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 Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Objective Baselessness [Doc. 555][1], Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Improper Subjective Motivation [Doc. 567], Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Plaintiffs' Substantive Antitrust Claims [Doc. 574], Watson Pharmaceuticals, Inc.'s Motion for Summary Judgment on Plaintiffs' Conspiracy Claims for Lack of Subjective Bad Faith [Doc. 579], Solvay Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc., and Abbott

[1]Unless otherwise noted, all document numbers refer to case number 1:09-MD-02084.

Products, Inc.'s Motion for Summary Judgment on Objective Baselessness [Doc. 587], Solvay Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc., and Abbott Products, Inc.'s Motion for Summary Judgment on Subjective Bad Faith [Doc. 589], the Direct Purchaser Plaintiffs' Motion to Exclude Portions of Dr. Norman Weiner's Expert Report [Doc. 598], the Direct Purchaser Plaintiffs and End-Payor Class Plaintiffs' Motions for Summary Judgment on Sham Litigation [Docs. 603 & 588], and the Direct Purchaser Plaintiffs' Motion to Strike the Declaration of Joseph A. Mahoney and Limit Dr. Stanley Kaplan's Testimony [Doc. 708]. For the reasons set forth below, the Court GRANTS Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Objective Baselessness [Doc. 555], DENIES AS MOOT Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Improper Subjective Motivation [Doc. 567], DENIES AS MOOT Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Plaintiffs' Substantive Antitrust Claims [Doc. 574], GRANTS Watson Pharmaceuticals, Inc.'s Motion for Summary Judgment on Plaintiffs' Conspiracy Claims for Lack of Subjective Bad Faith [Doc. 579], GRANTS Solvay Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc., and Abbott Products, Inc.'s Motion for Summary Judgment on Objective Baselessness [Doc. 587], DENIES AS MOOT Solvay Pharmaceuticals, Inc.,

Unimed Pharmaceuticals, Inc., and Abbott Products, Inc.'s Motion for Summary Judgment on Subjective Bad Faith [Doc. 589], DENIES the Direct Purchaser Plaintiffs' Motion to Exclude Portions of Dr. Norman Weiner's Expert Report [Doc. 598], DENIES the Direct Purchaser Plaintiffs and End-Payor Class Plaintiffs' Motions for Summary Judgment on Sham Litigation [Docs. 603 & 588], and DENIES AS MOOT the Direct Purchaser Plaintiffs' Motion to Strike the Declaration of Joseph A. Mahoney and Limit Dr. Stanley Kaplan's Testimony [Doc. 708].

I. Background

This case involves the patent for AndroGel, a testosterone replacement gel that has been a huge commercial success. In 1995, Unimed Pharmaceuticals and Besins Healthcare, S.A. ("Besins") agreed to develop a testosterone replacement product designed to treat male hypogonadism[2] [see Docs. 587-87 & 587-86]. To that end, Besins developed a pharmaceutical formula called AndroGel, granted Solvay[3] a license to sell AndroGel in the United States, and agreed to supply AndroGel to Solvay when and if Besins received approval to sell the drug (the "1995 Supply

[2]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.

[3] For purposes of this Order, "Solvay" refers collectively to Defendants Solvay Pharmaceuticals, LLC, Unimed Pharmaceuticals, LLC ("Unimed") and Abbott Products, Inc. ("Abbott").

Agreement") [see Doc. 587-87, ¶ 2.3]. Solvay began clinical trials of AndroGel in 1996.

In April 1999, Solvay filed a New Drug Application ("NDA") with the Food and Drug Administration, seeking approval to commercially market AndroGel [see Doc. 587-68]. See 21 U.S.C. § 355(a). The FDA approved the NDA in February 2000, and Solvay began marketing AndroGel in June 2000. On August 30, 2000, Solvay and Besins filed a patent application with the U.S. Patent and Trademark Office ("PTO") [see Doc. 587-68]. Initially, the PTO examiner rejected Solvay's patent claims based on public use and sales of AndroGel during clinical testing, but the examiner later withdrew his rejection [Doc. 587-70]. The examiner also initially rejected Solvay's patent claims disclosing a solution "comprising of" certain ingredients [Doc. 604-70]. Solvay subsequently amended its patent application to disclose claims for a "pharmaceutical composition . . . *consisting essentially of*" certain ingredients [Doc. 587-69] (emphasis added).

On January 7, 2003, the patent application issued as U.S. Patent No. 6,503,894 (the "'894 Patent") [Doc. 587-66]. Within thirty days after the PTO issued the '894 Patent, Solvay submitted the patent to the FDA for listing in the Orange Book. The Orange Book is a publication containing information about each FDA approved drug.

See 21 U.S.C. § 355(j)(7)(A). The FDA accepted Solvay's submission and listed the patent in the Orange Book.

AndroGel is the preferred embodiment of the '894 Patent. To that end, the specification discloses, in Table 5, the formula for AndroGel. The formula states that 100 grams of AndroGel contains: 1.0 g testosterone, 0.90 g Carbopol 980, 0.50 g isopropyl myristate, 72.5 g ethanol; Carbopol (0.9%); a gelling agent; 4.72 g .1 N sodium hydroxide (0.0188%); and water. The '894 Patent states that the ingredients can be varied within certain ranges. The patent recites 42 claims. Claims 1, 9, 10, 18, and 31 are independent claims, and the remaining claims are dependent. Claims 1, 10, and 18 each describe a formulation "consisting essentially of" about 1% to about 5 % sodium hydroxide. Claim 9 describes a formulation "consisting essentially of . . . about 1% to about 3% sodium hydroxide." Finally, Claim 31 recites:

> [a] method for administering an active agent to a human subject in need thereof, the method comprising: a. Providing a pharmnaceutical [sic] composition consisting essentially of: (i) about 0.5% to about 5% testosterone; (ii) about 0.1% to about 5% isopropyl myristate; (iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and (iv) about 0.1% to about 5% of a gelling agent; wherein the percentages are weight to weight of the composition.

Thus, Claim 31, upon which Claims 32-42 are dependent, states that the composition consists essentially of only four ingredients, none of which are water or sodium hydroxide.

The initial version of the '894 Patent provided a range of sodium hydroxide concentration in the specification that appeared to be much less than the range of sodium hydroxide listed in the claims. While the specification provided for 4.72g 0.1 N sodium hydroxide (resulting in a 0.0188% sodium hydroxide concentration in AndroGel), the claims recited different ranges. Specifically, Claims 1, 10, and 18 list ranges of sodium hydroxide at 1% to 5%, Claim 9 lists a range of 1% to 3%, and Claim 31 does not mention sodium hydroxide, only a "gelling agent." On June 12, 2003, Solvay filed a request for a certificate of correction to the '894 Patent [Doc. 587-75]. The request sought to replace the term "sodium hydroxide" in Claims 1-30 with the term "0.1 N sodium hydroxide" to reflect the language in Table 5 of the specification. The PTO issued the certificate of correction on December 16, 2003 [Doc. 587-66]. See 35 U.S.C. § 255.

Before the '894 Patent issued, Watson Pharmaceuticals, Inc. ("Watson") and Paddock Laboratories, Inc. ("Paddock") (collectively, the "Generics") began developing generic versions of AndroGel. The Generics attempted to copy AndroGel "as close as humanly possible"[4] [Doc. 555, Ex. 1, at 14]. The Generics completed

[4]The Generics did not realize that AndroGel was patent protected because Solvay's patent application was not public [see Doc. 555, Ex. 1, at 14]. Congress subsequently amended the patent laws to make pending patent applications public. See 35 U.S.C. § 122(b)(1)(A).

development even after learning of the '894 Patent. Watson filed a Paragraph-IV Abbreviated New Drug Application ("ANDA")[5] for generic AndroGel in May 2003 [Doc. 587-13]. See 21 U.S.C. § 355(j)(2)(A)(vii). Shortly thereafter, Paddock filed its own Paragraph IV ANDA for its own generic AndroGel [Doc. 587-22]. Watson's formulation of generic AndroGel contained 0.0158% sodium hydroxide and Paddock's contained 0.0144% sodium hydroxide [Doc. 603, at 18]. In July 2003, Paddock entered into an agreement with Par Pharmaceutical Companies, Inc. ("Par") (collectively "Par/Paddock") whereby Par agreed to share potential patent litigation costs with Paddock and to sell Paddock's generic AndroGel. In return, Paddock agreed to share profits with Par. See In re AndroGel, 687 F. Supp. 2d 1371, 1374 (N.D. Ga. 2010). As required by 21 U.S.C. § 355(j)(2)(A)(vii), both Watson and Par/Paddock notified Solvay of the ANDAs and asserted that the '894 Patent was invalid or would not be infringed by their generic drugs.

Solvay responded to the ANDA notices by asserting its rights under the '894 Patent, again pursuant to the procedure laid out in 21 U.S.C. § 355(j)(2)(A)(vii). In

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[5]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).

August 2003, Solvay's subsidiary, Unimed, filed patent infringement actions against Watson and Par/Paddock in this Court, and by filing automatically prevented the Generics from entering the market for 30 months. See Complaint, Unimed Pharm., Inc. v. Watson Pharm., Inc., No. 03 Civ. 2501 (N.D. Ga. Aug. 21, 2003) (2003 WL 23824320); Complaint, Unimed Pharm., Inc. v. Paddock Labs., Inc., No. 03 Civ. 2503 (N.D. Ga. Aug. 21, 2003) (2003 WL 23824347) (the "Underlying Litigation").

From late 2003 to the middle of 2005, the Underlying Litigation proceeded with discovery and other preliminary matters. By August 2005, the parties had filed claim construction motions. The parties agreed that 25 claim terms required construction. No party filed a Daubert motion in the Underlying Litigation. By December 2005, Watson and Par/Paddock had filed motions for summary judgment on the validity of the '894 Patent. They argued the certificate of correction improperly broadened the patent and that the '894 Patent did not meet the written-description requirement of 35 U.S.C. § 112. Solvay opposed summary judgment on both grounds, arguing that a skilled chemist would have understood that the certificate of correction merely fixed a drafting error and that the written description issue was a question of fact. The parties vigorously argued their positions.

Before the Court could resolve these issues, Solvay, Watson, and Par/Paddock settled the Underlying Litigation [see Docs. 604-87, 604-88, 604-89, 604-91, 604-90,

604-92, 604-93, & 604-94, collectively, the "Settlement and License Agreements"]. Under the Settlement and License Agreement with Watson, Solvay agreed to voluntarily dismiss the Underlying Litigation, 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 and License Agreements between Solvay and Par/Paddock, Solvay agreed to a consent judgment dismissing the infringement action, and Par/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. No other generic manufacturer has entered the market.

At the same time, Solvay entered into business promotion agreements with Watson, Par, and Paddock. 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. Similarly, 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 committed 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 Settlement and License Agreements prompted an investigation by the Federal Trade Commission (FTC) for violations of antitrust laws. In 2009, the FTC and a number of private parties filed these antitrust actions against Solvay, Watson, Par, and Paddock. All 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. All of the Plaintiffs alleged 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 Purchaser Plaintiffs also alleged that the Defendants violated the common law and antitrust laws of about forty states. All of the Plaintiffs asserted antitrust claims based on the settlements. They alleged that Solvay paid Watson, Par, and Paddock millions of dollars for agreeing not to sell generic AndroGel before August 31, 2015. The Plaintiffs claim 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.

In 2009, Par/Paddock and Solvay filed Motions to Dismiss [Docs. 8, 9, 22, 23, 24, 25, 26, 27, 28, & 29]. On February 22, 2010, the Court granted in part and denied in part the Defendants' motions [Doc. 50]. See In re AndroGel, 687 F. Supp. 2d 1371 (N.D. Ga. 2010). Specifically, the Court dismissed the Private Plaintiffs' and the FTC's claims that the reverse payments encompassed in the settlement agreements were antitrust violations. The Court noted that, under Eleventh Circuit precedent, the First Amendment protects the Settlement and License Agreements unless the Underlying Litigation was a sham. See id. at 1379-80. Therefore, the remaining claims, and the current motions for summary judgment, rest on whether the Private Plaintiffs can show that the Underlying Litigation and the settlements were a sham.

On January 20, 2012, Par/Paddock filed a Motion for Summary Judgment on Objective Baselessness [Doc. 555]. On February 15, 2012, Par/Paddock filed a Motion for Summary Judgment on Improper Subjective Motivation [Doc. 567]. On February 17, 2012, Par/Paddock filed a Motion for Summary Judgment on Plaintiffs' Substantive Antitrust Claims [Doc. 574]. On February 21, 2012, Watson filed a Motion for Summary Judgment on Plaintiffs' Conspiracy Claims for Lack of Subjective Bad Faith [Doc. 579]. On February 21, 2012, Solvay filed a Motion for Summary Judgment on Objective Baselessness [Doc. 587] and a Motion for Summary Judgment on Subjective Bad Faith [Doc. 589]. On February 21, 2012, the Direct

Purchaser Plaintiffs filed a Motion to Exclude Portions of Dr. Norman Weiner's Expert Report [Doc. 598]. The Direct Purchaser Plaintiffs and End-Payor Class Plaintiffs[6] also filed Motions for Summary Judgment on Sham Litigation [Docs. 603 & 588]. Finally, on May 10, 2012, the Direct Purchaser Plaintiffs filed a Motion to Strike the Declaration of Joseph A. Mahoney and Limit Dr. Stanley Kaplan's Testimony [Doc. 708]. These motions are now before the Court.

II. Summary Judgment Standard

Summary judgment is appropriate only when the pleadings, depositions, and affidavits submitted by the parties show that no genuine issue of material fact exists and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The court should view the evidence and any inferences that may be drawn in the light most favorable to the nonmovant. Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970). The party seeking summary judgment must first identify grounds that show the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986). The burden then shifts to the nonmovant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of material fact does exist. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986).

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[6]The End-Payor Class Plaintiffs include the Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund, George Steven Legrand, and Health Net, Inc. [see Doc. 588].

III. Discussion

A. Sham Litigation

As noted, the Court has previously dismissed the Plaintiffs' "reverse-payment" claims. See In re AndroGel, 687 F. Supp. 2d at 1379. In its order, the Court noted, however, 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." Id.

Sham litigation is an exception to the general principle that "[t]hose who petition government for redress are generally immune from antitrust liability." Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56 (1993) ("PRE"). However, this immunity does not extend to 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 and the application of the Sherman Act would be justified." Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961). "[T]o be a 'sham,' litigation must meet a two-part definition." PRE, 508 U.S. at 60:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail. Only if the challenged litigation is objectively meritless may a court examine the

> litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of governmental process – as opposed to the outcome of that process – as an anticompetitive weapon.

Id. at 60-61 (quoting Noerr, 365 U.S. at 144 and Omni, 499 U.S. at 380) (internal quotation marks omitted).

1. Objective Baselessness

All parties have moved for summary judgment with respect to objective baselessness arguing that there are no issues of material fact. "A finding of objective baselessness is to be determined by the record made in the infringement proceedings." iLOR, LLC v. Google, Inc., 631 F.3d 1372, 1380 (Fed. Cir. 2011). When there is no dispute over the predicate facts of the underlying suit, objective baselessness is a question of law to be decided by the Court. See Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., 682 F.3d 1003, 1007-08 (Fed. Cir. 2012).

The Plaintiffs must satisfy a heavy burden to show that the Underlying Litigation was objectively baseless. "Under this exacting standard, the plaintiff's case [in the Underlying Litigation] must have [had] no objective foundation." iLOR, 631 F.3d at 1377. "If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail." PRE, 508 U.S. at 60.

"When a court has found that an antitrust defendant claiming Noerr immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit." Id. at 63. "Probable cause to institute civil proceedings requires no more than a 'reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid upon adjudication.'" Id. at 62-63 (quoting Hubbard v. Beatty & Hyde, Inc., 343 Mass. 258, 262 (1961)). "The court must remember that '[e]ven when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable ground for bringing suit.'" PRE, 508 U.S. at 60 n. 5 (quoting Christiansburg Garment Co. v. EEOC, 434 U.S. 412, 422 (1978)). Importantly, "when the antitrust defendant has lost the underlying litigation, a court must 'resist the understandable temptation to engage in post hoc reasoning by concluding' that an ultimately unsuccessful 'action must have been unreasonable or without foundation.'" PRE, 508 U.S. at 60 n.5 (quoting Christiansburg, 434 U.S. at 421-422). "Neither the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability." C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1369 (Fed. Cir. 1998). Further, "the legality of objectively reasonable petitioning directed toward obtaining government action is not at all affected by any anticompetitive purpose the actor may have had." PRE, 508

U.S. at 59 (quoting Noerr, 365 U.S. at 140). Indeed, even in the absence of supporting authority, a litigant may reasonably offer a "good faith argument for the extension, modification, or reversal of existing law" without incurring sham liability. Id. at 65 (quoting Fed. R. Civ. P. 11); see also In re Terazosin Hydrochloride Antitrust Litigation, 335 F. Supp. 2d 1336, 1359-60 (S.D. Fla. 2004) (finding that legal argument "was a stretch, [but] it did not exceed the pale of an aggressive attempt to extend the existing law, and thus was not objectively baseless."); Honeywell International, Inc. v. Universal Avionics Systems Corp., 343 F. Supp. 2d. 272, 325-26 (D. Del. 2004) (finding suit was objectively reasonable when plaintiffs offered a qualified expert who was ultimately discredited); VAE Nortrak NA, Inc. v. Progress Rail Serv's. Corp., 459 F. Supp. 2d 1142, 1166 (N.D. Ala. 2006) (finding suit was objectively reasonable when summary judgment was a close call and litigation had been ongoing for three years); MarcTec, LLC v. Johnson & Johnson, 664 F.3d 907, 918-19 (Fed. Cir. 2012) (finding objective baselessness when patentee had disclaimed stents to gain PTO approval then filed infringement action against stent maker); Eon-Net LP v. Flagstar Bancorp, 653 F.3d 1314, 1326 (Fed. Cir. 2011) (finding objective baselessness when patentee, who had filed 100 infringement suits, argued patent for pulling data from 'hard document' applied to digital documents); In re Buspirone Patent Litigation, 185 F. Supp. 2d 363, 376 (S.D.N.Y. 2002) (finding objective

baselessness when defendant had "repeatedly argued for a position that requires establishing a number of claims, each one of which has no basis, and each one of which depends on reframing or mischaracterizing some critical issue or legal standard"). Finally, with respect to objective baselessness, "[i]t is not what the parties think of the merits of their positions that matters; it is whether there are, in fact, sufficient objective bases for the positions taken." In re Buspirone, 185 F. Supp. 2d 363 at 375. "At the same time, because the test is an objective one, the answer to this question will not depend on the quality of the lawyering [in the Underlying Litigation]." Id. at 375-376.

The Plaintiffs contend that each of the Defendants in the present suit took an objectively baseless position in litigating and settling the underlying suit. The Plaintiffs contend that Solvay chose to file an Orange Book listing for the '894 Patent despite the plain certainty that the '894 Patent did not cover AndroGel or its generic replicants. The Plaintiffs also contend that Watson and Par/Paddock's decisions to settle the claims were objectively baseless because an objective litigant would have discerned that the '894 Patent was so blatantly invalid that victory was assured. See FTC v. Watson, 677 F.3d 1298, 1308 (11th Cir. 2012) ("[A] court must judge the antitrust implications of a reverse payment settlement as of the time that the settlement was executed."). Thus, all of the Plaintiffs' arguments with respect to objective

baselessness contend that the '894 Patent was either invalid or not infringed. The Plaintiffs offer several theories as to why the patent was so facially invalid that an objective litigant would not have attempted to enforce the patent, and those arguments are addressed in turn below.[7]

a. Certificate of Correction

[7]Both sides make much of the parties' litigation positions in the Underlying Litigation. The Plaintiffs claim that Watson and Par/Paddock have changed their position on the reasonableness of Solvay's infringement arguments. Specifically, the Plaintiffs point to Watson and Par/Paddock's requests for attorney's fees under 35 U.S.C. § 285 in the Underlying Litigation. See iLOR, 631 F.3d at 1376 (under § 285, sanctions may be imposed only if defendant shows objective baselessness and subjective bad faith). Since Watson and Par/Paddock argued that Solvay's claims were objectively baseless in the Underlying Litigation, the Plaintiffs contend that the Defendants cannot now argue that Solvay's claims were reasonable. Conversely, the Defendants argue that the Underlying Litigation was not objectively baseless because Watson and Par/Paddock never filed summary judgment motions with respect to Claims 31-42 of the '894 Patent. Further, the Defendants note that Watson and Par/Paddock never filed Daubert motions seeking to disqualify Solvay's experts in the Underlying Litigation. Thus, the Defendants argue, the Underlying Litigation was headed to trial as a "battle of the experts." Both sides' arguments are misplaced. With respect to the Underlying Litigation, "[i]t is not what the parties think of the merits of their positions that matters; it is whether there [were], in fact, sufficient objective bases for the positions taken." In re Buspirone, 185 F. Supp. 2d 363, 375 (S.D.N.Y. 2002). Further, "because the test is an objective one, the answer to this question will not depend on the quality of the lawyering." Id. at 375-376. Thus, Watson and Par/Paddock's beliefs in the Underlying Litigation are irrelevant to the objective prong of PRE. Similarly, Watson and Par/Paddock's failure to file certain motions–whether omitted strategically or not–does not change the objective merits of the Underlying Litigation.

The Plaintiffs contend that Solvay could not rely upon the certificate of correction to correct fatal errors in the patent as issued. Originally, Claims 1-30 disclosed a formulation "consisting essentially of" about 1% to about 5 % "sodium hydroxide" [Doc. 587-66]. On December 16, 2003, the PTO issued a certificate of correction that changed the words "sodium hydroxide" in Claims 1-30 to ".1 N sodium hydroxide."

Specifically, the Plaintiffs argue that an objective litigant would have known that the certificate of correction did not apply to Solvay's claims against Watson and Par/Paddock in the Underlying Litigation because the certificate was issued six months after the lawsuit was filed. Without the certificate of correction, the Plaintiffs argue, the ranges of sodium hydroxide listed in Claims 1-30 obviously cannot encompass AndroGel or its generic replicates. The Patent Act provides for obtaining a certificate of correction as follows:

> Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

35 U.S.C. § 255. At the time of the Underlying Litigation, the Federal Circuit had held that a certificate of correction does not apply to causes of action arising before its issuance. Southwest Software, Inc. v. Harlequin Inc., 226 F.3d 1280, 1295 (Fed. Cir. 2000). The Plaintiffs argue that an objective litigant in Solvay's position would have known that a certificate of correction would not apply to the Underlying Litigation because the action was filed before the certificate was issued.

However, recent developments in case law show that Solvay's reliance upon the certificate of correction in the Underlying Litigation was not objectively unreasonable. In E.I. du Pont de Nemours & Co. v. MacDermid Printing Solutions, LLC, 525 F.3d 1353 (Fed. Cir. 2008), the plaintiff sued for infringement of a patent supplemented with a certificate of correction. The defendant countered that the certificate of correction had issued after the cause of action accrued. The court held that the certificate of correction covered all acts of infringement that occurred after the certificate of correction issued, despite the date the cause of action accrued. The court distinguished Southwest Software, noting that "only [the defendant's] future conduct (i.e., prospective infringement occurring after the issuance of the certificate of correction) is at issue." Id. at 1362; see also Eagle Iron Works v. McLanahan Corp., 429 F.2d 1375 (3d Cir. 1970) (noting that certificate of correction may be "given retroactive application in order that intervening rights may not be alleged.").

Similarly, in Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C., No. CV-00-2430, 2006 WL 4448613 (N.D. Ala. Jan. 13, 2006), *aff'd in part, vacated in part, rev'd in part*, 482 F.3d 1347 (Fed. Cir. 2007), the defendant argued that the patent holder's certificate of correction did not apply because it was issued after the first act of infringement. Distinguishing Southwest Software, the court held that the certificate of correction applied to all causes of action arising *after* the certificate issued, even if the suit was filed prior to the issuance of the certificate. Id. at *17.

The District of Delaware recently decided Pfizer Inc. v. Teva Pharmaceuticals U.S.A., Inc., No. 09-cv-307 (GMS), 2012 WL 2951367, at *44 (D. Del. July 19, 2012), a case, like the Underlying Litigation, involving a certificate of correction and an ANDA filing. That court concluded that "because infringement [under a Paragraph IV suit] is hypothetical and, therefore, cannot occur prior to the filing of a complaint, a certificate of correction can be applied where the defendants' ANDA products will prospectively infringe the patents-in-suit." Id. The court noted that "relevant case law has instructed that, for the purposes of determining whether a certificate of correction applies, the date on which the infringing conduct will occur, rather than the date a complaint is filed, dictates." Id. Notably, no party has identified a case decided before the Underlying Litigation involving a certificate of correction issued after an ANDA

filing. The decisions in Central Admixture, E.I. du Pont, and Pfizer demonstrate that reasonable litigants have argued successfully for application of certificates of correction after a lawsuit was filed. As the court in Pfizer noted, under 35 U.S.C. § 271(e)(2)(A), actual sales of generic AndroGel were artificially represented by Watson and Par/Paddock's ANDA applications. Thus, the Underlying Litigation represented a "hypothetical case . . . to determine whether the drug that will be sold upon approval of the ANDA will infringe the ['894 Patent]." In re Brimonidine Patent Litig., 643 F.3d 1366, 1377 (Fed. Cir. 2011). Based on the lack of factually similar precedent, a litigant could reasonably expect *a chance* that the certificate of correction would apply to Solvay's claims. See PRE, 508 U.S. at 62-63 (argument not objectively baseless if litigant has "reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid upon adjudication."); In re Terazosin, 335 F. Supp. 2d 1336, 1360-61 (finding that legal argument "was a stretch, [but] it did not exceed the pale of an aggressive attempt to extend the existing law, and thus was not objectively baseless."). For these reasons, Solvay's argument that the certificate of correction applied to its claims was not objectively baseless. By extension, Par/Paddock and Watson acted as objectively reasonable litigants when they recognized that the certificate of correction might apply in the Underlying Litigation and considered settlement.

Additionally, a reasonable litigant could have argued for a judicial correction of the '894 Patent in the Underlying Litigation. 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). District courts have the power to correct errors that would be obvious "from the point of view of one skilled in the art." CBT Flint Partners, LLC v. Return Path, Inc., 654 F.3d 1353, 1358 (Fed. Cir. 2011) (quoting Ultimax Cement Manufacturing Corp. v. CTS Cement Manufacturing Corp., 587 F.3d 1339, 1353 (Fed Cir. 2009). Here, Solvay's expert, Dr. Weiner, testified that someone skilled in the art "would understand that the concentration of water and sodium hydroxide would be in the form of a 0.1 N solution because this is the concentration disclosed in Table 5 of the '894 Patent" [Doc. 555, Ex. 31]. While it is not certain that the Court would have credited the testimony or granted the requested correction, Solvay could have reasonably argued that the inconsistency between the specification and the claims was correctable by judicial decree. See Honeywell, 343 F. Supp. 2d. at 325-26 (concluding action was not objectively baseless even when qualified expert had been discredited).

Next, the Plaintiffs argue that the certificate of correction should have appeared invalid to an objective litigant because it enlarged the scope of the '894 Patent. See 35 U.S.C. § 255 (certification of "correction [may] not involve such changes in the patent as would constitute new matter or would require re-examination."). Certificates of correction, like patent claims, are entitled to a presumption of validity. Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1367 n.1 (Fed. Cir. 2001) (noting that presumption "is related to the presumption that the PTO does its job properly."). However, "[a] mistake in a claim the correction of which broadens the scope of coverage of that claim and is not clearly evident from the specification, drawings, and prosecution history is not a 'mistake of a clerical or typographical nature' subject to correction under 35 U.S.C. § 255." Id. at 1376.

Here, Table 5 of the '894 Patent accurately discloses the formulation of AndroGel, including "0.1 N sodium hydroxide" [Doc. 587-66]. Thus, without correction, Claims 1-30 would exclude AndroGel, the '894 Patent's preferred embodiment. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) (interpreting patent to exclude preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support."). However, Solvay's expert, Dr. Weiner, testified that someone skilled in the art "would understand that the concentration of water and sodium hydroxide would be in the form of a 0.1 N solution

because this is the concentration disclosed in Table 5 of the '894 Patent" [Doc. 555, Ex. 31]. Dr. Weiner also testified that "[t]he skilled person knows [that] . . . sodium hydroxide would not be used in the range [given in uncorrected Claims 1-30] because it would highly irritate or even burn the skin" [Doc. 555, Ex. 29]. Thus, based on the specification, there was evidence that someone skilled in the art would have realized that the term "sodium hydroxide" was a clerical error. See 35 U.S.C. § 255. Although Dr. Weiner's opinion may not have been ultimately persuasive, the Plaintiffs have not overcome the presumption that the certificate of correction is valid and have not shown that the parties' litigation positions, which recognized that the certificate of correction might apply, were unreasonable. For these reasons, it was not objectively baseless for Solvay to seek to enforce its rights pursuant to the certificate of correction in the Underlying Litigation.

b. Claims 1-30

The Plaintiffs argue that Claims 1-30 should have been invalid to an objectively reasonable litigant for lack of a written description. Specifically, the Plaintiffs contend that the percentage of each ingredient listed in Table 5 does not support the ranges provided in Claims 1-30. However, "[t]he 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). Rather, "the test for sufficiency is

whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Ariad Pharms, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010). "This inquiry . . . is a question of fact." Id.

The Court concludes that a reasonable litigant could have sought a determination finding that the written description requirement was satisfied. In Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989 (Fed. Cir. 2000), the defendant argued that a patent for automobile fuel did not meet the written description requirement. "[T]he patent claim[ed] its inventive products in terms of ranges of chemical properties, which work[ed] in combination with ranges of other chemical properties to produce a gasoline that reduce[d] emissions." Id. at 997. The specification disclosed a broader range for certain ingredients than was disclosed in the claims. The court, however, held that "the specification supported the claimed range, even though the precise range of the claim was not repeated verbatim in the specification." Id. at 1000. The court reasoned "that it would 'let form triumph over substance' if it allowed the written description requirement to eviscerate claims that are narrowed during prosecution, simply because the patent applicant broadly disclosed in the original patent application but then narrowed his claims during prosecution." Id. (quoting In re Wertheim, 541 F.2d 257, 265 (CCPA 1976)).

Here, as amended by the certificate of correction, Claims 1-30 describe a composition containing 1%-5% 0.1 N sodium hydroxide. Table 5 refers only to 4.72% sodium hydroxide–the amount present in AndroGel. As in Union Oil, Dr. Weiner testified that someone skilled in the art would be able to determine the appropriate range of sodium hydroxide based on the information in the specification [Doc. 555, Ex. 26, ¶ 48]. Specifically, Dr. Weiner noted that the range of Carbopol listed in the specification would allow someone skilled in the art to determine the appropriate range of sodium hydroxide. The Direct Purchaser Plaintiffs' expert, Dr. Bozena Michniak-Kohn, admitted that someone skilled in the art would be able to divine a range of sodium hydroxide given the ranges of other ingredients[8] [Doc. 587-36, ¶¶ 64-65]. The Plaintiffs, however, argue that the range of sodium hydroxide determined from the specification does not specifically match the range given in Claims 1-30. (See Pls.' Resp. In Opp'n to Par/Paddock's Mot. for Summ. J. on Objective Baselessness, at 14-19.) As in Union Oil, the Plaintiffs' expert testified that

[8]The Plaintiff's expert, Dr. Michniak-Kohn, opined that someone skilled in the art could determine that Solvay was in possession of a formula with .5-26% 0.1 N sodium hydroxide [see Doc. 587-36, ¶ 65]. Dr. Michniak-Kohn goes on to state that this range does not overlap with the 1%-5% pure sodium hydroxide stated in the '894 Patent before the certificate of correction was issued. Dr. Michniak-Kohn's range *does*, however, overlap with the ranges given in the certificate of correction. As discussed above, it was not objectively baseless to argue that the certificate of correction governed Solvay's claims in the Underlying Litigation.

the ranges taught by the specification are much broader than the ranges claimed in Claims 1-30. Indeed, the Plaintiffs note that even Dr. Weiner testified that the sodium hydroxide ranges taught by the specification are different and broader than those listed in Claims 1-30. (See id., at 17; Doc. 605-65, at 222-223; 220-221.) As in Union Oil, however, "it would 'let form triumph over substance' if it allowed the written description requirement to eviscerate claims that are narrowed during prosecution, simply because the patent applicant broadly disclosed in the original patent application but then narrowed his claims during prosecution." Union Oil, 208 F.3d at 1000. As the Plaintiffs concede, the specification taught a broader range than the claims. Relying on Union Oil, Solvay could have reasonably argued that the specification nevertheless met the written description requirement. This position is, at the very least, a reasonable argument for the extension of Union Oil. See PRE, 508 U.S. at 65 (quoting Fed. R. Civ. P. 11) (A "good faith argument for the extension, modification, or reversal of existing law" is not objectively baseless).

Nevertheless, the Plaintiffs cite Nelson v. K2 Inc., No. C07-1660, 2008 WL 4603409 (W.D. Wash. Oct. 15, 2008), in support of their contention that Solvay's written description argument was a sham. In Nelson, the claimed ranges for length and width of the subject invention were narrower than those disclosed in the specification. The court found that the lack of specificity in the specification rendered

the patent invalid. Importantly, the defendant also brought a motion for fees, arguing that the plaintiff's infringement arguments were frivolous. See Nelson v. K2 Inc., 2009 WL 1160092 (W.D. Wash. April 27, 2009). The court found that although the plaintiff had lost the written description issue, it "was entitled to a judicial determination of this important issue and was not required to abandon the . . . patent simply because his competitors challenged its validity." Id. at *1. In the absence of controlling authority, and relying on Union Oil, it was not objectively baseless for Solvay to seek the same determination in the Underlying Litigation. For these reasons, Solvay's legal argument regarding the written description was not a sham.[9]

The Plaintiffs also attack the credibility of the Defendants' expert testimony with respect to Claims 1-30. Specifically, the Plaintiffs contend that the amount of sodium hydroxide present in AndroGel is "the minimum workable amount." (See Pls.' Resp. In Opp'n to Par/Paddock's Mot. for Summ. J. on Objective Baselessness, at 17.) Further, the Plaintiffs argue that Dr. Bowman's calculations regarding the level of sodium hydroxide taught by the specification are arbitrary and ignore important scientific principles. (Id. at 18.) This evidence tends to discredit Dr. Bowman's and Dr. Weiner's testimony. It does not, however, establish that there was no chance a

[9]Having determined that the Defendants' legal written description argument was not objectively baseless, the Court need not address whether it was objectively baseless to argue that there is no written description requirement.

reasonable litigant could hope the finder of fact would credit the Defendants' experts. See PRE, 508 U.S. at 65; Honeywell, 343 F. Supp. 2d. at 325-26 (concluding action was not objectively baseless even when qualified expert had been discredited). Further, as discussed above, Dr. Michniak-Kohn testified that it was possible to determine a broad range of sodium hydroxide based on the specification [see Doc. 587-36, ¶¶ 64-65]. For these reasons, Solvay's patent claims with respect to Claims 1-30 were not objectively baseless.

c. Claims 31-42

The Plaintiffs argue that Solvay's arguments regarding Claims 31-42 of the '894 Patent were objectively baseless because Claims 31-42 exclude water and sodium hydroxide as ingredients.[10] Those claims describe an invention "consisting essentially of" various ranges of testosterone, isopropyl myristate, alcohol, and a "gelling agent" [Doc. 587-66]. "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of

[10]In response, the Defendants stress that Watson and Par/Paddock did not move for summary judgment on Claims 31-42 in the Underlying Litigation [Doc. 435-1, at 34]. As discussed above, however, "because the [objective baselessness] test is an objective one, the answer to this question will not depend on the quality of the lawyering." In re Buspirone, 185 F. Supp. 2d at 375-376. The Court must therefore determine whether Solvay's arguments were objectively baseless without regard to Watson and Par/Paddock's litigation strategy in the Underlying Litigation.

the invention." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

First, the Plaintiffs contend that the "gel" state of the '894 Patent is a basic and novel property of the invention. The Plaintiffs assert that water and sodium hydroxide affect the gel composition of the claimed invention, and thus affect its basic and novel properties. In response, the Defendants rely on Dr. Weiner's expert testimony. Dr. Weiner testified that "the basic and novel properties of the invention disclosed and claimed in the '894 Patent include the unique and unexpected pharmacokinetic profile as well as the low incidence of skin irritation that results [from] the use of the compositions described and claimed in the '894 Patent" [Doc. 555, Ex. 31]. Dr. Weiner stated that "sodium hydroxide has no effect on these basic and novel properties." Further, Dr. Weiner opined that "[t]he formation of a gel and the viscosity of the gel are not 'basic and novel' properties of the invention" [Doc. 598-2]. Similarly, Dr. William Barr, Solvay's expert in the Underling Litigation, testified that "the basic and novel characteristics of the claimed invention include the unique and unexpected pharmacokinetic profile, as well as the low incidence of skin irritation" [Doc. 555, Ex. 30].

The Plaintiffs, however, point to certain inconsistencies in Dr. Weiner's testimony as rendering Solvay's arguments objectively baseless. Specifically, the

Plaintiffs contend that during Dr. Weiner's deposition, he admitted that the gel state was a basic and novel characteristic of the invention [see Doc. 598-8]. Reviewing the deposition transcript, however, Plaintiffs' counsel repeatedly asks Dr. Weiner whether a gel state is a basic and novel property of the invention. In response, Dr. Weiner *repeatedly* states his opinion that while the preferred embodiment of the '894 Patent–AndroGel–is a gel, the basic and novel properties of the invention are the "pharmacokinetics and the lack of irritation" [Doc. 620-5, at 243-49]. Dr. Weiner repeatedly states his opinion that "once you accept that you do have a gel and you accept that this is a new invention, from that point forward, the only basic and novel properties are the pharmacokinetics and lack of irritation" [id. at 249]. Contrary to the Plaintiffs' assertions, Dr. Weiner *does not* admit that a gel state is a basic and novel property of the claimed invention. Indeed, Dr. Weiner explains his position that a gel state *is not* a basic and novel property of the invention several times [see id., at 244-249]. In any event, by pointing out mild inconsistency or confusion in Dr. Weiner's testimony the Plaintiffs have not established that no reasonable litigant would believe there was a chance Dr. Weiner's testimony would be credited. PRE, 508 U.S. at 62-63 ("Probable cause to institute civil proceedings requires no more than a 'reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid upon adjudication.'");

Honeywell, 343 F. Supp. 2d. at 325-26 (concluding action was not objectively baseless when plaintiff's qualified expert had been discredited).

Indeed, the '894 Patent itself lends some support to Dr. Weiner's expert opinion. Claim 37 of the '894 Patent is a dependent claim that adds the limitation "wherein the composition is in the form of a gel" [Doc. 587-66]. "[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005)(citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)). The independent claims do not include the limitation given in Claim 37. This gives rise to the presumption that the invention includes non-gels. See Phillips, 415 F.3d at 1314-15. Though not dispositive, the dependent claim, in combination with expert testimony, establishes that a reasonable litigant would perceive some chance that a finder of fact would determine that being a gel was not a basic and novel property of Solvay's invention. Ultimately, Watson and Par/Paddock may have been successful in discrediting Solvay's expert testimony and claim interpretation. Solvay's evidence, however, was sufficient to show probable cause to seek a favorable judicial outcome. See PRE, 508 U.S. at 62 ("When a court has found that an antitrust defendant claiming Noerr immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the

defendant's position could realistically expect success on the merits of the challenged lawsuit."). For this reason, it was not objectively baseless to argue that a gel state was not a basic and novel property of the '894 Patent.

The Plaintiffs also claim that it was objectively baseless to argue that sodium hydroxide and water do not affect the pharmacokinetics of the claimed invention.[11] Again, Dr. Weiner testified that neither water nor sodium hydroxide affect the pharmacokinetics of the '894 Patent [see Doc. 587-65, at ¶¶ 33-56, & 58; Doc. 555, Ex. 31, ¶ 58]. Specifically, Dr. Weiner opined that the addition of water "would not alter the basic and novel properties of the invention disclosed in the '894 Patent" [id., at ¶ 37]. Similarly, Solvay's expert in the Underlying Litigation, Dr. William Barr, testified that "the addition of water to the claims of the '894 Patent would not materially affect [the unexpected pharmacokinetic profile or low incidence of skin irritation]" [Doc. 555, Ex. 30]. The Plaintiffs offer competing evidence on this issue including literature that potentially undercuts Dr. Weiner's testimony with respect to pharmacokinetics [see Doc. 598, at 13-14]. This competing evidence, however, does not establish that no reasonable litigant would perceive a chance of success. If anything, the competing testimony shows that a finder of fact would have to determine

[11]The Defendants concede that the unique pharmacokinetics of the invention are a basic and novel property.

the experts' credibility. Honeywell, 343 F. Supp. 2d. at 325-26 (concluding action was not objectively baseless even when plaintiff's qualified expert had been discredited). Thus, it was not objectively baseless to argue that water and sodium hydroxide did not affect the pharmacokinetics of the '894 Patent. For these reasons, Solvay's infringement claims with respect to Claims 31-42 were not objectively baseless.

d. On-Sale Bar

The Plaintiffs argue that the Underlying Litigation was objectively baseless because the '894 Patent was invalid under the "on-sale bar."[12] The on-sale bar renders a patent invalid where "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). The on-sale bar applies when two conditions are met before the critical date. "First, the product must be the subject of a commercial offer for sale." Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67 (1998). "Second, the invention must be ready for patenting." Id. "That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date

[12]Again, the Defendants note that Watson and Par/Paddock did not raise this argument in the Underlying Litigation. As discussed above, that is irrelevant. See In re Buspirone, 185 F. Supp. 2d 363, 375-6 (S.D.N.Y. 2002) (citing PRE, 508 U.S. at 63) ("[B]ecause the test is an objective one, the answer to this question will not depend on the quality of the lawyering.").

the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." Id. The critical date is the date one year before the filing of the patent application. Id. at 57; see also 35 U.S.C. § 102(b).

The Plaintiffs argue that the 1995 Supply Agreement constituted a commercial offer for sale and that reasonable litigants would have known that the '894 Patent was invalid because the patent was not applied for until August 30, 2000.[13] Under the 1995 Supply Agreement, Besins agreed to supply a testosterone gel to Unimed if and when the hypothetical drug complied with relevant government requirements, including approval from the FDA [see Doc. 587-87, § 2.3]. Unimed had no obligation to purchase the drug unless Besins complied with these requirements. The price of the potential drug would be determined by the cost required to manufacture it [see id., § 3.1]. Unimed did not pay Besins for any drugs under the 1995 Supply Agreement until the FDA approved AndroGel in February 2000 [see Doc. 587-15].

The Court concludes it was not objectively baseless for Solvay to bring suit despite the 1995 Supply Agreement. In Elan Corp. v. Andrx Pharmaceuticals, Inc., 366 F.3d 1336 (Fed. Cir. 2004), a patentee sued a generic drug manufacturer for

[13]Because Solvay filed the patent application on August 30, 2000, the critical date is August 30, 1999 [see Doc. 587-68].

patent infringement, and the generic manufacturer argued that the on-sale bar invalidated the patent. The patentee had written a letter to another company offering to license the drug. The letter suggested that the companies would partner in testing and eventually marketing the drug. The price would be determined by market conditions when and if the drug went on sale. The Federal Circuit concluded that the on-sale bar did not apply. The court noted that the letter was not an offer to sell the patented drug, but rather an "opportunity to become [a] partner in the clinical testing and eventual marketing of [the drug] at some indefinite point." Id. at 1341. The court reasoned that "[t]he [alleged offer] lacked any mention of quantities, time of delivery, place of delivery, or product specifications beyond the general statement that the potential product would be a 500 mg once-daily tablet containing naproxen." Id.

Here, as in Elan, the 1995 Supply Agreement joined Unimed and Besins as "partner[s] in the clinical testing and eventual marketing of [a testosterone replacement drug] at some indefinite point." Id. at 1341. Indeed, at the time they entered into the 1995 Supply Agreement, neither Besins nor Unimed had invented AndroGel. Even when AndroGel was invented, all sales were explicitly contingent upon Besins "hav[ing] complied with all relevant requirements from the appropriate Government Agencies to Manufacture and sell the Product in the respective jurisdiction (e.g., for sales of Product in the United States, UNIMED shall have

obtained FDA approval . . . under the NDA)" [Doc. 587-87, § 2.3]. As in Elan, "[t]he [1995 Supply Agreement] lacked any mention of quantities, time of delivery, place of delivery, or product specifications." Elan, 366 F.3d at 1341. Also as in Elan, the 1995 Supply Agreement did not specify a price for any potential sale. Thus, despite being issued after Solvay filed suit, Elan shows it was not objectively baseless for Solvay to contend that the on-sale bar did not invalidate the '894 Patent. See In re Terazosin, 335 F. Supp. 2d at 1360-61 (finding that legal argument "was a stretch, [but] it did not exceed the pale of an aggressive attempt to extend the existing law, and thus was not objectively baseless.").

e. Prior Public Use

The Plaintiffs contend that it was objectively baseless to argue that AndroGel was not in public use before the critical date, August 30, 1999.[14] The Plaintiffs argue that AndroGel was reduced to practice more than one year before Solvay applied for a patent because the AndroGel placebo was available for over a year before Solvay sought the patent. In general, a patent is invalid if "the invention was . . . in public use . . . more than one year prior to the date of the application for patent in the United

[14]The Plaintiffs do not argue that the clinical trial of AndroGel constituted an invalidating public use. (See Direct Purchaser Pls.' Resp. in Opp'n to Par/Paddock's Mot. for Summ. J. on Objective Baselessness, at 24 n.25; Direct Purchaser Pls.' Resp. in Opp'n to Solvay's Mot. for Summ. J. on Objective Baselessness, at 68.) Neither do the Plaintiffs argue that the '894 Patent was invalid due to obviousness. (Id.)

States." 35 U.S.C. § 102(b). "A public use under Section 102(b) includes any public use of the claimed invention by a person other than the inventor who is 'under no limitation, restriction, or obligation of secrecy to the inventor.'" Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 655 F.3d 1364, 1377 (Fed. Cir. 2011) (quoting Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1325 (Fed. Cir. 2009)). Since the AndroGel placebo did not include the active ingredient, testosterone, the Plaintiffs do not contend that AndroGel itself was publicly used.[15] Rather, the Plaintiffs assert that public use of the AndroGel placebo, along with public information in the prior art, made AndroGel obvious to a person of ordinary skill.

The Plaintiffs cite several instances in which AndroGel placebo was publicly distributed. (See Pls.' Resp. in Opp'n to Solvay's Mot. for Summ. J. on Objective Baselessness, at 70-73.) The placebo was allegedly applied to physicians, distributed at conferences, and shown in a Petri dish on television. Although these public uses of AndroGel did not teach its formulation, the Plaintiffs contend that these public uses inherently disclosed the formulation of the AndroGel placebo. Also, the Plaintiffs contend that in 1998, Solvay published that AndroGel was a "1% hydroalcoholic gel preparation of testosterone (T)." (Id. at 71.) Thus, the Plaintiffs contend that it would

[15]Nor do the Plaintiffs contend that the public uses of AndroGel placebo anticipated AndroGel. (See Pls.' Resp. in Opp'n to Solvay's Mot. for Summ. J. on Objective Baselessness, at 72.)

be obvious to someone skilled in the art to combine these instances of prior art to create the formulation for AndroGel.

In the obviousness context, inherent properties of prior art are relevant only where "that inherency would have been obvious to those skilled in the art when the invention . . . was made." Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1576 (Fed. Cir. 1986); see also DONALD S. CHISUM, CHISUM ON PATENTS § 5.03[3][a][i][A] ("An inherent feature may be relied upon to establish obviousness only if the inherency would have been obvious to one of ordinary skill in the art."); In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993)(quoting In re Spormann, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966)) ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."). "Inherency and obviousness are distinct concepts." Kloster, 793 F.2d at 1576.

Here, Solvay had a reasonable argument that the inherent properties in the AndroGel placebo were not obvious based on prior public use. AndroGel placebo was supplied to physicians, distributed at conferences, and shown in a Petri dish on television. From these prior uses, the composition of AndroGel placebo arguably would not "have been obvious to those skilled in the art when the invention . . . was made." Kloster, 793 F.2d at 1576. It would therefore not have been obvious to someone skilled in the art to combine the inherent and untaught formulation for

AndroGel placebo with 1% testosterone. For this reason, a reasonable litigant could have expected some chance that the '894 Patent was not invalid based on prior public use.

2. Subjective Motivation

All parties have moved for summary judgment as to the Defendants' subjective motivation in the Underlying Litigation. "Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation." PRE, 508 U.S. at 60. Here, as discussed above, the Court has concluded that the Underlying Litigation was not objectively baseless. Thus, the Court need not examine the Defendants' subjective motivations.

B. Substantive Antitrust Claims

"Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim." PRE, 508 U.S. at 61. As discussed above, however, the Court has concluded the Underlying Litigation was not objectively baseless. For this reason, Par/Paddock's Motion for Summary Judgment on the Plaintiffs' Substantive Antitrust Claims is moot.

C. Dr. Norman Weiner's Expert Report[16]

[16] On September 14, 2012, during the motion hearing, the Court made an oral ruling denying Motion to Exclude Portions of Dr. Norman Weiner's Expert Report [Doc. 598] and denying Motion to Strike the Declaration of Joseph A. Mahoney and

The Plaintiffs have moved to exclude portions of Dr. Norman Weiner's Report. Under Federal Rule of Evidence 702, "before admitting expert testimony a court must consider: (1) whether the expert is qualified to competently testify regarding the matters he intends to address; (2) whether the methodology used to reach his conclusions is sufficiently reliable; and (3) whether the testimony is relevant, in that it assists the jury to understand the evidence or determine a fact in issue." Watt v. Butler, 744 F. Supp. 2d 1315, 1319 (N.D. Ga. 2010) (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589 (1993)).

First, the Plaintiffs contend that during his deposition, Dr. Weiner conceded that the gel state is a basic and novel property of the invention described in the '894 Patent. The Plaintiffs argue that this concession contradicts Dr. Weiner's expert report [see Doc. 598, at 9]. Dr. Weiner's alleged inconsistency,[17] however, is not grounds to exclude his opinion under Daubert or Rule 702. Rather, contradictory expert testimony is grounds for cross-examination, not exclusion. See Janopoulos v. Harvey L. Walner & Assocs., Ltd., 866 F. Supp. 1086, 1096 (N.D. Ill. 1994) ("[D]iscrepancies in [expert's] testimony and declaration go to the weight rather than

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Limit Dr. Stanley Kaplan's Testimony [Doc. 708]. Sections C, D, and E of this Order are consistent with the Court's ruling.

[17]For purposes of this motion, the Court need not decide whether Dr. Weiner's deposition testimony does, in fact, contradict his expert report.

the admissibility of his opinions."). Indeed, the Plaintiffs do not explain how this inconsistency affects Dr. Weiner's qualifications or methodology. Nor do the Plaintiffs show that Dr. Weiner's opinion on this issue is irrelevant. Thus, Dr. Weiner's testimony regarding the basic and novel properties of the '894 Patent is admissible.

Next, the Plaintiffs argue that Dr. Weiner's writings are inconsistent with his expert report regarding the effect of water in AndroGel. As discussed above, any such inconsistency may be the subject of cross examination, but does not justify exclusion under Daubert and Rule 702.

Finally, the Plaintiffs contend that Solvay's admissions in the Underlying Litigation render Dr. Weiner's testimony inadmissible. Specifically, the Plaintiffs argue that Solvay conceded that the term "sodium hydroxide" in the '894 Patent means *pure* sodium hydroxide. Again, the Plaintiffs' argument fails to address any of the three grounds for exclusion under Daubert. Solvay's allegedly inconsistent position affects the credibility, not the admissibility, of Dr. Weiner's opinion. For these reasons, the Plaintiffs' Motion to Exclude should be denied.

D. Joseph Mahoney's Declaration

The Plaintiffs have moved to strike the declaration of Joseph Mahoney [see Doc. 708]. Mr. Mahoney was Solvay's patent counsel in the Underlying Litigation.

Mr. Mahoney's declaration "purports to express Solvay's counsel's analysis regarding Solvay's decision to apply for a Certificate of Correction . . . and also recites statements that the Patent Examiner allegedly made to Mr. Mahoney agreeing with his purported analysis." (Pls.' Mot. to Strike the Declaration of Joseph A. Mahoney and Limit Dr. Stanley Kaplan's Testimony, at 1.) The Plaintiffs argue that the Defendants should not be allowed to use the impressions of Solvay's counsel while invoking the protections of the attorney-client privilege. The Plaintiffs also assert that Mahoney's declaration includes inadmissible hearsay. Finally, the Plaintiffs contend that Watson and Solvay failed to identify Mahoney in accordance with Federal Rule of Civil Procedure 26.

The Court, however, does not rely on Mahoney's declaration–or the opinions of the PTO examiner–in deciding whether the Underlying Litigation was a sham. Clearly the PTO examiner believed that his interpretation of the '894 Patent was not objectively baseless. Further, the opinions of the PTO examiner are accounted for by the presumption that a patent is valid and that patent examiners act properly. See Superior Fireplace, 270 F.3d at 1367 n.1 (noting that presumption of patent validity "is related to the presumption that the PTO does its job properly."). Thus, the Plaintiffs' request to strike Mahoney's testimony is moot.

E. Dr. Stanley Kaplan's Testimony

The Direct Purchaser Plaintiffs seek to limit the testimony of Dr. Stanley Kaplan, the Indirect Purchaser Plaintiffs' expert witness. Specifically, the Direct Purchaser Plaintiffs assert that Dr. Kaplan conceded several points relevant to objective baselessness. The Direct Purchaser Plaintiffs contend that such concessions should be used *only* against the Indirect Purchaser Plaintiffs. The Court's objective baselessness inquiry, however, does not rely on the testimony of Dr. Kaplan. For this reason, the Direct Purchaser Plaintiffs' motion is moot.

IV. Conclusion

For the reasons set forth above, the Court GRANTS Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Objective Baselessness [Doc. 555], DENIES AS MOOT Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Improper Subjective Motivation [Doc. 567], DENIES AS MOOT Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion for Summary Judgment on Plaintiffs' Substantive Antitrust Claims [Doc. 574], GRANTS Watson Pharmaceuticals, Inc.'s Motion for Summary Judgment on Plaintiffs' Conspiracy Claims for Lack of Subjective Bad Faith [Doc. 579], GRANTS Solvay Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc., and Abbott Products, Inc.'s Motion for Summary Judgment on Objective Baselessness [Doc. 587], DENIES AS

MOOT Solvay Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc., and Abbott Products, Inc.'s Motion for Summary Judgment on Subjective Bad Faith [Doc. 589], DENIES the Direct Purchaser Plaintiffs' Motion to Exclude Portions of Dr. Norman Weiner's Expert Report [Doc. 598], DENIES the Direct Purchaser Plaintiffs and End-Payor Class Plaintiffs' Motions for Summary Judgment on Sham Litigation [Docs. 603 & 588], and DENIES AS MOOT the Direct Purchaser Plaintiffs' Motion to Strike the Declaration of Joseph A. Mahoney and Limit Dr. Stanley Kaplan's Testimony [Doc. 708].

SO ORDERED, this 28 day of September, 2012.

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