IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)	MDL DOCKET NO. 2084 ALL CASES 1:09-MD-2084-TWT

ORDER

This is a Multidistrict Litigation proceeding involving antitrust actions that are consolidated for pretrial proceedings. It is before the Court on the Defendants' Motions to Dismiss the Indirect Purchaser Plaintiffs' Complaints [MDL Doc. 8, 9]; the Defendants' Motions to Dismiss the Second Amended Complaint [MDL Doc. 22, 23, 24, 26 and 28]; and the Defendants' Motions to Dismiss the Private Plaintiffs' Second Amended Complaints [MDL Doc. 25, 27 and 29]. For the reasons set forth below, the Defendants' motions are GRANTED in part and DENIED in part.

I. Background

AndroGel is a prescription gel used to treat male hypogonadism. Male hypogonadism is a medical condition where the body does not produce normal levels of testosterone. Symptoms include depression, fatigue, loss of muscle mass, and decreased libido. Physicians prescribe AndroGel to increase levels of testosterone in

their patients. Patients apply the gel directly onto their skin. The testosterone penetrates the skin and gradually enters the bloodstream, providing for a sustained release of testosterone. AndroGel is not the only available method of testosterone replacement therapy. Physicians also prescribe testosterone injections or skin patches. But these other methods have not been as effective or as popular as AndroGel. AndroGel has quickly become the most popular form of testosterone replacement therapy. From 2000 to 2007, sales of AndroGel in the United States were over $1.8 billion.

Besins Healthcare, S.A. developed the pharmaceutical formulation for AndroGel. In August 1995, Besins granted Solvay Pharmaceuticals, Inc., a license to sell AndroGel in the United States. Besins also agreed to produce AndroGel and supply it to Solvay once Solvay received approval to sell the drug. To sell any new drug in the United States, a person must file a New Drug Application (NDA) with the Food and Drug Administration (FDA). 21 U.S.C. § 355(a). The NDA must contain a complete report about the drug, including safety and efficacy studies, the composition of the drug, description of how the drug is produced, and proposed labeling. 21 U.S.C. § 355(b). In April 1999, Solvay filed a NDA for AndroGel with the FDA. In February 2000, the FDA approved Solvay's NDA, and soon after Solvay began selling AndroGel.

Like most pharmaceutical companies that sell new drugs, Solvay sought legal protection against generic versions of AndroGel. Solvay first sought protection under federal drug laws. In April 1999, when Solvay filed its NDA for AndroGel, Solvay also asked the FDA for new drug product exclusivity. This exclusivity prevents the FDA from approving any other application to sell the same drug until the exclusivity period ends. The FDA will grant five years of exclusivity for any NDA that contains active ingredients never previously approved by the FDA. See 21 U.S.C. § 355(c)(3)(F)(ii). The FDA will grant three years of exclusivity for any NDA that contains an active ingredient that has previously been approved by the FDA but still includes new clinical investigations essential to approval of the NDA. See 21 U.S.C. § 355(c)(3)(F)(iii). AndroGel fell into the latter category, and so in February 2000, the FDA granted Solvay three years of exclusivity.

Solvay also sought protection under federal patent laws. In August 2000, employees from Solvay and Besins filed a patent application with the Patent and Trademark Office (PTO). The application claimed the gel formulation used in AndroGel. It did not claim testosterone itself or testosterone replacement therapy. In January 2003, the PTO granted the application and issued U.S. Patent No. 6,503,894

('894 patent).[1] In June 2003, Solvay requested that the PTO correct certain mistakes that it made in the patent. In December 2003, the PTO granted the request and issued a certificate of correction. See 35 U.S.C. § 255. Solvay and Besins jointly own the '894 patent. It expires in August 2020. Within thirty days after the PTO issued the '894 patent, Solvay submitted the '894 patent to the FDA for listing in the Orange Book. The Orange Book is a publication by the FDA containing information about each approved drug. 21 U.S.C. § 355(j)(7)(A). For any NDA, a person must also submit any patent that the person believes would be infringed by a generic drug. 21 U.S.C. § 355(b)(1). This requirement applies even if the PTO issues the patent after the person filed a NDA. 21 U.S.C. § 355(c)(2). The FDA accepted Solvay's submission and listed the '894 patent in the Orange Book.

Other pharmaceutical companies soon developed a generic version of AndroGel. To sell a generic drug, a person may file an Abbreviated New Drug Application (ANDA) with the FDA. 21 U.S.C. § 355(j). The Hatch-Waxman Act created the ANDA procedure. Pub. L. No. 98-417, 98 Stat. 1585 (1984). One goal of the Hatch-Waxman Act was to streamline the process for approving generic drugs. See id. As a result, an ANDA does not need to contain a complete report about the

[1]The Court takes judicial notice of the '894 patent. See Day v. Taylor, 400 F.3d 1272, 1276 (11th Cir. 2005) (taking notice of a document that was "(1) central to the plaintiff's claim and (2) undisputed").

drug. It can show that the generic drug is bioequivalent to a previously approved drug and then rely on that drug's NDA. See 21 U.S.C. § 355(j)(2)(A)(iv). But if there is a patent that claims the previously approved drug, the ANDA must contain an additional certification. The ANDA must certify that (1) the patent has not been listed in the Orange Book, or (2) the patent has expired, or (3) the patent will expire on a certain date, or (4) the patent is invalid or will not be infringed by the generic drug. See 21 U.S.C. § 355(j)(2)(A)(vii). When the ANDA certifies that the patent is invalid or will not be infringed, it is known as a Paragraph IV certification. For any ANDA with a Paragraph IV certification, the applicant must also notify the patent holder of the ANDA. 21 U.S.C. § 355(j)(2)(B).

Once Solvay's new drug product exclusivity expired in February 2003, the FDA was authorized to approve generic versions of AndroGel. In May 2003, two companies each submitted ANDAs with Paragraph IV certifications for generic AndroGel. Watson Pharmaceuticals, Inc. submitted the first ANDA, and Paddock Laboratories, Inc. submitted the second ANDA. Both companies also sent notice of their ANDAs to Solvay and Besins. In July 2003, Paddock reached an agreement with Par Pharmaceuticals, Inc. Par agreed to share any litigation costs with Paddock and to sell Paddock's generic AndroGel. In return, Paddock agreed to share profits with Par.

Solvay responded to the ANDAs by asserting its rights under the '894 patent. In August 2003, Solvay's subsidiary, Unimed Pharmaceuticals, Inc., filed patent infringement actions against Watson and Paddock in this Court. See Unimed Pharm., Inc. v. Watson Pharm., Inc., No. 1:03-CV-2501-TWT (N.D. Ga. Aug. 21, 2003); Unimed Pharm., Inc. v. Paddock Labs., Inc., No. 1:03-CV-2503-TWT (N.D. Ga. Aug. 21, 2003). Solvay alleged infringement based on the filing of the ANDAs. See 35 U.S.C. § 271(e)(2)(A). This is not an ordinary infringement action. It is an "artificial" one based solely on the filing of an ANDA. See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). If a patent holder files such infringement action within forty-five days of receiving notice of an ANDA with a Paragraph IV certification, the FDA will stay approval of that ANDA for thirty months. 21 U.S.C. § 355(j)(5)(B)(iii). But if before the thirty month period ends a district court decides that the patent is invalid or not infringed, the FDA may approve the ANDA effective on the date of such judgment. Id.; see In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 192 n.4 (2d Cir. 2006). Because Solvay filed infringement actions against Watson and Paddock within forty-five days of receiving notice, the FDA stayed approval of their ANDAs for thirty months.

For the next few years, Solvay, Watson, and Paddock litigated the infringement actions. The two infringement actions followed a similar schedule. From late 2003

to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. By August 2005, the parties had filed motions for claim construction. By December 2005, Watson and Paddock had filed motions for summary judgment on the validity of the '894 patent. All of the motions were fully briefed and ready for decision. While the motions were pending, Watson and Paddock moved towards entering the market with generic AndroGel. In January 2006, the thirty month stay ended, and the FDA approved Watson's ANDA. The FDA, however, continued to stay approval of Paddock's ANDA. The first person to file an ANDA with a Paragraph IV certification receives generic exclusivity. This exclusivity prevents the FDA from approving any subsequent person's ANDA for the same drug until 180 days after the earlier of (1) the date the first person begins commercial marketing of its generic drug or (2) the date a district court enters judgment that the patent is invalid or not infringed, whichever date is earlier. 21 U.S.C. § 355(j)(5)(B)(iv); see In re Tamoxifen, 466 F.3d at 193 n.5. Because Watson was the first to file an ANDA for generic AndroGel, it received generic exclusivity over Paddock. In February 2006, Watson prepared a report predicting that it would sell generic AndroGel by January 2007 and that the price would be 75 percent less than brand name AndroGel. In the same month, Par prepared a report predicting that Watson would sell generic AndroGel as early as March 2006 and that Par and

Paddock would follow in September 2006.

Before the Court decided any motions in the infringement actions, and before anyone sold generic AndroGel, Solvay, Watson, and Paddock settled. The parties began settlement negotiations in early 2006, and on September 13, 2006, Solvay entered into settlements with Watson and Paddock. Under the settlement between Solvay and Watson, Solvay agreed to voluntarily dismiss the infringement action, and Watson agreed not to market generic AndroGel until the earlier of August 31, 2015 or the date another company marketed generic AndroGel. Under the settlement between Solvay and Paddock, Solvay agreed to a consent judgment dismissing the infringement action, and Paddock agreed not to market generic AndroGel until the earliest of August 31, 2015, but only if Watson did not assert its 180-day generic exclusivity period, or the date another company launched generic AndroGel, or February 28, 2016.

On the same day as the settlements, Solvay also entered into business promotion agreements with Watson, Par, and Paddock. Under the agreement between Solvay and Watson, Solvay agreed to share profits of AndroGel with Watson, and Watson agreed to promote AndroGel to urologists. Solvay estimated that its annual payments to Watson would be between $15 and $30 million. Under the agreement between Solvay and Par, Solvay agreed to share profits of AndroGel with Par, and Par

agreed to promote AndroGel to primary care physicians. Solvay estimated that its annual payments to Par would be about $6 million. Under the agreement between Solvay and Paddock, Solvay agreed to share profits of AndroGel with Paddock, and Paddock agreed to serve as a backup supplier of AndroGel. Solvay estimated that its annual payments to Paddock would be about $2 million.

The settlements prompted an investigation by the Federal Trade Commission (FTC) for violations of antitrust laws. In 2008, the FTC completed its investigation. In 2009, the FTC and a number of private parties filed these antitrust actions against Solvay, Watson, Par, and Paddock. All of the actions were filed in other federal district courts and then transferred to this Court either by change of venue or by order of the United States Judicial Panel on Multidistrict Litigation. There are three groups of Plaintiffs: the FTC, the Direct Purchasers, and the Indirect Purchasers. All of the Plaintiffs allege that the Defendants violated various federal antitrust laws. See Sherman Antitrust Act §§ 1-2, 15 U.S.C. §§ 1-2; Federal Trade Commission Act § 5(a), 15 U.S.C. § 45(a). The Indirect Purchasers also allege that the Defendants violated the common law and antitrust laws of about forty states. All of the Plaintiffs assert antitrust claims based on the settlements. They say that Solvay paid Watson, Par, and Paddock millions of dollars for agreeing not to sell generic AndroGel before August 31, 2015. The Direct Purchasers, but not the other Plaintiffs, also assert

antitrust claims based on the Defendants' conduct before the settlements. They say that Solvay filed sham infringement actions against Watson and Paddock; Solvay improperly listed the '894 patent in the Orange Book; all of the Defendants participated in a scheme to monopolize the market for generic AndroGel; and Watson, Par, and Paddock agreed not to compete with each other in the market for generic AndroGel. The Defendants now move to dismiss all of the Plaintiffs' claims for failure to state a claim upon which relief can be granted.

II. Motion to Dismiss Standard

A complaint should be dismissed under Rule 12(b)(6) only where it appears that the facts alleged fail to state a "plausible" claim for relief. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009); Fed. R. Civ. P. 12(b)(6). A complaint may survive a motion to dismiss for failure to state a claim, however, even if it is "improbable" that a plaintiff would be able to prove those facts; even if the possibility of recovery is extremely "remote and unlikely." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007) (citations and quotations omitted). In ruling on a motion to dismiss, the court must accept factual allegations as true and construe them in the light most favorable to the plaintiff. See Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., S.A., 711 F.2d 989, 994-95 (11th Cir. 1983). Generally, notice pleading is all that is required for a valid complaint. See Lombard's, Inc. v.

Prince Mfg., Inc., 753 F.2d 974, 975 (11th Cir. 1985), cert. denied, 474 U.S. 1082 (1986). Under notice pleading, the plaintiff need only give the defendant fair notice of the plaintiff's claim and the grounds upon which it rests. See Erickson v. Pardus, 551 U.S. 89, 93 (2007) (citing Twombly, 550 U.S. at 555).

III. Discussion

A. Patent Infringement Settlements

All of the Plaintiffs assert antitrust claims based on the settlements. They say that the business promotion agreements were really just a way for Solvay to pay Watson, Par, and Paddock for agreeing not to sell generic AndroGel before August 31, 2015. They say that this was an antitrust violation because, without these "reverse payments," Solvay would have either lost its infringement actions or settled on a date for sale of generic AndroGel earlier than August 31, 2015. In either situation, Watson, Par, and Paddock would have sold generic AndroGel before August 31, 2015, and market competition would have substantially reduced the price of AndroGel.

To state an antitrust claim based on the settlements, the Plaintiffs must allege facts that show the settlements were unreasonable restraints of trade. See Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1303 (11th Cir. 2003). Ordinarily, courts decide whether a restraint is unreasonable by applying either a rule of reason or per se analysis. Schering-Plough Corp. v. Federal Trade Comm'n, 402 F.3d 1056, 1064

(11th Cir. 2005). Generally, when one company agrees to pay a competitor not to compete, the agreement is a per se antitrust violation. Valley Drug, 344 F.3d at 1304. But "neither the rule of reason nor the per se analysis is appropriate" when a patent settlement is involved. Schering-Plough, 402 F.3d at 1065. This is because the general approaches look at "whether the challenged conduct had an anticompetitive effect on the market. By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present." Id. at 1065-66. Instead of applying a rule of reason or per se analysis, the Eleventh Circuit has established a separate approach for antitrust actions involving a patent settlement. "[T]he proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." Id. at 1066.

The Plaintiffs do not allege that the settlements between the Defendants exceed the scope of the '894 patent. First, the settlements only exclude generic AndroGel from the market. The '894 patent claims the gel formulation used in AndroGel and that gel formulation is "necessary to the manufacture and sale of" generic AndroGel. See Andrx Pharms., Inc. v. Elan Corp., PLC, 421 F.3d 1227, 1235 (11th Cir. 2005). The settlements do not exclude any product other than generic AndroGel. Cf. In re

Tamoxifen, 466 F.3d at 213 (listing cases where the settlement did exclude "unrelated or non-infringed products"). Second, the settlements only exclude generic AndroGel from the market until August 31, 2015. This provides for five years less exclusion than the '894 patent, which does not expire until August 2020. Third, the settlements only prevent Watson, Par, and Paddock from selling generic AndroGel. The Plaintiffs do not allege, for example, any agreement to use Watson's 180-day generic exclusivity period to prevent other companies from selling generic AndroGel. See id. at 200. Indeed, Watson says that it relinquished its exclusivity as part of the settlement. (Mem. of Law in Supp. of Defs.' Mot. to Dismiss the FTC's Second Am. Compl., at 18.)[2]

In response, the FTC and the Private Plaintiffs say that the scope of a patent includes more than just the patent's claims and duration. They say that it also includes the likelihood that a patent holder could assert its claims in court and win. But this argument is inconsistent with the Eleventh Circuit's reasoning in Valley Drug. In Valley Drug, a brand name manufacturer settled its infringement actions against two generic drug manufacturers. One of the generic manufacturers agreed to a final settlement, while the other only agreed to an interim settlement. Under the interim

[2]Because the Plaintiffs do not allege that the settlements exceed the '894 patent, the Court does not need to go to the third step and examine "the resulting anticompetitive effect." See Valley Drug, 344 F.3d at 1312.

settlement, the generic manufacturer agreed not to sell its product until it got a final judgment in its favor. The brand name and generic manufacturer continued to litigate the infringement action, and eventually the district court held that the brand name manufacturer's patent was invalid. Later, some purchasers of the brand name drug filed antitrust actions against the brand name manufacturer and the two generic manufacturers. They said that per se analysis should apply because the brand name manufacturer's patent was invalid, and so it never really had any patent rights. The Eleventh Circuit disagreed. It held that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." Valley Drug, 344 F.3d at 1306-07. It explained that:

> Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent. This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation.

Id. at 1308; see also Schering-Plough, 402 F.3d at 1075; In re Tamoxifen, 466 F.3d at 204; In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1337 (Fed. Cir. 2008). Those same concerns apply equally here. Considering whether Solvay would have won its infringement actions creates the same uncertainty that the court

in Valley Drug believed would severely limit settlements.[3]

The Plaintiffs also say that it should be presumptively unlawful for companies to settle a patent dispute with reverse payments. But this argument is also inconsistent with the Eleventh Circuit's reasoning in Valley Drug. In Valley Drug, both settlements included substantial payments from the brand name manufacturer to the generic manufacturers. The plaintiffs said that per se analysis should apply because a patent does not include the right to pay for exclusion. The Eleventh Circuit disagreed. It held that per se analysis does not apply to reverse payments. Valley Drug, 344 F.3d at 1309. The court explained that:

> The failure to produce the competing . . . drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a per se rule would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

Id. (citation omitted). In Schering-Plough, the Eleventh Circuit reiterated its holding in Valley Drug and explained that reverse payments should not matter to an analysis

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[3]This does not, however, preclude the Plaintiffs from alleging that Solvay filed sham infringement actions against Watson and Paddock. Those allegations will be addressed later in this Order.

of antitrust liability:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.' . . . What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.

Schering-Plough, 402 F.3d at 1075-76 (quoting Valley Drug, 344 F.3d at 1310); see also In re Tamoxifen, 466 F.3d at 206; In re Ciprofloxacin, 544 F.3d at 1329. Because the Plaintiffs do not allege that the settlements exceed the scope of the '894 patent, it does not matter if the Defendants settled their patent disputes with reverse payments. The Plaintiffs' reverse payment settlement claims must be dismissed.

B. Sham Litigation

Although it is not entirely clear, it appears that the Eleventh Circuit's Hatch-Waxman cases allow antitrust Plaintiffs to assert a claim of "sham litigation" in the context of reverse payment patent infringement settlements. See Schering-Plough, 402 F.3d at 1072. The Direct Purchasers allege that Solvay engaged in sham litigation in filing and prosecuting the patent infringement actions against the generic Defendants. They allege that the generic Defendants conspired to restrain trade by entering into settlements of the sham litigation in exchange for a portion of Solvay's monopoly profits.

Solvay, Par and Paddock assert immunity under the Noerr-Pennington doctrine. The Noerr-Pennington doctrine provides that there is no antitrust liability for petitioning the government for an anticompetitive outcome. Andrx, 421 F.3d at 1235. It prevents federal antitrust laws from interfering with the First Amendment right to "petition the Government for a redress of grievances." U.S. Const. amend. I; see also Professional Real Estate Investors v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56 (1993). Courts have defined petitioning activity to include lobbying for government legislation and seeking redress through administrative or judicial proceedings. See Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961); United Mine Workers v. Pennington, 381 U.S. 657, 670 (1965); California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972).

It is well established that there is a sham litigation exception to Noerr-Pennington immunity. See Noerr, 365 U.S. at 144 (noting that there is no protection for petitioning activity that is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor"). In this context, the Eleventh Circuit has said that sham litigation has two elements: "(1) the lawsuit is objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits; and (2) the party bringing the allegedly baseless suit did so with a subjective motivation to interfere directly with the business

relationships of a competitor." Andrx, 421 F.3d at 1234 (internal quotation marks and emphasis omitted).

The Direct Purchasers say that Solvay's infringement actions were objectively baseless because generic AndroGel clearly did not infringe the original '894 patent.[4] The '894 patent claims a testosterone gel formulation. The formulation is made up of various ingredients; and the relevant ingredient for purposes of the patent litigation is sodium hydroxide. As originally issued, four of the five independent claims in the '894 patent describe a pharmaceutical composition containing 1% to 5% of sodium hydroxide. See '894 patent cls. 1, 9, 10, 18. The fifth independent claim does not describe any amount of sodium hydroxide. See '894 patent cl. 31. The Direct Purchasers say that neither brand name AndroGel nor generic AndroGel contains anywhere near 1% sodium hydroxide. Indeed, they say that any skilled chemist would recognize that a gel containing even 1% sodium hydroxide is harmful and would burn a patient's skin. The Direct Purchasers say that AndroGel actually contains a diluted sodium hydroxide solution that is 50 to 250 times less concentrated than the compositions described in the '894 patent. In other words, Solvay made a mistake in

[4]The original '894 patent matters because "[antitrust] analysis should focus on what the litigant knew or reasonably could have known at the time the suits were filed." In re Wellbutrin SR Antitrust Litig., No. Civ.A. 04-5525, 2006 WL 616292, *11 (E.D. Pa. Mar. 9, 2006). At the time Solvay filed its infringement actions, the PTO had not yet issued a certificate of correction.

drafting the '894 patent. Because of this mistake, the Direct Purchasers say that generic AndroGel clearly did not infringe the original '894 patent.

Solvay says that the error could be corrected by the Court. A district court can correct a patent error "if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." Novo Indus., L.P. v. Micro Molds Corp., 350 F.3d 1348, 1354 (Fed. Cir. 2003). These "determinations must be made from the point of view of one skilled in the art." Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp., 587 F.3d 1339, 1353 (Fed. Cir. 2009). Solvay says that the Court would have corrected its drafting mistake. First, Solvay says that there is no dispute that the claims should have referred to diluted sodium hydroxide. Agreeing with the Direct Purchasers, Solvay says that any skilled chemist would recognize that a gel containing even 1% sodium hydroxide is harmful and would burn a patient's skin. It also says that the specification includes a table listing the specific composition for brand name AndroGel. This table correctly lists sodium hydroxide as a diluted solution. See '894 patent cl.13 table 5 (listing sodium hydroxide as "0.1 N NaOH at 4.72g per 100g of gel [or 4.72%]"). Second, Solvay says that there is nothing in the prosecution history which suggests that it meant for the gel to contain a harmful amount of sodium hydroxide. Based on these arguments, which were made

during the patent litigation, Solvay says that it had "a reasonable belief that there [was] a chance" the Court would judicially correct Solvay's drafting mistake. See Professional Real Estate Investors, 508 U.S. at 63 (internal quotation marks omitted). The Direct Purchasers have alleged facts that may support a sham litigation theory of recovery. Therefore, the motions to dismiss should be denied.

The Direct Purchasers also say that Solvay's infringement actions were objectively baseless because the '894 patent clearly did not meet the written description requirement. The written description requirement provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. The Direct Purchasers say that there is no written description in the specification to support the ranges of sodium hydroxide described in the claims. Those claims describe a pharmaceutical composition containing 1% to 5% of sodium hydroxide. See '894 patent cls. 1, 9, 10, 18. The Direct Purchasers say that nothing in the specification mentions any range of sodium hydroxide. The only mention of sodium hydroxide in the specification is the table listing the composition for brand name AndroGel:

Table 5

Composition of AndroGel®

Substance	Amount (w/w) Per 100 g of Gel
Testosterone	1.0 g
Carbopol 980	0.90 g
Isopropyl myristate	0.50 g
0.1 N NaOH	4.72 g
Ethanol (95% w/w)	72.5 g (corresponding to 67 g of ethanol)
Purified water (qaf)	100 g

'894 patent cl.13 table 5. This table refers to a specific amount of sodium hydroxide—4.72% of diluted sodium hydroxide—and does not refer to any range. Id.

The Direct Purchasers' allegations regarding the written description requirement are sufficient to state a plausible antitrust claim. "The written description does not have to describe the invention exactly." Nelson v. K2 Inc., No. C07-1660, 2008 WL 4603409, at *1 (W.D. Wash. Oct. 15, 2008). For claims involving ranges, "[t]he question is whether the disclosure provides adequate direction which reasonably would lead one skilled in the art to the particular item or range claimed as the invention." Id.; see also Union Oil Co. v. Atlantic Richfield Co., 208 F.3d 989, 1000 (Fed Cir. 2000). This raises questions of fact that cannot be resolved at the pleading stage.

D. Overall Scheme

The Direct Purchasers also assert an antitrust claim that all of the Defendants participated in a scheme to monopolize the market for generic AndroGel. The components of this scheme include improper listing in the Orange Book, filing sham

infringement actions, and reverse payment settlements. As discussed above, only the sham litigation claim survives. The Direct Purchasers say that, even so, the Court may still consider their overall scheme claim because it would "be [im]proper to focus on specific individual acts . . . while refusing to consider their overall combined effect." Anaheim v. Southern Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992). But, while this principle is true, the Direct Purchasers do not actually identify any improper "combined effect" to the Defendants' actions. They simply repeat their allegations about the individual components and then conclude that the overall combined effect of the Defendants' actions was unlawful. See id. ("[I]f all we are shown is a number of perfectly legal acts, it becomes much more difficult to find overall wrongdoing."). Such legal conclusions "are not entitled to the assumption of truth." Iqbal, 129 S. Ct. at 1950.

E. Agreements Between Watson, Par, and Paddock

The Direct Purchasers also assert an antitrust claim that Watson, Par, and Paddock agreed not to compete with each other in the market for generic AndroGel. They say that this claim does not involve any patent rights, and so it should be subject to either a rule of reason or per se antitrust analysis. But the Direct Purchasers did not assert this claim or provide any supporting factual allegations in their complaints. The first time they mentioned an agreement between Watson, Par, and Paddock was in

their response brief to the Defendants' motions to dismiss. (Pls.' Mem. of Law in Opp'n of Defs.' Mots. to Dismiss the Second Am. Compl., at 55.) This was too late. "[A] plaintiff cannot amend the complaint by arguments of counsel made in opposition to a motion to dismiss." Kuhn v. Thompson, 304 F. Supp. 2d 1313, 1321 (M.D. Ala. 2004). In the post-Twombly world, the complaint is judged as it is and not on whether a set of facts could be imagined that would support the claim.

F. State Law Claims

In addition to violating federal antitrust laws, the Indirect Purchasers also allege that the Defendants violated the common law and antitrust laws of about forty states. But the factual allegations for both types of claims are the same. The Indirect Purchasers also do not identify any differences between federal antitrust laws and the relevant state laws. Because the Plaintiffs' allegations do not state a plausible antitrust claim under federal law, the Indirect Purchasers also do not state a plausible antitrust claim under state law. See In re Tamoxifen, 466 F.3d at 198 (noting that the district court "dismissed the plaintiffs' state law claims, which had alleged violations of the antitrust laws of seventeen states . . . , because those claims were based on the same allegations as the plaintiffs' federal antitrust claims"); R. J. Reynolds Tobacco Co. v. Phillip Morris, Inc., 199 F. Supp. 2d 362, 396 (M.D.N.C. 2002) ("Because [p]laintiffs do not allege any facts that suggest that [d]efendant's conduct is unlawful beyond the

conduct that is the basis for their federal claims, [p]laintiffs' state common law and statutory claims fail as well.").

G. Leave to Amend

The Indirect Purchasers ask for leave to file a consolidated amended complaint. But they made this request in a footnote within their response brief to the Defendants' motions to dismiss. "In the event that the Court grants Defendants any relief requested . . . , we request leave to file a Consolidated Amended Complaint." (End-Payor Pls.' Opp'n to Defs.' Mots. to Dismiss, at 6 n.5.) This is not an appropriate request for leave to amend. The request must be made by motion. See Fed. R. Civ. P. 7(b)(1); Posner v. Essex Ins. Co., 178 F.3d 1209, 1222 (11th Cir. 1999) ("Where a request for leave to file an amended complaint simply is imbedded within an opposition memorandum, the issue has not been raised properly."). The request must also either include "the substance of the proposed amendment or attach a copy of the proposed amendment." Long v. Satz, 181 F.3d 1275, 1279 (11th Cir. 1999).

IV. Conclusion

For the reasons set forth above, the Defendants' Motions to Dismiss [MDL Doc. 8, 9, 22 and 23] are GRANTED as to the claims of the FTC and the Indirect Purchasers. The Defendants' Motions to Dismiss [MDL Doc. 24, 25, 26, 27, 28 and 29] are GRANTED in part and DENIED in part as to the claims of the Direct

Purchasers.

SO ORDERED, this 22 day of February, 2010.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge