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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE LAMICTAL DIRECT PURCHASER ANTITRUST LITIGATION	:	**OPINION**
THIS DOCUMENT RELATES TO: ALL DIRECT PURCHASER ACTIONS	:	Civ. No. 12-995 (WHW)

Walls, Senior District Judge

This putative class action concerns the legality of a settlement between two drug companies. Plaintiffs are direct purchasers who allege that the terms of the settlement violate federal antitrust laws. Defendants move to dismiss on the grounds that the settlement did not involve a "reverse payment" in cash, so plaintiffs have not alleged a cause of action. The Court decides the motion without oral argument under Federal Rule of Procedure 78(b). Defendants' motion is granted.

FACTUAL AND PROCEDURAL BACKGROUND

GlaxoSmithKline ("GSK") sells Lamictal Tablets and Lamictal Chewables, which treat epilepsy and bipolar disorder. Am. Compl. ¶¶ 1, 46. This drug is very profitable. As example, from March 2007 to March 2008, GSK's domestic sales of Lamictal Tablets exceeded $2 billion. *Id.* ¶ 46. The lower-dosage Lamictal Chewable products had domestic sales of about $50 million from 2004 to 2005. *Id.* The active ingredient in Lamictal products is lamotrigine, covered by U.S. Patent No. 4,602,017 ("the '017 patent"). *Id.* ¶ 11. GSK's patent for lamotrigine expired in July 2008. *Id.*

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Teva is a generic pharmaceutical company that wanted to market a generic version of Lamictal and filed applications with the FDA seeking approval to do so. *Id.* ¶ 11, 50. GSK sued Teva in 2002 for patent infringement under Hatch-Waxman Act procedures, Pub. L. No. 98-417, 98 Stat. 1585 (1984). *Id.* ¶ 13.

I. *The Hatch-Waxman Act Procedures*

The Food and Drug Administration must approve any new drug that is introduced onto the market. 21 U.S.C. § 355(a). To apply for approval, the manufacturer files a New Drug Application ("NDA") containing detailed information about the drug, its chemical composition, reports about its safety and effectiveness as shown through extensive clinical trials, and descriptions of its production and packaging processes. *Id.* § 355(b)(1). The application must also identify the patent associated with the drug and its expiration date. *Id.* If the FDA approves the drug, it publishes the drug and patent information in a book called "Approved Drug Products with Therapeutic Equivalence and Evaluations," commonly referred to as the "Orange Book." *Id.* § 355(j)(7)(A).

Generic drugs are therapeutically and pharmaceutically equivalent to corresponding brand name drugs, but are sold at lower prices. Congress passed the Hatch-Waxman Act in 1984 to encourage the entry of generics onto the market. A generic manufacturer may file an Abbreviated New Drug Application ("ANDA"), which does not need to contain the same level of detail as is required for a NDA. 21 U.S.C. § 355(j). The ANDA must make one of four certifications:

(1) that no patent information for the brand name drug has been filed;

(2) that the patent for the brand name drug has expired;

(3) that the patent will expire on a specifically identified date;

(4) that the "patent 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) (emphasis added).

A paragraph IV certification leads to litigation because it constitutes a technical act of patent infringement. 35 U.S.C. § 271(e)(2)(A). If the applicant makes a certification under paragraph IV, the patent holder must be notified. 21 U.S.C. § 355(j)(2)(B). The patent holder then has 45 days to file an infringement lawsuit against the ANDA applicant. *Id.* § 355(j)(5)(B)(iii). When a suit is filed, the FDA stays the ANDA approval process until either (1) 30 months have run, or (2) the court decides that the patent is invalid or not infringed, whichever is earlier. *Id.*; Am. Compl. ¶ 6.

Generic manufacturers are incentivized to be the first to file a paragraph IV certification because the first ANDA applicant to do so is granted a 180-day "exclusivity period." During that time, the FDA will not grant final approval to any other ANDA for the same generic drug. *Id.* § 355(j)(5)(B)(iv). So the potential reward for the first filer is half-a-year's period when it is the only generic drug company on the market competing with the brand name drug company. The exclusivity period is triggered when the generic manufacturer enters the market with the drug. *Id.* § 355(j)(5)(B)(iv)(I); Am. Compl. ¶ 15. At the time relevant to this case, the exclusivity period could also be triggered by a final court decision that the patent is invalid. Pub. L. No. 108-173, § 1102(b)(1); Am. Compl. ¶ 15.

Another concept relevant to this case is pediatric exclusivity. Only a small fraction of drugs are tested on pediatric patients. To address this problem, the FDA will request that a drug company conduct pediatric trials. 21 U.S.C. § 355a.[1] If the company successfully completes the

[1] Congress amended 21 U.S.C. § 355a in 2007. The Court cites to the pre-2007 version, which was the law at the relevant time.

trials and the FDA accepts the results, then the FDA will award six months of additional market exclusivity. In practical terms, this means that after a drug company's patent expires, the FDA will not approve an ANDA for another six months, essentially protecting the market from the entry of generics. *Id.* § 355a(c)(2).

II. *GSK's Patent Litigation with Teva*

Teva filed ANDAs with the FDA in 2002 seeking approval to manufacture and sell generic versions of lamotrigine tablets and chewables. Am. Compl. ¶ 50. The ANDA applications contained a paragraph IV certification that every claim, except claim 5,[2] of the '017 patent was invalid, unenforceable, and/or not infringed by Teva's proposed generic products. *Id.* Teva gave notice to GSK of the paragraph IV certifications. Within 45 days, GSK filed suits in federal court in New Jersey alleging that Teva's two ANDAs infringed the '017 patent. *Id.* ¶ 54. The FDA then automatically stayed the processing of Teva's ANDAs for 30 months. *Id.*

The two lawsuits were consolidated. *Id.* After discovery, the patent litigation culminated in a bench trial held before Judge Bissell in January 2005. *Id.* ¶ 55. On the final day of trial, Judge Bissell ruled from the bench that claim I of the '017 patent was invalid as anticipated by prior art. *Id.* ¶ 56. Claim I claimed the chemical compound 3,5-diamino-6-(2,3-diocholorphenyl)-1,2,4-triazine. This is lamotrigine, the active ingredient in Lamictal products. *Id.*¶ 11. Judge Bissell then said that that he would deliberate on the validity of the remaining asserted and claims and try to reach a determination "in the course of the next week." *Id.* ¶ 60.

III. *The Settlement*

Following Judge Bissell's ruling, GSK and Teva quickly reached a settlement. The key terms were:

[2] Claim 5 purported to cover an injectable solution containing lamotrigine. This claim was not challenged because Teva was not seeking FDA approval to sell an injectable version of lamotrigine. Am. Compl. ¶ 50.

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1) Teva was permitted to sell generic lamotrigine chewables by June 1, 2005. *Id.* ¶ 70. This is approximately 37 months before the expiration of the '017 patent, and also before the FDA approved Teva's ANDA for lamotrigine tablets. *Id.* GSK supplied the chewables to Teva and Teva began selling them on May 25, 2005. *Id.*
2) Teva was permitted to sell generic lamotrigine tablets on July 21, 2008, the expiration date of the '017 patent. At this time, the FDA had requested GSK to conduct pediatric studies and GSK intended to comply. If GSK did *not* receive pediatric exclusivity, Teva would be allowed to market and sell the tablets six months earlier, on March 1, 2008. *Id.* ¶ 71; Ex. A at 11-12 (ECF No. 72-2) (License and Supply Agreement).
3) GSK granted Teva an exclusive waiver of any pediatric exclusivity that might be granted to GSK. *Id.* ¶ 71; Ex. A §§ 2.2(b), 2.3(b) (ECF No. 72-2) (License and Supply Agreement).
4) GSK further agreed not to launch its own authorized generic versions of Lamictal products until January 2009 by giving Teva an exclusive license. Am. Compl. ¶¶ 76, 81; Pl. Opp'n Br. at 21-22, 22 n.17 (ECF No. 86).

On April 4, 2005, the parties filed a Stipulation and Order of Dismissal seeking the dismissal of all claims and counterclaims. *Id.* ¶ 84. The Court also entered an order withdrawing the bench ruling that invalidated claim I of the '017 patent. *Id.*

The FDA approved Teva's ANDAs for lamotrigine tablets and chewables in 2006. *Id.* ¶ 51. This approval date was insignificant because Teva complied with the terms of the settlement: (1) Teva had already been selling GSK-supplied lamotrigine chewables since May of 2005, *id.* ¶ 70; (2) Teva waited until July 21, 2008 to launch its generic version of lamotrigine tablets, *id.* ¶ 85. GSK did not launch its own authorized generic version of either Lamictal Tablets or

Chewables until January 2009. *Id.* ¶ 86. As the first ANDA filer to declare a paragraph IV certification, Teva was also guaranteed that no other generics could enter the market for 180-days after its own market entry for lamotrigine tablets. *Id.* ¶ 89. By January of 2009, when the exclusivity period had passed, at least three other firms also launched generic versions of Lamictal Tablets. *Id.*

Plaintiffs bring five causes of action under the Sherman Act: (1) a conspiracy to delay generic competition for Lamictal tablets in violation of section 1; (2) conspiracy not to compete with generic Lamictal tablets in violation of section 1; (3) monopolization of the Lamictal tablets market in violation of section 2; (4) conspiracy to monopolize Lamictal tablets market in violation of section 2; (5) conspiracy not to compete with generic Lamictal chewables in violation of Section 1. Am. Compl. ¶¶ 108-151.

STANDARD OF REVIEW

When deciding a 12(b)(6) motion to dismiss, the Court accepts as true all facts alleged in the complaint and construes the complaint in the light most favorable to the plaintiff. *Fleisher v. Standard Ins. Co.*, 679 F.3d 116, 120 (3d Cir. 2012) (citations omitted). Legal conclusions asserted in the complaint are disregarded. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). The Court should determine whether the facts alleged are sufficient to show that the plaintiff has "'a plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "This 'plausibility' determination will be a 'context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Id.* (quoting *Iqbal*, 556 U.S. at 679). After the Supreme Court's decisions in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), "'threadbare recitals of the

elements of a cause of action, supported by mere conclusory statements, do not suffice.'" *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678). The Court may also take judicial notice of public records, including judicial proceedings. *Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999).

DISCUSSION

The Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint or commerce among the several States … is declared to be illegal." 15 U.S.C. § 1. And any person who attempts to monopolize interstate trade or commerce is guilty of a felony. *Id.* § 2. While the statute is worded very broadly, the Supreme Court has interpreted the Sherman Act to prohibit only unreasonable restraints on trade. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (3d Cir. 2012) (citing *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)). The inquiry is context specific and a court should take into account a variety of factors, "including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.*

The Third Circuit recently held that settlements between drug companies reached in the course of Hatch-Waxman Act litigation are subject to a "quick look rule of reason" analysis. *K-Dur*, 686 F.3d at 218. The settlements at issue in *K-Dur* involved both cash payments (in sums of $60 million and $15 million) and early entry dates for the generic challenger to enter the market. *Id.* at 205-06. The Third Circuit held that "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market" is "*prima facie* evidence of an unreasonable restraint of trade." *Id.* at 218. Defendants may rebut the *prima facie* evidence by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit. *Id.* As example, "a modest cash payment that enables a cash-starved generic

manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market," though the Third Circuit conceded that such a case would be rare. *Id.*

The Third Circuit's legal standard diverges from that of the Second Circuit, the Eleventh Circuit, and the Federal Circuit, who have all adopted the scope of the patent test. *Id.* at 211-14 (citing *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008)). Under that test, the district court must first determine whether any part of the agreement went beyond the protections afforded by the name brand manufacturer's patent. *Id.* at 211. If so, courts are to apply antitrust scrutiny only to those portions of the settlement. *Id.* Reverse payments are permitted so long as (1) the exclusion negotiated in the settlement does not exceed the patent's scope, (2) the patent holder's claim of infringement is not objectively baseless, and (3) the patent was not procured by fraud. *Id.* at 214. Under this standard, most settlements are not subject to antitrust scrutiny because defendants can usually show that the settlement is not outside the scope of the patent. *Id.* at 214 ("As a practical matter, the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny.").

The Third Circuit openly rejected the scope of the patent test of the other Circuits. As the Third Circuit explained, while that test promotes settlements, the legislative policy behind the Hatch-Waxman Act of encouraging generics to enter the market and to challenge weak patents is equally important. *Id.* at 217 ("litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers"). The concern is that the scope

of the patent test too easily allows the patent holder to buy off competition. *Id.* at 215. The Third Circuit stressed:

> We also emphasize that nothing in the rule of reason test that we adopt here limits the ability of the parties to reach settlements based on a negotiated entry date for marketing of the generic drug: the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger. Data analyzed by the FTC suggest that this will leave the vast majority of pharmaceutical patent settlements unaffected.

Id. at 217-18 (emphasis added) (citing FTC, Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2010*, 2 (2011), *available at* http://www.ftc.gov/os/2011/05/1105mm agreements.pdf) ("2010 FTC Study").

The resolution of this case turns upon how the Court should interpret the words "reverse payment." Defendants argue that this language is straightforward: "reverse payment" means cash payment. The settlement between GSK and Teva did not involving a cash payment; it only contained negotiated entry dates for Teva to enter the market. This is exactly the type of settlement that is not subject to antitrust scrutiny and would remain "unaffected" by the Third Circuit's ruling in *K-Dur*. Teva's Br. at 17-25 (ECF No. 71-1); GKS Br. at 19-23 (ECF No. 72-1).

On the other hand, Plaintiffs counter that "payment" does not only mean cash. Teva was paid to stay off the market for a certain period of time; whether that payment was in cash or in some other form is irrelevant. Pl. Opp'n Br. at 6. Teva received "significant consideration, incentives, and benefits" in exchange for its delayed entry. Am. Compl. ¶ 74.

The Court finds that the term "reverse payment" is not sufficiently broad to encompass any benefit that may fall to Teva in a negotiated settlement. The Third Circuit's *K-Dur* opinion is directed towards settlements when a generic manufacturer is paid off with money, which is not

the case here. Without doubt Teva received consideration in the settlement. Otherwise, there would be no incentive to settle. 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. Plaintiffs' position is undercut by their description about what kind of benefits Teva received: (1) permission to start selling lamotrigine chewables within three months of the settlement, (2) permission to start selling lamotrigine tablets in July of 2008, thus delaying the trigger of its 180-day exclusivity period (which was in danger of starting before Teva was ready to take advantage of it and before FDA even approved its ANDA), and (3) GSK's agreement not to launch its own authorized generic until January of 2009. *Id.* ¶¶ 74-76. This is a settlement based on negotiated entry dates. Under *K-Dur*, this settlement is not subject to antitrust scrutiny. 686 F.3d at 217-18.

First, a careful reading of *K-Dur* shows that the Third Circuit contemplates a cash payment when it uses the term "reverse payment." The scope of the patent test is criticized because it "enable[s] the holder of a patent . . . to *buy* its way out of both competition with the challenging competitor and possible invalidation of the patent." *Id.* at 215 (emphasis added). The goal of the Hatch-Waxman Act "is undermined by application of the scope of the patent test which entitled the patent holder to *pay* its potential generic competitors not to compete." *Id.* at 217 (emphasis added). *See also id.* (scope of patent test "nominally protects intellectual property, not on the strength of a patent holder's legal rights, but on the *strength of its wallet*") (emphasis added). When setting forth the "quick look" standard, the Third Circuit explains that "a patent holder may attempt to rebut plaintiff's *prima facie* case of an unreasonable restraint of trade by arguing that there is in fact no reverse payment because *any money that changed hands* was for something other than a delay in market entry." *Id.* at 218 (emphasis added). As example, the

Third Circuit hypothesizes a situation where "a modest *cash* payment . . . might have an overall effect of increasing the amount of competition in the market." *Id.* (emphasis added). At times, the opinion uses the terms "cash payment" and "reverse payment" almost interchangeably. *See, e.g.*, *id.* at 205 ("During settlement negotiations, Upsher requested both a *cash payment* and an early entry date…[but] Schering expressed concern about possible antitrust problems…if it made a *reverse payment.*") (emphasis added).

Second, the Third Circuit's reliance upon the 2010 FTC Study supports the Defendants' position. *Id.* at 218. This study shows 31 settlements that contain "compensation" to the generic manufacturer, 66 settlements that contain restricted entry but "no explicit compensation," and 16 settlements that contain no restrictions on entry. 2010 FTC Study. Looking at this data, the Third Circuit concluded that "the vast majority of pharmaceutical patent settlements" will remain "unaffected" because "nearly seventy-five percent of Hatch-Waxman infringement suits that settled in 2010 did so without reverse payment." *K-Dur*, 686 F.3d at 218. This conclusion demonstrates that the Third Circuit uses the term "reverse payment" settlements to include "compensation."

Third, the Court has not located, nor do the parties cite to, any case where a Hatch-Waxman settlement without cash payment was subject to antitrust scrutiny. By adopting the rule of reason analysis, the Third Circuit recognized that it was establishing a tougher standard on Hatch-Waxman settlements than the Second Circuit, the Federal Circuit, and the Eleventh Circuit. The Third Circuit was careful to limit its ruling. *Id.* at 216 ("We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry."); *id.* at 217-18 ("We also emphasize that nothing in the rule of reason test that we adopt here limits the ability of the parties to reach settlements based on a

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negotiated entry date for marketing the generic drug"). This Court will not stretch the holding of *K-Dur* beyond the contours articulated by the Third Circuit.

Lastly, from a policy perspective, this settlement did introduce generic products onto the market sooner than what would have occurred had GSK's patent not been challenged. *See* Stipulation and Order of Dismissal, *Smithkline Beecham Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 2-3779, ECF No. 89 (D.N.J. April 6, 2005) (Bissell, J.) ("The settlement allows generic entry of lamotrigine tablets and chewable dispersible tablets in advance of the expiration of Plaintiff's '017 patent and any period of pediatric exclusivity"). *K-Dur*'s pressing concern is about uneven bargaining power—companies with money buy off too easily generic challengers with lump payments. In settlement situations where monetary payments are off the table, companies with abundant cash have less leverage to delay entry of generic drugs. To be sure, the brand name company would need to find other bargaining chips to use in negotiation. GSK's promise not to enter the market with its own generic products is such an example. Nothing in *K-Dur* suggests that this would be an improper "reverse payment" subject to antitrust scrutiny.

Since there is no allegation that Teva's settlement with GSK involved cash payment for Teva to stay off the market, Plaintiffs have failed to allege a plausible claim for relief under the Sherman Act.

CONCLUSION

Defendants' motion to dismiss is granted.

December 6, 2012

s/ William H. Walls

United States Senior District Judge