UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re EFFEXOR XR ANTITRUST LITIGATION This Document Relates To: Direct Purchaser Class Actions	Civil Action No. 11-5479 (PGS) (LHG) **MEMORADUM**

SHERIDAN, U.S.D.J.

This matter comes before the Court on Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall Pharmaceuticals LLC, and Wyeth Pharmaceuticals Company's (collectively, "Wyeth Defendants" or "Wyeth") and Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd.'s (collectively, "Teva Defendants" or "Teva") Motion to Dismiss Plaintiffs Professional Drug Company, Inc., Rochester Drug Co-Operative, Inc., Stephen L. LaFrance Holdings, Inc., Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors, and Uniondale Chemists, Inc.'s (collectively, "Direct Purchaser Class Plaintiffs") Second Amended Consolidated Class Action Complaint for failure to state a claim pursuant to FED. R. CIV. P. 12(b)(6) (ECF Nos. 136, 138, 305). Direct Purchaser Class Plaintiffs allege that Defendant Wyeth engaged in an anticompetitive scheme to prevent and delay the approval and marketing of generic versions of its antidepressant drug Effexor XR, an extended release version of the compound venlafaxine hydrochloride, in violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1-2. Specifically, Plaintiffs allege that Wyeth: (1) fraudulently procured three patents for extended release formulations of venlafaxine hydrochloride; (2) wrongfully listed those patents in the FDA Orange Book as covering Effexor XR; (3) engaged in sham litigation to block and delay multiple generic companies from entering the generic Effexor XR market; (4) entered into

an illegal horizontal market-allocation and price-fixing reverse settlement agreement with Defendant Teva through which Wyeth paid Teva value worth over $500 million in exchange for Teva's agreement not to market its own generic version of Effexor XR until an agreed-upon entry date; and (5) negotiated settlements with subsequent generic applicants for the sole purpose of preserving and protecting its alleged monopoly and market-division agreement with Teva. The Court held oral argument in this matter on September 10, 2013, April 3, 2014 and June 5, 2014. For the reasons set forth herein, Defendants' Motion to Dismiss is granted in part and denied in part.

I. BACKGROUND

A. Parties

1. Plaintiffs

Plaintiff Professional Drug Company, Inc. ("Professional Drug") is a corporation organized under the laws of the State of Mississippi with its principal place of business in Biloxi, Mississippi. (Direct Purchaser Class Pls.' Second Am. Consolidated Class Action Complaint ("Second Am. Compl.") at ¶ 17). It purchased Effexor XR directly from Wyeth during the class period. (*Id*.).

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a stock corporation organized under the laws of the State of New York with its principal place of business in Rochester, New York. (*Id*. at ¶ 18). It purchased Effexor XR directly from Wyeth, and generic Effexor XR directly from Teva, during the class period. (*Id*.).

Plaintiff Stephen L. LaFrance Holdings, Inc. is a holding company with interests in retail and wholesale distribution whose corporate office is located in Pine Bluff, Arkansas. (*Id*. at ¶ 19.). Plaintiff Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors (collectively with Stephen L. LaFrance Holdings, Inc., "LaFrance") is a wholly owned subsidiary of Stephen L. LaFrance

Holdings, Inc. which operates as its distribution company. (*Id*.). Its corporate office is similarly located in Pine Bluff, Arkansas. (*Id*.). LaFrance is the assignee of McKesson Corporation which purchased Effexor XR directly from Wyeth during the class period. (*Id*.).

Plaintiff Uniondale Chemists, Inc. is a retail pharmacy located in Uniondale, New York. (*Id*. at ¶ 20). Uniondale Chemists is the assignee of QK Healthcare, Inc. which purchased Effexor XR directly from Wyeth during the class period. (*Id*.).

2. Defendants

Defendant Wyeth – a/k/a Wyeth LLC, f/k/a Wyeth, Inc., f/k/a American Home Products - is a corporation organized under the laws of the State of Delaware with its principal place of business in Madison, New Jersey. (*Id*. at ¶ 21). It operates as a wholly owned subsidiary of Pfizer. (*Id*.).

Defendant Wyeth Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business in Collegeville, Pennsylvania. (*Id*. at ¶ 22.). Wyeth Pharmaceuticals, Inc. is a member of Wyeth Pharmaceuticals Division and is a wholly owned subsidiary of Wyeth. (*Id*.).

Defendant Wyeth-Whitehall Pharmaceuticals ("Wyeth-Whitehall") is a corporation organized under the laws of the Commonwealth of Puerto Rico with its principal place of business in Guayama, Puerto Rico. (*Id.* at ¶ 23.). Wyeth-Whitehall is in the business of pharmaceutical preparation and is a subsidiary of Wyeth. (*Id*.).

Defendant Wyeth Pharmaceuticals Company ("WPC") is a corporation organized under the laws of the Commonwealth of Puerto Rico with its principal place of business in Guayama, Puerto Rico. (*Id.* at ¶ 24.). WPC is in the business of pharmaceutical wholesale products and is a subsidiary of Wyeth. (*Id*.).

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized under the laws of the State of Delaware with its principal place of business in North Wales, Pennsylvania. (*Id*. at ¶ 27). Teva USA, which is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., is in the business of developing, manufacturing and marketing pharmaceutical products in the United States. (*Id*.).

Defendant Teva Pharmaceutical Industries Ltd. is an international corporation headquartered in Petach Tivka, Israel which is in the business of developing, manufacturing and marketing pharmaceutical products. (*Id*. at ¶ 28). It has major manufacturing operations in the United States and conducts a large portion of its sales in the United States through its subsidiaries. (*Id*.).

B. Regulatory Framework

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the United States Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a)-(b). When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in the FDA's book of Approved Products with Therapeutic Equivalence Evaluations (the "Orange Book").

The Hatch-Waxman Amendments to the FDCA simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"). Pursuant to Hatch-Waxman, a generic manufacturer seeking

approval to sell a generic version of a brand name drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug is bioequivalent to the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.

To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications. Most relevant for purposes of this action is a Paragraph IV certification in which the generic manufacturer certifies that the patent for the brand name drug "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]" 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA by suing the ANDA applicant for patent infringement. If the brand name manufacturer brings a patent infringement action against the generic filer within forty –five (45) days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (1) the passage of thirty (30) months, or (2) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). As an incentive to encourage generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification is entitled to a 180-day exclusivity period to market its generic version of the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute less-costly AB-rated generic equivalents for

branded prescriptions. (Second Am. Compl. at ¶ 44). As a result, the launch of AB-rated generics usually results in a rapid decline in price and a large-scale shift in sales from the branded to the generic manufacturer. (*Id.*). According to Plaintiffs, once a generic equivalent hits the market, the generic quickly captures sales of the branded drug, often in excess of 80 percent of the market within the first six months. (*Id.*). In a recent study, the Federal Trade Commission ("FTC") found that, within a year of generic entry, generics had, on average, captured 90 percent of branded sales and that prices had dropped 85 percent with multiple generics on the market.[1] (*Id.*). In the end, total payments to brand manufacturers for the drug decline to a small fraction of the amounts paid prior to generic entry.

While later ANDA-approved generic manufacturers must wait six months after the first filer's market entry to seek FDA approval, a branded manufacturer's "authorized generic" may enter the market at any time. Authorized generics are essentially prescription drugs manufactured by brand pharmaceutical companies that are marketed under a private label and sold at generic prices. Authorized generics compete with generics on price and are usually marketed to consumers during the first filer's 180-day exclusivity period. A 2006 study sponsored by the Pharmaceutical Research and Manufacturers of America found that generic prices were 16 percent lower when an authorized generic was marketed. (*Id*. at 58).So, while the first ANDA filer enjoys the exclusive right to sell the only ANDA-approved generic product during its 180-day exclusivity period, the prices at which it may do so are often lowered by price competition from authorized generics. (*Id*. at ¶ 61). Without the entry of an authorized generic, the first filer is essentially left with all generic sales during that time period.

[1] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS: A FEDERAL TRADE COMMISSION STAFF STUDY (Jan. 2010), *available at* http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff.

C. Factual Background

1. Prosecution History of the Effexor XR Patents

On August 13, 1985, the United States Patent and Trademark Office ("PTO") issued a patent for the compound venlafaxine hydrochloride ("venlafaxine"), U.S. Patent No. 4,535,186 (the "Husbands patent" or the "'186 patent"). (*Id*. at ¶ 62) The inventor of the patent, G.E. Morris Husbands, subsequently assigned the Husbands patent to Wyeth's predecessor American Home Products. (*Id*.). Eight years later, in December 1993, the FDA approved Wyeth's New Drug Application ("NDA") for Effexor, an antidepressant whose active pharmaceutical ingredient is venlafaxine.[2] (*Id*. at ¶ 63). According to Plaintiffs, "[t]he Husbands patent protected venlafaxine generally, and thus it protected any kind of Wyeth venlafaxine products from generic competition before June 13, 2008."[3] (*Id*. at ¶ 64). As a result, Wyeth had market exclusivity for venlafaxine products – whether instant release or extended release – for fourteen and a half years. (*Id*. at ¶ 65).

In 1991, spurred by drawbacks associated with the immediate release form of the drug, Wyeth's marketing department requested development of an extended release version of venlafaxine hydrochloride. (*Id*. at ¶ 67). According to Plaintiffs, Wyeth sought development of an extended release version because early clinical trials showed that some patients who took the instant release form of Effexor reported experiencing negative side effects such as nausea and vomiting. (*Id*.). A group of Wyeth chemists from upstate New York initially attempted to create an extended release venlafaxine formulation using hydrogel tablet technology through which the active ingredient is combined with cellulose ethers and then compressed into a tablet. (*Id.* at ¶ 70). According to

[2] Effexor is a tablet that dissolves rapidly, resulting in a rapid increase in blood plasma levels of venlafaxine shortly after administration. (Second Am. Compl. at ¶ 63). Compounds with such rapid dissolution profiles are referred to as "instant release" formulations. (*Id*.). Levels of venlafaxine in the blood gradually decrease, reaching sub-therapeutic levels in about twelve hours. (*Id*.).

[3] The Husbands patent would have expired much earlier than 2008, but Wyeth "received a significant extension to reflect the time it took the FDA to approve its NDA for Effexor and an additional six month extension for having conducted pediatric studies[]." (*Id*.).

Plaintiffs, Inventor Deborah M. Sherman "had previous experience with this approach, and in the second half of 1991 set out to make an extended release hydrogel tablet containing venlafaxine." (*Id.*). By December 1991, however, Wyeth abandoned its hydrogel approach "because the tablets were dissolving too rapidly." (*Id.*).

Following its failed attempt at using hydrogel tablet technology, Wyeth: (1) began in-house development of a conventional coated spheroid approach based on its prior experience with extending the release of a similar chemical, propanolol, which it marketed as Inderal[4] and (2) entered into a business venture with Alza, a pharmaceutical company specializing in extended release technology that possessed an available "OROS" technology that could potentially be used to extend the release of venlafaxine. (*Id.* at ¶¶ 71-72). Plaintiffs contend that the Effexor XR inventors implemented the coated spherical approach by simply substituting venlafaxine for the propanolol in Wyeth's Inderal LA formulation. (*Id.* at ¶ 75). In 1992, within six months of implementing the spheroid approach, Wyeth deemed the approach successful. (*Id.* at ¶ 77).

At the same time Wyeth pursued the spheroid approach, it also sought to develop an osmotic shell extended release venlafaxine through the use of Alza's OROS technology. (*Id.* at ¶ 78). In 1992, Wyeth entered into a cooperation agreement with Alza to develop an extended release formulation of venlafaxine hydrochloride using Alza's proprietary drug delivery system. (*Id.*). The collaboration agreement granted Alza ownership rights in any information generated or acquired during the collaboration and the patents resulting from the collaboration. Alza also retained the right to use, disclose, and license information obtained through the collaboration to third parties. (*Id.*). By the end of 1992, Alza was also successful in developing an extended release formulation of

[4] Inderal LA, a "longer acting" or extended release product, had been formulated over a decade earlier and received marketing approval from the FDA in April 1983. (*Id.* at ¶ 72).

venlafaxine. (*Id*. at ¶ 80). Wyeth, however, "chose to pursue its own, encapsulated spheroid approach." (*Id*. at ¶ 81).

Following development of the encapsulated spheroid extended release venlafaxine, Wyeth conducted clinical studies to establish the efficacy and safety of its new formulation. (*Id*. at ¶ 82). In some studies, Wyeth compared the extended release formulation to the instant release formulation; in others, it compared the extended release to a placebo. (*Id*.). According to Plaintiffs, "[w]hile the studies established the FDA minima of efficacy as compared to a placebo, the studies failed to establish any statistically significant improvement of the extended release over the instant release with respect to side effects such as nausea." (*Id*. at ¶ 82). As a result, Plaintiffs contend that "Wyeth could not truthfully claim [that] there was any valid scientific basis for claiming that the extended release version reduced side effects when compared to the instant release." (*Id*.).

In addition to clinical testing of its extended release form of venlafaxine, Wyeth "began some early efforts to secure further patent protection for venlafaxine."[5] (*Id*. at ¶ 83). In June 1993, a group of Wyeth employees based in eastern Pennsylvania filed a patent application seeking a method-of-use patent for using venlafaxine for a number of medical conditions. (*Id*.). The application claimed as the "invention . . . a method of treating obesity, generalized anxiety disorder, post-traumatic stress disorder, late luteal phase disphoric disorder (premenstrual syndrome), attention deficit disorder, with and without hyperactivity, Gilles de la Tourette syndrome, bulimia nervosa or Shy Dragger Syndrome . . . by administering . . . an effective amount of [venlafaxine]." (*Id*. at ¶ 83). In 1995, after

[5] In the early 1990s, Alza also sought patent protection for its extended release osmotic approach for venlafaxine. On May 27, 1993, Alza filed patent application No. 08/068,480 listing the inventors as Edgren, *et al.* (the "Edgren application"). (*Id*. at ¶ 88). On August 27, 2002, the Edgren application issued as U.S. Patent No. 6,440,457 (the "Edgren patent" or the "'457 patent"). On December 8, 1994, the World Intellectual Property Organization in Geneva, Switzerland published WO 94/27589, assigned to Alza (the "'589 PCT application"). (*Id*. at ¶ 89). According to Plaintiffs, the '589 PCT application "claims priority to the Edgren application and disclosed to the public all features of the Edgren application." (*Id*.). Alza's '589 PCT application allegedly "describes, repeatedly, the broader notion that the use of extended release venlafaxine would reduce the daily spiking in blood plasma levels that result from multiple daily usage of venlafaxine." (*Id*. at ¶ 90).

abandoning the original application, Wyeth filed a series of applications which reiterated that "sustained release compositions" of venlafaxine were the likely favored form of administering venlafaxine. (*Id*. at ¶ 85). These applications eventually led to several method-of-use patents for specific medical conditions. (*Id*.).

In January 1995, several of the Wyeth employees based in eastern Pennsylvania filed Patent Application No. 08/380,093 (the "Upton application") which sought a method-of-use patent for using venlafaxine to treat hypothalamic menopause in non-depressed woman. (*Id*. at ¶ 86). According to Plaintiffs, the Upton application "did not seek approval of any formulations of venlafaxine[,]" but disclosed a "sustained oral administration form or time-release form [of venlafaxine], which may be used to spread the dosage over time, such as for one-a-day applications." (*Id*.).

In late 1995 or early 1996, the PTO allegedly notified Wyeth that the Upton application would soon issue as a patent. According to Plaintiffs, "Wyeth knew that particular disclosures that would appear in this patent – those describing extended release venlafaxine as a method to smooth the dosage over time – would be prior art relevant to later patent applications seeking to claim as a new invention the use of extending the release of venlafaxine as a method to control dose rates." (*Id*. at ¶ 109). On March 25, 1996, therefore, the Wyeth applicants filed a provisional utility patent application, No. 60/014,006 (the "'006 application"), with the PTO that included method-of-use claims for decreasing incidences of nausea and vomiting and for minimizing the troughs and peaks in drug concentration in a patient's blood plasma. (*Id*. at ¶ 110). According to Plaintiffs, the Wyeth applicants did so "to avoid the Upton [p]atent standing as prior art to future extended release venlafaxine claims." (*Id*.). On April 9, 1996, following the filing of the '006 application, the Upton application issued as U.S. Patent No. 5,506,270 (the "Upton patent" or the "'270 patent"). (*Id*. at ¶

87). According to Plaintiffs, "[t]he Upton patent contained the same reference to sustained and time release forms of venlafaxine to spread the dosage over time[.]" (*Id*.). One month later, on May 16, 1996, Wyeth sought FDA approval to sell an encapsulated extended release formulation of venlafaxine hydrochloride called Effexor XR. (*Id*. at ¶ 97).

On March 20, 1997, within a year of filing the provisional '006 application, the Wyeth applicants filed a non-provisional application, No. 08/821,137 (the "'137 application") which claimed priority to the '006 application. (*Id*. at ¶ 100). The '137 application was assigned to Examiner Amy Hulina. (*Id*. at ¶ 119). According to Plaintiffs, the '137 application was "virtually identical to the '006 [provisional application] in all respects, setting forth the Wyeth-developed, encapsulated film-coated spheroid formulation to extend the release of venlafaxine." (*Id*. at ¶ 120). The '137 application also set forth the same eight formulation claims as the '006 application as well as two method-of-use claims. (*Id*.). Claim 1 recited an extended release formulation of venlafaxine hydrochloride with spheroids. (*Id*. at ¶ 121). Claim 9 recited a method-of-use claim for reducing incidences of nausea and vomiting associated with venlafaxine. (*Id*. at ¶ 122). Claim 10 recited a method-of-use claim for reducing the disparities in concentration of venlafaxine in a patient's blood serum. (*Id*. at ¶ 123).

On July 10, 1997, the Wyeth applicants submitted an information disclosure statement ("IDS") to the PTO which listed five U.S. patents. (*Id*. at ¶ 125). According to Plaintiffs, Wyeth did not list the original Husbands patent on the IDS, but rather, referenced it in the specification. (*Id*.). Furthermore, Plaintiffs contend that Wyeth neglected to list or otherwise disclose both the Upton patent and Alza's '589 PCT application to Examiner Hulina. (*Id*. at ¶ 126). Despite the Wyeth applicants' alleged failure to disclose the existence of the Upton patent, Examiner Hulina discovered

the patent when conducting her own prior art search.[6] (*Id*. at ¶ 127). During a telephone interview on July 30, 1997, Examiner Hulina informed Wyeth that its two method-of-use claims were not patentable as independent claims in light of the disclosure of extended release formulations of venlafaxine in the Upton patent. (*Id*. at ¶ 128). She further informed Wyeth that these method-of-use claims would be patentable if Wyeth amended them to depend on the specific encapsulated spheroid formulation of extended release venlafaxine recited in Claim 1 of the '137 application. (*Id*.). Based on Examiner Hulina's conclusion, Wyeth authorized the examiner to amend the method-of-use claims to depend on Wyeth's encapsulated spheroid formulation. (*Id*. at ¶ 130). On August 5, 1997, Examiner Hulina issued a notice of allowance for the two amended method-of-use claims. (*Id*. at ¶ 131). The examiner also allowed the seven remaining formulation claims that described the encapsulated film-coated spheroid extended release venlafaxine invention. (*Id*.). According to Plaintiffs, despite having received the notice of allowance, the Wyeth applicants allegedly "decided to abandon the '137 application . . . in the hopes that a new application might draw a different examiner . . . unfamiliar with the Upton patent's disclosure of extended release venlafaxine [who] . . would [potentially] . . . allow independent nausea/vomiting and 'troughs and peaks' method-of-use claims." (*Id*. at ¶ 133). In the meantime, the FDA approved Wyeth's NDA for Effexor XR on October 20, 1997. (*Id*. at ¶ 97).

On November 5, 1997, prior to abandoning their '137 application, the Wyeth applicants filed a continuation-in part application, No. 08/964,328 (the "'328 application), which claimed priority to the '137 and '006 applications. (*Id*. at ¶¶ 101-02). The application was assigned to Examiner James Spear and proposed sixteen formulation claims. (*Id*. at ¶¶ 137-38). The '328 application also

[6] According to Wyeth, because Examiner Hulina had identified the Upton patent during her independent search for prior art and rejected certain claims over it, "the Upton patent . . . was known to the PTO from the very beginning of the prosecution." (Defs.' Mem. in Supp. of Wyeth Defs. Mot. to Dismiss All Direct Purchaser Compls. ("Wyeth Br.") at 6) (ECF No. 138).

contained two independent method-of-use claims which, according to Plaintiffs, were nearly identical to the two method-of-use claims of the '137 application rejected by Examiner Hulina.

On February 9, 1998, the Wyeth applicants submitted an IDS identifying the same five U.S. patents identified in the IDS for the '137 application. (*Id*. at ¶ 140). On August 13, 1998, they submitted a supplemental IDS, listing three foreign patent documents. (*Id*.). According to Plaintiffs, while the Wyeth applicants listed the Upton patent and '589 PCT application in these IDSs, they failed to identify Examiner Hulina's prior rejection of the broad method-of-use claims recited in the '137 patent application despite their knowledge that such a rejection constituted material information required to be disclosed to the PTO.[7] (*Id*. at ¶ 141).

After reviewing the application, Examiner Spear issued a first office action on October 14, 1998. (*Id*. at ¶ 143). Examiner Spear (1) found that the formulation claims that quantified the amount and ratio of materials to be used for film-coating of the venlafaxine spheroids would be patentable; (2) allowed Claim 11 because, as an independent claim that quantified those amounts, it was a patentable formulation; and (3) rejected Claim 1 because its general formulation claim of using any amounts of materials to extend the release of venlafaxine was obvious. (*Id*.). According to Plaintiffs, "[i]n allowing the encapsulated extended release formulation of venlafaxine in Claim 11, [Examiner Spear] also allowed Claims 13 and 14, the two claims for methods of diminishing nausea/vomiting or eliminating troughs/peaks by 'adminstering . . . an encapsulated extended release formulation . . . [of] venlafaxine.'" (*Id*.). In doing so, Examiner Spear essentially "allowed the method-of-use claims (claims 13 and 14) to issue as independent claims" despite Wyeth's previous agreement to amend

[7] Wyeth contends that the "family history of the '137 application (before Examiner Hulina) . . . was [actually] before Examiner Spear, including the fact that Examiner Hulina had initially rejected claims in view of Upton and the proposed amendment of the claims, [since] the history is listed in each Effexor XR application and on the first page of each Effexor XR Patent." (*Id*. at 6-7). Wyeth further contends that it disclosed Alza's '589 PCT application in each of its patent applications beginning with the '328 application. (*Id*. at 8). Moreover, according to Wyeth, "[b]eginning with the '137 application, in each of its patent applications Wyeth disclosed . . . [the] patent covering Inderal LA[.]" (*Id*. at 9).

those very same claims to be dependent. (*Id*. at ¶ 144). While Wyeth obtained allowance of the method-of-use claims as a result of the first office action, as previously mentioned, the examiner rejected the general formulation in Claim 1 of the '328 application. The Wyeth applicants allegedly responded to that rejection by "canceling, amending, and adding new claims." (*Id*. at 146). After Examiner Spear again rejected Claim 1 as obvious on July 21, 1999, the Wyeth applicants ultimately abandoned the '328 application. (*Id*.).

On January 20, 2000, several weeks prior to abandoning the '328 application, the Wyeth applicants filed a continuation-in-part application, No. 09/488,629 (the "'629 application), that claimed priority to the '328 application, the '137 application, and the '006 application. (*Id*. at ¶¶ 103, 147). The '629 application was again assigned to Examiner Spear. According to Plaintiffs, the '629 application "contained a nearly identical specification to the '328 application." (*Id*. at ¶ 148). Specifically, "Claim 1, again, recited an extended release version of venlafaxine hydrochloride in spheroids that was substantially similar to the claim rejected by Examiner Spear during the prosecution of the '328 application in light of the prior art." (*Id*.). Moreover, "Claims 21 and 22, again recited the same independent method-of-use claims originally presented in (rejected) claims 9 and 10 of the '137 application and (allowed but abandoned) claims 13 and 14 in the '328 application[.]" (*Id*.). Plaintiffs allege that Wyeth informed Examiner Spear of neither Examiner Hulina's prior rejection of those method-of-use claims nor its agreement to amend those claims to be dependent.

On January 4, 2001, Examiner Spear allowed the two method-of-use claims. (*Id*. at ¶ 149). In response, the Wyeth applicants added additional method-of-use claims which, according to Plaintiffs, were again "substantially similar" to those claims rejected by Examiner Hulina. (*Id*. at ¶ 150). The additional independent claims were similarly allowed by Examiner Spear and, on August

14, 2001, the '629 application issued as U.S. Patent No. 6,274,171 B1 (the "'171 patent"). (*Id*. at ¶¶ 150-51). The '171 patent contains twenty-five claims in total, including claims for (1) an extended release form of venlafaxine hydrochloride using spheroids; (2) method-of-use claims for decreasing incidences of nausea and vomiting; and (3) method-of-use claims for minimizing the troughs and peaks in drug concentration in a patient's blood plasma. (*Id*. at ¶ 104). It is assigned to Wyeth and expires on March 20, 2017. (*Id*.).

On June 19, 2001, two months prior to the issuance of the '171 patent, the Wyeth applicants filed a divisional application, No. 09/884,412 (the "'412 application), which claimed priority to the '629 application (which resulted in the '171 patent), the '328 application, the '137 application, and the '006 application. (*Id*. at ¶ 105). The application was again assigned to Examiner Spear. According to Plaintiffs, Examiner Spear rejected some claims within the application, the Wyeth applicants canceled one claim and added new claims that were "substantially similar to claims issued in the '171 patent." (*Id*.). Again, Plaintiffs allege that the Wyeth applicants never informed Examiner Spear that the Upton patent had identified the existence of an extended release formulation of venlafaxine hydrochloride that rendered their method-of-use claims unpatentable. (*Id*. at 154). Moreover, according to Plaintiffs, the Wyeth applicants never disclosed that "a previous examiner [had] determined [that] the method-of use claims [which were] virtually identical to claims 23 and 24 [in the '412 application] were unpatentable . . . [or] that they had agreed to amend virtually identical claims in order to avoid a rejection over the prior art disclosed by . . . [the] Upton patent." (*Id*.).

On January 13, 2002, Examiner Spear rejected claims 23 and 24 as being unpatentable over claims 20 and 21 of the '171 patent. (*Id*. at ¶ 155). The Wyeth applicants subsequently contested that claims 23 and 24 were obvious in light of the '171 patent, but filed a terminal disclaimer confirming

that Wyeth would not seek an additional time period of patent protection beyond that afforded by the '171 patent – that is, through March 20, 2017. (*Id*. at ¶¶ 106, 155). The Wyeth applicants also added additional independent method-of-use claims which recited methods to decrease incidences of nausea and vomiting and minimize the troughs and peaks in drug concentration in a patient's blood plasma. (*Id*. at ¶¶ 106, 156). Those claims were similarly allowed by Examiner Spear and, on July 16, 2002, the '412 application issued as U.S. Patent No. 6,419,958 B2 (the "'958 patent"). (*Id*. at ¶¶ 156-57).

Two months later, on September 12, 2001, Wyeth filed a continuation-in-part application, No. 09/950,965 (the "'965 application") that claimed priority to the '412 application (which resulted in the '958 patent), the '629 application (which resulted in the '171 patent), the '328 application, the '137 application, and the '006 application. (*Id*. at ¶ 107). The application was again assigned to Examiner Spear. The '965 application allegedly "contained the same specification and claims as the '412 application (and corresponding '958 patent)." (*Id*. at ¶ 159). Specifically, the Wyeth applicants canceled claims 2-22 and added new claims 23-34. (*Id*.). According to Plaintiffs, "Claim 23 recited a method-of use claim for diminished incidences of nausea and vomiting . . . [that was] substantially similar to rejected claim 9 of the '137 application[.]" (*Id*.). As they had allegedly done with their prior applications, the Wyeth applicants failed to disclose to Examiner Spear that a previous examiner had determined that a claim substantially similar to claim 23 was unpatentable. (*Id*. at ¶ 160). In addition, the Wyeth applicants allegedly never disclosed that Wyeth had agreed to amend a substantially similar claim in order to avoid rejection due to prior art disclosed in Wyeth's own Upton patent. (*Id*.). Examiner Spear allowed claim 23 and objected to claims 24-34. (*Id*.). After Wyeth amended claims 24 and 25 to depend on the previously allowed claim 23, the amended claims were also allowed by the examiner. (*Id*. at ¶ 161). On June 11, 2002, the '965 application

issued as U.S. Patent No. 6,403,120 B1 (the "'120 patent"). Similar to the '171 and '958 patents, the '120 patent also expires on March 20, 2017. (*Id*. at ¶ 108).

In total, Wyeth filed information for seven patents with the FDA in connection with Effexor XR, including the original compound patent (the '186 patent) and the three Effexor XR patents (the '171, '958, and '120 patents). The '186 patent covering the venlafaxine hydrochloride molecule expired on June 13, 2008. As previously mentioned, the three Effexor XR patents expire on March 20, 2017.

2. Wyeth's Settlement Agreement with Teva

On December 10, 2002, Teva filed an ANDA seeking approval of a generic version of Effexor XR. (*Id.* at ¶ 264). Teva USA's ANDA included Paragraph IV certifications that Wyeth's '171, '120, and '958 patents were invalid, unenforceable, and would not be infringed by its generic extended release venlafaxine capsules. (*Id*. at ¶ 264). Pursuant to the Hatch-Waxman Act, as the first ANDA applicant to submit a substantially complete ANDA, Teva USA was entitled to be the only non-authorized generic on the market during the statutorily prescribed 180-day exclusivity period. (*Id*. at 265).

On March 24, 2003, Wyeth brought suit against Teva in the United States District Court for the District of New Jersey for infringement of the '171, '120, and '958 patents. (*Id*. at ¶ 266). In its Complaint, Wyeth alleged that Teva's proposed manufacture, marketing and sale of a generic version of Effexor XR would infringe claims 20-25 of the '171 patent, claims 1,2 13, and 14 of the '120 patent, and claims 1-6 of the '958 patent. (*Id*.). All of these are method-of-use claims for either reducing the incidences of nausea and vomiting or smoothing out the troughs and peaks in a patient's blood serum. (*Id*.). According to Plaintiffs, Wyeth "did not assert [that] Teva infringed any of the formulation claims . . . [or] infringed any other patents." (*Id*.). In its June 2, 2003 Answer to Wyeth's

Complaint, Teva denied the allegations and asserted that the patents in issue were invalid and not infringed. (*Id*. at ¶ 267).

Throughout the course of the litigation, the parties disputed the term "extended release formulation" – the term that defines the method-of-use claims broadly or limits those claims to the spheroid formulation developed by Wyeth. (*Id*. at ¶ 268). After conducting a *Markman* hearing on August 29, 2005, the Hon. William J. Martini, U.S.D.J ("Judge Martini") issued an Opinion on September 6, 2005 concluding that "[w]hen the term 'extended release formulation' is looked at in its proper context in the specification, . . . one of ordinary skill in the art would construe the term to include specific ingredients." *Wyeth v. Teva Pharms. USA, Inc.*, 2005 U.S. Dist. LEXIS 20034, at *18 (D.N.J. Sept. 6, 2005). According to Plaintiffs, "Wyeth knew this ruling meant that loss of the litigation was right around the corner." (Second Am. Compl. at ¶ 269).

In October 2005, one month after the Court issued its *Markman* ruling, Wyeth and Teva entered into an agreement (the "Wyeth-Teva agreement") to settle the litigation. (*Id*. at ¶ 270). As part of the agreement, Wyeth and Teva agreed that the prior *Markman* ruling of the *Teva* court would be vacated. (*Id*. at ¶ 272). In addition, with respect to the instant release version of Effexor ("Effexor IR"), Wyeth: (1) permitted Teva to sell a generic version of Effexor IR before the original compound patent for venlafaxine expired in June 2008 and (2) agreed that it would not compete with Teva's marketing of a generic version of Effexor IR by launching its own authorized generic during that period. (*Id*. at ¶ 273). According to Plaintiffs, Wyeth also agreed "to refrain from selling an authorized generic version of [Effexor IR] until the Husbands patent expired – giving Teva at least a year and a half of being the *only* instant release generic on the market."[8] (*Id*. at ¶ 275). Plaintiffs contend that by the end of 2007, approximately 96 percent of Wyeth's sales of instant release

[8] In October 2006, with Wyeth's permission, Teva obtained FDA approval and began selling generic instant release venlafaxine. (Second Am. Compl. at ¶ 274). In June 2008, the Husbands patent expired. (*Id.*).

Effexor tablets worth about $100 million had converted to Teva generic instant release venlafaxine tablets. (*Id*. at ¶ 294).

Also under the Wyeth-Teva agreement, Teva allegedly agreed to delay market entry for its ANDA-approved, AB-rated extended release venlafaxine ("Effexor XR") until as late as July 2010, two years after the expiration of the original venlafaxine compound patent.[9] (*Id*. at 276). According to Plaintiffs, to induce Teva to agree to the delay period, Wyeth promised Teva that Wyeth would not market an authorized generic version of Effexor XR during Teva's 180-day exclusivity period. (*Id*.).[10] Teva, in turn, allegedly "agreed to delay the launch of generic Effexor XR until two years after the expiration of the only Wyeth patent actually capable of blocking generic competition to Effexor XR" – namely, the original venlafaxine compound patent. (*Id*. at ¶ 277). By performing its contractual obligation not to compete with Teva, Wyeth allegedly "provided Teva with a substantial financial inducement amounting to over $500 million in value in exchange for Teva's agreement to delay selling its generic version of Effexor XR for two years." (*Id*. at ¶ 281). According to Plaintiffs, "Wyeth's fulfillment of its contractual obligation not to compete with Teva constituted a [reverse] payment to Teva[,]" and, as a result of that payment, the Direct Purchasers and members of the class were deprived of the price-reducing benefits of timely generic competition.[11] (*Id*. at 281-281).

In October 2005, Wyeth and Teva submitted the proposed terms of the Settlement and License Agreements to Judge Martini and asked that those terms be embodied in a consent order resolving the litigation. On October 24, 2005, Judge Martini issued a scheduling order requiring the

[9] The agreement to delay included a provision for an earlier launch by Teva if another generic entered earlier than July 2010, or if another generic was successful in invalidating the '171, '120 and '958 patents. (*Id*. at ¶ 276).
[10] According to Defendants, pursuant to the Wyeth-Teva agreement, Wyeth granted Teva an exclusive license to sell generic versions of Effexor years before expiry of the relevant patents – seven years early in the case of Effexor XR and two years early in the case of Effexor IR. (Defs.' Mem. in Supp. of Mot. to Dismiss Direct Purchaser Class Pls.' Second Am. Compl. ("Defs.' Supp. Br.") at 6) (ECF No. 305).
[11] Defendants, in contrast, contend that "Wyeth did not pay one dollar to Teva . . . so that the generic challenger would 'stay out.'" (*Id*.). Rather, according to Defendants, "Teva *paid Wyeth* for the procompetitive right to sell generic versions of Effexor, through substantial royalties." (*Id*.)

parties to provide the FTC with the proposed settlement and associated license agreements and soliciting the FTC's views on any antitrust issues concerning the proposed settlement.[12] The scheduling order stated, in relevant part: "(2) The execution-ready Definitive Agreements shall be delivered to the Federal Trade Commission for its review not later than November 2, 2005; (3) If the Federal Trade Commission has any objection to the Definitive Agreements, it shall file such objection with the Court not later than December 2, 2005[.]" *Wyeth v. Teva Pharms. USA, Inc.*, No. 03-cv-1293 (D.N.J. Oct. 24, 2005) (ECF No. 156). Judge Martini also established a briefing schedule for addressing such objections and indicated that he would hold a hearing if needed to address any objections raised by the FTC. Wyeth provided this information to the FTC and furnished Judge Martini with both a stipulation of dismissal and a full copy of the proposed settlement documents.

On December 1, 2005, the FTC responded in a letter signed by Acting Assistant Director of the Bureau of Competition David R. Pender. Assistant Director Pender wrote:

> We have received Wyeth's notice of its proposed settlement with Teva, as required by the Federal Trade Commission's Decision and Order. We understand that Wyeth and Teva do not intend to independently raise with the Court the competitive implications of their proposed settlement agreement. As a consequence, you may advise the Court that we will not file an objection to the Court entering an injunction based on the joint stipulation of the parties. (Letter from David R. Pender, Acting Asst. Dir., Bureau of Competition, FTC to Michael N. Sohn, Esq., Arnold & Porter (Dec. 1, 2005) (ECF No. 339-1)

[12] The court hearing the underlying patent case solicited the FTC's views pursuant to a 2002 Consent Decree in which the FTC had secured the right to weigh in on Wyeth's settlements and to raise objections in advance. *See In the Matter of Schering-Plough Corp., Upsher-Smith Labs, Inc., & Am. Home Prods. Corp.*, Decision and Order, Docket No. 9297 (Apr. 2, 2002). According to Defendants, "the Consent Decree required Wyeth to (1) produce to the FTC not only the settlement and all related agreements themselves, but also a variety of additional materials, including documents prepared internally at Wyeth for the evaluation of the settlement, (2) provide the patent court with a copy of the Consent Decree and Analysis to Aid Public Comment, and (3) 'not oppose any effort by the Commission to participate, in any capacity permitted by the [patent] court, in the court's consideration' of the settlement." (Letter from Liza M. Walsh, Connell Foley LLP to Judge Peter G. Sheridan, U.S. Dist. Ct. for the Dist. of N.J., at 2 (June 13, 2014) (ECF No. 320).

The FTC further emphasized that "[its] decision to not file an objection with the Court is not to be construed as a determination that the proposed settlement agreement does not violate Section 5 of the FTC Act[.]" (*Id*.). Moreover, the Commission "reserve[d] the right to take such further action as the public interest may require." (*Id*.).

After the FTC chose not to object to the proposed settlement, the parties moved before Judge Martini for a Stipulated Order and permanent injunction requiring Wyeth and Teva to abide by the terms of the agreement. On December 7, 2005, Judge Martini entered the proposed order. *See* Stipulated Order, *Wyeth v. Teva Pharms. USA, Inc.*, No. 03-1293 (D.N.J. Dec. 7, 2005) (ECF No. 169). The parties also moved to vacate the prior *Markman* decision, which Judge Martini granted on January 12, 2006. *See* Order Vacating Markman Rulings, *Wyeth v. Teva Pharms. USA, Inc.*, No. 03-1293 (D.N.J. Jan. 12, 2006) (ECF No. 168). On January 20, 2005, Judge Martini entered an order dismissing the action.

3. Wyeth's Settlements with Other Generic Manufacturers

According to Plaintiffs, "[t]he agreement between Wyeth and Teva was structured to encourage Wyeth to resolve all subsequent challenged to the '171, '120, and '958 patents prior to a court finding of invalidity, non-infringement, or unenforceability." (Second Am. Compl at ¶ 293). As such, between April 2006 and April 2011, Wyeth brought infringement suits against sixteen additional generic companies which sought to market a generic version of Effexor XR. [13]

[13] The sixteen additional patent infringement suits instituted by Wyeth are as follows: (1) *Wyeth v. Impax Labs, Inc.*, Civ. Action No. 06-0222 (D. Del. 2006); (2) *Wyeth v. Anchen Pharms., Inc.*, Civ. Action No. 06-0386 (C.D. Cal. 2006); (3) *Wyeth v. Lupin Ltd.*, Civ. Action No. 07-0632 (D. Md. 2007); (4) *Wyeth v. Osmotica Pharm. Corp.*, Civ. Action No. 07-0067 (E.D.N.C. 2007); (5) *Wyeth v. Sandoz, Inc.*, Civ. Action No. 07-0234 (E.D.N.C. 2007); (6) *Wyeth v. Mylan Pharms., Inc.*, Civ. Action No. 07-0091 (N.D.W. Va. 2007); (7) *Wyeth v. Wockhardt Ltd.*, Civ. Action No. 07-5166 (C.D. Cal. 2007); (8) *Wyeth v. Biovail Corp.*, Civ. Action No. 08-0390 (D. Del. 2008); (9) *Wyeth v. Apotex, Inc.*, Civ. Action No. 08-22308 (S.D. Fla. 2008); (10) *Wyeth v. Torrent Pharms., Ltd.*, Civ. Action No. 09-0019 (D. Del. 2009); (11) *Wyeth v. Cadila Healthcare Ltd.*, Civ. Action No. 09-0239 (D. Del. 2009); (12) *Wyeth v. Orgenus Pharma, Inc.*, Civ. Action No. 09-3235 (D.N.J. 2009); (13) *Wyeth LLC v. Aurobindo Pharma Ltd.*, Civ. Action No. 10-2084 (D.N.J. 2010); (14) *Wyeth, LLC v. Intellipharmaceutics Int'l Inc.*, Civ. Action No. 10-

(*Id*. at ¶ 364). In answering Wyeth's claims of infringement, each of the generic companies claimed that the patents were invalid. (*Id*.). Several of the generic companies also alleged that the patents were unenforceable due to inequitable conduct. (*Id*.). Wyeth subsequently settled each and every Effexor XR infringement suit before a federal court could render an opinion on the validity or enforceability of Wyeth's Effexor XR patents. (*Id*. at ¶ 365).

D. Procedural History

On May 2, 2011, Direct Purchaser Plaintiff Professional Drug Company, Inc. filed a Class Action Complaint against Defendant Wyeth, Inc. in the United States District Court for the Southern District of Mississippi. (ECF No. 1). On May 5, 2011, Direct Purchaser Plaintiffs Stephen L. LaFrance Holdings, Inc. and Stephen L. LaFrance Pharmacy, Inc. filed a similar lawsuit against the Wyeth Companies in the Mississippi District Court. Direct Purchaser Plaintiff Rochester Drug Co-Operative, Inc. also filed suit against Wyeth on May 27, 2011. On June 21, 2011, the Mississippi Court granted an unopposed motion to consolidate the three actions pursuant to FED. R. CIV. P. 42. (ECF No. 18). Pursuant to the Court's Consolidation Order, Direct Purchaser Plaintiffs filed a Consolidated Class Action Complaint and Jury Demand on June 22, 2011. (ECF No. 19). On July 5, 2011, Direct Purchaser Plaintiff Uniondale Chemists, Inc. also filed a lawsuit against Wyeth which was subsequently consolidated with the other three actions. On September 21, 2011, the Mississippi Court approved a transfer of venue of the consolidated action to the United States District Court for the District of New Jersey. (ECF No. 44).

Following the transfer, twelve Indirect Purchaser (or End-Payer) class actions and one additional Individual Direct Purchaser action were filed in the New Jersey District Court. On

5072 (S.D.N.Y. 2010); (15) *Wyeth LLC v. Dr. Reddy's Labs., Ltd.*, Civ. Action No. 10-cv-4551 (D.N.J. 2010); and (16) *Wyeth LLC v. Nostrum Pharms., LLC*, Civ. Action No. 11-2280 (D.N.J. 2011).

December 13, 2011, this Court issued a Case Management Order consolidating all Direct Purchaser Class Actions and designating *Professional Drug Co., Inc. v. Wyeth, Inc.*, Civ. Action No. 11-cv-5479 as the Lead Direct Purchaser Class Action. (ECF No. 86). The following day, on December 14, 2011, the Direct Purchaser Class Plaintiffs filed a First Amended Consolidated Class Action Complaint and Jury Demand. (ECF No. 91). On April 6, 2012, Defendants Wyeth and Teva filed separate Motions to Dismiss the Direct Purchaser Class Plaintiffs' First Amended Consolidated Class Action Complaint pursuant to Fed. R. Civ. P. 12(b)(6). (ECF Nos. 136, 138).

On July 16, 2012, the United States Court of Appeals for the Third Circuit issued its decision in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), which involved an antitrust challenge to a patent litigation settlement agreement between a brand-name pharmaceutical manufacturer and a generic manufacturer. In light of the Third Circuit's decision, and the likelihood that the United States Supreme Court would grant *certiorari*, Defendants filed a Motion to Stay the instant action pending the Supreme Court's decision on September 10, 2012 (ECF No. 184). On October 23, 2012, this Court granted Defendants' motion and stayed this action pending the conclusion of proceedings in the Supreme Court. (ECF No. 191).

On June 17, 2013, the Supreme Court issued a decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), which set forth the standard to assess the legality of reverse payment settlement agreements between branded and generic pharmaceutical companies. Based on the *Actavis* decision, the Supreme Court vacated and remanded *In re K-Dur Antitrust Litigation* for further consideration. *See Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013). One month later, on July 17, 2013, this Court vacated the stay in this matter and reopened the case. (ECF No. 211). The Court also granted the parties' request to file

supplemental briefs on the pending Motions to Dismiss in light of the Supreme Court's decision in *Actavis*. (ECF No. 222).

On August 14, 2013, the FTC filed a Motion for Leave to appear *amicus curiae*. (ECF No. 236).[14] The FTC's motion was opposed by both the Wyeth and Teva Defendants. (ECF Nos. 249-50). On August 28, 2013, Direct Purchaser Class Plaintiffs filed a Motion for Leave to file a Second Amended Consolidated Class Action Complaint. (ECF No. 248). On September 10, 2013, this Court heard oral argument on the pending Motions to Dismiss as well as the FTC's and the Direct Purchaser Class Plaintiffs' motions. (ECF No. 265). On September 12, 2013, the Court granted the FTC's motion to appear *amicus curiae*. (ECF No. 263). The FTC's brief was filed the following day and all parties subsequently responded. (ECF Nos. 264, 271-74).

On October 23, 2013, the Court granted the Direct Purchaser Class Plaintiff's Motion for Leave to File a Second Amended Consolidated Class Action Complaint. (ECF No. 282). The Second Amended Consolidated Class Action Complaint was filed later that day. (ECF No. 287).

On December 13, 2013, pursuant to a December 5, 2013 Letter Order issued by the Court (ECF No. 303), Defendants filed the instant Motion to Dismiss the Direct Purchaser Class Plaintiffs' Second Amended Consolidated Class Action Complaint pursuant to FED. R. CIV. P. 12(b)(6). (ECF No. 305). Direct Purchaser Plaintiffs filed their Opposition to Defendants' motion on January 24, 2014 and Defendants replied on February 14, 2014. (ECF Nos. 316-17). The Court held additional argument on Defendants' Motions to Dismiss on April 3, 2014 and June 5, 2014.

[14] The FTC had previously filed a motion for leave to appear *amicus curiae* in this matter on August 10, 2012. (ECF No. 173). That motion was denied by the Hon. Joel A. Pisano on October 3, 2012. (ECF No. 187). Judge Pisano ruled without the Supreme Court's decision in *Activas*.

II. DISCUSSION[15]

A. FED. R. CIV. P. 12(b)(6) Standard of Review

FED. R. CIV. P. 12(b)(6) provides for the dismissal of a complaint if the plaintiff "fail[s] 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 Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (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 the standard of review for a 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 and 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*. 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

[15] Several sections herein are the same or similar to those set forth in *In Re Lipitor*, as they were written simultaneously. (Cite)

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. at 570). 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 betwen 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. 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. Cnty 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 antitrust cases. *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, 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 (quoting 5 Wright & Miller, Federal Practice & Procedure – Civil Rules: 2010 Quick Reference Guide, Vol. 12B, § 1216, at 233-34). As one treatise has acknowledged, "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).

This Court must apply the *Twombly* and *Iqbal* standards against the factors of *Actavis* in analyzing the Plaintiff's complaint. Specifically, where the anticompetitive effects of a settlement agreement might fall 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.

B. Summary of the Supreme Court's Decision in *Actavis*

The Supreme Court has described a reverse payment settlement agreement ("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, p. 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 (internal citation and quotation omitted).

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 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 an unreasonable restraint of trade. *See In re K–Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), vacated, *Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013); *Upsher–Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). This

essentially shifts to "a defendant the burden to show empirical evidence of [the settlement's] procompetitive effects." *Actavis*, 133 S. Ct. at 2237 (quoting *Cal. Dental Ass'n. v. FTC*, 526 U.S. 756, 776 n.12, 119 S. Ct. 1604, 143 L. Ed. 2d 935 (1999).

In *Actavis*, the Supreme Court rejected both camps and, in lieu thereof, instructed courts to employ a 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. *See 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 thirty month litigation period, all the parties settled. *Id*. The terms of the settlement between Solvay and Actavis were that (1) Actavis agreed to not bring its generic to market sixty-five (65) months before Solvay's patent expired (unless someone else marketed a generic sooner); and (2) 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 FTC subsequently filed suit against Solvay and the three generics alleging a 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 the 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 Pharms., Inc.*, 677 F.3d at 1312.

In rejecting the Eleventh Circuit's "scope-of-the-patent" test, the Supreme Court noted that 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 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 Supreme 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 as original). 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 2235-3737. 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, 1074-75 (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 2235-37. 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 presumptively illegal "quick look" approach advocated by the Third Circuit in *K-Dur*. *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 must be "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: (1) whether the restraint at issue has the "potential for genuine adverse effects on competition"; (2) whether there are justifications for the anticompetitive consequences; (3) 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; (4) 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 (5) 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 Defendants' Motions to Dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

1. Payment

In providing the rule of reason analysis for reverse payment settlement agreements, *Actavis* does not define payment or provide 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.

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).[16] Another decision (by one of my esteemed New Jersey colleagues)

[16] 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 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).

found 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. 12-0995, 2014 WL 282755, at *6-7 (D.N.J. Jan. 24, 2014)[17]. 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.

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, 460–461, 106 S. Ct. 2009, 90 L. Ed. 2d 445 (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 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

[17] 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 its Paragraph IV certification and arguing in the resulting litigation. In return, GSK agreed to 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* scruitiny."

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 previously noted, *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 Medical Center, 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 FTC has concluded that "[a]llowing pharmaceutical companies to sidestep antitrust review by using non-cash payments to purchase delayed generic entry would significantly undermine the holding in *Actavis*." (FTC *Amicus Curiae* Br. "FTC Br.") at 18). The FTC has performed recent studies on the competitive effects of authorized generic drugs and found that no-authorized generic agreements have become commonplace and "a recognized mode of

compensation to generics for restrictions on entry."[18] Though a no-authorized generic agreement does have value, in order to be assessed, it must be converted to a specific value. When an alleged reverse payment involves a non-monetary payment of any kind, it must be valued in terms of a monetary amount in order to determine if it is "large" within the meaning of *Actavis*.

In the instant case, Direct Purchaser Plaintiffs allege that the reverse payment was an agreement "that Wyeth would not launch an authorized generic version of Effexor XR during the 180-day exclusivity period." (Second Am. Compl. at ¶ 12). Plaintiffs believe that by not having to compete with an authorized generic during this time period, "Teva would realize about double the volume of generic sales at significantly higher, supra-competitive prices than Teva otherwise would receive absent Wyeth's promise." (*Id.*). Plaintiffs value this benefit at over $500 million. (*Id*. at ¶¶ 12, 281, 285, 292).

The value of the no-authorized generic agreement in the Complaint appears to be based on a comparison between the $2.39 billion in reported sales of Effexor in 2009 (the year before generic competition) and the $2.31 billion in reported sales of a similarly situated drug, Paxil. The first-filer generic manufacturer of that drug, Apotex Corp., allegedly informed the FDA that the presence of an authorized generic for Paxil cost the company approximately $400 million in sales during its 180-day exclusivity period. (*Id*. at ¶ 292). While this comparison is useful for purposes of showing that a no-authorized generic agreement has value, it does not specifically value the monetary amount of the no-authorized generic agreement in the instant case.[19]

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[18] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT: A REPORT OF THE FEDERAL TRADE COMMISSION, at 145-46 (August 2011), *available at* http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission.

[19] The FTC Authorized Generic Study has data on the revenue share that transfers from the brand manufacturer to the first-filer generic manufacturer during the exclusivity period, even amongst those without authorized generic competition, even amongst those with a similar market size. *FTC AG Study* at 60, Figure 3-6. The Complaint fails to sufficiently explain why a generic version of Effexor XR would have a similar revenue share as a generic version of

While the Direct Purchaser Plaintiffs' Complaint provides some background on the effect of generic competition and provides estimates of the expected market sales of a generic, it does not provide any explanation as to how those estimations are used to formulate the approximate value of the no-authorized generic agreement. Simply alleging some sort of value of a no-authorized generic agreement, absent a reliable foundation supporting that value, does not establish the plausibility required by Rule 12(b)(6).[20] In essence, Plaintiffs' calculation of the monetary value of the no-authorized generic agreement is vague and amorphous. In this Court's view, in order to raise a right to relief above the speculative level, Plaintiffs must provide some reliable foundation to show that a reverse payment agreement was actually entered and present specific facts showing how the alleged non-monetary payment was calculated. For example, in one article explaining the *Actavis* analysis, the authors noted that a plaintiff must "valu[e] the consideration flowing from the patentee to the claimed infringer."[21] The use of the term "value" contemplates that it is based on a reliable foundation used within the industry.

The Court sees the "payment" between Wyeth and Teva as including more than the no-authorized generic agreement. The *Actavis* decision provides that a payment could be made in exchange for "avoided litigation costs or fair value for services". *Actavis*, 133 S. Ct. at 2236. To establish the payment, the Court finds it appropriate to apply the following analysis:

Paxil or why the presence of an authorized generic would have a similar impact on the revenue of a generic manufacturer.

[20] While the Plaintiffs later submitted a letter to the Court on May 19, 2014 discussing a methodology used to calculate the no authorized generic agreement having a value of over $500 million, this methodology was not included in the second amended complaint and therefore does not constitute the allegations on which this motion can be based and the Court has not ruled on whether the methodology is plausible. Letter from Peter S. Pearlman, May 19, 2014 (ECF No. 332). It was filed very late and beyond the scope of what the Court had requested to be submitted and, accordingly, it will not be considered. Plaintiffs were provided the opportunity to amend the complaint in light of *Actavis* and re-brief their opposition to the motion to dismiss and did not include the details of the calculation of the payment.

[21] Aaron S. Edlin, Scott Hemphill, Herbert Hovencamp & Carl Shaprio, *Activating Actavis*, ANTITRUST, Vol. 28, No. 1 (Fall 2013).

> 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). The resulting net payment is "otherwise unexplained"

Activating *Actavis*, 16 Antitrust, Vol. 28, at 18. Therefore, the total payment here is seen as the value of the no authorized generic promise for Effexor XR for eleven months (as Plaintiffs also allege that Wyeth kept all other generic companies off the market until June 2011), added to the value of the allowing Teva to release a generic of Effexor IR before the expiration of the Husbands patent, subtracted by the value of the avoided litigation costs and the royalties Teva would pay to Wyeth during those eleven months.

A rough approximation of the value of the no-authorized generic agreement could be based upon the difference in market expectations with and without an authorized generic. That calculation would include assumptions such as the share of the market that converts from the brand to the generic, the retail price of the generic during the 180-day exclusivity period, with and without an authorized generic, and the share of the generic market that would have been retained by the authorized generic if there had been one. Those assumptions must be analyzed in the Complaint and, in the view of this Court, Plaintiffs are obligated to explain why they provide a reasonable foundation. While Plaintiffs' counsel argues that the Court should accept Plaintiffs' allegation as true, the Court is reluctant to do so because Plaintiffs do not set forth a reliable foundation substantiating their claim. The Complaint simply does not rely on any knowledge of business practitioners in the pharmaceutical industry. As such, more focused allegations are necessary.

Direct Purchaser Plaintiffs allege that, in approximate sixteen months following Teva's release of Effexor IR, Wyeth's sales of Effexor IR that had converted to Teva generic IR venlafaxine tablets were likely worth about or less than $100 million. (Second Am. Compl. at ¶ 294). Again, the Complaint provides no reliable foundation of this value or any explanation for the calculation of this amount. This is an insufficient allegation for the Court to simply accept as true. Plaintiffs also project that Wyeth's litigation costs for the *Teva* litigation "could not have been larger than a range of about $5 million to $10 million". (*Id*. at ¶ 285). Plaintiffs, however, again fail to provide any reasonable foundation. In contrast, the Complaint could have alleged that a reliable foundation is what is set forth in *Actavis* - that is "[o]ne study found that the cost of litigation in this specific context—a generic challenging a brand name pharmaceutical patent—was about $10 million per suit." *Actavis*, 133 S. Ct. at 2243-44 (citing *Herman* at 1795, n. 41 (citing M. Goodman, G. Nachman, & L. Chen, Morgan Stanley Equity Research, Quantifying the Impact from Authorized Generics 9 (2004)). Such an allegation may have met the reliable foundation standard. In addition, the Complaint also does not allege the value of the royalty payments paid by Teva to Wyeth. In the view of the Court, at the very least, some general industry guidelines should have been alleged in order to be used as a reliable foundation.

Since the Direct Purchaser Plaintiffs fail to provide appropriate evidence for the Court to determine the value of the payment, the allegations in the Complaint do not reach the plausibility standard established in *Iqbal* and *Twombly*.

2. Reverse

Actavis provides two examples of settlements that take "commonplace forms" and then provides that there is "something quite different" about reverse payment settlements where "a party with no claim for damages (something that is usually true of a paragraph IV litigation

defendant) walks away with money simply so it will stay away from the patentee's market." *Actavis,* 133 S. Ct. at 2233. Therefore, within the context of pharmaceutical patent cases, a payment is reverse when a net positive payment flows from the patentee to the alleged infringer. *Id.*

According to the Plaintiffs, Wyeth's no-authorized generic promise constituted a substantial net payment by Wyeth to Teva in exchange for Teva agreeing to delay generic entry much later than it otherwise would have. (Second Am. Compl. at ¶ 281). The Court views the payment as including more than just the no-authorized generic promise, as described above. Defendants argue that there was no reverse payment because "[n]othing in *Actavis* supports treating an early-entry settlement as a 'reverse payment settlement' simply because there is consideration supporting the agreement on both sides". (Defs.' Br. at ¶ 7). Using the three-step methodology to formulate the payment may have still resulted in a net reverse payment. Since the Plaintiffs' conclusion about the value of the payment cannot be supported without sufficient factual matter provided in the Complaint, the value of the non-monetary payment cannot be determined and, therefore, the direction of the payment cannot be established.

3. Large

Throughout the *Actavis* opinion, the Court repeatedly states that the payment must be "large." *Actavis,* 133 S. Ct. at 2236-2237. *Actavis* again does not define what makes a payment "large" and provides only slight guidance for making this determination. Perhaps, at the extreme, a "large" payment is "a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market." *Id.* at 2235. At the other extreme, perhaps a "large" payment is anything more than the value of the avoided litigation costs, when there are no other services provided from the generic to the brand manufacturer. *See Activating Actavis* at

18. The question still remains how large of a payment creates a suspicion that "[t]he rationale behind a payment of this size cannot . . . be supported by traditional settlement considerations." *Actavis,* 133 S. Ct. at 2235.

The Court cannot plausibly establish the value of the non-monetary payment in order to determine if it is large, whether the value of the non-monetary payment was a substantial amount of annual sales of the brand product maybe an appropriate fact, as it must be a payment that appears to be large from the perspective of the brand company making the payment. During oral argument, the discussion turned to the definition of "large." Plaintiffs' counsel noted that $500 million "may not be an awful lot of money to . . . Wyeth. I'll bet it's a lot of money to Teva." Tr. 60:8-60:14, April 3, 2014 (ECF No. 339-2). The problem with Plaintiff's counsel's analysis is that it does not have a reliable foundation. "Betting" it is a large number to Teva is not a sufficient plausible fact to withstand Defendants' motion to dismiss.

4. Unexplained

Actavis has provided examples of valid explanations that account for the payment and, therefore, do not invite antitrust scrutiny. These include the cost of anticipated litigation, payments for other services promised to be rendered by the generic challenger and "any other convincing justification." *Actavis,* 133 S. Ct. at 2237. Other convincing justifications are left open to interpretation by the district courts. *Actavis* also suggests that a justification can be seen in the intent of the parties in settling, "[i]f 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 forbid the arrangement." *Id.* at 2237. Here, any alleged antitrust intent held by the parties is negated by the fact that the settlement and license agreements were forwarded to the FTC evidencing the parties' willingness to submit those agreement for review prior to the settlement becoming effective. The steps ordered by Judge Martini show that the proposed

settlement of the patent case was in light of appropriate antitrust concerns. Judge Martini's Scheduling Order does far more than simply inform the FTC of the settlement, as would a submission to the FTC under the MMA. His entry of the Order and signing of the Consent Decree shows strong judicial intervention in the antitrust inquiry. The FTC's letter would lead Judge Martini to conclude that the agency had no interest in the case. With such forethought by Judge Martini, it is difficult for this Court to set aside the settlement agreement contained in the consent decree.

The FTC responded to Judge Martini that they reserved the right to take further action regarding the settlement. The Court finds such a reservation to be unconvincing. When a governmental agency receives an invitation from the Court to intercede in a matter by way of an Order, that agency should respond appropriately, not simply reserve that right for the future. Here the FTC filed an amicus brief. There is no reason suggested therein that FTC's position or knowledge of this case differed between the time of the Consent Decree and the filing of the amicus brief. As such, the comprehensive review suggested by the judiciary makes the FTC's lackluster response to same distinguishable from the settlement discussed in *Actavis* and is a sufficient justification that the agreement between Wyeth and Teva did not constitute an unexplained payment.

Walker Process Claim

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 to the PTO which would have prevented issuance of the 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).

Plaintiffs allege that Wyeth "engaged in distinct *Walker Process* frauds." (ECF No. 298, ¶ 416). Plaintiffs allege four different instances where *Walker Process* fraud occurred; the Court mentions two of them. They are:

1. By fraudulently claiming that extended release venlafaxine reduced the incidence of nausea and vomiting, when it did not. (ECF No. 276, ¶ 417.) According to Plaintiffs, Wyeth conducted clinical studies to establish the efficacy of Effexor XR and the studies failed to demonstrate any statistically significant decline in the incidence of nausea. (see *supra*, p. 9).

2. By failing to disclose to a second patent examiner (Spear) that a prior examiner (Hulina) had found all method-of-use claims of Effexor XR unpatentable in light of the Upton patent which had been issued earlier. (ECF 287, ¶ 418.) (See *supra*, p. 10-11).

In response to Plaintiffs' *Walker Process* claims, Wyeth refutes the factual contentions. For example, at oral argument, Wyeth's attorney (Mr. Drivas) focused on the second claim wherein he argued that the interview summary of Examiner Hulina as set forth in the prosecution history concerning method-of-use claims and the Upton patent did not show that Wyeth concealed

Examiner Hulina's action from Spear, when Examiner Spears initialed that he reviewed Examiner Hulina's work. (Effexor T. 21, 6 through T. 23, 24). Similarly, Mr. Drivas attacked the "materiality" of the Upton patent. (Effexor T. 24, L. 5) since the Upton patent does not deal with depression and there is "no disclosure of a sustained release." (Effexor T. 24, L. 5 – T. 25, L. 3). Wyeth's arguments appeared to be more like summary judgment than a motion to dismiss on the *Walker Process* claim. As noted in the standard of review section (see *supra*, p. 25-27) Plaintiffs' obligation is to provide grounds of his entitlement to relief, meaning that the "factual 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. Here, the facts in the Complaint are plausible, and even if one was skeptical about the truth of the facts, they survive on a motion to dismiss. The Complaint sets forth in a clear and plain statement of facts showing that the pleader is entitled to relief. *Iqbal*, 556 U.S. at 677-78.

Wyeth also argues that the plaintiffs failed to show intent, i.e. Wyeth knowingly and willfully undertook the above actions to defraud the Patent Office. Such an intent is an element of proof to ascertain a *Walker Process* claim. Generally, lack of proof of intent within the four corners of the pleading is not a reason to dismiss a complaint. In order to dismiss on such a ground, the defendant must show that the Plaintiff has failed to allege any facts that can support an inference of bad faith or an intent to deceive. *See Wechsler v. Steinberg*, 733 F. 2d 1054, 1057-58 (2d Cir. 1984). Scienter or intent to defraud is usually an issue of fact that should not typically be resolved on a pretrial motion. *Lau v. Mezei*, 2012 U.S. Dist. LEXIS 116608, *11 (S.D.N.Y. 2012). The facts concerning Wyeth's interactions with the Patent Office, *e.g.* failing to disclose the Upton patent, and failing to advise Spear about Hulina's findings, are sufficient to infer fraudulent intent.

III. CONCLUSION

For the reasons stated above, Defendants' Motion to Dismiss the Direct Purchaser Plaintiffs' Second Amended Consolidated Class Action Complaint is granted in part and denied in part. An appropriate Order follows.

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

October 6, 2014