaintiff." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). "In deciding motions to dismiss pursuant to Rule 12(b)(6), courts generally consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *Lum v. Bank of Am.*, 361 F.3d 217, 222 n.3 (3d Cir. 2004).

II. Choice of Law

In Defendants' opening briefs, they argued that Federal Circuit law applies to the antitrust analysis the Court would undertake. At the time the Defendants made that argument, its primary

import was thought to be the resulting decision's effect on Plaintiffs' reverse payment theory, because of the differing standards applied to such claims in the Third and Federal Circuits. *Compare In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012) (reverse payments are presumptively anticompetitive) *with In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008) (settlements are not anticompetitive unless they exceed the "scope of the patent"). This split has since been resolved by the Supreme Court. *See FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). Nevertheless, the question of what law to apply remains, even if the impact of its resolution is less clear.

The United States Court of Appeals for the Federal Circuit has "exclusive jurisdiction of an appeal from a final decision of a district court of the United States . . . in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents." 28 U.S.C. § 1295(a)(1). The corollary of that jurisdictional grant is that a "district court must . . . follow Federal Circuit precedent in a case arising under the patent laws." *Foster v. Hallco Mfg. Co., Inc.*, 947 F.2d 469, 475 (Fed. Cir. 1991). A case "aris[es] under the patent laws" if a plaintiff's complaint establishes that "plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988). If a plaintiff presents a claim "supported by alternative theories in the complaint," i.e., theories other than patent law theories, that claim does not depend on patent law and accordingly the Federal Circuit lacks jurisdiction. *Id.* at 810. In other words, an antitrust claim only gives rise to Federal Circuit jurisdiction and only necessitates the application of Federal Circuit law, if "patent law is essential to each of [the] theories" of liability under the antitrust claims alleged in the complaint.

Id.

Here, the DP Complaint alleges, among other things, that Pfizer and Ranbaxy's settlement was a "reverse payment" settlement that gives rise to antitrust liability. A reverse payment theory is independent of patent law. *See Joblove v. Barr Labs., Inc.* (*In re Tamoxifen Citrate Antitrust Litig.*), 466 F.3d 187, 199-200 (2d Cir. 2006). Thus, Plaintiffs can obtain relief on their antitrust claims by resting on their non-patent theories, such as the reverse payment theory, without relying on the arguably patent-related aspects of the alleged scheme, such as the *Walker Process* fraud theory. Plaintiffs' *Walker Process* theory is just that, a theory, and one of several theories of recovery alleged in support of the antitrust claim. This theory of recovery does not make Plaintiffs' antitrust claims dependent on patent law. The presence of an "alternative, non-patent theory compels the conclusion that [Plaintiffs' antitrust claims] do not 'arise under' patent law." *Christianson*, 486 U.S. at 813. Accordingly, Third Circuit, not Federal Circuit law, applies to the antitrust claims before the Court.

III. Section 2 Claims

Under section 2 of the Sherman Act, persons "who . . . monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of . . . trade or commerce," may be subjected to civil liability for their actions. 15 U.S.C. § 2. To state a claim for monopolization, a plaintiff must plead two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Race Tires America, Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir. 2010) (quoting *Eastman Kodak Co. v. Image Tech. Svcs.*, Inc., 504 U.S. 451, 481, 112 S. Ct. 2072, 119 L. Ed. 2d 265 (1992)). Plaintiff's Section 2 claims are based on

several different theories, including Plaintiffs' allegations of *Walker Process* fraud, sham litigation, a sham citizen petition to the FDA, false Orange Book listing, a reverse payment settlement, and an overarching scheme.

A. *Walker Process*

In *Walker Process Equipment Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172, 86 S. Ct. 347, 15 L. Ed. 2d 247 (1965), the Supreme Court specifically addressed monopoly allegations linked to patents that were allegedly procured by fraud. The Court held that proof that a patent holder knowingly and willfully misrepresented facts indicating invalidity to the PTO would deny the patent holder its exemption from the antitrust laws provided by that patent. *Id.* at 176-80. Courts have stated the elements of a *Walker Process* claim as:

> (1) the patent at issue was procured by knowing or willful fraud on the USPTO; (2) the defendant was aware of the fraud when enforcing the patent; (3) there is independent evidence of a clear intent to deceive the examiner; (4) there is unambiguous evidence of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission; and (5) the necessary additional elements of an underlying violation of the antitrust laws are present.

Jersey Asparagus Farms, Inc. v. Rutgers Univ., 803 F. Supp. 2d 295, 306 n.9 (D.N.J. 2011) (quoting *Nobelpharma AB v. Implant Innov., Inc.*, 141 F.3d 1059 (Fed.Cir. 1998)). Hence, in addition to alleging that the patent-holder obtained the patent through an actual fraud perpetrated on the PTO, a Walker Process plaintiff "'must also [allege] the basic elements of an antitrust violation defined by the regional circuit's law. . . .'" *Id.* (quoting *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337,1346-48 (Fed. Cir. 2007).

1. *Walker Process* Standing

Pfizer argues that the Direct Purchaser Plaintiffs have no standing to assert their *Walker*

Process claim, because "courts have generally held that purchasers have no standing to indirectly challenge pharmaceutical patents through antitrust claims based on fraud on the PTO, particularly absent no prior findings that the patents are 'tarnished' by inequitable conduct." Pfizer Mem. at 19-20.[9] Pfizer argues that this Court should refuse purchaser standing in this case – where, Pfizer says, the patents at issue have been affirmatively upheld as valid and enforceable after litigation and reissue proceedings before the PTO – for at least three reasons: (1) granting standing would conflict with the limits on standing to challenge patents established in the Declaratory Judgment Act and the Hatch-Waxman Act, which Plaintiffs argue limit who can attack patents in order to preserve the incentives to innovate, *see* Pfizer Mem. at 20-23; (2) granting standing would "upset the delicate balance between the patent and antitrust laws," which Plaintiffs say would also "disturb[] the incentives for innovation" underlying the patents system, *see id.* at 23 (citing *DDAVP*, 585 F.3d at 688-92); (3) and purchasers' claims are derivative of generic manufacturers' claims, such that purchasers have not "suffer[ed] the sort of 'direct' injury necessary for antitrust standing," *see id.* at 26 (quoting *Kaiser*, 2009 WL 3877513, at * 4).

As a general matter, purchasers of goods or services have standing to assert antitrust overcharge claims under § 4 of the Clayton Act, which has been the case for over a century. *Chattanooga Foundry & Pipe Works v. City of Atlanta*, 203 U.S. 390, 396 (1906). Antitrust standing is not limited to competitors of the alleged monopolist. *Blue Shield of Va. v. McCready*, 457 U.S. 465, 478-79 (1982). The Supreme Court has held that direct purchasers are generally

[9] Citing, e.g., *In re DDAVP Direct Purchaser Antitrust Litig*., 585 F.3d 677, 688-92 (2d Cir. 2009); *Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 963 (S.D. Ohio 2010); *Kaiser Found. v. Abbott Labs*., No. CV 02-2443, 2009 WL 3877513, at *4-5 (C.D. Cal. Oct. 8, 2009); *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 363 F. Supp. 2d 514, 541 (E.D.N.Y. 2005); *In re Remeron Antitrust Litig*., 335 F. Supp. 2d 522, 528-29 (D.N.J. 2004); *Carrot Components Corp. v. Thomas & Betts Corp*., 229 U.S.P.Q. 61, 64 (D.N.J. 1986); cf. *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 990-92 (N.D. Ill. 2003).

the preferred plaintiffs to bring overcharge claims. *Illinois Brick Co.*, 431 U.S. at 725-26; *Hanover Shoe*, 392 U.S. at 489.

More particularly, though, courts have been cautious about exposing patent-holders to ancillary attacks, including antitrust attacks, because the threat of vexatious litigation would "disturb[] the incentives for innovation" underlying the patent system. *See DDAVP*, 585 F.3d at 688-92; *see also* U.S. Const., Art. I, § 8; *Therasense*, 649 F.3d at 1288-89; *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981). Thus, some courts have declined to "open the door to all direct purchasers otherwise unable to challenge a patent's validity being able to do so by dressing their patent challenge with a *Walker Process* claim." *Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 960-61 (S.D. Ohio 2010); *see also Ciprofloxacin*, 363 F. Supp. 2d at 542; *Kaiser*, 2009 WL 3877513, at *4-5. In *DDAVP*, the Second Circuit narrowly held that where the patent in question *already* had been "tarnished" by a finding of inequitable conduct in the underlying patent case, a direct purchaser could have standing to pursue a *Walker Process* claim. 585 F.3d at 691-92.

Until very recently, only two district courts, both outside the Third Circuit, took the opposite view and granted standing to purchasers without requiring a patent already tarnished by a finding in prior litigation, and neither case involved pharmaceuticals or Hatch-Waxman. *See Molecular Diagnostics Labs. v. Hoffmann-La Roche Inc.*, 402 F. Supp. 2d 276 (D.D.C. 2005), and *Ritz Camera & Image, LLC v. SanDisk Corp.*, 772 F. Supp. 2d 1100 (N.D. Cal. 2011). While the instant motions to dismiss were pending, however, the Federal Circuit decided an appeal in the *Ritz Camera* case, and held that the direct purchaser plaintiffs had standing to bring antitrust claims alleging fraud on the PTO. The appeal in *Ritz Camera* was,

> limited to a single question: Whether direct purchasers who cannot challenge a patent's validity or enforceability through a declaratory judgment action (and have not been sued for infringement, and so cannot assert invalidity or unenforceability as a defense in the infringement action) may nevertheless bring a *Walker Process* antitrust claim that includes as one of its elements the need to show that the patent was procured through fraud.

See Ritz Camera & Image, LLC v. SanDisk Corp., 700 F.3d 503, 506 (Fed. Cir. 2012). The Federal Circuit held that direct purchasers have standing to bring antitrust claims stemming from fraud on the PTO, "even if [they] could have not sought a declaratory judgment of patent invalidity or unenforceability." *Id.* at 507. Significantly, whereas "the Second Circuit 'decline[d] to decide whether purchaser plaintiffs *per se* have standing to raise *Walker Process* claims,' and held 'only that purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct,'" the Federal Circuit "[saw] no reason to limit the scope of *Walker Process* standing to cases in which the patents have been 'tarnished' in another proceeding." *Id.* at 507 n. 2 (internal citations omitted) (quoting *DDAVP*, 585 F.3d at 691-92). The Federal Circuit based its broader holding on the fact that *Walker Process* itself suggested no limitation on purchaser standing, and on the court's estimation that "applying such a requirement would have the undesirable effect of subjecting injured parties' claims to the litigation strategies of others . . . [and would] be likely to generate unproductive wrangling over what counts as a sufficiently 'tarnished' patent to support a *Walker Process* claim." *Id.*

Although this Court is not bound by the Federal Circuit's holding, it is persuasive authority, both by virtue of the Circuit's jurisdiction over many patent appeals and because of its thorough and careful treatment of this issue. The Federal Circuit is correct that the Supreme Court's *Walker Process* decision does not support the argument that the rules governing standing

to bring patent validity challenges should be imported into antitrust cases. *See id.* at 506; *Walker Process*, 382 U.S. at 175-76. For this reason, the Court declines to follow other courts in this district that have categorically restricted purchaser standing. *See In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 528-29 (D.N.J. 2004); *Carrot Components Corp. v. Thomas & Betts Corp*., 229 U.S.P.Q. 61, 64 (D.N.J. 1986). But this Court is not entirely convinced that there should be no limits on purchaser standing. While the Federal Circuit rejected a need for purchaser plaintiffs to show that a patent is already "tarnished", it did not speak to the unique situation now before this Court where Plaintiffs' antitrust claims implicate the enforceability of a patent that has been upheld after extraordinary scrutiny by U.S. and foreign courts, and the PTO. That is, although the Federal Circuit expressly declined to limit standing to purchasers' challenging already tarnished patents, it did not speak to patents whose validity has been confirmed after repeated scrutiny, and where repeated challenges failed to result in findings of intentional misconduct. In *Ritz Camera*, claims that the patent was procured by intentional fraud survived summary judgment in the underlying patent litigation. *Id.* at 506. The Federal Circuit implied that this fact was not necessary to its decision. But, to this Court at least, it is still unclear what the Courts of Appeals would do if, as is the case here, the patent at issue had been subjected to multiple challenges by generic competitors, upheld after a trial on claims of inequitable conduct virtually identical to the purchaser plaintiffs', and the PTO later confirmed the patent's validity and enforceability even though it was on notice of and in possession of the pertinent materials from the foreign and domestic litigations. *See* Compl. ¶ 306.

The Court's decision here, however, does not need to rest on the denial of purchaser standing, and thus it does not. As will be discussed in the next section, Plaintiffs' *Walker Process* claims fail because the allegations are implausible in light of the results of the previous

litigations and proceedings before the PTO. As the *Ritz Camera* court noted, any "flood" of *Walker Process* litigation will be discouraged by "the demanding proof requirements of a *Walker Process* claim." *Id.* at 508. Here, although the Court does not deny Plaintiffs standing or require that Plaintiffs show that the '995 patent, or any other, has already been tarnished, the Court explains in the next section that a previous court's determinations that the patent was valid after intense scrutiny had been brought to bear on it, and the PTO's reissuance after same, renders it difficult for the Plaintiffs to make *plausible* allegations that meet "the demanding proof requirements of a *Walker Process* claim." *Id.*

2. Merits of *Walker Process* Claim

Defendants challenge the sufficiency of Plaintiffs' *Walker Process* allegations, arguing that they are implausible in light of the District of Delaware's finding of inequitable conduct in the '995 patent litigation. Defendants argue that Plaintiffs here allege the same theory of misrepresentations to the PTO which was advanced by Ranbaxy during previous litigation. Noting that Ranbaxy's allegations of inequitable conduct were decided under what Defendants characterize as the more lenient *Therasense* standard applicable when the Delaware District court issued its decision, Defendants argue that Plaintiffs claim in this litigation must fail under *Walker Process*'s more rigorous standard. *See* DP Opp. at 37-39 (citing *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011)). Defendants further argue that Pfizer's disclosure to the PTO during reissue proceedings of adverse foreign decisions from Canada and Australia concerning foreign counterparts to the '995 patent, and the PTO's eventual reissuance of the patent, confirm the implausibility of Plaintiffs' allegations. *See id*. at 43-49. In opposition, Plaintiffs argue that they have adequately plead a *Walker Process* allegation, including that they have met the heightened pleading standard of Rule 9(b) as it applies to their

claim. Plaintiffs also argue that: (1) they are not bound by Judge Farnam's findings, and in any event his findings support rather than call into question Plaintiffs' allegations; (2) Judge Farnam did not have critical evidence of Pfizer's misconduct before him when he rendered the decision, nor did the foreign courts that have reviewed foreign counterparts to the '995 patent; and (3) reissuance of the '995 patent does not cure Pfizer's alleged violations.

Plaintiffs say that their *Walker Process* claim may one day depend on a jury believing that the active enantiomer possesses a surprising or ten-fold increase in activity over the racemate, but Plaintiffs assert that today is not that day. According to Plaintiffs, "[t]oday's question is whether the complaint alleges that Pfizer's claim of surprising ten-fold activity is false, that Pfizer intended to deceive the PTO, and that the '995 patent would not have issued but for that misrepresentation." DPP Opp. at 42. However, under *Twombly*, the question is actually whether the Complaint *plausibly* alleges these things. *See Twombly*, 550 U.S. at 556-57. A plaintiff's claim "is facially plausible 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Wyeth Holdings Corp.*, 2012 U.S. Dist. LEXIS 26912, at *11 (quoting *Iqbal*, 556 U.S. at 678). For the reasons that follow, the Court holds that it is not reasonable to infer that Pfizer is liable for the *Walker Process* fraud alleged in the Complaint.

In essence, Plaintiffs' *Walker Process* claim is premised on the allegation that Pfizer submitted affirmatively "false" or "misleading" CSI data to the PTO to show that the cholesterol-synthesis inhibition activity of the active enantiomer was surprising and unexpected, and submission of that data was intended to, and did, deceive the PTO into issuing the '995 patent. This decision does not rest on any failure on Plaintiffs' part under Fed. R. Civ. P. 8(a) or 9(b) to spell out these allegations. This decision rests on the fact that these allegations were presented at

trial in the litigation before Judge Farnam, in Australia and Canada, and in reissue proceedings before the PTO.

In the Delaware litigation, Judge Farnam considered whether Pfizer "intentionally withheld certain CSI data and manipulated CSI data that was disclosed to deceive the PTO and support its assertions concerning the activity of atorvastatin calcium." *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495, 524 (D. Del. 2005), *aff'd in part*, 457 F.3d 1284 (Fed. Cir. 2006). Ranbaxy also alerted the Court to Pfizer's use of averages rather than head to head comparisons. *Id.* Ranbaxy claimed that Pfizer withheld data from the PTO that contradicted the proposition that the active enantiomer was ten times more active than the racemate, including adverse data from CSI-107 and CSI-118, and from an AICS screen. *Id.* at 522, 524. Judge Farnam was also made aware of solubility issues in CSI-118. *Id.* at 524 n.12.

Plaintiffs admit that Judge Farnam concluded that the allegations before him were insufficient to support a finding of inequitable conduct under the then-existing standard. Compl. ¶ 208; Walgreen Compl. ¶ 164; Meijer Compl. ¶ 160. Judge Farnam disposed of many, if not all, of the allegations Plaintiffs make here on his way to finding that there was no evidence of any intent to deceive by Pfizer. For example, Judge Farnam disposed of the allegation that Pfizer's decision to use averages rather than head-to-head comparisons of the CSI data was improper. *See Pfizer*, 405 F. Supp. 2d at 524. Judge Farnam likewise found no evidence of an intent to deceive with respect to material allegedly withheld from the PTO, such as the CSI-107 assay. *Id.* at 524-25. In addition, despite Plaintiffs' assertions to the contrary, they have not convincingly shown through the Complaint, briefing, or oral argument, that Judge Farnam lacked any of the

alleged evidence of fraud that is now before the Court.[10]

As Plaintiffs' fraud theory is premised on the same allegations that Judge Farnam held did not constitute inequitable conduct in the underlying patent case, it is implausible to suggest that those allegations meet the higher standard for stating a *Walker Process* claim. *See Daiichi Sankyo*, 2009 WL 1437815, at *6 (dismissing as matter of law *Walker Process* counterclaims in view of prior finding of no inequitable conduct, stating that "if the finding of no inequitable conduct stands, there can be no *Walker Process* fraud"); *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A.*, 384 F. Supp. 2d 1334, 1353-54 (S.D. Iowa 2005) (granting motion to dismiss *Walker Process* counterclaims where patents-at-issue were previously held valid and enforceable).

The Canadian and Australian litigations referenced in the Complaint, during which Plaintiffs say "many of the facts recounted [in the Complaints relating to the alleged fraud] have come to light," do nothing to alter the Court's conclusion that Plaintiffs' *Walker Process* allegations are implausible. *See* Compl. ¶ 13 n.1, at 28 n.7; Compl. ¶¶ 209-14; *Walgreen* Compl. at 21 n.8; *Meijer* Compl. at 19 n.8. The Canadian decision was overturned on appeal while the '995 patent reissue proceedings were pending, s*ee Pfizer Canada Inc. v. Minister of Health*, Docket: A-79-07, 2008 FCA 108, at 84 (Mar. 20, 2008), Woodard Decl., Ex. 19; and while the Australian court reviewing a counterpart to the '995 patent found that Pfizer was guilty of "false suggestion", the court specifically held that Pfizer did not intentionally misrepresent anything to the relevant patent office.

The PTO's reissuance of the '995 patent despite its awareness of all of the foregoing is

[10] For examples of allegations and arguments made in the Complaint that Plaintiffs say were not before Judge Farnam, but which Defendants have shown were indeed presented to the Court in the Delaware litigation, *see* Pfizer Reply Br., Docket No. 343, at 20-22.

also instructive and detrimental to Plaintiffs' claims. Pfizer submitted the foreign decisions to the PTO during the reissue prosecution (Ranbaxy also specifically referenced them as well in its protests to reissuance), and the PTO nevertheless reissued the patent. *See* Woodard Decl., Ex. 8, at 2; *id.*, Ex. 7, at 21, 28-31; Ranbaxy Protest (May 21, 2007), Woodard Decl., Ex. 11, 19-20, 25. Pfizer also specifically informed the PTO that it had become aware of other errors in the biological data it had relied on during the Canadian and Australian litigations to show the active enantiomer's "unexpected activity" as compared to the racemate (*i.e.* Pfizer had become aware of errors besides the alleged errors in the CSI data at issue in the Delaware trial). Compl. ¶¶ 223-26; *Walgreen* Compl. ¶¶ 172-74; *Meijer* Compl. ¶¶ 168-70.

Pfizer's disclosures to the PTO of the foreign decisions, as well as its clarifications regarding certain biologic data submitted in support of the '995 patent, undermines the plausibility of Plaintiff's allegation that Pfizer intended to deceive the PTO. *See Twombly*, 550 U.S. at 556-57; *Iqbal*, 129 S. Ct. at 1949. The PTO's reissuance of the '995 patent also suggests that Plaintiffs' claim that the PTO would not have issued the patent but for the alleged misrepresentations or omissions is implausible. The PTO examines a reissue application in the same manner and subject to the same rules as if being presented for the first time in an original application. 37 C.F.R. § 1.176; MPEP § 1440. Thus reissue examiners independently consider the same issues of patentability an examiner would during examination of an original application, *see In re Tanaka*, 640 F.3d 1246, 1251 n.1 (Fed. Cir. 2011), including whether a reissue patent would be unenforceable because of fraud or inequitable conduct during the original prosecution, *see* MPEP § 2012. The PTO was aware of the findings in the Canadian and Australian decisions and that certain data was allegedly withheld in the original prosecution, and the PTO still reissued the patent. This is contrary to Plaintiffs' allegation that the '995 patent

would not have issued if the PTO had been aware of this information during the original prosecution. Of course, inequitable conduct cannot be cured by a reissue or reexamination. *Taro Pharm.*, 2012 WL 2513523, at *4. But reissue of the '995 patent contributes to the Court's determination that Plaintiffs' *Walker Process* claims are implausible, because reissuance of a patent "is dispositive of whether the PTO would have issued the original [patent]," and here the PTO reissued the '995 patent despite being aware of the allegedly new evidence of fraud now before the Court. *RB Rubber Prods., Inc. v. Encore Int'l, Inc.*, No. 11-cv-319, 2012 WL 860416, at *8 (D. Or. Mar. 13, 2012).

In sum, Plaintiffs' *Walker Process* claim rests on a glimmer of hope that a factfinder will somehow be convinced that Pfizer intentionally lied to the PTO, when a District Court has already found after a trial that Pfizer did not misrepresent anything to the PTO, let alone that Pfizer lied intentionally. Plaintiffs' claim also rests on the hope that this Court will find Pfizer's conduct before the PTO fraudulent, when the PTO itself implicitly condoned Pfizer's conduct by reissuing the '995 patent. The Court finds these glimmers of hope to be wholly speculative, indeed, implausible, in light of the facts before it, particularly where Plaintiffs fail to clearly and accurately, let alone convincingly, explain what allegations in the Complaint were not made before Judge Farnam or presented to the PTO during the reissuance process. Accordingly, Pfizer's motion to dismiss the Direct Purchaser Complaints is granted insofar as it argues for dismissal of the *Walker Process* claims.

B. "Sham" Litigation and False Orange Book Listing

Insofar as Plaintiffs allege other theories of liability under Section 2 of the Sherman Act that are based on the fraud theory underlying their *Walker Process* allegation, those theories are also dismissed. Specifically, Plaintiffs' allegations regarding Orange Book listing and "sham"

litigation to enforce the '995 patent are based entirely on the purported fraud in obtaining that patent. But listing presumptively valid patents in the Orange Book and enforcing them against infringers are not bases for an antitrust claim; Orange Book listing is a statutory obligation and enforcement is a statutory right. 21 U.S.C. § 355(b)(1) (1992); *see also, e.g.*, *Daiichi Sankyo, Inc. v. Apotex, Inc.*, Civ. No. 030937, 2009 WL 1437815, at *9 (D.N.J. May 19, 2007); *Ciprofloxacin*, 363 F. Supp. 2d at 546. Accordingly, these allegations cannot form the basis for antitrust liability and will be dismissed.

The complaint also alleges the process patent suit was meritless and was filed to provide cover for Pfizer and Ranbaxy to reach an agreement not to compete. DPP Opp. at 30-31, 61-63. But to the extent that the "sham" litigation allegation is based on the litigation over the process patents, the claim still must be dismissed. To show that the process patent litigation was a sham, Plaintiffs must establish, among other things, that "no reasonable litigant" could have expected Pfizer to succeed on the merits. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc*., 508 U.S. 49, 60 (1993); *Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000); *Nobelpharma AB v. Implant Innovations,* 141 F.3d 1059, 1107 (Fed. Cir. 1998). Plaintiffs do not meet this standard, as the Complaints allege no plausible basis, and therefore should be dismissed. When Ranbaxy moved to dismiss the infringement claims against it for lack of subject matter jurisdiction, arguing that "any harm to Pfizer from alleged infringement of the [process patents is] much less imminent now than in the ['995 patent] case when the Court found no imminent threat of harm or injury," *id.* ¶ 301, the court permitted jurisdictional discovery rather than grant Pfizer's motion to dismiss. This fact alone strongly suggests that the Pfizer's complaint was not objectively baseless. In addition, in making their sham litigation allegation, Plaintiffs make no effort to explain why subject matter jurisdiction was lacking under

the standard for declaratory judgment jurisdiction in *MedImmune, Inc. v. Genentech, Inc.* *See* 549 U.S. 118, 130-32 (2007). Finally, Plaintiffs ignore that the timing of the process patent litigation was consistent with the typical duration for litigating infringement claims, and for obtaining an injunction under the process patents to prevent a potential at-risk launch by Ranbaxy in March 2010 when the injunction under the '893 patent expired. The assertion that the process patent litigation was a sham and merely "provided cover" for the settlement is not justified. Pfizer's motion to dismiss the Section 2 claims is therefore granted insofar as the claims are based on sham litigation and false Orange Book listing allegations

C. "Sham" Citizen Petition

Plaintiffs also allege that a citizen petition submitted by Pfizer purporting to alert the FDA to stability and safety issues in certain generic versions of Lipitor was a "sham" and intended to cause the FDA to delay approval of generic ANDAs, including Ranbaxy's. Compl. ¶ 275; *Walgreen* Compl. ¶ 209; *Meijer* Compl. ¶ 205. Defendants argue, however, that Plaintiffs cannot allege that Pfizer's citizen petition was "objectively baseless", which is the applicable standard.

FDA citizen petitions are generally immune from antitrust liability under the *Noerr-Pennington* doctrine subject to a narrow exception, which requires that the petition be: (i) objectively baseless; and (ii) "an attempt to interfere with the business relationships of a competitor through the use of the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon." *DDAVP*, 585 F.3d at 685-86. To be "objectively baseless," a citizen petition must have been such that no reasonable pharmaceutical manufacturer could have "realistically expected the FDA to grant the relief sought." *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343, 2009 WL 2708110, at *4 (S.D.N.Y. Aug. 28, 2009).

Here, Plaintiffs argue that Pfizer's citizen petition was objectively baseless because it "lacked any reasonable regulatory, scientific, medical or other reasonable basis," it lacked evidence, and it was "contrary to FDA's expressed views regarding drug substance polymorphic forms," Compl. ¶ 275; *Walgreen* Compl. ¶ 209; *Meijer* Compl. ¶ 205. However, Pfizer's petition was supported by scientific evidence, and was duly considered on its merits (albeit ultimately rejected) by the FDA. *See* Citizen Petition (Nov. 9, 2005),Woodard Decl., Ex. 21, Letter from FDA to Pfizer, Docket No. 2005P-0452/CPI (May 4, 2006), Woodard Decl., Ex. 22. Six months after receiving Pfizer's petition, the FDA stated it had not reached a decision because the petition raised "complex issues requiring extensive review." It then took the FDA a total of more than six years to finally issue a decision on Pfizer's petition. *See* Compl. ¶¶ 272-77. In 2011 – more than five years after Pfizer originally submitted the petition – the FDA represented to a federal court in the District of Columbia that it was still reviewing and analyzing the issues in the petition. *See* Woodard Decl. Ex. 23. The FDA's statement shows that it viewed the petition as raising more than trivial concerns, i.e., that the FDA itself did not consider Pfizer's petition objectively baseless. *See La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343, 2009 WL 2708110, at *4 (S.D.N.Y. Aug. 28, 2009) (objectively baseless petition is one no drug company could have "realistically expected FDA to grant"). The FDA never expressed a view that Pfizer's petition was baseless, despite the fact that the FDA has previously suggested that certain citizen petitions were baseless in its denials and even raised concerns about the anticompetitive intent of the petitioner. *See, e.g.*, *In re Flonase Antitrust Litig.*, No. 08-cv-3301, at 24 (E.D. Pa. July 14, 2008), Woodard Reply Decl. Ex. M (FDA stated petition not supported with evidence and petitioner used regulatory process to "shield its market share" from competing generic drug products in manner inconsistent with "[t]he policies behind Hatch-Waxman"); *La. Wholesale*

Drug Co. v. Sanofi-Aventis, No. 07-cv-7343, at 3,6 (S.D.N.Y. Aug. 17, 2007) , Woodard Reply Decl. Ex. N (FDA stated petition based on "false premise" and out-of-date citations and "intend[ed] (at least in part) to delay generic competition**"**); *In re Prograf Antitrust Litig*., 1:11-md-2242-RWZ, at 9 (D. Mass. Feb. 1, 2012), Woodard Reply Decl. Ex. O (FDA stated petitioner provided no "data or analysis" for certain claims and some studies submitted were "highly questionable"). The FDA made no such statements in response to Pfizer's petition here.

As the allegations in the Complaint fail to show that Pfizer's citizen petition was "objectively baseless", Pfizer's submission is protected by the *Noerr Pennington* doctrine, and thus the Pfiizer's motion to dismiss Direct Purchaser Plaintiffs' Section 2 claims is granted insofar as the claims are based on Pfizer's citizen petition to the FDA.

D. Remaining Section 2 Claims

The only theories of Pfizer's liability under the Sherman Act's Section 2 which remain to be addressed are the Direct Purchaser Plaintiffs' allegation that Pfizer paid Ranbaxy to settle the process patent litigation and to stay off the Lipitor market until an agreed upon entry date, and the allegation that Pfizer is liable for an overarching anticompetitive scheme consisting of all of the aforementioned conduct. Plaintiffs so-called "reverse payment" allegations under Section 2 are identical to the allegations that underlie their Section 1 claims, so they will be addressed in the section of this opinion which addresses the Section 1 claims, *infra*. The Court finds Plaintiffs' "overarching anticompetitive scheme" allegation to be without merit. Having already determined that all of the specific allegations of conduct in violation of Section 2, except for the reverse payment allegations, are meritless and insufficient to state a claim for relief, the Court finds that a claim based on the purported "combined" impact of Plaintiffs' claims is also without merit. *See e.g.*, *Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, 486 F. App'x 186, 191

(2d Cir. 2012) ("Because these alleged instances of misconduct are not independently anti-competitive, we conclude that they are not cumulatively anti-competitive either."); Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1367 (Fed. Cir. 1999). Accordingly, Pfizer's motion to dismiss is also granted as to Plaintiffs' Section 2 allegations insofar as they are based on Pfizer's alleged overarching anticompetitive scheme, and the only allegations of Direct Purchaser Plaintiffs that remain to be addressed are the "reverse payment" allegations. However, before the Court addresses the reverse payment allegations, it will address Pfizer's standing arguments as relevant.

III. Standing

To have standing, Plaintiffs must allege facts sufficient to show that they suffered the type of injury the antitrust laws were intended to prevent and that the alleged injury flows from the Defendants' allegedly unlawful or anti-competitive acts (*i.e.*, causation). *Alberta*, 826 F.2d at 1249 (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)). Plaintiffs allege that they were injured by the absence of generic Lipitor between March 24, 2010 (when the '893 patent expired) and November 30, 2011 (when Ranbaxy entered the market). However, Pfizer argues that Plaintiffs lack standing because Plaintiffs cannot assert that Pfizer's conduct directly caused their injuries. Instead, Pfizer argues, the failure of generic competitors to enter the market sooner had independent causes such as Ranbaxy's failure to obtain FDA approval until its entry date in November 2011, and perhaps more importantly, Pfizer's other Lipitor patents (other than the '893 and '995 patents) – the RE '667, '971, '104 and '156 patents – which gave Pfizer the right to exclude others from making, using, and selling a generic copy of Lipitor until January 8, 2017, when the last patent is due to expire. *See* Compl. ¶ 322; *Walgreen* Compl. ¶ 227; *Meijer* Compl. ¶ 223; Woodard Decl., Ex. 4. Pfizer argues that Plaintiffs' injury

allegations are predicated on Plaintiffs' assertion – which Pfizer labels "speculation" – that upon expiration of the '893 patent in March 2010, generic challengers would have been able to secure FDA approval for and launch generic versions of atorvastatin in the face of the other Lipitor Patents. Pfizer argues that "[s]uch speculation fails" because it is either based on the premise that Ranbaxy could design around the other Lipitor Patents and obtain FDA approval for a new product or process before November 30, 2011, which Plaintiffs fail to support with facts, or on the premise that Ranbaxy would have prevailed in eventual infringement litigation over the Lipitor Patents, which is the kind of hypothesizing about future litigation that is "repeatedly foreclosed by the courts." Pfizer Br. at 32.

The parties each rely heavily on dueling cases bearing on this issue. Defendants cite *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), in which a district court in the Second Circuit rejected as speculative two theories of injury applicable here – that absent a reverse payment agreement a generic challenger would have been successful in its litigation with a brand name manufacturer, and that the generic challenger would have entered the market upon FDA approval without awaiting the outcome of the patent litigation. *See id.* at 199-201. Plaintiffs cite *King Drug Co. of Florence, Inc. v. Cephalon, Inc. et al.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010), where a district court in this Circuit found plaintiffs' allegation – that but for a settlement agreement, generic entry would have occurred earlier than it actually did – sufficient at the pleading stage, and dismissed as "conjecture" the defendants' assertion that no generic manufacturer would have entered "at risk." *See id.* at 535, 537. Here, the Court sides with Plaintiff.

The Court disagrees with Pfizer, and holds that Plaintiffs have adequately alleged that their injuries flow from Defendants' anticompetitive conduct. Plaintiffs need only allege that

Defendants' conduct was a "material cause" of their injury. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969); *see also Cardizem*, 332 F.3d at 911; *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 401 (7th Cir.1993); *In re Neurontin Antitrust Litig.*, MDL 1479, 2009 WL 2751029 (D.N.J. Aug. 28, 2009). In addition, causation is generally a factual issue, and particularly here where Defendants contest the allegation that generic competition would have and could have entered the market sooner but for Defendants' conduct. Specifically, there are factual disputes to be resolved about, *inter alia*, the ability of generic competitors, including Ranbaxy, to design around the Lipitor Patents, to prevail in any infringement litigation, and to gain FDA approval for whatever product they sought to market. Each of these factual issues is addressed in the Complaint, which alleges: (1) generic makers could design around the Orange-book listed Lipitor Patents, Compl. ¶ 196; (2) before entering into the Delay Agreement, Ranbaxy announced its willingness to launch at risk, and gained additional insurance though its partnership with Teva, (who had a history of launching at risk), Complaint ¶¶352, 367-369; and (3) in December 2009, before the expiration of the '893 patent, Ranbaxy transferred its manufacturing site for generic Lipitor from India to New Jersey and the FDA later approved that transfer, Complaint ¶363-366. Any doubts about these assertions as they relate to causation "should be resolved against the person whose behavior created the problem," at least at this stage of the litigation. *See* III Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW ¶651c. Accordingly, the Court sides with Plaintiffs and follows *King Drug*, in holding that Plaintiffs' allegation – that absent the Defendants' anticompetitive conduct, Plaintiffs would have been able to purchase generic Lipitor at significantly reduced prices – to be sufficient to confer standing upon Plaintiffs. *King Drug*, 702 F. Supp. 2d at 537.

However, given the Court's decision to grant Pfizer's motion to dismiss the majority of the theories underlying Plaintiffs' Section 2 claims, including most importantly the allegation that the '995 patent was procured by fraud, and limit the litigation going forward to the "reverse payment" allegations, the potential damages period will begin at the earliest on June 28, 2011, when the reissued '995 patent expired, because the '995 patent was an independent bar to generic entry before that time.

IV. Reverse-Payment Allegations and Direct Purchaser Class Plaintiffs' Motion For Leave to Amend

Plaintiffs' reverse-payment allegations underlie both their Section 1 and Section 2 claims. In Section 1, the Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. If read literally, this would make every agreement in restraint of trade illegal. *See Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 342, 102 S. Ct. 2466, 73 L. Ed. 2d 48 (1982). However, the Supreme Court has long construed this section of the Act to prohibit only unreasonable restraints. *See State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S. Ct. 275, 139 L. Ed. 2d 199 (1997).

Whether a restraint qualifies as unreasonable and therefore conflicts with the statute is normally evaluated under the "rule of reason." *Id.* Applying this approach, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." [11] *Id.* Courts have recognized, however, that "[s]ome types of restraints . . .

[11] This inquiry has been divided into three parts. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (3d Cir. 2012). First, the plaintiff must show that the challenged conduct has produced anti-competitive effects within

have such predictable and pernicious anticompetitive effect, and such limited potential for pro-competitive benefit, that they [should be] deemed unlawful per se." *State Oil Co.*, 522 U.S. at 10. In other situations, courts apply an antitrust analysis that falls between the full rule of reason inquiry and the per se approach. This so-called "quick look" or "truncated rule of reason" analysis has generally been applied where the plaintiff has shown that the defendant has engaged in practices similar to those subject to per se treatment, and its application means that plaintiff is not required to make a full showing of anti-competitive effects within the market; rather defendant has the burden of demonstrating pro-competitive justifications. *See Brown Univ.*, 5 F.3d at 669.

When the instant motions to dismiss were originally briefed, different Circuits had reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements. *Compare, e.g.*, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (Fed. Cir. 2012) (settlements generally "immune from antitrust attack"), with *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 214-218 (3d Cir. 2012) (settlements presumptively unlawful). However, while the motions were pending, the Supreme Court issued its decision in *FTC v. Actavis*, thereby setting the standard for how so-called "reverse payment" settlements must be scrutinized under the Sherman Act. *See FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

After the parties in this case submitted supplemental briefing to address the Supreme Court's decision in *Actavis*, and after oral argument was held, Direct Purchaser Class Plaintiffs moved to amend their Complaint to clarify their "reverse payment" allegations. *See* Dkt. Entry No. 435. Other Direct Purchaser Plaintiffs have also informed the Court of their desire to amend

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the market. *Id.* (citing *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993)). If the plaintiff meets the initial burden, "the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective." *Id.* Finally, the plaintiff can rebut the defendant's purported pro-competitive justification by showing that the restraint is not reasonably necessary to achieve the pro-competitive objective. *Id.*

their respective complaints. Pfizer opposes Plaintiffs' motion to amend. Pfizer argues that the motion should be denied because the amendments would be futile, Plaintiffs have unduly delayed seeking leave to amend, and because Defendants would allegedly be prejudiced if leave to amend is granted.

Federal Rule of Civil Procedure 15(a)(2) permits a plaintiff to amend its complaint with leave of court, and "[t]he court should freely give leave when justice so requires." *See* Fed. R. Civ. P. 15(a)(2). Whether to grant leave to amend is within the Court's discretion. *Sesta v. Bank of America*, 2013 U.S. Dist. LEXIS 91097, *2 (D.N.J. June 28, 2013). "[I]n the absence . . . undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment[,]" leave to amend should be "freely given." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

Here, Plaintiffs' seek to clarify and augment the "reverse payment" allegations already contained in the Complaint, because of new information it has learned in discovery. Plaintiffs seek to demonstrate that the Pfizer/Ranbaxy settlement of their Accupril litigation, which was referenced in the Complaint, was, in reality, a payment by Pfizer to Ranbaxy to delay Ranbaxy's launch of its generic version of Lipitor, regardless of the fact that Ranbaxy made a $1 million payment to Pfizer. Defendants argue that the proposed amendment would be futile because the amended allegations still fail to allege an actionable reverse payment under the Supreme Court's standard in *Actavis*, which Defendants say only applies to settlements involving large monetary payments from the brand name manufacturer to the generic. The Court disagrees, and holds that the proposed amendments are not futile; although the Court declines to decide whether the proposed amendments will be sufficient to survive a motion to dismiss, it notes that nothing in

Actavis strictly requires that the payment be in the form of money, and so it declines to hold that the amendments would be futile on that basis. Nor does the Court agree that Plaintiffs have unduly delayed seeking leave to amend their complaints or that Defendants were prejudiced in any way. It seems that Plaintiffs did not believe they needed to amend their Complaint until Defendants' complained Plaintiffs' allegations were ambiguous at a recent oral argument, and in any event, Defendants have been on notice of the nature of Plaintiffs' amended allegations for many months. As such, Plaintiffs cannot be said to have unduly delayed amendment. In addition, Defendants bear the burden of demonstrating they would be prejudiced by the amendment, and they have not done so. *See Bechtel v. Robinson*, 886 F. 2d 644, 652 (3d Cir. 1989). Defendants cannot argue that they would be unduly prejudiced by Plaintiffs' amendments because Plaintiffs are not seeking to add a new claim, but are merely seeking to clarify the factual allegations underpinning an already-existing claim – factual allegations that Defendants have been on notice of since at least when Plaintiffs filed their opposition to the motions to dismiss.

Simply put, it is the Court's view that justice would be aided by Plaintiffs filing amended complaints focused solely on the "reverse payment" allegations now that the Court has dismissed the remainder of the allegations. After the amended complaints are filed, Defendants may file new motions to dismiss, at which time the Court can rule on both Plaintiffs' and Defendants' "best shots" which incorporate evidence uncovered in discovery to date as well as their understanding of the law as it was laid out recently in *Actavis*.

CONCLUSION

For the reasons stated above, the Court grants Pfizer's motion to dismiss the Direct Purchaser's Complaints in part, and denies it without prejudice in part. The Court also grants Direct Purchaser Class Plaintiff's motion to amend. The Court dismisses the Direct Purchaser Complaints insofar as they allege theories of liability premised on anything other than Pfizer's alleged payment to Ranbaxy in connection with their settlement of the process patent litigation, denies Pfizer's motion to dismiss without prejudice insofar as it seeks to dismiss the reverse payment claims, and grants Direct Purchaser Plaintiffs leave to amend only their reverse payment claims. Direct Purchaser Class Plaintiffs, and any other Plaintiffs that wish to, may amend their complaint in a manner consistent with this opinion within thirty days.

ORDER

IT IS on this 5th day of September, 2013,

ORDERED that Pfizer's motion to dismiss (Dkt. Entry No. 246) is GRANTED in part and DENIED without prejudice in part; Pfizer's motion is GRANTED and the claims in the Direct Purchaser Complaints are dismissed to the extent they are based on anything but the Pfizer/Ranbaxy settlement agreement; Pfizer's motion is DENIED without prejudice insofar as it seeks to dismiss claims in the Direct Purchaser Complaints based on the Pfizer/Ranbaxy settlement agreement; and it is further

ORDERED that Direct Purchaser Class Plaintiffs' motion for leave to amend (Dkt. Entry No. 435) is GRANTED; and it is further

ORDERED that Direct Purchaser Plaintiffs may file amended complaints consistent with this opinion within thirty days.

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.