

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

IN RE OPANA ER ANTRITRUST  
LITIGATION

MDL Docket No. 2580

Case No. 14 C 10150

Judge Harry D. Leinenweber

MEMORANDUM OPINION AND ORDER

In addition to the claims brought by Direct Purchaser Plaintiffs (the "DPPs") and End-Payor Purchaser Plaintiffs (the "EPPs"), two groups of retailers, Walgreen Co., et al., and Rite Aid Corporation, et al. (collectively, the "Opt-Out Plaintiffs"), have brought claims in this multi-district litigation against Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Penwest Pharmaceuticals Co. (collectively, "Endo"), and Impax Laboratories, Inc. ("Impax") (collectively, the "Defendants"), pursuant to the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S.Ct. 2223 (2013). Opt-Out Plaintiffs, like DPPs and EPPs, allege that Defendants violated the Sherman Act when they entered into an illegal reverse payment agreement to settle ongoing patent infringement

litigation thereby delaying the entry of generic versions of Opana ER to the Oxymorphone ER Market.

Currently before the Court is Defendants' Motion to Dismiss Opt-Out Plaintiffs' Complaints pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) [ECF No. 119]. For the reasons stated herein, the Motion to Dismiss is granted.

## **I. BACKGROUND**

Except where noted, the following facts are contained in both of Opt-Out Plaintiffs' Complaints, as well as documents attached to, referenced in, and critical to, the Complaints. *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012).

### **A. Hatch-Waxman Regulatory Framework**

For a complete discussion of the Hatch-Waxman regulatory framework underpinning this case, the Court incorporates by reference the discussion on pages 2-6 of its February 10, 2016 Memorandum Opinion and Order [ECF No. 151].

### **B. Endo-Impax Patent Litigation**

Up until early spring of 2012, Defendant Endo manufactured Opana ER, an extended release form of oxymorphone hydrochloride marketed for the relief of moderate to severe pain. Rite Aid Complaint ("RAC") ¶ 53; Walgreen Complaint ("WC") ¶ 57. Endo began selling Opana ER on or about June 21, 2006. RAC ¶ 55; WC ¶ 59. At the time, Endo had three years of regulatory

protection from generic competition, which prevented the Food and Drug Administration ("FDA") from approving an Abbreviated New Drug Application ("ANDA") for Opana ER through June 22, 2009, after which point Endo's Opana ER monopoly would be subject to generic competition. RAC ¶ 57; WC ¶ 61. Knowing this, Endo purchased the rights to four patents – U.S. Patent No. 5,128,143 (the "'143 patent"), No. 5,958,456 (the "'456 patent"), No. 5,662,933 (the "'933 patent"), and No. 7,276,250 (the "'250 patent") (collectively, the "Penwest Patents") – that could be used to block generic entry beyond those three years. RAC ¶¶ 51-52, 68; WC ¶¶ 55-56, 72. Endo then listed the '143 patent in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Opana ER, and later added the '250, '456 and '933 patents. RAC ¶¶ 65, 68; WC ¶¶ 69, 72.

In November of 2007, Impax filed an ANDA seeking to market a generic version of Opana ER, and submitted a Paragraph IV certification stating that the Penwest Patents would not be infringed by Impax's generic. See, 21 U.S.C. § 355(j)(2)(A) (vii); RAC ¶ 70; WC ¶ 74. On December 13, 2007, Impax sent Endo notice of its Paragraph IV filing. RAC ¶ 72; WC ¶ 76. On January 25, 2008, Endo sued Impax for patent infringement – triggering the 30-month Hatch-Waxman stay. RAC ¶ 73; WC ¶ 76. Other generic companies later filed ANDAs seeking to market

generic versions of Opana ER before the expiration of the Penwest Patents, and Endo sued each for patent infringement. RAC ¶¶ 84-109; WC ¶¶ 80-105. Because Impax was the first company to file a Paragraph IV ANDA (commonly known as the "first-filer") for the 5, 10, 20, 30, and 40 mg strengths of Opana ER, upon obtaining FDA approval it was entitled to 180 days of exclusivity for those strengths as against the other ANDA filers. RAC ¶¶ 74, 77; WC ¶¶ 78, 81. Thus, by filing suit and delaying Impax's entry for 30 months, Endo delayed all generics from launching 5, 10, 20, 30 and 40 mg strengths of generic Opana ER.

On May 13, 2010, a month before the 30-month stay was set to expire, the FDA tentatively approved Impax's ANDA for all strengths of Opana ER. RAC ¶ 111; WC ¶ 115. This meant that, upon the expiration of the 30-month stay on June 14, 2010, Impax was free to make an "at-risk" launch of its generic without waiting for the trial court's final ruling in the Impax patent litigation. RAC ¶ 112; WC ¶ 116. But, for whatever reason, Impax agreed not to launch its generic through the last day of trial. RAC ¶ 113; WC ¶ 117. The bench trial commenced on June 3, 2010, and proceeded for two days. RAC ¶ 114; WC ¶ 118. On June 8, 2010, Endo and Impax settled. RAC ¶ 116; WC ¶ 120.

### **C. Endo-Impax Settlement**

The Endo-Impax Settlement consisted of two agreements entered into simultaneously: (1) the Settlement and License Agreement ("SLA"), and (2) the Development and Co-Promotion Agreement ("DCA"). Under the SLA, Impax agreed to delay its launch of generic Opana ER until the earlier of: (i) January 1, 2013, (ii) thirty days after a non-appealable federal court decision finding that Endo's patents were invalid or not infringed, or (iii) Endo's withdrawal of its patents from the Orange Book. SLA § 3.2. Impax further agreed to refrain from challenging the validity or enforceability of the '933 and '456 patents, as well as the '250 patent, which Endo had not even accused Impax of infringing. SLA § 3.3. In return, Endo covenanted not to sue Impax on, and granted Impax a license as to, any then-existing or subsequently obtained patents relating to Opana ER. *Id.* at § 4.1(a), (b). Additionally, Endo agreed to refrain from launching an Authorized Generic ("AG") version of Opana ER marketed under Endo's NDA during Impax's 180-day exclusivity period ("No-AG Agreement"). *Id.* at § 4.1(c).

The SLA was also structured so that, depending on the volume of Opana ER sales at the time Impax's generic entered the market, one of three things would occur. First, if at the time Impax entered the market sales of Opana ER had declined below a certain threshold defined in the SLA, then Endo was required to

pay Impax under the "Endo Credit" provision. *Id.* at § 4.4. The amount of the Endo Credit payment depended on the amount of decline in Opana ER sales – the greater the decline in sales, the larger the payment required under the Endo Credit provision. *Id.* Second, if Opana ER sales exceeded a certain threshold defined in the SLA by the time Impax entered the market, then Impax was required to pay Endo a 28.5% royalty on net sales of Impax's generic under the "Royalties" provision. *Id.* at § 4.3. Finally, if sales of Opana ER remained somewhere between the Endo Credit and the Royalties threshold amounts, neither party was required to pay anything.

The other aspect of the Endo-Impax Settlement was the DCA, which resulted in a \$10 million cash payment from Endo to Impax. DCA § 3.1. Under the DCA, Endo and Impax agreed to work together on the development and promotion of a drug for the treatment of Parkinson's disease. *Id.* at § 2.1. Among other things, Endo agreed to support the product's development through a \$10 million up-front payment, and to make additional future payments to Impax if Impax successfully completed various clinical and commercial milestones. *Id.* at §§ 3.1, 3.2, 3.3. In return, Endo received an exclusive license to promote the product to non-neurologists in the United States. *Id.* at §§ 2.1, 2.2. Endo also received the right to keep between 75%

and 100% of the profits from the sale of the drug to non-neurologists in the United States. *Id.* at § 3.4.

#### **D. Aftermath**

Endo knew that when generics for Opana ER entered the market in 2013 there would be "substantial share erosion" for brand Opana ER, so it immediately set about "working at multiple levels to combat that." RAC ¶ 148; WC ¶ 152. Accordingly, shortly after entering into the Endo-Impax Settlement, Endo set about switching the market from Opana ER to a crush resistant formula of Opana ER ("Opana ER CRF"). RAC ¶ 149; WC ¶ 153. The FDA approved Endo's supplemental new drug application ("sNDA") for Opana ER CRF on December 9, 2011. RAC ¶ 150; WC ¶ 154. To accomplish the switch between Opana ER and Opana ER CRF, Endo discontinued the sale of Opana ER, thus forcing physicians desiring to prescribe extended release oxymorphone hydrochloride to prescribe Opana ER CRF instead. RAC ¶ 150; WC ¶ 154.

Generic drugs that are "therapeutically equivalent" to their brand counterpart receive an "AB" rating from the FDA. An AB-rated generic may be automatically substituted at the pharmacy counter for the brand drug. Because generic versions of Opana ER are not AB-rated equivalents of Opana ER CRF and therefore are not automatically substitutable, they were unable to capture the sales of Opana ER CRF when they eventually entered the market in 2013. RAC ¶ 151; WC ¶ 155. Without

generic competition, Endo continues to sell Opana ER CRF at supracompetitive prices. RAC ¶ 152; WC ¶ 156.

As a result of Endo's market shift from Opana ER to Opana ER CRF, by the time Impax's generic entered the market in line with the terms of the Endo-Impax Settlement Agreement, in January 2013, sales of Opana ER had declined below the threshold defined in the SLA, triggering the Endo Credit provision. SLA § 1.1. The amount Endo was required to pay Impax under the Endo Credit was determined based on the sales of Opana ER in the quarter immediately prior to the launch of Impax's generic. SLA § 1.1; RAC ¶ 5; WC ¶ 123. Ultimately, in April 2013, Endo paid Impax \$102,049,000 pursuant to the Endo Credit provision. RAC ¶ 5; WC ¶ 123.

#### **E. Assignment of Claims to Opt-Out Plaintiffs**

Opt-Out Plaintiffs bring suit as assignees of pharmaceutical wholesalers Cardinal Health, Inc. ("Cardinal"), McKesson Corporation ("McKesson"), and AmeriSource Bergen Drug Corporation ("ABDC") (collectively, "the Wholesalers"). Each of the Wholesalers, in turn, purchased Opana ER directly from Endo pursuant to Distribution Service Agreements ("DSAs"). The DSAs govern Endo's sale of Opana ER to the Wholesalers, and include general provisions for product distribution, inventory management services, and distribution channel information, among other services.



Each DSA includes a provision that prohibits the Wholesalers from assigning the agreement without Endo's consent. Specifically, the Cardinal DSA states, "[n]either party may assign this Agreement without the prior written consent of the other party. . . ." Cardinal DSA § 4.3. The McKesson DSA states, "[n]either party may assign this Agreement or delegate any of its respective duties or responsibilities under this Agreement without the prior written consent of the other party which consent shall not be unreasonably withheld." McKesson DSA § 5.3. Similarly, the ABDC DSA states, "[n]either Party may assign this Agreement or delegate any of its respective duties or responsibilities [sic] this Agreement without prior written consent of the other Party which shall not be unreasonably withheld. . . ." ABDC DSA § 13.2. Endo did not consent to the assignment of claims by the Wholesalers to any of the Opt-Out Plaintiffs.

## **II. ANALYSIS**

Opt-Out Plaintiffs, like DPPs and EPPs, make claims against Defendants based on the Supreme Court's opinion in *FTC v. Actavis*, which decided whether it is illegal for a brand-name company to provide a payoff to a potential generic competitor, to keep it from entering the market earlier than it otherwise might have. *Actavis*, 133 S.Ct. at 2223. The Supreme Court held that a reverse settlement payment, that is, a payment by a

patentee to a claimed infringer, may be a restraint of trade under a "rule of reason" analysis when the payment is large and unjustified. *Id.* at 2230, 2237-38. The Court explained, 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." *Id.* at 2237. For a complete discussion of the *Actavis* decision, the Court incorporates by reference the discussion on pages 12-15 of its February 10, 2016 Memorandum Opinion and Order [ECF No. 151].

Following the Court's lead in *Actavis*, Opt-Out Plaintiffs allege that the Endo-Impax Settlement contained a large and unjustified reverse settlement payment that satisfies a "rule of reason" analysis. Defendants, in their Motions to Dismiss Opt-Out Plaintiffs' Complaints, make five arguments: (1) the Endo-Impax Settlement Agreement did not involve a reverse payment at the time the settlement was entered; (2) the alleged reverse payment was not large and unjustified; (3) Out-Out Plaintiffs have failed to allege antitrust injury; (4) Opt-Out Plaintiffs lack standing to bring these claims; and (5) Opt-Out Plaintiffs claims may only be pursued as part of DPP class, and therefore must be dismissed or at least stayed until DPPs achieve class certification. The Court will address the last two arguments

first, as they go to the Court's power to consider Opt-Out Plaintiffs' claims. *Warth v. Seldin*, 422 U.S. 490, 498 (1975) (stating that whether a plaintiff has standing is "the threshold question in every federal case, determining the power of the court to entertain the suit.").

#### **A. Standing**

The doctrine of standing acts as a limitation on the power of the federal courts. It "requires federal courts to satisfy themselves that 'the plaintiff has alleged such a personal stake in the outcome of the controversy as to warrant *his* invocation of federal-court jurisdiction.'" *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009) (quoting *Warth*, 422 U.S. at 498-499 (internal quotation marks omitted)).

Private suits to enforce the Sherman Act are authorized by Section 4 of the Clayton Act, 15 U.S.C. § 15(a), which provides that "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor. . . ." Despite the apparent breadth of the phrase "any person," numerous doctrines have arisen to clarify the circumstances under which a particular person may recover from an antitrust violator. At times these doctrines are referred to as "antitrust standing." The Supreme Court, however, has made clear that these doctrines are separate and distinct from Article III standing, which tests "whether a

plaintiff has suffered a redressable injury in fact, entitling the federal courts to hear such a 'case or controversy'. . . ." *Loeb Indus., Inc. v. Sumitomo Corp.*, 306 F.3d 469, 480 (7th Cir. 2002) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). There is no dispute that Opt-Out Plaintiffs allege that they have been injured by paying supracompetitive prices for Opana ER and Opana ER CRF as a result of the illegal agreement between Endo and Impax, and therefore they have Article III standing. The more difficult question is whether, under the Sherman Act, Opt-Out Plaintiffs have antitrust standing to bring this suit for antitrust damages.

To establish antitrust standing a plaintiff must prove that he or she has been (1) "injured in his business or property"; (2) "by reason of anything forbidden in the antitrust laws. . . ." See, 15 U.S.C. § 15(a). Under the first element, a plaintiff must demonstrate injury to his or her business or property interests, which injury is causally linked to an antitrust violation. Generally speaking, an allegation that plaintiff consumers paid higher prices for goods purchased due to defendants' conduct satisfies this element. See, e.g., *Reiter v. Sonotone Corp.*, 442 U.S. 330, 342 (1979) ("[W]here petitioner alleges a wrongful deprivation of her money because the price of the [good] she bought was artificially inflated by reason of respondents' anticompetitive conduct, she has alleged

an injury in her 'property' under § 4." ). Under the more critical second element, a plaintiff must also demonstrate "injury of the type the antitrust laws were intended to prevent" (commonly referred to as "antitrust injury"). See, *Atl. Richfield Co. v. USA Petroleum*, 495 U.S. 328, 334 (1990).

Even assuming, however, that a plaintiff is able to show antitrust injury, it is "not always sufficient to establish standing under section 4 because a party may have suffered antitrust injury but may not be the proper plaintiff under section 4 for other reasons." *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 110 n.5 (1986). For example, where a plaintiff's injury is derivative of a more direct injury to some other person, and that person would have a strong motivation to pursue its own antitrust claim against the defendant, standing is likely to be denied. This is the rationale underlying *Illinois Brick*, in which the Supreme Court held that indirect purchasers are too remote to suffer true antitrust injury, and therefore do not have standing under federal antitrust law to pursue antitrust claims. *Illinois Brick v. Illinois*, 431 U.S. 720, 728 n.7, 745-46 (1977).

Defendants argue that Opt-Out Plaintiffs lack antitrust standing pursuant to *Illinois Brick* because their injury is derivative of the Wholesalers' direct injury. Opt-Out Plaintiffs respond that their injury is not derivative because

they are standing in the shoes of the Wholesalers by virtue of the assignments. Defendants, in turn, contend that the assignments under which Opt-Out Plaintiffs purportedly bring their claims are invalid. Ultimately, whether Opt-Out Plaintiffs have antitrust standing to recover against Defendants turns on whether the assignments are valid.

The validity of assignments under the Sherman and Clayton Acts is a matter of federal common law. *Gulfstream III Associates, Inc. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 437 (3d Cir. 1993). There is no serious doubt that an antitrust claim can be expressly assigned. In many cases, such assignments are accepted *sub silentio*. See, e.g., *Jefferson Cnty. Pharm. Ass'n, Inc. v. Abbott Lab.*, 460 U.S. 150 (1983); *Chiropractic Coop. Ass'n of Michigan v. Am. Med. Ass'n*, 867 F.2d 270 (6th Cir. 1989); *Hahn v. Oregon Physicians' Service*, 786 F.2d 1353 (9th Cir. 1985); see also, *In re Fine Paper Litig.*, 632 F.2d 1081, 1090 (3d Cir. 1980) (recognizing validity of assignment after discussion); *D'Ippolito v. Cities Service Co.*, 374 F.2d 643, 647 (2d Cir. 1967) (same); *Hicks v. Bekins Moving & Storage Co.*, 87 F.2d 583, 585 (9th Cir. 1937) (same); *Mercurey Industries, Inc. v. Bristol-Myers Co.*, 392 F.Supp. 16, 18 (S.D.N.Y.), *aff'd mem.*, 508 F.2d 837 (2d Cir. 1974) (same).

However, this does not answer fully the question raised by Defendants: whether the particular assignments upon which Opt-

Out Plaintiffs base their claims are valid. Defendants argue they are not because a provision in each DSA prohibited the Wholesalers from assigning "this Agreement" and/or from "delegate[ing]" any "duties or responsibilities" under the agreement without Endo's consent. Opt-Out Plaintiffs argue that this language does not affect the validity of their assignments because the Wholesalers did not assign the DSAs to Opt-Out Plaintiffs, nor did they assign or delegate any of their duties or obligations under the DSAs. Instead, Opt-Out Plaintiffs argue that the Wholesalers have simply assigned their antitrust overcharge claims against Endo and its co-conspirators.

The Court agrees with Opt-Out Plaintiffs. Unless intent to the contrary is shown, a contractual prohibition against "assignment of the contract" is presumed as a matter of law to refer only to delegation of contractual duties, not assignment of rights. *See, Cedar Point Apartments, Ltd. v. Cedar Point Inv. Corp.*, 693 F.2d 748, 753 (8th Cir. 1982); *Charles L. Bowman & Co. v. Erwin*, 468 F.2d 1293, 1297-98 (5th Cir. 1972); Restatement (Second) of Contracts § 322(1) (1981); 3 S. Williston, *A Treatise on the Law of Contracts* § 422, at 138-39 (3d ed. 1961); 4 A. Corbin, *Corbin on Contracts* § 872, at 484 (1951). The non-assignment provision in each DSA may be read to prohibit the assignment of the parties' contractual duties and

obligations under the DSA, but it cannot be read to prohibit the assignment of the parties' rights.

Even under a broad reading of the non-assignment provisions, the prohibition on assigning "this Agreement" or "delegat[ing]" any "duties or responsibilities" would only serve to limit the parties' ability to assign their rights and obligations under the DSA. The Court does not read this language to include statutorily-based antitrust claims, because such claims are not based on any substantive right or duty found in the DSAs themselves. *See, e.g., United Food & Comm. Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 2015 WL 4397396, at \*4 (N.D. Cal. July 17, 2015); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 2011 WL 3475408, at \*4 (N.D. Cal. 2011); *Meijer, Inc. v. Barr Pharm., Inc.*, 572 F.Supp.2d 38, 64 (D.D.C. 2008); *Cedar Point Apartments v. Cedar Point Inv. Corp.*, 693 F.2d 748, 753 (8th Cir. 1982). The existence of a boilerplate duty to abide by applicable law does not manifest the requisite intent to expand the scope of the non-assignment provisions beyond their plain language. The DSAs do not specifically mention antitrust law or the assignment of legal claims.

It is undisputed that the wholesalers did not delegate their duties or obligations under "th[e] Agreement" – the DSA – nor was the DSA as a whole assigned to Opt-Out Plaintiffs. What



was assigned is a *cause of action* that arose from the DSA. Such an assignment is not prohibited by the language of the non-assignment provisions. Accordingly, the Court finds that Defendant's standing argument lacks merit.

**B. Dismiss or Stay Pending DPP Class Certification**

Defendants next argue that even if the assignments are valid, they are only partial assignments, and therefore Opt-Out Plaintiffs should be required to pursue their claims as part of the direct purchaser class under FED. R. CIV. P. 19. Defendants contend that a partial assignment multiplies the number of lawsuits brought against Defendants on the basis of the Wholesalers' purchases and impermissibly forces Defendants to face a multiplicity of suits. While normally a class member with an individual claim may opt out of the class to pursue his or her claim separately, Defendants propose that a different rule applies when a class member partially assigns his or her claim to a third party. Under such circumstances, Defendants assert that the holder of the partially-assigned claims loses the right to opt out and must litigate its claims as part of the relevant class. Opt-Out Plaintiffs contend that Defendants' proposed rule has been repeatedly rejected by the federal courts and that this multidistrict litigation sufficiently consolidates the cases to alleviate any of the concerns raised by Defendants.

Class members with individual claims for actual damages may always opt out of the class to pursue their claims separately. *Murray v. GMAC Mortg. Corp.*, 434 F.3d 948, 953 (7th Cir. 2006). A different rule applies, however, when a class member partially assigns its claim to a third party:

An assignment of a fractional part of a single and entire right against an obligor is operative as if the part had been a separate right. But unless the obligor has consented, the partial assignee may not maintain the original suit against the obligor unless all parties having the collective right to the entire claim are joined in the proceeding.

Restatement (Second) of Contracts § 326 (1981).

The Third Circuit extensively examined this principle in *Fine Paper* when it addressed whether the holder of partially-assigned claims may opt out of a certified class action. *Fine Paper*, 632 F.2d at 1089. The court first concluded that partial assignments "pose no threat to the rule of law enunciated in [*Illinois Brick*]." *Id.* at 1090. In fact, the court found that both of the policies behind *Illinois Brick* – the risk of multiple liability and complex problems of proof and apportionment – weigh in favor of recognizing partially-assigned claims in class actions. *Id.* Specifically, the Court stated:

Adjudicating the partial assignments at this stage will provide defendants with assurance against multiple liability. With all the claims in one proceeding, . . . the parties and the court can monitor each claim against the defendants. Moreover, the presence of the partial assignments will not add to the complexity of the lawsuit. Proof of the

assignment bears no resemblance to attempts to ascertain the numbers of indirect purchases or overcharges in the *Illinois Brick* setting.

*Id.* Therefore the court held that the partially-assigned claims should be included in the class action, as this would provide the defendants with assurance against multiple liabilities. *Id.*

But the court went on to conclude that the holder of the partially-assigned claims, "unlike other class members, [did] not have the right to opt out" of the class action. *Id.* at 1090-91. The court explained that although partial assignments are recognized, "the rights of the obligor to be free of successive and repeated suits growing out of the same basic facts" must also be protected. *Id.* at 1091. Thus, the court held that "[t]he compulsory joinder provisions of Rule 19" required the holder of the partially-assigned claims to pursue those claims as a member of the relevant class. *Id.*

The Court agrees with the reasoning and the rule announced by the Third Circuit in *Fine Paper*, and believes that its application to this case would compel a certain result but for a key factual distinction that renders the issue premature. Specifically, in *Fine Paper*, the partially-assigned claims were assigned by *members* of the certified direct purchaser class. *Id.* at 1089. In the instant case, the direct purchaser class has not been certified, and therefore its membership is indeterminate. Although the Wholesalers – Cardinal, McKesson,

and ABDC – fit the description of membership for the direct purchaser class, it is uncertain whether the class will ultimately obtain certification. Moreover, even if the class is certified, there remains a chance that the Wholesalers will exercise their right to opt out. Under such circumstances, the *Fine Paper* rule would require Opt-Out Plaintiffs to be joined in the Wholesalers' opt-out suit (should they choose to pursue one) – not in the direct purchaser class suit. See, *Fine Paper*, 632 F.2d at 1091 (“[U]nless the obligor has consented, the partial assignee may not maintain the original suit against the obligor unless all parties having the collective right to the entire claim are joined in the proceeding.”).

Thus, the current status of this litigation makes a decision to dismiss or stay Opt-Out Plaintiffs' partially-assigned claims premature. Although DPPs have filed a class action complaint, none of the Wholesalers appear as named plaintiffs, and DPPs have not yet moved for class certification. At this stage, it remains unclear whether the Wholesalers have reserved for themselves any portion of their right to sue Defendants, and if so, how they will choose to pursue that right. Therefore, Defendants' Motion to Dismiss or Stay Opt-Out Plaintiffs' claims is denied.

### **C. Sherman Act Arguments**

Turning to Defendants' remaining arguments, the Court finds Opt-Out Plaintiffs' pleadings substantially similar in many relevant respects to DPPs' and EPPs' pleadings; thus, in the interests of judicial economy, the Court will restate briefly its findings as Defendants' Sherman Act arguments, and discuss any meaningful distinctions in Opt-Out Plaintiffs' pleadings. The Court incorporates by reference its more thorough analysis of Defendants' Sherman Act arguments on pages 16-27 of its February 10, 2015 Memorandum Opinion and Order [ECF No. 151].

Defendants first argue that the Endo Credit was not a reverse payment. The Court disagrees. When the Court views the components of the Endo-Impax Settlement as a whole, it finds plausible and persuasive Opt-Out Plaintiffs' allegation that the Endo Credit and No-AG Agreement worked in conjunction with one another to ensure payment to Impax. Specifically, Plaintiffs allege that the settlement guaranteed Impax would receive a large reverse payment either through the Endo Credit if sales of Opana ER dropped, or through the No-AG Agreement if sales of Opana ER remained steady or rose after two-and-one-half years. Moreover, even if Impax had been required to pay Endo under the Royalties provision, Impax would still have received significant value through the Settlement in the form of the No-AG Agreement.

This is because the Royalties provision was only triggered if sales of Opana ER rose by a predefined amount. If this rise in sales occurred, by the time Impax entered the market with its generic there would be more Opana ER sales for it to capture, and Endo's promise not to compete through an AG during Impax's 180-day exclusivity period would become even more valuable.

In *Actavis*, the Supreme Court recognized generally that the 180-day exclusivity period is "possibly 'worth several hundred million dollars,'" and may be where the bulk of the first-filer's profits lie. *Actavis*, 133 S.Ct. at 2229 (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). At the same time, Endo's commitment not to produce an AG means that it gave up the valuable right to capture profits in the new two-tiered market. As such, the No-AG Agreement transferred the profits Endo would have made from its AG to Impax – plus potentially more, in the form of higher prices, because it enabled Impax to have a generic monopoly instead of a generic duopoly. See, *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015). Thus, even though Endo was free to compete with Impax in other areas of the market, by agreeing not to launch an AG during Impax's 180-day exclusivity period, Endo conveyed significant value to Impax.

Despite the form and amount of the reverse payment under the settlement being contingent on future occurrences, taking the Plaintiffs' allegations as true, it was certain at the time of the Endo-Impax Settlement that Impax would at least receive a reverse payment of significant value in the form of the No AG-Agreement, and an additional \$10 million under the DCA. Therefore, Opt-Out Plaintiffs have alleged sufficiently that the Endo-Impax Settlement contained a reverse payment.

Next, Defendants contend that Opt-Out Plaintiffs have failed to establish sufficiently that the alleged reverse payment was large or unjustified. Defendants argue that Opt-Out Plaintiffs do not even attempt to value the reverse payment, and only allege summarily that the No-AG Agreement was worth "many millions of dollars" to Impax. RAC ¶¶ 120, 122; WC ¶¶ 124, 126. In this respect, Opt-Out Plaintiffs' Complaints differ significantly from the complaints of DPPs and EPPs. This variance in the pleadings leads the Court to reach a different outcome than in the Motion to Dismiss DPPs' and EPPs' Complaints.

When, as here, "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 re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at \*21 (D.N.J. Oct. 6, 2014). Simply alleging

that the No-AG Agreement was worth "many millions of dollars," absent a reliable foundation supporting that value, does not establish the plausibility required by Rule 12(b)(6). The Court is aware that a precise valuation may require discovery, as it will likely depend on evidence in Defendants' exclusive possession and on expert analysis. *In re Aggrenox Antitrust Litig.*, 94 F.Supp.3d 224, 244 (D. Conn. 2015). But in order to raise a right to relief above the speculative level, Opt-Out Plaintiffs must provide some reliable foundation to show an estimated value of the reverse payment and how that estimate was calculated. Further, Opt-Out Plaintiffs' allegation that the reverse payment was "an amount far above any litigation costs saved by Endo (or Impax) by settling," RAC ¶ 119; WC ¶ 123, fails to calculate what those saved costs actually were. Without this information, it is impossible to determine whether the payment was "large" or "unjustified" in comparison to the avoided litigation costs and any other services provided from Impax to Endo. *See, Actavis*, 133 S.Ct. at 2236; *see also, In re Lipitor Antitrust Litig.*, 46 F.Supp.3d 523, 547 (D.N.J. 2014) ("Plaintiffs failed to plausibly allege an estimate of the monetary value of the non-monetary payment. . . .").

Therefore, the Court grants Defendants' Motion to Dismiss Opt-Out Plaintiffs' Complaints for failure to state a Sherman Act claim under *Actavis*. Opt-Out Plaintiffs are granted leave



to file an amended complaint within 21 days of the date of this memorandum opinion and order.

In light of this conclusion, the Court will not delve into an in-depth analysis of Defendants' argument that Out-Out Plaintiffs have failed to allege antitrust injury. But to save time and energy on future briefing, the Court notes that this argument, which is identical to that made in the Motion to Dismiss DPPs' and EPPs' Complaints, is unavailing. See, February 10, 2016 Memorandum Opinion and Order, p. 24-27. [ECF No. 151].

The anticompetitive harm, under *Actavis*, is that the reverse-payment settlement seeks to prevent the risk of competition. *Actavis*, 133 S.Ct. at 2236. Opt-Out Plaintiffs contend that: (1) Endo used a large reverse payment to buy itself freedom from generic competition; (2) but for Endo's unlawful and large reverse payment, Impax would have launched its generic earlier than it finally did; (3) Endo and Impax conspired to allocate the Oxymorphone ER Market in a manner that gave each company more exclusivity than it was lawfully entitled to in order to maximize profits; (4) Endo used that market exclusivity to further stifle generic competition by switching the market to its new formulation, Opana ER CRF; and (5) Impax ensured it received full compensation either through the valuable No-AG Agreement if Endo did not switch the market or

through the Endo Credit and less valuable No-AG Agreement if Endo did switch the market. These allegations, if true, raise a reasonable expectation that discovery will reveal evidence sufficient to prove that the reverse payment was made to prevent competition on various fronts. *Aggrenox Antitrust Litig.*, 94 F.Supp.3d. at 245-46.

### **III. CONCLUSION**

For the reasons stated herein, Defendants' Motion to Dismiss Opt-Out Plaintiffs' Complaints [ECF No. 119] is granted. Opt-Out Plaintiffs are granted leave to replead within twenty-one (21) days of the date of this Memorandum Opinion and Order.

**IT IS SO ORDERED.**

A handwritten signature in black ink, appearing to read 'Leinenweber', is written above a horizontal line.

Harry D. Leinenweber, Judge  
United States District Court

Dated: 2/25/2016