UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re LIPITOR ANTITRUST LITIGATION This Document Relates To: Direct Purchaser Class Actions	Civil Action No. 3:12-cv-02389 (PGS) **MEMORANDUM**

This matter comes before the Court on two motions to dismiss the Amended Complaint for failure to state a claim. Fed. R. Civ. P. 12(b)(6). It is an antitrust action which concerns the legality of a settlement between two drug manufacturers, Pfizer and Ranbaxy, regarding the pharmaceutical drug atorvastatin calcium under the brand name Lipitor® ("Lipitor"). Plaintiffs are direct purchasers of Lipitor seeking recovery of overcharges that were allegedly caused by the delayed entry provision of the settlement. In their amended complaint (ECF No. 472), Plaintiffs allege that a Settlement and License Agreement ("Settlement Agreement") was entered between the defendants which involved a non-monetary "reverse payment" of absolving Ranbaxy from satisfying a claim of damages from the Accupril litigation in exchange for Ranbaxy's promise to stay out of the Lipitor market until an agreed-upon entry date (November 30, 2011). In addition, the Amended Complaint alleged that defendants blocked generic competition in the Lipitor market. Defendants Pfizer and Ranbaxy move to dismiss the Amended complaint. (ECF No. 493 and 490, respectively.)

This matter is part of multi-district litigation coordinated by this Court involving four groups of plaintiffs: (1) a proposed class of direct purchaser plaintiffs asserting claims under the Sherman Act ("Direct Purchaser Plaintiffs"); (2) several opt-out groups of direct purchaser plaintiffs asserting nearly identical claims to the direct purchaser class; (3) a proposed class of end-

payor plaintiffs asserting claims under various states' laws; and (4) the RP Healthcare plaintiffs, a group of pharmacist plaintiffs, asserting claims under California law. This memorandum addresses the Direct Purchaser Plaintiffs' Amended Complaint only; however, portions of this memorandum including the legal analysis may pertain to the other groups of plaintiffs as they rely on the same allegations.

Procedural History

On April 23, 2012, the cases comprising the In Re: Lipitor Antitrust Litigation (MDL 2332) were transferred to this Court by the United States Judicial Panel on Multidistrict Litigation.

On May 16, 2012, this Court abstained from determining the motions to dismiss in anticipation of a decision by the Supreme Court of the United States in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), because there was a split in the circuits as to what standard was to control (the scope of the patent test or the quick look test) in evaluating a reverse payment settlement agreement (RPSA). (ECF No. 397.)

On August 21, 2012, this Court granted in part and denied in part the Plaintiffs' Motion to Compel Documents, ordering limited discovery. (ECF No. 447.) Because of the Court's inclination to await the *Actavis* decision, the Court allowed limited discovery during the interim period.

On June 17, 2013, the *FTC v. Actavis*, 133 S. Ct. 2223 (2013), decision was published.

On September 5, 2013, this Court issued a Memorandum and Order dismissing some of the claims based on *Walker Process*, [1] sham litigation, and sham citizen petition theories of Plaintiffs' prior Complaint. [2] (See reference on pages 5 and 8). Allegations under Sherman Act's

[1] *Walker Process Eqpt., Inc. v. Food Machinery Corp.*, 382 U.S. 172 (1965).
[2] *In Re Lipitor Antitrust Litig.*, No. 3:12-cv-2389, 2013 U.S. Dist. LEXIS 126468 (D.N.J. Sept. 5, 2013).

Section 2 were also dismissed insofar as they were based on Pfizer's alleged overarching anticompetitive scheme; hence, the only allegations of Plaintiffs that remain to be addressed are the reverse payment allegations. At the same time, the Court also granted Plaintiffs' Motion for Leave to Amend the Complaint. (ECF No. 455.) The rationale was that an amended complaint would update the facts of the complaint that were disclosed during discovery, and would incorporate changes based upon the recently decided *Actavis* case.[3]

Plaintiffs filed the Consolidated Amended Class Action Complaint against the Defendants on October 14, 2013. (ECF No. 472.) The Amended Complaint consists of three causes of action; the first two counts are properly before this Court, while the third count has already been decided. Count I alleges a violation of Section 1 of the Sherman Act. (Am. Compl. ¶ 296-305 ("Agreement in restraint of trade against all defendants.").) Count II alleges a violation of Section 2 of the Sherman Act. (Am. Compl. ¶ 306-312 ("Conspiracy to monopolize against all defendants.").) Count III alleges a violation of "15 U.S.C. §§ 1 and 2," but plaintiffs acknowledge "the Court dismissed this count" and that it was being "restated here for purposes of appellate rights." (Am. Compl. ¶ 313-315.) As such, this memorandum only addresses the first two counts.

In November 2013, Ranbaxy and Pfizer each filed a Motion to Dismiss the Amended Complaint. (ECF Nos. 490 and 493.)

On January 17, 2014, Plaintiffs filed a Brief in Opposition to the Defendants' Motions to Dismiss. (ECF No. 509; ECF No. 510 (redacted).)

On February 7, 2014, Defendants Pfizer and Ranbaxy filed a Reply Brief to Plaintiffs' Opposition to Motion. (ECF No. 524; 533 (redacted).)

The Court held oral argument regarding this matter on March 6, 2014 (ECF No. 532).

[3] At this time, the Court also ordered monthly meetings to discuss ongoing case management issues.

Parties

The following six direct purchaser plaintiffs are referred to collectively as the "Plaintiffs."

Plaintiff Stephen L. LaFrance Holdings, Inc. is a corporation organized under the laws of Delaware and located in Pine Bluff, Arkansas. Plaintiff Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors (collectively with Stephen L. LaFrance Holdings, Inc., "SAJ") is a wholly owned subsidiary of Stephen L. LaFrance Holdings, Inc., organized under the laws of Arkansas and located in Pine Bluff, Arkansas. During the class period, McKesson Corp., SAJ's assignor, purchased Lipitor directly from Pfizer and alleges injury as a result of all of the defendants' alleged unlawful conduct. McKesson Corp. resold, and will continue to resell, some of that Lipitor to SAJ. SAJ is the assignee of the claims of McKesson Corp. to the extent of those direct purchases from Pfizer. (Am. Compl. ¶ 14, ECF No. 472.)

Plaintiff Burlington Drug Co., Inc. is a corporation organized under the laws of the State of Vermont and located at 91 Catamount Drive, Milton, Vermont, 05468. During the class period, Burlington Drug Co. purchased Lipitor directly from Pfizer, and purchased generic Lipitor directly from Ranbaxy, and alleges injury as a result of all of the defendants' alleged unlawful conduct. (Am. Compl. ¶ 15.)

Plaintiff Value Drug Company is a corporation organized under the laws of the Commonwealth of Pennsylvania and located at One Golf View Drive, Altoona, Pennsylvania 16601. During the class period, Value Drug Company purchased Lipitor directly from Pfizer, and purchased generic Lipitor directly from Ranbaxy, and alleges injury as a result of all of the defendants' alleged unlawful conduct. (Am. Compl. ¶ 16.)

Plaintiff Professional Drug Company, Inc. is a corporation organized under the laws of the State of Mississippi with its principal place of business in Biloxi, Mississippi. During the class period, Professional Drug Company, Inc. purchased Lipitor directly from Pfizer. (Am. Compl. ¶ 17.)

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business located at 50 Jet View Drive, Rochester, New York 14624. During the class period, RDC purchased branded Lipitor directly from Pfizer, and purchased generic Lipitor directly from Ranbaxy. (Am. Compl. ¶ 18.)

Plaintiff American Sales Company LLC is a Delaware corporation with its principal place of business located in Lancaster, New York. During the class period, Cardinal Health, Inc., American Sales Company's assignor, purchased Lipitor directly from Pfizer and alleges injury as a result of all of the defendants' alleged unlawful conduct. Cardinal Health, Inc. resold, and will continue to resell, some of that Lipitor to American Sales Company. American Sales Company is the assignee of the claims of Cardinal Health, Inc., to the extent of those direct purchases from Pfizer. (Am. Compl. ¶ 19.)

The defendants referenced in the following three paragraphs are referred to collectively or alternatively as "Pfizer."

Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business at 235 East 42nd Street, New York, New York 10017. At all relevant times, Pfizer, Inc. sold branded Lipitor directly to the direct purchasers and/or their assignors, and to the other members of the Direct Purchaser Class. Pfizer, Inc. is also alleged to have engaged in the conduct challenged in this case and attributed to Pfizer, itself and/or through

its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith. (Am. Compl. ¶ 21.)

Defendant Pfizer Manufacturing 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, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals, a wholly-owned indirect subsidiary of defendant Pfizer, Inc., was the exclusive licensee of the '995 patent and other patents (need full cite of patent). At all relevant times, Defendant Pfizer Manufacturing Ireland engaged in the conduct challenged in this case and attributed to Pfizer, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith. (Am. Compl. ¶ 22.)

Defendant Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. In 1997, Warner-Lambert and Pfizer began co-promotion of Lipitor. On June 19, 2000, Pfizer completed its merger with Warner-Lambert whereby Pfizer purchased all outstanding shares of Warner-Lambert common stock. Each share of Warner-Lambert stock was converted into 2.75 shares of Pfizer common stock. The merger qualified as a tax-free reorganization and was accounted for as a pooling of interests. Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. At the end of 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC. (Am. Compl. ¶ 23.)

The Defendants named in the following three paragraphs are referred to collectively or alternatively as "Ranbaxy."

Defendant Ranbaxy, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540. (Am. Compl. ¶ 26.)

Defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540. (Am. Compl. ¶ 27.)

Defendant Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon - 122001 (Haryana), India. (Am. Compl. ¶ 28[4].)

Facts

The facts provided herein are limited to those pertinent to the issues impacting an alleged reverse payment settlement agreement (RPSA).[5] Noted above, the Complaint pleads that Pfizer made a reverse payment to Ranbaxy through forbearance of a claim of damages in the Accupril litigation and resolution of Lipitor patent claims in foreign jurisdictions. However, the Settlement Agreement resolved and terminated patent litigation on three drugs, Lipitor, Caduet and Accupril. Each is discussed below.

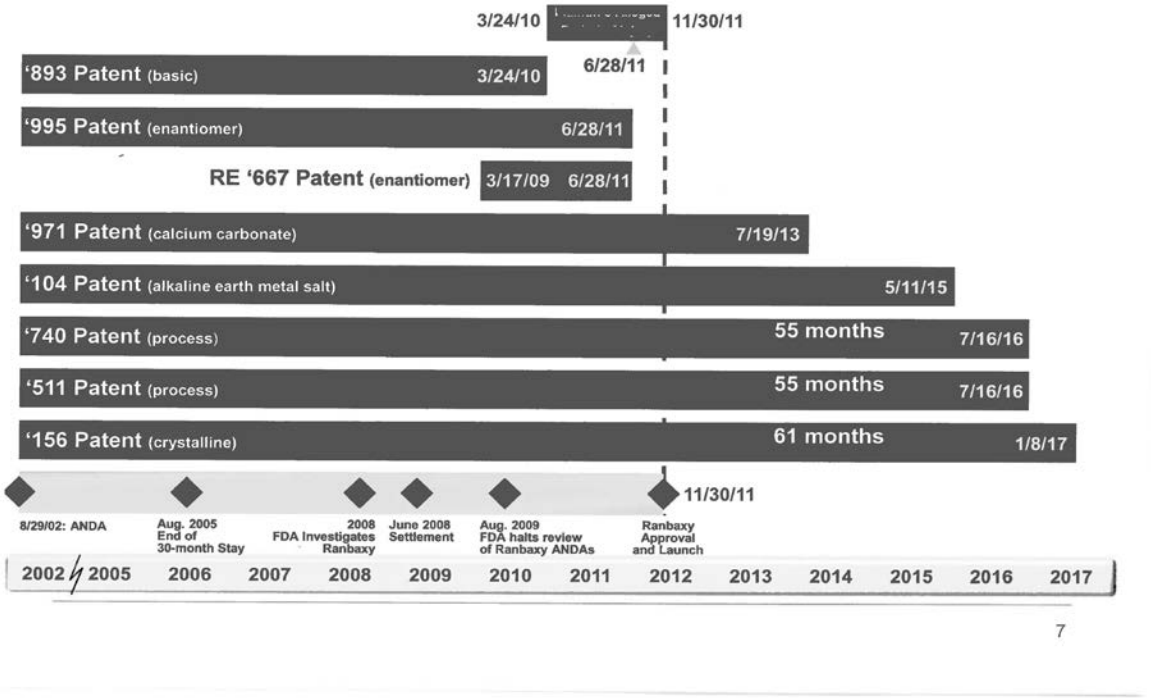
Lipitor

Lipitor was developed and launched by Pfizer in 1997. (Am. Compl. ¶ 70.) The active ingredient in Lipitor is called atorvastatin calcium. (Am. Compl. ¶ 46.) It belongs to a class of drugs called statins, which lower cholesterol by inhibiting a liver enzyme that controls the rate of the metabolic production of cholesterol. High cholesterol is widely recognized to be associated

[4] Often, Pfizer and Ranbaxy are referred to collectively as defendants.
[5] Additional information may be obtained from this Court's September 5, 2013 opinion: *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389, 2013 U.S. Dist. LEXIS 126468 (D.N.J. Sept. 5, 2013).

with coronary heart disease and atherosclerosis. *Id*. It is characterized as a "blockbuster" drug with sales of about $1 billion per month.

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 later as U.S. Reissue Patent No. 40,667); 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.*, Am. Compl. ¶ 68-69, 72-74. Presented below is a graph which shows the expiry of the seven patents, and how they relate to Ranbaxy's launch date under the Settlement Agreement.



The '893 and '995 patents cover the active ingredient of Lipitor (atorvastatin calcium ingredient patents). The remaining five patents cover other aspects of Lipitor: the '156 patent covers the crystalline form of atorvastatin as used in Lipitor; the formulation of Lipitor is covered by the '971 and '104 patents (the "Formulation Patents"); and the '740 and '511 patents are directed to specific processes of making amorphous atorvastatin calcium using crystalline Form I atorvastatin as a starting material (the "Process Patents").

At the time of the 1997 launch of Lipitor, only the '893 and '995 patents were listed by Pfizer in the Food and Drug Administration's (FDA's) book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). (Am. Compl. ¶ 65.) Following the 1997 launch, Pfizer procured the remaining five patents. (Am. Compl. ¶ 71-74.) The Formulation Patents and the '156 patent were then listed in the Orange Book. (Am. Compl. ¶ 75.) However, the Process Patents are not listed in the Orange Book, because they are directed to processes of making amorphous atorvastatin, rather than a new drug.

On August 19, 2002, Ranbaxy filed an Abbreviated New Drug Application ("ANDA") to seek approval to sell a generic version of Lipitor. (Am. Compl. ¶ 76.) Ranbaxy was the first generic manufacturer to file an ANDA for generic Lipitor. (Am. Compl. ¶ 76-77.) By this time, all Lipitor patents except the Process Patents were listed in the Orange Book. (Am. Compl. ¶ 75, 78.) Beginning in late 2002, Ranbaxy sent four Paragraph IV certifications[6] based on an amorphous form of atorvastatin to Pfizer with respect to all patents listed in the FDA Orange Book (*i.e.*, the '893, '995, '156, '971 and '104 patents). (Am. Compl. ¶ 94.) In its Paragraph IV

[6] Pursuant to the Hatch-Waxman Act, 21 U.S.C. § 301, *et. seq*., in order to obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. An ANDA must contain one of four certifications. A "Paragraph IV" certification must state "that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product." (Am. Compl. ¶ 36.) The impact of Hatch-Waxman on a pharmaceutical patent is discussed at length in *Actavis*. As such, it is not discussed here in length.

certifications, Ranbaxy certified that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's amorphous ANDA product. (Am. Compl. ¶ 78, 94.) Ranbaxy was not required to — and did not — file any certification with respect to the non-listed Process Patents ('740 and '511 patents). (Am. Compl. ¶ 129.)

In response to Ranbaxy's Paragraph IV certifications for generic Lipitor, Pfizer filed an action in the United States District Court for the District of Delaware on February 21, 2003, alleging that Ranbaxy's ANDA product would infringe the '893 and '995 patents (Active Ingredient Patent). (Am. Compl. ¶ 79.) In pre-trial proceedings, Pfizer attempted to amend its complaint to add new patent infringement claims based on the Process Patents. (Am. Compl. ¶ 82.) However, the district court denied Pfizer's motion because claims under the Process Patents would be "premature." (Am. Comp. ¶ 82.) In 2005, the district court rejected all challenges to the validity and enforceability of both the Active Ingredient Patents. (Am. Compl. ¶ 84.) On November 2, 2006, the Federal Circuit affirmed the district court's ruling that the '893 patent was valid and would be infringed by Ranbaxy's product. (Am. Compl. ¶ 86.) However, the Federal Circuit reversed the district court's ruling regarding the validity of the '995 patent, holding that claim 6 was invalid due to improper dependent claim structure. (35 U.S.C. § 112-14.) Claim 6 was the only claim Pfizer alleged was infringed by Ranbaxy's ANDA product. Based upon the Federal Circuit's mandate in late 2006, the district court amended its final judgment order to enjoin any approval of Ranbaxy's ANDA for generic Lipitor until March 24, 2010 (the expiration date 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. (Am. Compl. ¶ 87.)

In January of 2007, Pfizer initiated reexamination proceedings with the United States Patent and Trademark Office ("PTO") 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. (Am. Compl. ¶ 100.) In theory, this placed the entire '995 patent in jeopardy, because "a reissue application, including all the claims therein, is subject to 'be examined in the same manner as a non-reissue, non-provisional application.'" Manual of Patent Examining Procedure Ed. 8, Rev. 5, § 1445 (quoting 37 C.F.R. 1.176). "Accordingly, the claims in a reissue application are subject to any and all rejections which the examiner deems appropriate . . . . Claims in a reissue application enjoy no 'presumption of validity.'" *Id.* (citing *In re Doyle*, 482 F.2d 1385, 1392, 179 USPQ 227, 232-233 (CCPA 1973); *In re Sneed*, 710 F.2d 1544, 1550 n.4, 218 USPQ 385, 389 n.4 (Fed. Cir. 1983)). However, in light of the federal circuit decision, it did not appear to be a highly significant issue, as it was characterized as a scrivener's error. *Pfizer Inc. v. Ranbaxy Labs.*, 457 F.3d 1284, 1291-1292 (Fed. Cir. 2006).

Beginning in May 2007, Ranbaxy filed multiple protests against reissuance of the reissue application with the PTO. (Am. Compl. ¶ 102.) On April 24, 2008, the PTO issued a non-final rejection of claims 6, 13, and 14 of the reissue application based on obviousness. (Am. Compl. ¶ 108.) During the reissue process, Pfizer changed its rationale to overcome the obviousness rejection by arguing that the commercial success of Lipitor showed that the '995 patent could not have been obvious. (Am. Compl. ¶ 232.) On April 6, 2009, the PTO evidently agreed with Pfizer's commercial success rationale and reissued the '995 patent as U.S. Reissue Patent No. 40,667.

On March 24, 2008, Pfizer filed a declaratory judgment suit in the United States District Court for the District of Delaware alleging that Ranbaxy's generic Lipitor would infringe the Lipitor Process Patents on the same grounds that had resulted in dismissal of Lipitor's ANDA litigation. (Am. Compl. ¶ 138.) Because the process patents were not listed in the Orange Book, no automatic 30-month stay of FDA approval of Ranbaxy's pending ANDA occurred. (Am.

Compl. p. 35, n. 6.) During the course of the ligation, the case was settled pursuant to the Settlement Agreement wherein the parties filed a Consent Order and Stipulated Injunction with Prejudice on or about June 20, 2008, entered on June 24, 2008. Consent Order and Stipulated Injunction, *Pfizer Inc. v. Ranbaxy Laboratories Limited*, No. 1:08-cv-00164 (D. Del. June 24, 2008), ECF No. 20.

***Accupril* I Litigation (No.: 99-cv-922-DRD)**

In January 1999, a generic manufacturer Teva Pharmaceuticals USA, Inc. ("Teva") filed ANDA with Paragraph IV certification as the first filer to seek approval to market generic Accupril® ("Accupril"), another brand drug of Pfizer. (Am. Compl. ¶ 150.) On March 2, 1999, Pfizer responded by filing suit against Teva ("*Accupril* I" litigation). (Am. Compl. ¶ 151.) In December 2002, Ranbaxy filed an ANDA with Paragraph IV certification for generic Accupril. (Am. Compl. ¶ 150.) Pfizer did not take any action under the Hatch-Waxman Act with respect to Ranbaxy's Paragraph IV certification letter. (Am. Compl. ¶ 151.[7])

During the course of the *Accupril* I proceedings, Pfizer and Teva had contested the meaning of the term "saccharide" as used in the Accupril patent.[8] (Am. Compl. ¶ 153.) Eventually, the parties stipulated that as used in the Accupril patent, the term "saccharide" means a "sugar" and includes only lower weight molecular carbohydrates. (Am. Compl. ¶ 153.)

In October 2003, Pfizer established on summary judgment that Teva's generic Accupril product infringed numerous claims including claims 6 and 17 of Pfizer's Accupril patent. (Am. Compl. ¶ 152 (citing *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 289 F. Supp. 2d 515, 520 (D.N.J. 2003).) Teva did not challenge on appeal the district court's grant of summary judgment

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7 See page 13, *infra*, discussion of *Accupril* II litigation.

8 U.S. Patent No. 4,743,450.

for Pfizer regarding Teva's infringement of claims 16 and 17. (Am. Compl. ¶ 152, 165.) Teva did, however, challenge certain aspects of the district court's grant of summary judgment on infringement for other claims (*i.e.*, claims 1, 4-10, and 12), which the Federal Circuit remanded to the district court. (Am. Compl. ¶ 165.) On remand, the district court granted Pfizer's motion for summary judgment on infringement of those claims as well. *Id*.

On June 29, 2004, Judge Debevoise issued an opinion rejecting Teva's obviousness and anticipation arguments as to claims 16 and 17 and its enablement argument, as well as its allegations of inequitable conduct. (Am. Compl. ¶ 154.) On the same day, Judge Debevoise entered an injunction barring Teva from selling the generic quinapril product described in its ANDA.

In August 2005, the Federal Circuit affirmed the finding of enforceability and validity of the Accupril patent, except as to the enablement issue, aspects of which were remanded to the district court. (Am. Compl. ¶ 165.) On remand, the district court held in Pfizer's favor – *i.e.*, that all claims were enabled. *Id*. On January 18, 2008, Judge Debevoise entered a final judgment finding the Accupril patent valid. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. 2**:**99-cv-922 (D.N.J. Jan. 18, 2008), ECF No. 343.

***Accupril* II Litigation**

On August 26, 2004 — after the *Accupril* I court's order enjoining Teva from launching generic Accupril — Teva and Ranbaxy entered into a distribution and supply agreement pursuant to which Teva was appointed as the exclusive distributor of *Ranbaxy's* generic Accupril product. (Am. Compl. ¶ 155.) In return, Teva relinquished its 180-day exclusivity. Under the agreement, Ranbaxy would provide Teva with its FDA-approved product for sale, the profits of which would be shared by the parties equally. (Am. Compl. ¶ 156.) The agreement also provided that Ranbaxy

would fully indemnify Teva for any liability related to Ranbaxy's launch.

Ranbaxy's position of noninfringement was that, in light Pfizer's narrow claim construction in *Accupril* I and the stipulation entered into by the parties in that case (defining saccharide as a sugar, limited to mono- and disaccharides), the microcrystalline cellulose contained in Ranbaxy's ANDA product did not constitute a "sugar" and therefore was outside the scope of the Accupril patent. (Am. Compl. ¶ 158.)

Ranbaxy obtained final approval of its ANDA product in December 2004 and launched at risk[9] a generic version of Accupril in December 16, 2004. (Am. Compl. ¶ 157.) Prior to this event, the Complaint alleges that Pfizer had sales in 2004 of approximately $525 million for branded Accupril, but a year later in 2005, the sales of branded Accupril were $71 million. (Am. Compl. ¶ 160.) Pfizer sued Ranbaxy and Teva for patent infringement on January 28, 2005, over which Judge Debevoise again presided ("*Accupril* II" litigation). (Am. Compl. ¶ 159; ECF No. 493 at 3.)

With respect to infringement of the Accupril patent, Ranbaxy conceded that if the court in *Accupril* II adopted the broader claim construction as Pfizer argued – namely that as used in the '450 patent "saccharide" was *not* limited to "sugar" and encompassed polysaccharides – then it "absolutely" infringed. (Am. Compl. ¶ 162.) On March 31, 2015, about 105 days after the suit was commenced, Pfizer successfully obtained a preliminary injunction against Ranbaxy and Teva, as Judge Debevoise had adopted the broad claim construction, and halted all generic sales. (Am. Compl. ¶ 159-162l ECF No. 493.) The Court of Appeals for the Federal Circuit unanimously

[9] "At risk" launch, in the context of Hatch-Waxman Act, occurs when a generic manufacturer launches a generic version of the branded drug while the patent(s) on the branded drug is in litigation. Such a launch is called "at risk" because the court could find that the launched generic drug infringes the patent(s), in which case the generic manufacturer would owe damages to the branded company.

affirmed the district court's preliminary injunction order (Am. Compl. ¶ 159) upon the condition that Pfizer post a $200 million bond. (Am. Compl. ¶ 160.)

Teva informed the court that it would not seek to re-litigate the issues of validity and enforceability of the Accupril patent because of the previous rulings in *Accupril* I. (Am. Compl. ¶ 161.) Pfizer agreed that Teva had exhausted all of its validity and enforceability defenses and requested that the district court enhance the damages based on a willful infringement theory. (Am. Compl. ¶ 163, 172.) Prior to the preliminary injunction decision, Ranbaxy, on the other hand, advised the court that it was relying entirely on its non-infringement position, and did not have any invalidity or unenforceability theory. (Am. Compl. ¶ 164.) But thereafter Ranbaxy asserted that it was entitled to present different variations of the same invalidity theories (including, *inter alia*, obviousness, anticipation, and non-enablement) on which Teva had lost in *Accupril* I. (Am. Compl. ¶ 166.) As of February 2008, when most of the discovery in *Accupril* II was complete (Am. Compl. ¶ 169) and Pfizer was denied summary judgment, the case was settled as part of the alleged Settlement and License Agreement with the filing of Consent Order on or about June 19, 2008. That Consent Order dismissed all claims and counterclaims of Ranbaxy, Pfizer, and Teva. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, No. 05-cv-620 (D.N.J. June 19, 2008), ECF No. 187.

Caduet ANDA and Process Litigations

The following two lawsuits are not mentioned in the Plaintiffs' Complaint, but they are germane because they were settled as part of the Settlement Agreement.[10] (ECF No. 493 at 13.)

"Caduet ANDA" litigation was filed on March 9, 2007 by Pfizer in the United States District Court for the District of Delaware in response to Ranbaxy's Paragraph IV certifications for generic Caduet® ("Caduet"). (ECF No. 493, at 13.) Caduet is Pfizer's product which is a

[10] See page 26 for use of judicial proceedings as part of the record on a motion to dismiss.

combination of atorvastatin and amlodipine. *Id*. Pfizer argued that Ranbaxy's generic Caduet would infringe the '893 patent and another U.S. patent not relevant to the case at bar.[11] *Pfizer Inc. v. Ranbaxy Laboratories Limited*, No. 1:07-cv-00138 (D. Del. Mar. 9, 2007), ECF No. 1. As part of the Settlement Agreement, a Consent Order dismissing the case was filed on June 20, 2008, entered on June 24, 2008. *Pfizer Inc. v. Ranbaxy Laboratories Limited*, No. 1:07-cv-00138 (D. Del. June 20, 2008), ECF No. 65.

"Caduet Process" litigation was a declaratory judgment suit filed on March 24, 2008 by Pfizer in the United States District Court for the District of Delaware, in which Pfizer alleged that Ranbaxy's generic Caduet would infringe the Process Patents. *Pfizer Inc. et al v. Ranbaxy Laboratories Limited*, No. 1:08-cv-00162 (D. Del. Mar. 24, 2008), ECF No. 1. Similar to above, as part of the Settlement Agreement, a Consent Order dismissing the case was filed on June 20, 2008, entered on June 24, 2008. *Pfizer Inc. et al v. Ranbaxy Laboratories Limited*, No. 1:08-cv-00162 (D. Del. June 24, 2008), ECF No. 20.

Settlement Agreement

On June 17, 2008, Pfizer and Ranbaxy executed the Settlement Agreement. (Am. Compl. ¶ 145.) The Settlement Agreement identifies multiple legal proceedings within the United States as well as foreign jurisdictions as being resolved "without further litigation." This includes the proceedings discussed in the previous pages. Settlement Agreement at 1. Specifically, the U.S. actions identified were *Accupril* II litigation, Lipitor Process litigation, Caduet ANDA litigation, and Caduet Process litigation. (Am. Compl. ¶ 26.)

With respect to Lipitor Process litigation, Ranbaxy agreed to, *inter alia*, refrain from participating in the atorvastatin market until November 30, 2011. Settlement Agreement at 2, 24.

[11] U.S. Patent No. 6,455,574.

Ranbaxy also agreed not to challenge, directly or indirectly, the validity or enforceability of the Process Patents (the '511 or the '740 patents). Settlement Agreement at 2.

In addition, Caduet ANDA litigation and Caduet Process litigation were dismissed on terms that, *inter alia*, Ranbaxy would be enjoined from offering for sale or selling in the United States any generic Caduet, until November 30, 2011. Settlement Agreement at 3, 24. Ranbaxy also allegedly promised not to challenge, directly or indirectly, the validity or enforceability of the patent specific to Caduet. Settlement Agreement at 3. Since there is very little mentioned about Caduet within the Amended Complaint, it cannot be discerned whether the Caduet portion of the Settlement Agreement is a substantive factor in the settlement, or whether it is a pro or anti-competitive factor.

Accupril II litigation was different because it was not a Hatch-Waxman suit and Ranbaxy was subject to damages for any infringement that may have occurred in the *Accupril* II case. As such, Ranbaxy paid $1 million to Pfizer "in full and complete settlement of all past damages claimed by [Pfizer] in the [*Accupril* II litigation] as to all parties in that action." The Settlement Agreement also stipulated that $200 million bond posted by Pfizer was released to Pfizer. Settlement Agreement at 3.

In addition to the settlement of the above litigations in the United States, 23 proceedings in 13 foreign countries were also terminated as a result of this Settlement Agreement. *Id*., at 1, 26-29. Many of the foreign settlement terms prohibited Ranbaxy from selling its generic atorvastatin products until an agreed upon date. *Id*., at 4-10. Also in conjunction with the termination of proceedings in Canada, Ranbaxy agreed to appoint Pfizer as its exclusive supplier of the active ingredients of Ranbaxy's generic form of Lipitor until Ranbaxy notified Pfizer that it was capable of manufacturing the bulk active pharmaceutical ingredient, atorvastatin. *Id*., at 8, Exhibit 9, at

11. The Settlement Agreement also contains royalty-free licensing provisions for patents related to Lipitor in several countries including U.S., Germany, Italy, Belgium, the Netherlands, Sweden, Australia, and Canada. *Id*. at 10-13.

On June 18, 2008, Ranbaxy publicly announced its Settlement Agreement with Pfizer, including the Ranbaxy's launch date of November 30, 2011 for generic Lipitor. (Am. Compl. ¶ 192.) Ranbaxy submitted this information to the FDA shortly thereafter. *Id*. Ranbaxy also informed the FDA its proposed generic product was now crystalline atorvastatin calcium, as opposed to the amorphous version, pursuant to a license from Pfizer. *Id*.

In short, the Plaintiffs contend that this Settlement Agreement was Pfizer and Ranbaxy's purposeful intent to restrain and monopolize trade by extending the Lipitor patent duration until November 30, 2011, when Ranbaxy's generic amorphous version would not have infringed the Lipitor process patents. Plaintiff allege that this was accomplished by Pfizer forgiving its claim for infringement damages by settling the Accupril claim for $1 million when the value of the Accupril claim was far higher; and allowing the defendants to market generic Lipitor in foreign markets. As a result, Ranbaxy agreed to delay entry of its generic until November 30, 2011. This delay injured the direct purchasers through the payment overcharges.

Supreme Court Decision in *Federal Trade Commission v. Actavis, Inc.*

Since this case revolves around the propriety of an alleged reverse payment settlement agreement (RPSA), and *Actavis* addresses the issue as it applies to pharmaceutical related patent litigation settlements, it is discussed below.

The Supreme Court has described a RPSA as "unusual" because "'where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle a lawsuit.'" *FTC v. Actavis, Inc.* 133 S. Ct. 2223, 2235 (2013) (quoting 1 H. Hovenkamp, M.

Janis, M. Lemley, & C. Leslie, IP and Antitrust § 15.3, at 15–45, n. 161 (2d ed. Supp. 2011)). The Court explained that a RPSA occurs as follows:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars.

Actavis, 133 S. Ct. at 2227. "Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, it is often called a 'reverse payment' settlement agreement." *Id.* Some of this atypical behavior occurs due to the workings of the Hatch-Waxman Act, wherein the first generic to file enjoys the 180 day exclusivity period during which the "'vast majority of potential profits for a generic drug manufacturer materialize . . . .'" *Id*. at 2229 (quoting Pet'r Br. 6)).

Prior to the *Actavis* decision, there was a dispute within the circuits as to the standard for analyzing a RPSA. Some circuits applied the scope-of-the-patent test, under which an antitrust attack will be dismissed so long as the anticompetitive effects fall within the exclusionary potential of the patent. *See, e.g.*, *FTC v. Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012). In contrast, the Third Circuit implemented a "quick look" approach wherein a RPSA is considered *prima facie* evidence of unreasonable restraint of trade. *In re K–Dur Antitrust Litigation ("K–Dur")*, 686 F.3d 197 (3d Cir. 2012), *vacated*, *Merck & Co. v. La. Wholesale Drug Co.*, 133 S.Ct. 2849, (2013) (mem.), *Upsher–Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S.Ct. 2849 (2013) (mem.). This in effect shifts to "a defendant the burden to show empirical evidence of [the settlement's] procompetitive effects." *Actavis*, 133 S. Ct. at 2237 (quoting *California Dental Assn. v. FTC*, 526 U.S. 756, 776 n. 12 (1999)).

In *Actavis*, the Supreme Court rejected both camps and in lieu thereof employed the rule-of-reason approach in order to strike a balance "between the lawful restraint on trade of the patent

monopoly and the illegal restraint prohibited broadly by the Sherman Act." *Actavis*, 133 S. Ct. at 2231. The basic question before the Supreme Court was "whether . . . an agreement [between a patentee and a generic] can sometimes unreasonably diminish competition in violation of the antitrust laws." *Id*. at 2227; *see also* 15 U.S.C. §1 (Sherman Act prohibition of "restraint[s] of trade or commerce").

In *Actavis*, Solvay Pharmaceuticals initiated patent litigation against Actavis, Inc. and Paddock Laboratories, in response to their Paragraph IV certifications that Solvay's listed patent for its drug AndroGel was invalid and not infringed. *Actavis*, 133 S. Ct. at 2229. Par Pharmaceutical did not file an ANDA with the FDA, but agreed to share the litigation costs with Paddock in exchange for a share of profits if Paddock gained approval for its generic drug. *Id*. FDA approved Actavis' first-to-file generic product, but in 2006, within the 30 month litigation period, all the parties settled. *Id*. The terms of the settlement between Solvay and Actavis were that (a) Actavis agreed to not bring its generic to market 65 months before Solvay's patent expired (unless someone else marketed a generic sooner); and (b) Actavis agreed to promote AndroGel to urologists. *Id*. The other two manufacturers made similar promises. *Id*. In return, Solvay agreed to pay millions of dollars to each generic—$12 million in total to Paddock; $60 million in total to Par; and an estimated $19–$30 million annually for nine years to Actavis. *Id*.

The Federal Trade Commission (FTC) filed suit against Solvay and the three generics alleging violation of § 5 of the Federal Trade Commission Act, 15 U. S. C. §45, by unlawfully agreeing "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years." *Id*. at 2229-30 (internal quotation and citation omitted). The District court, later affirmed by the Eleventh Circuit, applied the scope-of-the-patent test and found that FTC had no standing because "absent

sham litigation or fraud in obtaining the patent, a [RPSA] is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Watson Pharm.*, 677 F.3d at 1312.

In rejecting the Eleventh Circuit's "scope-of-the-patent" test, the Supreme Court noted there was "reason for concern" that RPSAs "tend to have significant adverse effects on competition." *Actavis,* 133 S. Ct. at 2231. While the court conceded that settlement on terms of permitting the patent challenger to enter the market before the expiration of the patent bring about competition, it also noted that a payment for staying out of the market causes anticompetitive harm. *Id.* at 2234-35. Such an arrangement "simply keeps prices at patentee-set levels" at the consumers' expense, *i.e.*, the resulting benefit is shared only between the patentee and the challenger. *Id*.

The scope-of-the-patent test finds support in a general policy favoring settlements and thus, truncates any inquiry into patent validity or infringement regardless of the merits of the patent. *Id.* at 2230-31. The court cautioned that "whether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* . . . not . . . its starting point." *Id.* at 2231-32 (emphasis in original) (internal quotations omitted). An invalid patent confers its owner no right to exclude others from the market. Even if a patent is valid, it does not carry with it the power to exclude products or processes that do not infringe upon it. *Id.* at 2231. While recognizing that settling parties may have other reasons to prefer RPSA, the Supreme Court found that the scope-of-the-patent test overlooked the possibility that "the patentee has serious doubts about the patent's survival" and "the payment's objective is to maintain supracompetitive prices." *Id.* at 2235, 2236-37. The majority opinion wrote:

> In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.

Id. at 2237.

On the other hand, the Supreme Court was cognizant of the value of settlements and the strong interest in settling complex and expensive patent infringement litigations. *Id.* at 2234 (citing *Schering–Plough Corp. v. FTC,* 402 F.3d 1056, 1074–1075 (11th Cir. 2005); *In re Tamoxifen Citrate,* 466 F.3d 187, 202 (2d Cir. 2006) (noting public's "'strong interest in settlement'" of complex and expensive cases)). The Court made clear that "it is not normally necessary to litigate patent validity to answer the antitrust question." *Actavis*, 133 S. Ct. at 2236. Rather, the court proposed to initially look at the size of a reverse payment. *Id*. According to the Supreme Court, an "unexplained large reverse payment" may "provide strong evidence" of antitrust activity, because it "can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 2235, 2236-37. The Court further noted that the size of a reverse payment can also serve as "a strong indicator of power" possessed by the patentee to bring about anticompetitive harm. *Id.* at 2236.

The Supreme Court in *Actavis* further rejected the presumptive illegality of the "quick look" approach. *Id.* at 2237. Because some reverse payments could be justified under antitrust analysis, the court held that a finding of reverse payment alone is insufficient to conclude its illegality. *Id.* The court reasoned that:

> the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.

Id. Additionally, the Court commented that presumptive rules like the "quick look" approach are appropriate only where "an observer with even a rudimentary understanding of economics could

conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Id.* (internal quotation marks omitted). Since the complexity of a RPSA is far beyond "rudimentary," the Court determined that the "quick-look" approach was not applicable. *Id.*

In formulating the rule of reason analysis, the Supreme Court enumerated several factors to consider: (1) there must be a "payment"; (2) it must be a "reverse" payment, i.e., the payment must be from the alleged patentee to the alleged infringer; (3) it must be "large" which to the Supreme Court is a "surrogate for a patent's weakness" and a "strong indicator of power" — namely, "the power to charge prices higher than the competitive level"; and (4) the large reverse payment is "unexplained." *Id.* at 2236-37. Regarding the fourth factor, valid explanations include the cost of litigation, payments for other services promised to be rendered by the generic challenger and "any other convincing justification." *Id.* at 2237.

Sometimes there are types of settlements that do not fall within the *Actavis* rationale. The Supreme Court provided two types of "commonplace forms" of settlement that are not subject to *Actavis* scrutiny. The first one is when A sues B for patent infringement and demands $100 million in damages; and then B pays A $40 million as settlement. *Actavis*, 133 S. Ct. at 2233. The "implicit net payment" or reduction in demand of $60 million by A does not trigger antitrust scrutiny. *Id.* The second situation occurs when B has a counterclaim for damages against A, the patentee, and A pays B to settle B's counterclaim. *Id.* Such settlements between a patentee and a generic manufacturer are permissible.

Furthermore, the Supreme Court specifically raised the following five sets of considerations to guide its rule of reason analysis: (i) whether the restraint at issue has the "potential for genuine adverse effects on competition"; (ii) whether there are justifications for the anticompetitive consequences; (iii) whether the patentee has the market power to bring about the

anticompetitive harm, which tends to be true when a reverse payment threatens to work unjustified anticompetitive harm; (iv) whether the size of the unexplained settlement payment suggests a workable surrogate for the patent's weakness, which in turn suggests the intent of the patentee to maintain supracompetitive prices; and (v) whether the parties could have settled in a way that did not involve the use of reverse payment. *Id.* at 2234-2237.

The Supreme Court left "to the lower courts the structuring of the present rule-of-reason antitrust litigation." *Id.* at 2238. With this new *Actavis* framework in mind, this Court will analyze the Defendants' motion to dismiss under Fed. R. Civ. P. 12(b)(6).

Twombly* and *Iqbal

Under FED. R. CIV. P. 12(b)(6), a court may grant a motion to dismiss if the complaint fails to state a claim upon which relief can be granted. The Supreme Court explained the standard for addressing a motion to dismiss under Rule 12(b)(6) in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). The *Twombly* Court stated that, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555 (internal citations and quotations omitted); *see also Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007)(stating that standard of review for motion to dismiss does not require courts to accept as true "unsupported conclusions and unwarranted inferences" or "legal conclusion[s] couched as . . . factual allegation[s]" (internal quotation marks omitted)). Therefore, for a complaint to withstand a motion to dismiss under 12(b)(6), the "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact) . . . ." *Twombly*, 550 U.S. at 555 (internal citations quotations omitted).

In *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009), the Court built upon its decision in *Twombly*. *Id.*, 556 U.S. at 684. The Court acknowledged that although a complaint need only contain a "short and plain statement of the claim showing that the pleader is entitled to relief" *id.* at 677-78 (quoting Fed. R. Civ. P. 8(a)(2)), this statement must nevertheless contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. *Iqbal* reiterated two benchmarks of *Twombly*. That is, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. 544, 570 (2007)). Plausibility as explained by the court "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678 (quoting *Twombly*, 550 U.S. at 556).

Thus, when assessing the sufficiency of a complaint, a district court must distinguish factual contentions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* at 678. When evaluating a motion to dismiss for failure to state a claim, district courts must conduct a three-part analysis:

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1947, 173 L. Ed. 2d 868 (2009). Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 1950. Third, "whe[n] there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* This means that our inquiry is normally broken into three parts: (1) identifying the elements of the claim, (2) reviewing the complaint to strike conclusory allegations, and then (3) looking at the well-pleaded components of the complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged.

Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011) (alterations in original).

A complaint will be dismissed unless it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully"; mere consistency with liability is insufficient. *Id.* at 678. A plaintiff may not be required to plead every element of a prima facie case, but he must at least make allegations that "'raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556).

Significantly, the dilemma the Supreme Court faced in deciding *Twombly* is before the Court now, because as in *Twombly* the Court is concerned with an antitrust case. *Twombly*, 550 U.S. at 558-59. The Supreme Court explained "that something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with 'a largely groundless claim' be allowed to 'take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value.'" *Id.* at 557-558 (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347, 125 S. Ct. 1627, 161 L.Ed.2d 577 (2005)). Most notably, "'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Twombly*, 550 U.S. at 558 (alterations in original) (quoting 5 Wright & Miller, Federal Practice & Procedure - Civil Rules: 2010 Quick Reference Guide, Vol. 12B, § 1216, at 233-234). As one hornbook writer has noted, "this standard is best understood as a flexible pleading benchmark that varies depending on the type of claim chosen and the type of allegations pleaded: a 'plausible' auto accident may be very concisely pleaded, whereas a 'plausible' antitrust or RICO case may

demand a far fuller factual presentation." Wright & Miller, 2010 Quick Reference Guide, Vol. 12B, at 152 (2014).

Here, Defendants allege, among other things, that Plaintiffs have not presented sufficient facts to show that Defendants' Settlement Agreements violated antitrust laws. This Court applies the *Twombly* and *Iqbal* standards with the factors of *Actavis* in analyzing the Plaintiff's Complaint. Specifically, where the anticompetitive effects of a settlement agreement which falls within the scope of the exclusionary potential of a patent, a court must determine whether there was a reverse payment that is large and unjustified.

The facts of this case are educed from the Consolidated Amended Class Action Complaint (the "Complaint," ECF No. 472), which was filed on Oct. 14, 2013 and after limited discovery was obtained including the Settlement Agreement between Pfizer and Ranbaxy. This Court also considers public records, including judicial proceedings and relevant patents. *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 Cir. 1993). Based on same, the Court addresses the plausibility of Plaintiff's complaint.

In *Actavis*, the Supreme Court dealt with only one patent for AndroGel which was the subject of the Paragraph IV litigation involving three generic companies. Yet the Supreme Court declined to "measure the length or amount of a restriction solely against the length of the patent's term or its earning potential." *Actavis*, 133 S. Ct. at 2231. Here, the Defendants claim that Lipitor is protected by seven patents; and three of those expire in 2016 (the '511, '740, and '156 patents). (Am. Compl. ¶ 73, 74) (see chart on page 8). In the Court's prior opinion, it found the expiration

date of the '995 patent concerning the active ingredient atorvastatin calcium would have ended on June 28, 2011, but the Court made no judgment upon the five other patents.[12]

Here, Plaintiffs have set forth a plausible fact that the five "back up" patents — the '156 patent, the two Formulation Patents (the '971 and '104 patents), and the Process Patents (the '740 and '511 patents) — were designed around by Ranbaxy. This seems plausible because the Paragraph IV certifications of Ranbaxy, in and of themselves, are sworn statements of Ranbaxy's management to a governmental agency (FDA) with specifications on how to do so.[13] Moreover, courts often find that companies are able to design around Process Patents. In one study, generic applicants prevailed seventy-three percent of the time in lawsuits involving patent infringement of drug products. See, Generic Drug Entry Prior to Patent Expiration: An FTC Study, p. 16 (July 2002). See also *In Re K-Dur Antitrust Litigation*, 686 F. 3d 197, 218 (3d Cir. 2012) vacated *Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013) (mem.). Taking that fact as plausible, the Court focuses on the antitrust allegations.

The heart of the issue here is whether there was a settlement agreement between Pfizer and Ranbaxy that constituted a RPSA that warrants antitrust scrutiny. According to the Complaint, the parties entered into a RPSA on June 17, 2008 by signing the Settlement Agreement. (Am. Compl. ¶ 145.) The Settlement Agreement resolved multiple litigations pending worldwide, including law

[12] As held in *In re Lipitor Antitrust Litig*., 2013 U.S. Dist. LEXIS 126468 (D.N.J. Sept. 5, 2013).

[13] The Court had some difficulty with the Plaintiff's rationale underlying plausibility. That is, Plaintiffs contend that Ranbaxy's amorphous atorvastatin would have been approved by FDA because the FDA was "under immense pressure" to approve generic Lipitor. (Am. Compl. ¶ 194.) For example, Plaintiffs allege that Senate Health, Education, Labor, and Pensions Committee Chairman Tom Harkin and other public officials sent a letter to FDA on March 10, 2011, urging FDA to "clarify the relevant regulatory issues" so the public could afford generic atorvastatin. (Am. Compl. ¶ 195.) This statement does not meet the plausibility standard because a public statement by public officials about an active political issue is not a plausible conclusion without other support, especially when the statements, like Senator Harkin's letter, have no other legally binding effect. In addition, Ranbaxy's amorphous atorvastatin was never approved by the FDA because Ranbaxy amended with a crystalline version after the Settlement Agreement was entered.

suits on three brand drugs pending in the United States. Settlement Agreement at 1 and Ex. 2; ECF No. 493, at 11. According to the Plaintiffs, the alleged RPSA constituted an unlawful contract, combination and conspiracy to allocate the entire United States market for atorvastatin calcium to Pfizer until November 30, 2011. (Am. Compl. ¶ 6.)

Evidently, Pfizer sought the delay because it had a significant economic reason, which was that Lipitor grossed $1 billion per month – the largest selling drug of all time.

In exchange for Ranbaxy's agreement to delay its launch of generic Lipitor until November 30, 2011, Pfizer allegedly gave substantial financial inducements to Ranbaxy, including: (a) Pfizer's "sweetheart" agreement to dismiss damages claims likely worth hundreds of millions of dollars in *Accupril* II litigation in exchange for a token "pretextual" payment of $1 million; and (b) the right to market generic Lipitor in at least eleven foreign markets outside the United States. (Am. Compl. ¶¶ 7, 148.) The Plaintiffs assert that Pfizer and Ranbaxy characterized the Settlement Agreement as, in part, settling the "Lipitor Process" litigation in order to "disguise the [Agreement's] true anticompetitive purpose." (Am. Compl. ¶ 146.) Although not specifically addressed in the Complaint, the Settlement Agreement also resolved two other U.S. litigations: Caduet Process litigation, which involved the same Process Patents as Lipitor Process litigation; and Caduet ANDA litigation, which involved the '893 patent and another U.S. patent which Plaintiffs argue is not relevant to the case at bar and is not alleged in the Complaint. ECF No. 493 at 13; *see supra* note 9. Furthermore, the Settlement Agreement also settled twenty-three legal actions pending overseas. ECF No. 493 at 13; Settlement Agreement p. 26 Exhibit 2. Plaintiffs maintain that the financial inducements from Pfizer were "extraneous" to any possible results that Ranbaxy might achieve in any U.S. Lipitor patent disputes that were, or ever could, exist between Ranbaxy and Pfizer. (Am. Compl. ¶ 7.)

Ranbaxy allegedly agreed, in exchange for payments by Pfizer, that it would: (a) not enter the market or compete with Pfizer in the atorvastatin calcium market in the United States until November 30, 2011; (b) not relinquish or selectively waive its first-to-file 180-day marketing exclusivity such that any other ANDA filer would be unable to market a generic version of Lipitor in the United States before November 30, 2011 (which had the effect of creating a "bottleneck" that blocked FDA approval of any later would-be generic); (c) not contest the validity of process patents that Pfizer was allegedly misusing to delay the efforts of other would-be generic entrants; and (d) stop protesting Pfizer's application for reissuance of the '995 patent that had been declared invalid, in part, by the Federal Circuit and pending before the PTO. (Am. Compl. ¶ 8.)

Obviously, use of the words "sweetheart agreement" and "pretextual" payment of "extraneous" inducements are characterizing rather than factually analyzing the settlement in order to meet the *Twombly*/*Iqbal* standard. But in light of *Actavis*, this Court examines whether the terms of the Settlement Agreement constitute a RPSA and violate antitrust laws. More specifically, the Court examines whether the factual allegations are sufficient to make plausible that Pfizer made a large and unexplained reverse payment to Ranbaxy in support of antitrust activities.

Payment

In providing the rule of reason analysis to a RPSA, *Actavis* does not define payment or provide any clarity as to whether a payment can be something other than a monetary payment. Since the *Actavis* decision, there has been much discussion by other courts, the parties, and commentators regarding the question of what constitutes a payment.

The common use of the term payment is described as something given to discharge a debt or obligation and does not require the payment to be in the form of money. *See Hill v. United*

States, 263 F.2d 885, 886 (3d Cir. 1959); *Staff Builders of Philadelphia, Inc. v. Koschitzki*, 989 F.2d 692, 695 (3d Cir. 1993). In Black's Law Dictionary, payment is defined as "performance of an obligation by the delivery of money or some other valuable thing accepted in partial or full discharge of the obligation." Black's Law Dictionary (9th ed. 2009). Payment may also be defined as "the discharge of a pecuniary obligation by money or what is accepted as the equivalent of a specific sum of money." 60 Am. Jur. 2d Payment § 1. Furthermore, it is widely held that a payment may refer to a transfer of something of value other than money. *See* 60 Am. Jur. 2d Payment § 26; *Sousa v. First Cal. Co.*, 101 Cal. App. 2d 533, 540, 225 P.2d 955, 960 (1950); *Dynair Electronics, Inc. v. Video Cable, Inc.*, 55 Cal. App. 3d 11, 18, 127 Cal. Rptr. 268, 272 (Cal. Ct. App. 1976). A non-monetary payment includes something of value that can be converted to a concrete, tangible or defined amount which yields a reliable estimate of a monetary payment. In this case, the Plaintiffs principally argue that the settlement of Pfizer's claim in Accupril is a non-monetary payment.

Other courts have reviewed whether *Actavis* requires that the payment must be cash. One court held that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).[14] Another decision (by one of my esteemed New Jersey colleagues) found

[14] In *In re Nexium*, AstraZeneca and three generic defendants—Ranbaxy, Teva, and Dr. Reddy's, were alleged to have entered into reverse payment agreements to keep a generic version of Nexium off the market. All three generic defendants agreed to refrain from selling generic versions of Nexium until May 27, 2014 when some (but not all) of the patents had expired, though this was years after the generic defendants were initially proposing in their Paragraph IV certifications and arguing in the resulting litigations. In return, AstraZeneca agreed to not to produce its own authorized generic version of Nexium during Ranbaxy's 180–day exclusivity period, allegedly accruing a value to Ranbaxy of over $1 billion. It is unclear from the opinion if there was a cash payment made to Ranbaxy. Also, AstraZeneca forgave contingent liabilities of both Teva and Dr. Reddy's related to "at risk" launches of generic versions of non-related products. The generic defendants urged the court to read *Actavis* to apply only to monetary payments and the court declined. At the motion to dismiss stage, the *In re Nexium* court found the allegations sufficient to allege an antitrust violation. *In re Nexium (Esomeprazole) Antitrust Litig*., 968 F. Supp. 2d

otherwise and held that "the Supreme Court considered a reverse payment to involve an exchange of money" and therefore did "not extend the holding of *Actavis* to the non-monetary facts before it." *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-CV-995 WHW, 2014 WL 282755, at 6-7 (D.N.J. Jan. 24, 2014).[15] This Court somewhat agrees with the analysis of both cases. That is, it is true that Actavis never indicated that a reverse payment had to be a cash payment; but it is also true that *Actavis* emphasized cash payments. In applying *Actavis* here, the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors such as whether it is "large" once the subtraction of legal fees and other services provided by generics occurs.

The Supreme Court's general concern is to determine if there are "genuine adverse effects on competition." *Actavis*, 133 S. Ct. at 2234 (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, at 460–461, 106 S.Ct. 2009 (citing 7 Areeda ¶ 1511, at 429 (1986))). Although *Actavis* addressed cash payments, reading the opinion as a whole, it is clear that the Supreme Court focuses on the antitrust intent of the settling parties rather than the manner of payment. For example, Justice Breyer stated: "the relevant antitrust question is: What are [the] reasons [for preferring reverse payment settlements]? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to

367, 392 (D. Mass. 2013). Later, at the summary judgment stage, the court denied summary judgment made on similar grounds. *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-02409-WGY (D. Mass. Sept. 4, 2014), ECF No. 977.

[15] In this case, GlaxoSmithKline (GSK) and the generic defendant Teva are alleged to have entered into reverse payment agreements to keep a generic version of Lamictal off the market. GSK allowed certain generic forms of Lamictal to enter the market before all patent claims had expired, though later than Teva was initially proposing in the Paragraph IV certification and arguing in the resulting litigation. In return, GSK agreed not to produce its own authorized generic version of Lamictal during Teva's 180-day exclusivity period. The court held that application of *Actavis* did require a monetary payment to have occurred in the settlement and the no-authorized generic agreement was not a payment within Actavis. The court concluded that "the settlement was reasonable and not the sort that requires Actavis scrutiny."

forbid the arrangement." *Actavis*, 133 S. Ct. at 2237.

The distinction between non-monetary and cash payments impacts the plausibility standard of Rule 12(b)(6). When Justice Breyer explained RPSA through the use of a simple hypothetical "Company A, the patentee, to pay [Company] B [the claimed infringer] many millions of dollars," it is easy to identify the reverse payment; however, in a non-monetary payment it is not as easily recognized. *Actavis*, 133 S. Ct. at 2227. The pleading must show some reliable foundation for estimating the alleged reverse payment. *Cf.* IIA Phillip E. Areeda, Herbert Hovenkamp, *et al*., Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶397, at 417 (3d ed. 2007).

As noted previously, *Twombly* and *Iqbal* establish a flexible pleading benchmark, and in a case where a non-monetary payment is alleged in an antitrust suit, the pleading must demonstrate the reliable foundation showing a reliable cash value of the non-monetary payment through the use of more facts upon which Plaintiff depends. As the Third Circuit noted in an antitrust case:

> [i]t is, of course, true that judging the sufficiency of a pleading is a context-dependent exercise. Some claims require more factual explication than others to state a plausible claim for relief. For example, it generally takes fewer factual allegations to state a claim for simple battery than to state a claim for antitrust conspiracy.

W. Penn Allegheny Health Sys., Inc. v. Univ. Pittsburg Med. Ctr., 627 F.3d 85, 98 (3d Cir. 2010) (internal citations omitted). It is not like changing plausibility to probability; it simply requires a showing of a reliable foundation used within the industry to convert the non-monetary payment to a monetary value. The Complaint here does not do so.

Plaintiffs allege that Pfizer made two "payments" to Ranbaxy in order to keep Ranbaxy off the atorvastatin market: (i) the forfeiture of Pfizer's claim for damages in the *Accupril* II litigation in exchange for Ranbaxy's payment of $1 million; and (ii) foreign patent litigation settlements

permitting Ranbaxy to launch generic Lipitor in at least eleven non-U.S. markets prior to patent expiration. (Am. Compl. ¶ 7, 148, 178, 182.) To this Court, Plaintiffs must plead a reliable foundation upon which to estimate the value of the compromise of Pfizer's damages in the Accupril II litigation. In defining the payment prong of the *Actavis* rule of reason analysis, one commentator noted where the non-monetary payment is consideration, it must be valued. The commentator wrote:

> The payment prong involves the following steps: (a) valuing any consideration flowing from the patentee to the claimed infringer, which may be made over time and may take forms other than cash; (b) deducting from that payment the patent holder's avoided litigation costs; and (c) deducting from that payment the value of goods, services, or other consideration provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions)....
>
> Valuing this consideration, step (a) above, is sometimes an intricate proposition. For example, the payment could include forgiving a debt owed by the claimed infringer to the patent holder. The debt may include patent infringement damages. The claimed damages could pertain to the product whose infringing entry is at issue (if there has been entry) or another product.... Although sometimes intricate, handling this complexity is well within the competence of a district court. (emphasis added)

(quoting Aaron Edlin, et. al., *Activating Actavis*, 28 Antitrust 16, 18 (2013) (hereinafter "*Activating Actavis*")). In this case, in order to approximate the amount of Pfizer's alleged consideration to Ranbaxy, it is necessary to consider the monetary value of Pfizer's claim at the time of the settlement. As the commentator stated, this can be "intricate" because Pfizer's claim for damages was still contingent, i.e., Pfizer's claim "[had] not yet accrued and [was] dependent on some future event that may never happen." Black's Law Dictionary (9th ed. 2009). In other words, the success of Pfizer's full claim for damages in *Accupril* II was dependent upon the court's judgment finding the Accupril patent valid and infringed, i.e., a "future event that may never happen." Moreover, circumstances surrounding the parties often change as a litigation progresses. Because the parties settled before the actual judgment, it is unclear what Ranbaxy's liability would have been if a trial

occurred.

In considering the monetary value of a patent infringement claim Plaintiff must allege facts as if Plaintiff was standing in the shoes of the parties at the time of settlement. *Cf. Singh v. Bradford Regional Med. Center*, 752 F. Supp. 2d 602, 619-20 (W.D. Pa. 2010). That is, to value the claim for damages in *Accupril* II, one must demonstrate the evidence upon which Pfizer would have most likely relied upon at that time. In the *Accupril* matter, the claim was for an alleged award of profits lost because of diverted sales, price erosion and increased costs, or a royalty fee due to Ranbaxy's infringement. Patent Law and Practice *§ 8.11, p. 228-231 (Fed. Jud. Center 6th Ed. 2008).* To prove profits lost, the patent owner must show he would have made some or all of the infringers' sales. In addition, the patent owner must show four major elements: (1) demand for the product; (2) absence of noninfringing substitutes; (3) manufacturing and marketing capability; and (4) the amount of profit. *Id.*; *see also Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F. 2d 1152, 1156 (6th Cir. 1978). Some of the major elements have subparts. For example, the fourth element, the amount of profit, has three components, including the number of sales the patentee would have made, the price change for those sales, and the cost to produce and market same. Patent Law and Practice, Sixth Edition (BNA), Herbert F. Schwartz; Robert J. Goldman § 8.11, p. 2 (2008) Here, the Complaint does not allege any such formulation. Plaintiffs generally argue that the non-monetary payment could be the same amount as the bond posted ($200 million) or it could be the difference in gross sales ($525 million to $70 million); however, the Plaintiffs never attempt to value this non-monetary payment to a reliable measure of damages as articulated in the *Panduit* case. As noted above, neither of Plaintiff's figures easily plug into the lost profits criteria; hence, they are not plausible because they do not provide a reliable foundation or methodology to estimate the monetary value of Pfizer's claim for infringement damages.

Assuming Plaintiffs relied on a reliable foundation (which Plaintiffs did not), the amount of a settlement varies due to the mindset of the parties at the time of the settlement as to the risk of trial. Hence, the monetary value of the claim must include some evaluation of those risks. For example, the Third Circuit set forth factors the district court should use approving a class action. Some of those factors such as the risks of establishing liability or damages, the ability of the defendant to withstand a greater judgment and the range of reasonableness in light of the best possible recovery. *Girsh v. Jepson*, 521 F. 2d 153, 157 (3d Cir. 1973). Although *Girsh* normally has a different application than here, the fact remains that some acknowledgement of settlement consideration must be plead. Here, the Complaint does not do so except that it characterizes Pfizer's claim as "slam dunk" and Pfizer had Ranbaxy "over the barrel." In a RPSA case, the facts rather than broad characterizations must be alleged. More specifically, one recent law review article listed some other settlement factors to be considered in an *Actavis* analysis. Such factors include: the branded company's perceived probability of winning the patent litigation; the branded company's monopoly profits and duopoly profits (if the generic were to enter the relevant market); the remaining lifetime of the patent at issue and the proposed market entry date for the generic manufacturer; and the branded company's litigation costs and the amount of payment from the brand to the generic. *Activating Actavis* at 14. As part of the conversion from a non-monetary payment to an estimate of the monetary payment for the claim, Plaintiff cannot bypass those settlement factors by declaring it was a "slam dunk" case. Most experienced lawyers would acknowledge that most claims are discounted in order to achieve settlement. Again, Plaintiffs must plead the allegations of the Complaint as if they were standing in the shoes of the parties at the time the alleged wrong occurred. This means Plaintiffs must allege a measure of damages accepted within the industry and a discussion of the settlement factors relating to the claim of damages

settled at that time. None of this is adequately alleged in the Complaint.

The lack of any reliable foundation pervades the entire Complaint. For example, Pfizer's second alleged payment to Ranbaxy is even more challenging. That is, Plaintiffs allege that Pfizer allowed Ranbaxy to market generic Lipitor in at least eleven foreign countries in the form of license agreements. (Am. Compl. ¶ 7, 148, 178.) These provisions allegedly "added to the financial inducements provided by Pfizer to Ranbaxy, and were not of a kind that Ranbaxy could ever expect to achieve through success in any litigation of U.S. Lipitor patents." (Am. Compl. ¶ 178.) Again, when looking at this from the *Actavis* rationale, the Complaint lacks any foundation to estimate the cash value of the alleged licenses granted in other countries. Since no such allegations were pled, the allegations are implausible[16].

Legal Fees

Within *Actavis*, a reverse payment occurs when a net positive payment flows from the patentee to the alleged infringer. *Id.* Even if the reverse payment is shown, any traditional settlement considerations or services provided by the generic are deducted to determine whether there is a net positive payment flowing from the patentee to the alleged infringer. That is, Ranbaxy's prior litigation costs may be deducted from the total payment made by Pfizer. *Actavis* provides a rationale for this framework by stating: "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Actavis* at 2236; *see also generally Activating Actavis* at 18.

[16] The Complaint seems to set forth "bottlenecking" as a separate cause of action. The Court views bottlenecking as an effect of the RPSA. Hence, the restraint of trade, if any, focuses on the RPSA rather than the bottlenecking. *See Actavis*, 133 S. Ct. 2223, 2231.

In this case, with the exception of paragraphs 180 and 255, the Complaint is devoid of any discussion about saved litigation costs to either party. This is far from fulfilling "a plaintiff's obligation to provide the grounds of his entitlement to relief that requires more than labels and conclusions." *Twombly*, 550 U.S. at 555 (citations omitted). Plaintiffs failed to cite to two published surveys regarding legal fees which may have constituted a reliable foundation within the industry. According to a survey reported in 2005, a median expense of patent litigation was $4.5 million and the patentee is "likely to spend more, as it has more at stake in the case." C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1623 n. 89 (2006) (citing American Intellectual Property Law Association, Report of the Economic Survey). Another study cited by the dissenting Justices in *Actavis* suggests that the cost of patent infringement litigation for a *generic* challenging a brand name pharmaceutical patent can be as much as $10 million per suit. *Actavis*, 133 S. Ct. at 2243-44 (Roberts, J., dissenting) (citations omitted). In light of the two surveys, it is readily conceivable that the cost of patent litigation for Ranbaxy may have been between $4.5 million and $10 million per suit. Considering that the Agreement settled three other U.S. patent infringement or ANDA litigations and 23 foreign legal actions, the saved cost of litigation for Ranbaxy may have been between $117 million (26 suits at $4.5 million) and $260 million (26 suits at $10 million each). Despite the value, the Complaint fails to consider the legal fees aspect of the case in such a light. Since Plaintiffs failed to adequately address this point, the Complaint is implausible.

Large Payment

The Supreme Court in *Actavis* did not define what constitutes "large." Instead, the court noted that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's

objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Actavis*, 133 S. Ct. at 2236. Therefore, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness" (*Actavis*, 133 S. Ct. at 2236-37) as well as "'a strong indicator of power' — namely, the power to charge prices higher than the competitive level. *Actavis*, 133 S. Ct. at 2236 (citation omitted).

One way to measure the "largeness" of a reverse payment is to assess whether the amount is larger than what the generic would gain in profits if it won the Paragraph IV litigation and entered the market. The *Actavis* majority found this to be "strong evidence" of anticompetitive activity. *Actavis* 133 S. Ct. at 2235 (citing See Hemphill, 81 N.Y.U. L.Rev. at 1581) *See also* Br. for 118 Law, Economics, and Business Professors et al. as *Amici Curiae* 25. Whatever the definition "large" is meant to represent, this Court looking at the Complaint is unable to perform the analysis, as the Plaintiffs failed to plausibly allege an estimate of the monetary value of the non-monetary payment, and the amount of legal fees of Ranbaxy should have been subtracted from same.

Statements by Pfizer's Management

There are several statements of Pfizer's management upon which Plaintiffs rely in order to show plausibility of their RPSA cause of action. The first concerns a statement by Hank McKinnell, Pfizer's former Chairman and Chief Executive Officer (CEO) concerning the date on which the exclusivity period of the Lipitor patents ended. The quote is an excerpt from a book he authored and published in 2005. The quote reads:

> There are dozens of generic drug manufacturing companies with a red circle around June 28, 2011. That's the day the patent for our anti- cholesterol medication Lipitor expires. . . . Shortly thereafter a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets containing

atorvastatin calcium[.]

(Am. Compl. ¶ 205.) The Plaintiffs argue that the statement constitutes an admission by Pfizer's former CEO about the final expiration date (June 28, 2011). It shows Pfizer's mindset about the life of the Lipitor patents. Plaintiffs argue that the June 28, 2011 is a key date because it recognizes that the Formulation Patents, the Process Patents, and the '156 patent could not block generics from entering the market . (Am. Compl. ¶ 206 (see chart, page 8). This quote may constitute an admission under Federal Rule of Evidence 801(d)(2)(D), which provides that a statement is not hearsay if it "was made by the party's agent or employee on a matter within the scope of that relationship and while it existed." *See also Davis v. Mobil Oil Exploration & Producing Se., Inc.*, 864 F.2d 1171 (5th Cir. 1989). In the Court's view, it is difficult to rely upon five lines from a book, or its context, without analyzing the gist of the entire book. As a result, the quote, on its own, cannot be the sole basis of a cause of action. It does not meet the plausibility standard or support Plaintiffs' argument that the five patents are irrelevant without further plausibility. Moreover, broad assumptions about the quote are not warranted because it was written three years before the Settlement Agreement was entered, and it was not directly connected with the negotiations concerning the Settlement Agreement.

The second statement was made by Pfizer's Chief Executive Officer Kindler to company shareholders wherein he declared that "[Pfizer] had very, very substantial damages in the way of lost profits that we intend to recover from Ranbaxy" in the Accupril case. (Am. Compl. ¶ 170.) Since the statement does not disclose the monetary value of a non-monetary payment, it is of little impact as to its measurement within the *Actavis* rationale.

The third statement is by a Pfizer attorney who in a brief submitted to the Federal Circuit in the Accupril I litigation, wrote "Pfizer will be claiming hundreds of millions of dollars in

damages in for the infringing sales that were made prior to the injunction." Br. for Plaintiffs-Appellees at 5, *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. 08-1150-1190, 2008 WL 2444724 (Fed. Cir. May 28, 2008). This statement sounds more like a demand than a plausible value of the claim.

These statements are corroborative evidence, but plausibility requires some reasonable foundation to estimate the cash value of the non-monetary reverse payment.

Agreement Must be Considered as a Whole

As outlined, the Agreement concerns the settlement of patent litigation concerning three drugs – Lipitor, Accupril and Caduet. In order to analyze whether an alleged RSPA occurred to delay entry of generic Lipitor, as plaintiffs allege, the terms of the entire Settlement Agreement must be analyzed to determine plausibility. To rely only on certain sections (Accupril) of the Settlement Agreement and disregard other sections (Caduet) is not a reasonable analysis. The Complaint does not plead the Settlement Agreement as a whole. In the rule of reason analysis, "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." *In re Tamoxifen Citrate Antitrust Litig*. 466 F.3d 187, 201 n. 13 (2d Cir. 2006), *cert. denied sub. nom., Joblove v. Barr Labs, Inc*., 127 S.Ct. 3001 (2007) (*Tamoxifen* II") (quoting *State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997)). Generally, "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003); *see also In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 WL 4403848, *11 and n.13 (E.D. Pa. Sept. 5, 2014) (holding, where three separate settlement agreements had been entered by the antitrust defendants, that defendants were

not entitled to examine "each of the three settlement agreements in isolation," but should be read as one agreement). Here, the Complaint fails to adequately address (1) the Caduet litigation; (2) the costs of all litigation; (3) the agreement to utilize Pfizer's bulk active pharmaceutical ingredient, atorvastatin, in Canada. As such, the claim is implausible for failure to consider the Settlement Agreement as a whole, and to "account [for] a variety of factors." *In Re Tamoxifen Citrate Antitrust Litigation*, 466 F. 3d at 201.

To the Court, the analysis of Caduet and the other terms which resolved other litigation globally appear critical to determining the monetary value of the settlement claim under *Actavis*. The contention that other provisions of the Agreement do not matter (like Caduet) makes little sense. At the very least, those factors must be plead to show why they do not alter Plaintiffs antitrust claims. Hovenkamp, Sensible Antitrust Rules for Pharmaceutical Competition, 39 U. S. F. L. Rev. 11, 24 (2004). Moreover, there is a sliding scale in appraising reasonableness. *California Dental Assn.*, 526 U. S. at 780. As such, this selective look at certain provisions of the agreement and bypassing others renders the complaint implausible.[17] The Court must look at the Settlement Agreement as a whole and cannot extricate individual provisions. *In re: The Prudential Insurance Company of America Sales Practice Litigation*, 962 F. Supp. 459 (D.N.J. 1997), *aff'd*

[17] Similarly, Defendants argue that Pfizer's forbearance of Ranbaxy's potential liability did not constitute a "payment" because *Accupril* II settlement falls within an exception to *Actavis* and is a "safe harbor" from RPSA liability. ECF No. 490, p. 19-20; *see also* ECF No. 493, p. 20. That is, the *Accupril* II resolution stands on its own and is not related to Lipitor Process settlement or the Caduet settlement. The Court disagrees. The Agreement was signed at one single time, and the corporate management of each party most likely comingled the facts to determine the settlement's adequacy. To divide the Settlement Agreement into segments, as defendants propose, is opposite of what most likely occurred. Here, the facts give rise to the conclusion that the *Accupril II* settlement was likely reviewed in conjunction with the other litigations, and other terms of the Agreement. The settlements of three branded drugs in one Agreement circumstantially combines all three drugs into one contemporaneous settlement. Settlement Agreement at 26 This is an obvious indication that the parties negotiated each settlement with other cases in mind, it is implausible to analyze the agreement unless it is considered as a whole. See *Weiss v. Mercedes-Benz of North America*, 899 F. Supp. 1297, *aff'd* 66 F. 3d 314 (D.N.J. 1995). Thus, Pfizer's safe harbor argument does not hold water.

148 F. 3d 283, *cert. denied, Krell v. Prudential Ins. Co. of America,* 525 U.S. f1114, 119 S.Ct. 890 (1999).

Re-Pleading the Matter

Plaintiffs have failed to plead their Amended Complaint with the plausibility required by the Federal Rules of Civil Procedure and the relevant case law. The Amended Complaint constitutes the plaintiffs' second attempt to plead the relevant facts. However, the pleading itself has changed little from the original Complaint filed in this matter. The plaintiffs have not argued that they should be given leave to re-plead facts in a second Amended Complaint, nor have they asserted any facts that would meet the required standard of pleading. Therefore, the Amended Complaint is dismissed with prejudice. *LaFlamme v. Societe Air Fr.*, 702 F. Supp. 2d 136, 155 (E.D.N.Y. 2010) (citing *Horoshko v. Chase Manhattan Mortgage Corp*., 373 F.3d 248, 249 (2d Cir. 2004); *Nat'l Union of Hosp. & Health Care Employees v. Carey*, 557 F.2d 278, 282 (2d Cir. 1977); *Trautenberg v. Paul, Weiss, Rifkind, Wharton, Garrison LLP*, 351 Fed. App'x 472, 474 (2d Cir. 2009); and *Anatian v. Coutts Bank (Switz.) Ltd*., 193 F.3d 85, 89 (2d Cir. 1999)).

Conclusion

Plaintiffs argue that "this court need not, now, engage in . . . the 'intricate proposition' of valuing the payment from Pfizer to Ranbaxy." (ECF No. 509 at 44). The Court disagrees. Pursuant to *Twombly* and *Iqbal*, the standard for considering a motion to dismiss a complaint is a based upon a flexible pleading benchmark. In this case, where Plaintiffs rely on a non-monetary reverse payment of an inchoate claim, they must plead plausible facts including an estimate the monetary value of same so the *Actavis* rationale can be applied. The Plaintiffs have failed to delineate any type of methodology to connect the claim to its monetary value. To meet this standard, Plaintiffs must stand in the shoes of the underlying parties at the time of the settlement, and determine an

estimate of the monetary value of the settlement at that time. The Complaint as pleaded does not do so, despite it being the second attempt by Plaintiffs to plead their causes of action. The flexible pleading benchmark established by *Twombly* requires such pleading same in these difficult cases. Remember, this is not a car accident where plausible facts are easily set forth; it is a non-monetary payment in an antitrust suit which is at the opposite end of the benchmark scale. Guesswork -- like the use of the bond amount ($200 million) or the difference in sales ($225 million to $70 million) -- coupled with non-specific statements of Pfizer management is insufficient. A reliable foundation need not yield a precise amount of the alleged non-monetary payment, but one that fits within the ballpark like using the loss of profit standard. *See infra* at 34-36. The Complaint fails to provide same. For the reasons stated above, Defendant's motion to dismiss the Direct Purchaser's Complaint is granted with prejudice.

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

September 12, 2014