UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

IN RE LOESTRIN 24 FE ANTITRUST LITIGATION	)	MDL No. 13-2472-S-PAS
THIS DOCUMENT RELATES TO: ALL ACTIONS	)	No. 1:13-md-2472-S-PAS

OPINION AND ORDER

WILLIAM E. SMITH, Chief Judge.

This multidistrict litigation was consolidated and transferred to this Court by the United States Judicial Panel on Multidistrict Litigation. It arises in the wake of the Supreme Court's seminal holding in F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (2013), which held that "reverse payments" – settlement payments in patent infringement suits made by a patent holder to an alleged infringer in exchange for the alleged infringer's promise not to produce the patented product until a later date – may violate federal antitrust law.[1]

The plaintiffs allege that pharmaceutical firms involved in the sale of Loestrin 24 FE ("Loestrin 24"), a widely-used oral contraceptive, violated state and federal antitrust and consumer protection law by exchanging reverse payments in connection with a scheme to delay generic competition. There are two separate

[1] Fittingly, these arrangements are also known as "pay for delay." Aaron Edlin et al., Activating Actavis, 28 Antitrust 16 (2013).

consolidated complaints – the first by so-called direct purchasers (the "Direct Purchasers") and the second by so-called end payors (the "End Payors" and, together with the Direct Purchasers, the "Plaintiffs"). The defendants have filed two corresponding Motions to Dismiss (ECF Nos. 74 and 76), seeking to test the parameters of Actavis. For the reasons that follow, these Motions to Dismiss will be GRANTED.

I. Factual and Regulatory Background

A. The Parties

The Direct Purchasers are corporate entities that purchased Loestrin 24 directly from Warner Chilcott, one of the defendants.[2] The End Payors, generally, are employee welfare benefit programs that reimbursed subscribers who purchased Loestrin 24.[3] The End

[2] The Direct Purchasers whose claims are the subject of the Motion to Dismiss decided in this Order are American Sales Company, LLC and Rochester Drug Co-Operative, Inc. The additional Direct Purchasers (Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P., and Albertson's LLC) filed a complaint on February 25, 2014, after the defendants had already moved to dismiss. By stipulations entered July 17, 2014 and August 12, 2014, defendants' response to the February 25, 2014 complaint is due 45 days after the date of this Order.

[3] These parties are: City of Providence; A.F. of L. – A.C.G. Building Trades Welfare Plan; Allied Services Division Welfare Fund; Electrical Workers 242 and 294 Health & Welfare Fund; Fraternal Order of Police, Fort Lauderdale Lodge 31 Insurance Trust Fund; Laborers International Union of North America, Local 35 Health Care Fund; Painters District Council No. 30 Health & Welfare Fund; Teamsters Local 237 Welfare Benefits Fund; and United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund.

Payors also include three individuals who purchased Loestrin 24 for their own use.[4]

The defendants are pharmaceutical companies. Warner Chilcott Company, LLC ("Warner Chilcott") is the holder of an approved New Drug Application from the Food and Drug Administration (the "FDA") for Loestrin 24 and has marketed and sold Loestrin 24 since 2006.[5] The remaining defendants are Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc., and referred to herein as "Watson")[6] and Lupin Pharmaceuticals, Inc. ("Lupin" and, together with Warner Chilcott and Watson, the "Defendants").

In brief, the Plaintiffs allege that Warner Chilcott made what amount to reverse payments to Watson and Lupin in exchange for Watson and Lupin's agreement not to launch generic versions of Loestrin 24. This, the Plaintiffs contend, illegally extended Warner Chilcott's monopoly and resulted in higher prices for consumers.

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[4] These individuals are: Denise Loy; Melissa Chrestman; and Mary Alexander.

[5] Along with Warner Chilcott Company, LLC, the defendants include an assortment of Warner Chilcott's subsidiaries and other affiliates: Warner Chilcott Public Limited Company; Warner Chilcott Company, Inc.; Warner Chilcott (US), LLC; Warner Chilcott Laboratories Ireland, Limited; Warner Chilcott Holdings Company III, Ltd; Warner Chilcott Corporation; and Warner Chilcott Sales (US), LLC. Collectively, these entities are referred to as "Warner Chilcott."

[6] The Court refers to Watson rather than Actavis in order to avoid confusion with the recent Supreme Court decision in F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (2013).

B. Generics and the Hatch-Waxman Regulatory Framework[7]

We rely on pharmaceutical companies to develop and bring to market the medical advances that keep us healthy. For this reason, our patent laws afford substantial protection to firms whose innovation leads to the development of new and beneficial medications. Typically, a company that has developed such a medication will enjoy a period of time during which it can sell it exclusively and at a supracompetitive price, thereby recovering its development costs and turning a profit. This period of exclusivity is considered to be an essential incentive for further healthcare and biopharmaceutical research and innovation. See Wendy H. Schacht and John R. Thomas, Cong. Research Serv., RL30756, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act") 2-5 (2000).

Once the period of exclusivity expires, however, the entry by generic competitors severely undercuts the manufacturer's pricing scheme and eliminates most of the innovator's profits. (EP Compl. ¶ 65, ECF No. 40.) For instance, data suggests that where there is a single generic competitor, the generic tends to be priced approximately 25% lower than the brand name counterpart. (DP Compl. ¶ 62, ECF No. 39.) And, where there are multiple generic

[7] Citing references are to the Direct Purchaser Class Plaintiffs' Consolidated Amended Class Action Complaint and Jury Demand (cited as "DP Compl.") and to the Consolidated Class Action Complaint of the End Payors (cited as "EP Compl.").

alternatives, the price of the generics typically falls to 50% to 80% below the brand name product. (Id.)

Because every state permits pharmacies to substitute generics for brand name drugs (unless the prescribing doctor orders otherwise), generally within a year of generic market entry, generics will capture 90% of sales and prices will fall by as much as 85%. (Id. at ¶ 63.) Not surprisingly, then, brand manufacturers view generic competition as a grave threat to profits. (Id.)

The Drug Price Competition and Patent Term Restoration Act of 1984 (more commonly known as the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), as amended, prescribes the process by which pharmaceutical firms may gain approval from the FDA to bring medications to market. There are four key features to the Hatch-Waxman Act's architecture.

First, a drug manufacturer that wishes to market a new product must submit a New Drug Application ("NDA") to the FDA and undergo a rigorous approval process. See Hatch-Waxman Act, 21 U.S.C. § 355(b)(1)(A) (requiring, inter alia, that the manufacturer provide "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use"). By all accounts, this approval process is arduous and hugely expensive. But, once the FDA has approved an NDA, the manufacturer is entitled to list the drug in the FDA's

Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book"). (DP Compl. ¶ 47.) The Orange Book entry provides a measure of protection for the manufacturer by allowing it to list any patents that the manufacturer believes could be asserted against generic competitors. (Id.)

Second, the Hatch-Waxman Act recognized that if manufacturers who have gained FDA approval were allowed to charge supracompetitive prices indefinitely, this would harm consumers. Therefore, the Act creates a mechanism to promote the availability of cheaper generic alternatives by allowing generic manufacturers to bypass many of the onerous aspects of the NDA process. Instead of filing an NDA, a generic manufacturer may instead file an Abbreviated NDA ("ANDA"). 21 U.S.C. § 355(j). An ANDA incorporates the findings of safety and effectiveness of the previously-approved NDA, and generally assures that the proposed generic contains the same active ingredients and is otherwise equally safe and effective as the brand name counterpart. Id. at § 355(j)(2). Thus, the ANDA process allows a generic manufacturer to obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval for a "pioneer drug." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990).

Third, the Hatch-Waxman Act sets forth procedures for resolving patent disputes between brand and generic manufacturers. A generic manufacturer filing an ANDA must certify to the FDA that

the proposed generic does not infringe any patents listed in the Orange Book. 21 U.S.C. § 355(j)(2)(A)(vii). This certification can be made in one of several ways. The generic manufacturer may represent that: (1) the brand manufacturer has not filed any relevant patents; (2) any relevant patents have expired; or (3) a relevant patent is soon to expire and the generic will not be marketed until after the expiration. Id. at §§ 355(j)(2)(A)(vii)(I)-(III). Or, alternatively, the generic manufacturer could represent that the patent covering the brand drug is invalid or will not be infringed by the proposed generic (a so-called "Paragraph IV certification"). Id. at § 355(j)(2)(A)(vii)(IV).

An ANDA filer that relies on a Paragraph IV certification will almost certainly be sued by the brand manufacturer. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1677 (2012) ("Filing a paragraph IV certification means provoking litigation."). Indeed, if the brand manufacturer brings an infringement suit within 45 days of the generic manufacturer's filing of the ANDA, under the Hatch-Waxman Act, the FDA must withhold approval of the generic for a 30-month period during which the parties may litigate the validity of the underlying patent. 21 U.S.C. § 355(j)(5)(B)(iii).

Finally, the Hatch-Waxman Act serves to incentivize generic manufacturers that incur the cost and risk stemming from Paragraph

IV certification litigation. In order to encourage generic competition, the Hatch-Waxman Act affords the first successful Paragraph IV ANDA filer a 180-day post-approval exclusivity period during which that manufacturer is the only authorized generic seller.[8] Id. at § 355(j)(5)(B)(iv). Because the price of a drug drops precipitously as more and more generics become available, this initial period of exclusivity can generate substantial profits for the first generic manufacturer. C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1579 (2006) (describing first-filed ANDA status as "worth several hundred million dollars to a generic firm that successfully challenges the patents on a major drug").

C. Loestrin 24 and the '394 Patent

The active ingredients in Loestrin 24, norethindrone acetate and ethinyl estradiol, have been approved by the FDA as a means of oral contraception since 1973. (DP Compl. ¶¶ 89-90.) Prior oral contraceptives containing these compounds were generally marketed for use over a 21-day period; women would take the contraceptive for 21 consecutive days, then take a placebo for the following seven days, before starting the cycle anew. (Id. at ¶ 90.)

[8] Importantly, a brand manufacturer is not prohibited from offering its own generic during this 180-day period. When a brand manufacturer does so, its generic is referred to as an "authorized generic." Of course, a brand manufacturer's decision not to offer an authorized generic has the potential to increase profits for the initial generic manufacturer.

Occasional inter-menstrual bleeding, or "spotting," is a common occurrence among women taking birth control. (Id. at ¶ 100.) In the early 1990s, scientists at the Eastern Virginia Medical School ("EVMS") conducted a series of studies to assess whether administering the active ingredients for longer than 21 days might decrease incidences of spotting. Though these studies produced mixed results, the EVMS scientists applied for, and were granted, a patent for use of the norethindrone acetate and ethinyl estradiol compounds for 23 to 25 consecutive days as a means of oral contraception. (Id. at ¶¶ 113-16.)

The resulting patent, U.S. Patent No. 5,552,394 (the "'394 Patent"), is titled "Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy." (Id. at ¶ 114.) Before the '394 Patent expired in July 2014, Warner Chilcott was its fifth owner, after a predecessor-in-interest acquired it in 2003. (Id. at ¶ 119.)

In 2005, Warner Chilcott submitted an NDA and received FDA approval to market the dosing regimen that would become Loestrin 24. (EP Compl. ¶ 75.) At approximately the same time, Warner Chilcott listed Loestrin 24 in the Orange Book. (DP Compl. ¶ 132.)

D. Watson Challenges the '394 Patent

In 2006, just several months after Warner Chilcott's NDA was approved, Watson filed an ANDA to market a Loestrin 24 generic based on a Paragraph IV certification that the generic would not

infringe the '394 Patent.[9] (EP Compl. ¶ 79.) Not unpredictably, Warner Chilcott responded by filing suit against Watson.[10] (Id. at ¶ 80.) By doing so, Warner Chilcott triggered the 30-month stay provision of the Hatch-Waxman Act, preventing the FDA from approving Watson's ANDA for at least 30 months. (Id. at ¶ 81.)

In January 2009, at approximately the same time that the 30-month stay would have expired, the parties filed a dismissal stipulation and entered into an Exclusion Payment Agreement (the "Watson EPA"). (DP Compl. ¶ 162.) Pursuant to the Watson EPA, Watson agreed to delay the launch of a Loestrin 24 generic until January 2014, approximately six months prior to the expiration of the '394 Patent.[11] (Id. at ¶ 163.) In return, Warner Chilcott: (1) agreed not to launch an authorized generic within Watson's first 180 days on the market;[12] (2) agreed not to license other generics during that same period; (3) granted Watson a license to market Loestrin 24 worldwide beginning in January 2014; (4) agreed

[9] Watson based its Paragraph IV certification principally on its belief that the '394 Patent was invalid by virtue of the failure of the EVMS scientists to accurately report the mixed results of their studies to the United States Patent and Trademark Office.

[10] See Warner Chilcott Co. v. Watson Pharms., Inc., C.A. No. 2:06-cv-3491-HAA-ES (D.N.J.).

[11] This date was subject to acceleration in the event that Warner Chilcott allowed another generic earlier market entry.

[12] A pledge by a brand manufacturer not to launch an authorized generic is often referred to as a "no authorized generic agreement."

to pay Watson annual fees and a percentage of net sales in connection with the co-promotion of a separate Warner Chilcott drug called Femring; and (5) gave Watson the exclusive right to earn brand sales of a separate Warner Chilcott oral contraceptive known as Generess Fe. (EP Compl. ¶¶ 90-94.) Both complaints suggest that this quid pro quo was of immense value to Watson. (EP Compl. ¶ 96; DP Compl. ¶ 172.)

E. Lupin Challenges the '394 Patent

If the Watson EPA bought Warner Chilcott a respite, it was a brief one. Six months after its execution, in June 2009, Lupin notified Warner Chilcott that it too had filed an ANDA seeking to market a generic alternative to Loestrin 24. (DP Compl. ¶ 175.) Like Watson, Lupin based its ANDA on a Paragraph IV certification that Lupin's generic would not infringe the '394 Patent. (Id.) And, as before, Warner Chilcott responded by filing suit.[13] (Id. at ¶ 176.) Again, merely by filing suit, Warner Chilcott triggered a 30-month stay of the Lupin generic under the Hatch-Waxman Act. (Id. at ¶ 177.)

In October 2010, Warner Chilcott dismissed the suit and entered into an Exclusion Payment Agreement with Lupin (the "Lupin EPA"). (Id. at ¶ 181.) Pursuant to the Lupin EPA, Lupin agreed not to market its Loestrin 24 generic until July 2014, around the

[13] See Warner Chilcott LLC v. Lupin Ltd., C.A. No. 1:09-cv-673-JCJ (D. Del.).

same time that the '394 Patent was to expire and roughly six months after Watson had been authorized to market its generic. (Id.)

Like Watson, Lupin is alleged to have benefitted from its agreement to delay the introduction of its generic. First, Warner Chilcott granted Lupin a license to market Femcon Fe, a separate oral contraceptive manufactured by Warner Chilcott. (EP Compl. ¶ 107.) And second, Lupin was given the right to sell a generic version of Asacol 400, an anti-inflammatory drug supplied by Warner Chilcott.[14] (Id. at ¶ 108.)

F. Harm to Consumers

The net effect of Warner Chilcott's entry into agreements with Lupin and Watson was to delay generic competition until January 2014 at the earliest. Absent these agreements, the Plaintiffs allege, Loestrin 24 would have faced generic competition as early as September 2009 when the FDA approved Watson's ANDA. (DP Compl. ¶ 237.) At that time, Warner Chilcott would have lost its monopoly and consumers would have enjoyed lower prices. Instead, Loestrin 24 continued to generate substantial revenues for Warner Chilcott, exceeding $1.75 billion in total sales from 2006 to 2012. (Id. at ¶ 131.)

[14] In addition, Lupin allegedly received approximately $4 million to defray certain costs associated with the parties' prior litigation. (DP Compl. ¶ 185.)

G. Claims Brought

The Direct Purchasers have brought a single claim for violation of the Sherman Antitrust Act, 15 U.S.C. § 1, et. seq. (the "Sherman Act"), against Warner Chilcott and Watson. The End Payors have brought a total of seven claims sounding in state and federal antitrust law, state consumer protection law and unjust enrichment against Warner Chilcott, Watson and Lupin. The End Payors' federal antitrust claims are brought under § 1 of the Sherman Act and under § 16 of the Clayton Antitrust Act, 15 U.S.C. § 26, et. seq.

II. Standard of Review

Complaints in antitrust cases that fail to plausibly state a claim must be dismissed at the outset. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 558 (2007). "[A] complaint must plead 'more than labels and conclusions,' and its factual allegations must be sufficient to 'raise a right to relief above the speculative level.'" In re New Motor Vehicles Canadian Exp. Antitrust Litig., 533 F.3d 1, 6 (1st Cir. 2008) (quoting Twombly, 550 U.S. at 545). "Naked assertion[s]," "threadbare recitals of the elements of a cause of action," and "mere conclusory statements" are insufficient to survive dismissal. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

"[T]he costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood

that the plaintiffs can construct a claim from the events related in the complaint." Twombly, 550 U.S. at 558 (citations omitted). Nevertheless, the Court accepts all well-pleaded facts as true and analyzes those facts "in the light most hospitable to the plaintiff's theory, [] drawing all reasonable inferences for the plaintiff." New York v. Amgen, Inc., 652 F.3d 103, 109 (1st Cir. 2011) (citations omitted).

III. Discussion

In June 2013, the Supreme Court issued its much-anticipated opinion in Actavis. See 133 S. Ct. 2223. To briefly set the stage, and borrowing Justice Breyer's rhetorical device to identify the parties, Actavis involved the following scenario: a pharmaceutical company, Company A, had FDA approval to market a brand name drug, and held the related patent. Id. at 2229. Two other pharmaceutical companies, Companies B and C, filed ANDAs containing Paragraph IV certifications suggesting that generics that Company B and Company C intended to market did not infringe Company A's patent. Id. A fourth would-be generic manufacturer, Company D, agreed with Company C to share certain litigation costs and related profits. Id. Predictably, Company A initiated patent infringement litigation against Companies B and C, triggering the 30-month stay under the Hatch-Waxman Act. Id.

Later, Companies A, B, C and D entered into a settlement agreement. Id. Pursuant to the agreement, Companies B, C and D

agreed to delay the marketing of their generics for approximately nine years.[15] Id. In exchange, Company A paid Companies B, C and D total cash consideration of several hundred million dollars. Id. The Federal Trade Commission ("FTC") brought antitrust claims against all four companies, alleging that they had conspired in restraint of trade when Companies B, C and D agreed to share in Company A's monopoly profits by accepting payment in exchange for agreeing not to compete.

The district court dismissed the FTC's antitrust claims on grounds that the agreement between Companies A, B, C and D did not exceed the scope of the underlying patent. In re AndroGel Antitrust Litig. II, 687 F. Supp. 2d 1371, 1377-79 (N.D. Ga. 2010). The district court reasoned that Company A's patent gave Company A the exclusive right to manufacture and sell the product in question, and the agreement merely prohibited the generic manufacturers from marketing an identical product. Id. at 1377. The Eleventh Circuit affirmed on the same grounds. F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012) ("[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.").

[15] Companies B, C and D also agreed to promote the brand name product on behalf of Company A in the interim. Actavis, 133 S. Ct. at 2229.

These holdings were in line with the "scope-of-the-patent" test in use by a majority of the courts of appeal at the time. See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2006). The Third Circuit, however, employed an alternative "quick-look" approach that instructed juries to regard reverse payments as prima facie evidence of an unreasonable restraint of trade, which could be rebutted in certain circumstances. See, e.g., In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).

The Supreme Court granted certiorari in Actavis in order to resolve the circuit split. 133 S. Ct. at 2230. But Actavis did not settle on either the scope-of-the-patent test or the quick-look inquiry. Rather, the majority in Actavis rejected both and settled instead on use of the "rule of reason," which is commonly applied in antitrust settings.[16] Id. at 2237. The majority summarized its holding as follows:

> [A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive

[16] Rule of reason analysis demands a determination as to "whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition." Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 343 (1982). Courts engaging in rule of reason analysis consider three primary factors: (1) whether "the alleged agreement involved the exercise of power in a relevant economic market," (2) whether "this exercise had anti-competitive consequences," and (3) whether "those detriments outweighed efficiencies or other economic benefits." Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I., 373 F.3d 57, 61 (1st Cir. 2004).

> effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.

Id.

Thus, Actavis appears to impose a three-part inquiry. See In re Lamictal Direct Purchaser Antitrust Litig., No. 12-cv-995 (WHW), 2014 U.S. Dist. LEXIS 9257, at *13 (D.N.J. Jan. 24, 2014). "In Step One, a district court must ask, is there a reverse payment? . . . In Step Two, a district court must ask, is that reverse payment large and unjustified? . . . Step Three is the rule of reason." Id. at *13-14. The first inquiry, then, is whether the consideration paid by the patent holder to the generic competitor constitutes a "reverse payment" at all. If it does not, the Court does not reach steps two or three.

The discussion of patent settlements in Actavis fixates on the one form of consideration that was at issue in that case: cash. Id. at *21 ("Both the majority and the dissenting opinions reek with discussion of payment of money."). This fixation is apparent from the first paragraph of Justice Breyer's majority opinion:

> 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. Because the settlement requires the patentee to pay the

> alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

Actavis, 133 S. Ct. at 2227 (emphasis added). And that is just the tip of the iceberg. See, e.g., id. at 2233 ("In reverse payment settlements . . . a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market." (emphasis added)); id. at 2231 ("The FTC alleges that . . . the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market . . . there is reason for concern that settlements taking this form tend to have significant adverse effects on competition." (emphasis added)); id. at 2233 (describing reverse payments as generally involving "A, the plaintiff" who "pays money to defendant B purely so B will give up the patent fight" (emphasis added)); id. at 2234 ("multimillion dollar payoffs by the brand company").

While it is true, of course, that "words have meaning," Chesapeake & Ohio Canal Co. v. Hill, 82 U.S. 94, 100 (1872), it would be rash to conclude that these repeated references to cash consideration, alone, demonstrate that Actavis' holding is necessarily limited solely to patent settlements in monetary form. After all, as others have noted, in Actavis the Supreme Court was confronted with a settlement arrangement that principally involved a cash payment and little else, so the Court had no imperative to consider other types of consideration that might flow from the

patentee to the alleged infringer. See In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("Actavis only involved a brand manufacturer's bargain . . . to pay millions of dollars to each generic so the Supreme Court's confined analysis hardly seems surprising." (citations omitted) (internal quotation marks omitted)). It is more than merely the choice of words describing the consideration, however, that suggests that the majority in Actavis intended for it to apply only to cash settlements.

Ostensibly to assist the lower courts, Actavis set forth five "considerations" to guide the inquiry as to whether a settlement payment satisfies the rule of reason. First, courts are to consider whether the payment has the "potential for genuine adverse effects on competition." Actavis, 133 S. Ct. at 2234 (quoting F.T.C. v. Indiana Fed'n of Dentists, 476 U.S. 447, 460-61 (1986)). This factor, the majority suggested, requires a comparison of the anticipated supracompetitive profits associated with continued monopoly sale of the product, and the sum paid to the generic competitor. Id. at 2234-35. The majority noted that "[t]he payment may . . . provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." Id. at 2235.

Second, courts are to assess whether the payment is "unjustified" in light of "a rough approximation of the litigation expenses saved through the settlement" and "compensation for other services that the generic has promised to perform." Id. at 2235-36. A payment may satisfy the rule of reason where it reflects these "traditional settlement considerations." Id. at 2236.

Third, the Court must consider whether the size of the reverse payment indicates that the patentee held sufficient market power to "work unjustified anticompetitive harm." Id. To that end, we are advised that "the 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power' – namely, the power to charge prices higher than the competitive level." Id. (quoting 12 P. Areeda & H. Hovenkamp, Antitrust Law ¶ 2046, p. 351 (3d ed. 2012)).

Fourth, Actavis instructed a focus on the size of the payment as a measure of the patentee's confidence in the strength of the patent. Id. "In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness . . . ." Id. at 2236-37.

Finally, courts are to assess the payment in light of the reasons given for its having been made. Id. at 2237. "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." Id.

Critically, each of these five factors requires, on the part of the plaintiff, and ultimately the reviewing court (or the jury), an ability to assess or calculate the true value of the payment made by the patentee to the generic competitor. For example, it would be all but impossible to assess the "potential for genuine adverse effects on competition" without the ability to compare the expected monopoly profits to the size of the patentee's payment. Id. at 2234 (quoting Indiana Fed'n of Dentists, 476 U.S. at 460-61). Likewise, without knowing the monetary value of the settlement payment, a plaintiff would be unable to demonstrate that the payment was "unjustified" in light of "traditional settlement considerations." Id. at 2236. Nor for that matter could the size of the payment be used as a proxy to measure the patentee's market power to "work unjustified anticompetitive harm," id., or as a "surrogate for a patent's weakness," id. at 2236-37. Finally, without a firm grasp of the monetary value of the settlement vis-à-vis the expected monopoly profits, it would be difficult to discern whether the "basic reason" for the settlement was "a desire to maintain and to share patent-generated monopoly profits." Id. at 2237. All of these five factors can be reasonably measured when the reverse payment is a cash payment; a non-cash settlement, particularly one that is multifaceted and complex (like the arrangement here), is almost impossible to measure against these five factors.

These issues were highlighted by Chief Justice Roberts in a dissenting opinion in which he criticized the majority's holding, which, he said, "cannot possibly be limited to reverse-payment agreements, or those that are 'large.'" Id. at 2245 (Roberts, C.J., dissenting). The Chief Justice went on to note that "if antitrust scrutiny is invited for such cash payments, it must also be required for 'other consideration' and 'alternative arrangements.'" Id. (citations omitted); see also id. at 2243 (describing the disparate treatment of cash and non-cash settlements as a "distinction without a difference"). What then is this Court to make of the Chief Justice's prescient observation? Does the fact that the Chief Justice's argument that Actavis' holding must sweep more broadly was not adopted by the majority signal that the majority was, as yet, unwilling to hold that reverse payments involving other forms of consideration could trigger antitrust scrutiny? Or, should his commentary be interpreted as an indication that non-cash settlements must inevitably be treated the same as cash settlements regardless of whether the majority was willing to say so? Either reading would be a reasonable one, and the few district judges that have considered this question have predictably different views. Compare In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d at 392 ("Nowhere in Actavis did the Supreme Court explicitly require some sort of monetary transaction . . . to constitute a reverse

payment"), and In re Wellbutrin XL Antitrust Litig., No. 08-2431, Doc. No. 534 (E.D. Pa. Jan. 17, 2014) ("The Court is not prepared at this point to accept [the] argument that only a large cash payment . . . is subject to antitrust analysis under Actavis."), with In re Lamictal Direct Purchaser Antitrust Litig., 2014 U.S. Dist. LEXIS 9257, at *23 ("[T]he overwhelming evidence [is] that when the Supreme Court said 'payment' it meant a payment of money.").

The Plaintiffs go to great lengths to argue that the consideration paid by Warner Chilcott to Watson and Lupin, though not in the form of cash, was of substantial value. And, the Defendants do not seriously dispute this point in their motions. But, courts have long recognized that merely because a settlement is of some value (even of great value) does not mean that it constitutes a reverse payment. See Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("[A]ny settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is . . . classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements."); see also In re Lamictal Direct Purchaser Antitrust Litig., 2014 U.S. Dist. LEXIS 9257, at *24 ("A law student learns in the first semester that consideration is an

essential element of any enforceable contract. In this sense, there is 'payment' in every settlement.").

In assessing the argument advanced by the Plaintiffs that Actavis should be read to capture cash and non-cash settlements alike, as is almost always the case, context matters. By rejecting the scope-of-the-patent test and the quick-look inquiry in favor of the rule of reason, Actavis marked a dramatic departure from the approach of the courts of appeal, and an important shift in the common law. This departure is likely to have significant implications for firms involved in patent litigation, and for the consumers who purchase their products. These considerations militate in favor of a cautious approach by the district courts, and against a cavalier extension of the Actavis holding to virtually any non-cash settlement package that has presumably substantial value.

The common law is a "knowable judicial corpus and, as such, serves the important social value of stability; although the common law does evolve, that evolution takes place gradually and incrementally and usually in a direction that can be predicted." State of Rhode Island v. Lead Indus. Ass'n, Inc., 951 A.2d 428, 445 (R.I. 2008) (citing Wheaton v. Peters, 33 U.S. 591, 671 (1834)). Given the significant change in direction that Actavis represents, the Court is hesitant to extend its holding beyond the terms that the opinion itself describes.

A further consideration informs the Court's conclusion that Actavis should be applied only to cash settlements, or to their very close analogues. Though miles apart in most respects, both the majority and the dissent suggest that public policy favors the settlement of patent litigation. See Actavis, 133 S. Ct. at 2234 (Justice Breyer, for the majority, noting that "[w]e recognize the value of settlements and the patent litigation problem"); see also id. at 2239 (Chief Justice Roberts, in dissent, observing that "[o]rdinarily, we would think [the settlement of patent litigation] is a good thing").

Whether one thinks that the majority got it right or not, there can be no dispute that the holding in Actavis and the abandonment of the scope-of-the-patent test will make it more difficult for patent litigants to settle. See, e.g., Kevin D. McDonald, Because I Said So: On the Competitive Rationale of FTC v. Actavis, 28 Antitrust 36, 42 (2013) (Noting that, after Actavis, "[t]he incentive to settle a patent case [] plummets"). The Plaintiffs would have the Court read Actavis to demand rule of reason scrutiny in most instances, regardless of whether the settlement was in the form of cash or not. But, the fact that the majority and the dissent recognize and promote the public policy value of patent settlements, suggests that Actavis should be read to apply solely to the cash settlements that it describes, and to

exclude non-cash settlements, preserving for litigants a viable path to resolve their disputes.

In the end, had the Supreme Court intended for rule of reason scrutiny to apply to non-cash settlements, it could simply have said so. Fuesting v. Zimmer, Inc., 448 F.3d 936, 940 (7th Cir. 2006) ("Had the Supreme Court intended to create such a broad rule, we presume the Court would have done so explicitly."). But the Supreme Court said no such thing. Reading Actavis, this Court cannot help but find that it applies solely to monetary settlements; the narrowness of the Supreme Court's language and the cash-focused guidance for applying the rule of reason permit no other conclusion until and unless the Supreme Court expands its holding. Therefore, because the Plaintiffs have not pled facts suggesting that a cash payment was made,[17] their complaints must be dismissed.

The Court reaches this conclusion because, as explained above, it is dictated by the language and meaning of Actavis and considerations of public policy, but does so not without significant reservations. The conclusion that Actavis applies only to cash settlements is vexing for at least two reasons. First, there is tension between Actavis and the pleading standards articulated in Twombly, itself a Sherman Act § 1 case. Twombly instructed that stating a Sherman Act claim merely "requires a

[17] Aside from the modest cost defrayment paid to Lupin.

complaint with enough factual matter (taken as true) to suggest that an agreement was made. Asking for plausible grounds to infer an agreement does not impose a probability requirement . . . it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement." Twombly, 550 U.S. at 556.

Here, the Plaintiffs have asserted, in two robust complaints, facts demonstrating illegal contracts or combinations in restraint of trade undertaken by the Defendants. See Sherman Act, 15 U.S.C. § 1. But, because Warner Chilcott's "payment" for delay was not made in cash, the Plaintiffs (understandably) struggle to affix a precise dollar value to it. This should come as no surprise because pleading facts sufficient to glean the monetary value of non-cash settlements is a tall task, one that would typically require considerable discovery to achieve. This is particularly true where, as here, the settlement involves licenses and co-promotion arrangements for other drugs and a "no authorized generic" agreement on the part of the brand manufacturer. In these circumstances, even a ballpark estimate is difficult to conjure. See, e.g., DP Compl. ¶ 165 ("The agreement by Warner Chilcott not to launch an authorized generic during Watson's exclusivity period had a cash value to Watson of tens or hundreds of millions of dollars . . . ." (emphasis added)); id. at ¶ 172 ("To avoid

competition . . . Warner Chilcott agreed to pay Watson what amounts to tens or hundreds of millions of dollars." (emphasis added)).

Of course, it is easier to plead facts demonstrating the revenues generated by a particular pharmaceutical product. Those figures may be reported to the Securities and Exchange Commission in public filings, or otherwise made available by the manufacturer. See, e.g., id. at ¶ 131 (listing annual revenues generated by sales of Loestrin 24). But, without a better grasp of the true value of the consideration paid by the brand manufacturer, it is impractical (if not impossible) to assess and compare these revenues to the alleged reverse payment, as each of the five Actavis factors plainly requires.

As such, the Court is left with an irreconcilable quandary. On the one hand, the Plaintiffs have adequately pled the existence of a Sherman Act § 1 violation under Twombly. 550 U.S. at 556. But, on the other hand, Actavis counsels that in reverse payment contexts where rule of reason scrutiny is not applicable, dismissal is required. 133 S. Ct. at 2237-38. Given this dynamic, if courts apply the literal holding of Actavis, non-cash pay for delay arrangements are likely to evade Sherman Act scrutiny so long as pharmaceutical companies take the obvious cue to structure their settlements in ways that avoid cash payments.

The conclusion that Actavis can be fairly applied only to cash settlements is vexing for a second reason. Even prior to Actavis,

trends in the pharmaceutical industry suggested that, increasingly, patent settlements were taking unconventional, non-cash forms.

> The initial wave of settlements involved an explicit payment from brand to generic. Recent settlements, in contrast, have been more complicated. No longer are brand firms making simple cash payments for generics not to enter the market. Instead, they are paying generics for IP licenses, for supplying raw materials or finished products, and for helping to promote products. They are paying milestones, up-front payments, and development fees for unrelated products. In many cases, they are guaranteeing that the settling generic will enjoy the exclusivity period. And, in the latest trend . . . they are agreeing not to launch authorized, brand-sponsored, generics.

Michael A. Carrier, Solving the Drug Settlement Problem: The Legislative Approach, 41 Rutgers L.J. 83, 93 (2009).

Many observers welcomed Actavis as a necessary step in confronting the scourge of pay for delay agreements that they contend benefit the pharmaceutical industry at the expense of consumers.[18] See, e.g., Zombie Patents, The Economist, June 21, 2014, at 72 ("[P]ay-for-delay deals are a terminal illness. They impose huge, unnecessary costs on consumers . . . . Happily, pay-for-delay may itself be on the verge of losing protection. A ruling by [the] Supreme Court last year [Actavis] should make it easier to challenge such deals under competition laws."). But, ultimately, Actavis can only serve as the solution to anticompetitive pay for delay arrangements insofar as it

[18] In fact, the Actavis majority seems to acknowledge this reality. See 133 S. Ct. at 2234-35 (noting that when there is "payment in return for staying out of the market . . . [t]he patentee and the challenger gain; the consumer loses").

encompasses both cash and these increasingly prevalent non-cash settlements. Of course, it is of relatively little import whether a payment for delay is made in the form of cash or some other form of consideration. When a patent holder pays a would-be generic competitor to stay out of the market – regardless of the form of the payment – value is exchanged and the brand manufacturer is able to continue on with fewer competitors. At the very least, "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition." Actavis, 133 S. Ct. at 2231.

Given the clear trend away from cash settlements, one is left to wonder why the Supreme Court, given the opportunity to speak to the reality of the market, chose to cabin its holding to settlements that seem almost anachronistic. The answer, perhaps, is the "rule of five." See Mark Tushnet, Themes in Warren Court Biographies, 70 N.Y.U. L. Rev. 748, 763 (1995) (describing Justice William Brennan's "rule of five" as meaning that "it takes five votes to do anything"). So perhaps the Supreme Court went as far as it could in Actavis, leaving for another day the question posed here.

The Court notes these reservations to highlight the obvious: the decision to grant the motions to dismiss was not an easy one. It was a close call, involving a challenging interpretation of a very recent and confusing Supreme Court case, complicated by

principles of law that seem at cross purposes. The positions taken by the few courts that have confronted this issue since Actavis are divergent. All of this is to say that today's ruling obviously does not end the matter and the First Circuit (and perhaps later the Supreme Court, in this case or another) may well reach a different conclusion. We are confronting this issue early in a law refinement process that will take some time to shake out; as Yogi Berra would say, "it ain't over 'til it's over." And it certainly ain't over yet.

IV. Conclusion

In his dissent, Chief Justice Roberts sardonically wished "[g]ood luck to the district courts" that must contend with reverse payment settlements in the wake of Actavis. 133 S. Ct. at 2245. The Chief Justice clearly saw that the holding in Actavis was likely to cause district courts – and courts of appeal as well – much difficulty for all of the reasons chronicled above, and probably more. These motions have certainly proven the Chief Justice's concerns to be well-founded.

Because in this Court's view, Actavis requires cash consideration in order to trigger rule of reason scrutiny, and because the Plaintiffs have not adequately alleged payment in the form of cash by Warner Chilcott in exchange for Watson and Lupin's agreement to stay out of the market for Loestrin 24, the Plaintiffs have failed to state a claim upon which relief may be granted under

the current state of the law. As such, the Defendants' Motions to Dismiss must be GRANTED.[19]

IT IS SO ORDERED.

William E. Smith
Chief Judge
Date: September 4, 2014

[19] While today's ruling resolves the Sherman Act claim brought by the Direct Purchasers, as well as the federal antitrust claims brought by the End Payors, the End Payors' state antitrust, consumer protection and unjust enrichment claims remain. The Court is aware that the Plaintiffs may wish to seek interlocutory review before the End Payors proceed with these claims. For this reason, the Plaintiffs are invited to file a motion under 28 U.S.C. § 1292(b) (or another relevant provision of law) within 45 days of the date hereof.

In addition, the Court notes that the parties extensively briefed a separate series of questions, including whether the Plaintiffs adequately pled market power in a relevant market, whether the federal antitrust claims were brought within the statute of limitations, and whether many of the state law-based claims are subject to dismissal on standing and other grounds. Based on the holding set forth above, the Court need not address these issues. In the event that the First Circuit or the Supreme Court reverse this Court's decision and remand the action for further proceedings, the Defendants will be given an opportunity to seek dismissal on these grounds.