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

FEDERAL TRADE COMMISSION, Plaintiff, v. WATSON PHARMACEUTICALS, INC. PAR PHARMACEUTICAL COMPANIES, INC. PADDOCK LABORATORIES, INC., and SOLVAY PHARMACEUTICALS, INC., Defendants.	**Case No. 1:09-cv-955-TWT**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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Eleventh Circuit precedent requires dismissal of the FTC's complaint. In *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005), the Eleventh Circuit held that a final settlement of a good-faith patent dispute does not violate the antitrust laws as long as the patent was not procured by fraud and the conduct prohibited under the settlement falls within the exclusionary scope of the patent. In this case, the FTC challenges as anti-competitive two settlement agreements reached after three years of patent litigation in this Court. But the FTC does ***not*** allege that the underlying patent was fraudulently obtained, that the ensuing litigation was anything other than a bona fide dispute, or that the conduct prohibited under the settlement agreements extends beyond the patent's exclusionary scope. As the FTC's now-Chairman has frankly acknowledged, the type of settlement that the FTC contends occurred here is "legal in the Eleventh Circuit."[1] Chairman Leibowitz is plainly correct—*Schering-Plough* leaves no room for doubt—which explains why the FTC initially fled this Circuit and filed this lawsuit in California.

[1] Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 110th Cong. 53 (2007) (statement of Jon Leibowitz, Comm'r, FTC), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_ house_hearings&docid=f:38992.pdf.

Thus, as explained in more detail below, the complaint should be dismissed with prejudice.

I. FACTUAL BACKGROUND

A. The '894 Patent and FDA Approval of AndroGel®

In 1995, prior to its acquisition by Solvay, Solvay subsidiary Unimed Pharmaceuticals partnered with Laboratoires Besins Iscovesco to develop a novel drug treatment for low testosterone levels in males, a condition known as hypogonadism. Their development efforts resulted in AndroGel®, the first testosterone-gel product approved by the Food and Drug Administration. (*See* Second Am. Compl. ("SAC") ¶¶ 31-33.)

Unimed filed a New Drug Application ("NDA") for AndroGel® in April 1999, which the FDA approved on February 28, 2000. (SAC ¶ 33.) The FDA also awarded Unimed three years of statutory exclusivity with its NDA.[2] This meant that for three years after approval, the FDA would not approve any Abbreviated New Drug Application ("ANDA") for AndroGel® under the Hatch-Waxman Act.[3]

By the end of 2000, AndroGel® sales had exceeded Unimed's sales projections, and the product was the preferred treatment for hypogonadism among

[2] 21 C.F.R. § 314.108(b)(4) (2009).

[3] Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of titles 21 and 35 of the U.S. Code).

many patients. Unimed filed a patent application for the AndroGel® formulation on August 30, 2000 (U.S. Patent Application No. 09/651,777), which issued as U.S. Patent No. 6,503,894 ("the '894 Patent") on January 7, 2003. (SAC ¶¶ 39, 42.) The '894 Patent expires on August 30, 2020, but the FDA has awarded Unimed pediatric exclusivity through March 1, 2021. (SAC ¶ 43.)

B. The Underlying Infringement Litigation and the Settlements

In May 2003, Watson Pharmaceuticals, Inc. through a wholly-owned subsidiary, and Paddock Laboratories, Inc. independently filed ANDAs with the FDA to market generic AndroGel®. (SAC ¶ 44.) Their ANDAs included "Paragraph IV" certifications that the '894 Patent was invalid and that their respective ANDA products did not infringe it. (*Id*.) By filing before Paddock, Watson received a 180-day period of marketing exclusivity, during which the FDA would not approve any other ANDA with a Paragraph IV certification regarding AndroGel®. (SAC ¶ 45.)

In August 2003, Unimed sued Watson, Paddock, and Paddock's ANDA partner, Par Pharmaceutical Companies, Inc., for patent infringement in the Northern District of Georgia. (SAC ¶ 47.) Because Unimed sued within 45 days of receiving the Paragraph IV certifications, Unimed triggered statutory 30-month stays of the FDA's final approval of the ANDAs. (*Id*.) These 30-month stays

expired in January 2006. (*Id*.)

The parties vigorously litigated both infringement cases for three years. The parties conducted extensive discovery, submitted claim-construction briefs, and filed motions for partial summary judgment. While those motions were pending, the parties negotiated settlement agreements. (SAC ¶¶ 65, 76.) Under the settlement agreements, Watson and Par/Paddock each obtained licenses to market their generic versions of AndroGel® starting August 31, 2015, which is more than five years prior to the expiration of the '894 Patent. (SAC ¶ 76.) In addition, Watson relinquished its 180-day marketing exclusivity. For reasons more fully discussed below, this addressed competitive concerns raised by Eleventh Circuit cases by removing a barrier that would otherwise have prevented other generic manufacturers from challenging the '894 Patent.

On September 14, 2006, this Court entered a Stipulation of Dismissal in the case against Watson and a Consent Judgment and Order of Permanent Injunction ("Consent Judgment") in the case against Par/Paddock. Stipulation of Dismissal, Dkt. No. 174, *Unimed Pharms., Inc. v. Watson Pharms., Inc.*, No. 1:03-cv-2501 (N.D. Ga. filed Sept 14, 2006); Consent J. and Order of Permanent Inj., Dkt. No. 131, *Unimed Pharm., Inc. v. Paddock Labs., Inc.*, No. 1:03-cv-2503 (N.D. Ga. filed Sept. 15, 2006). The Par/Paddock Consent Judgment decrees, among other

things, that the '894 Patent is valid and that Paddock's ANDA product would infringe it.

In conjunction with the two settlement agreements, Solvay also entered into separate contracts with a Watson subsidiary, Watson Pharma, Inc., and with Par. Under Solvay's contract with Watson, Watson agreed to dedicate substantial resources to marketing AndroGel® to urologists (SAC ¶ 66), a vital physician segment that Solvay's sales force could not service efficiently, and for which Watson already maintained a substantial sales force. Watson agreed to promote AndroGel® to urologists in return for a percentage share of the actual profits derived from the sales to those physicians. (*Id.*) Under Solvay's contract with Par, Par promotes AndroGel® to primary-care physicians. (SAC ¶ 77.) In addition, Solvay and Par agreed that Paddock would serve as a backup manufacturer for AndroGel®, protecting Solvay against supply disruptions at Besins, which is located in France and was previously the only source of AndroGel®. (*Id.*)

C. The FTC's Response to *Schering-Plough*

At the time the parties were settling the patent suits, the FTC was already searching for a new case to correct what it believed was an erroneous ruling by the Eleventh Circuit. On December 18, 2003, the FTC in an administrative proceeding had held that two agreements settling patent litigations, entered into by Schering-

Plough Corporation ("Schering") and two generic pharmaceutical companies, violated Section 5 of the FTC Act. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 973 (2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005). Respondents appealed the Commission's decision to the Eleventh Circuit, which vacated the Commission's decision. *Schering-Plough Corp. v. F.T.C.*, 402 F.3d at 1073.

Recognizing that the Eleventh Circuit's decisions in *Schering-Plough* and *Valley Drug Co. v. Geneva Pharmaceuticals, Inc*, 344 F.3d 1294 (11th Cir. 2003), would "preclude[] meaningful Commission review of patent settlements"[4] and create "a virtual *per se* rule of legality for such payments as long as generic entry isn't delayed beyond the full patent term,"[5] the FTC urged the Supreme Court to grant certiorari, but the Supreme denied the FTC's petition. Pet. for Writ of Cert., *F.T.C. v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273).

Less than one month later, then-Commissioner Leibowitz testified at a Senate Hearing that, under Eleventh Circuit law, reverse-payment settlements "are legal unless the patent was obtained by fraud or . . . the infringement suit itself was a sham." The Generic Drug Maze: Speeding Access to Affordable, Life Saving

[4] Reply Brief for Pet'r at 9, *Schering-Plough*, 402 F.3d 1056 (No. 05-273), 2005 WL 2652617.

[5] Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!, Remarks at In-House Counsel's Forum on Pharmaceutical Antitrust, at 1, 3-4 (Apr. 24, 2006) (statement of Jon Leibowitz, Comm'r, FTC), *available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

Drugs, Hearing Before the S. Special Comm. on Aging, 109th Cong. 14 (2006) (statement of Jon Leibowitz).[6]

Characterizing the Eleventh Circuit's decision as "misguided," the FTC has since then publicly denounced the *Schering-Plough* decision and all circuit court opinions consistent with it. Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing Before the H. Subcomm. on Courts and Competition Policy Comm. on the Judiciary, 111th Cong. 6 (2009) (statement of Richard A. Feinstein, Dir. of FTC's Bureau of Competition)[7] ("The Commission believes that the courts' permissive approaches in *Cipro*, *Tamoxifen*, and *Schering* are misguided . . . ").

The FTC has testified before Congress that it is "public knowledge" that the FTC will continue to pursue patent litigation settlement cases because it is "looking to bring a case that will create a clearer split in the circuits." Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited? Hearing Before the S. Comm. on the Judiciary, 110th Cong. 8 (2007)

[6] *Available at* http://aging.senate.gov/events/hr161jl.pdf.

[7] *Available at* http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf.

(statement of Jon Leibowitz);[8] *see, e.g.,* FTC Litigation at the Antitrust/Intellectual Property Interface, at 3 (Apr. 26, 2007) (remarks of J. Thomas Rosch, Comm'r, FTC)[9] ("The Commission is hopeful that the Supreme Court will review and reverse *Tamoxifen* in a fashion that will discredit *Schering*.").

D. The FTC's Claims

On January 27, 2009, the FTC and the Attorney General of the State of California instituted this action by filing a complaint against Solvay, Par, Paddock, and Watson in the Central District of California. On April 9, 2009, U.S. District Court Judge Mariana R. Pfaelzer transferred the FTC's case here. *FTC v. Watson Pharms., Inc.*, No. 1:09-cv-955 (Dkt. # 71) (N.D. Ga. entered Apr. 8, 2009).

At bottom, the FTC alleges that under the Defendants' settlement agreements and business arrangements entered at the same time, Solvay paid Watson and Par/Paddock disguised compensation to induce them to delay their entry into the AndroGel® market. (SAC ¶¶ 4-6.) But even if that characterization—which Defendants vigorously dispute—is assumed to be true for purposes of this motion, it is immaterial. As explained below, "reverse payments" are plainly permissible under binding Eleventh Circuit law.

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[8] *Available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110senate_hearings&docid=f:33401.pdf.

[9] *Available at* http://www.ftc.gov/speeches/rosch/070426si_pharma.pdf.

E. This Court's Order Allowing Further Amendment of the FTC Complaint

Having received leave to do so, the FTC filed a Second Amended Complaint on May 28, 2009. In contrast to the prior complaints, the Second Amended Complaint drops the State of California as a plaintiff and omits all reference to California law. The complaint also no longer seeks relief under the Sherman Act, and instead asserts a claim only under Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(a).

The gravamen of the complaint, however, remains the same. According to the FTC, the agreements in question supposedly constitute unfair methods of competition (SAC ¶¶ 106-08) and Solvay allegedly engaged in unlawful monopolization (SAC ¶¶ 109-11). The only new factual allegations offered in support of those claims are (i) additional detail about a single, internal Solvay document collected by the FTC in its two-year investigation and (ii) if Solvay had settled with Watson alone, that Par/Paddock would have had an incentive to continue to litigate the Solvay patent dispute even after Watson had settled. (SAC ¶¶ 57, 95.)

The Second Amended Complaint, the subject of this motion, is most notable for what it does not allege: It does not allege that the '894 Patent was obtained by fraud. It does not allege that the Defendants' three-year litigation over the '894

Patent was a sham. And it does not allege that their subsequent settlement agreements prohibit conduct beyond the exclusionary potential of the '894 Patent.

II. ARGUMENT

A. Patent Settlements Are Lawful If Any Alleged Anticompetitive Effects Do Not Exceed the Scope of An Objectively Reasonable Patent Claim

The Eleventh Circuit, like each of the other circuits to have addressed the issue, has squarely held that a final patent settlement between pioneer and generic drug companies, even one that contains a so-called "reverse payment," does not violate the antitrust laws so long as any exclusion produced by settlement is "no more broad than the patent's own exclusionary power." *Schering-Plough*, 402 F.3d at 1064, 1075-76. The FTC itself has asserted as much in the Supreme Court, arguing that under the law of the Eleventh Circuit "settlements within the outer, nominal bounds of patent claims are presumed lawful." *See* Pet. for Writ of Cert., at 15, *Schering-Plough*, 548 U.S. 919 (No. 05-273), 2005 WL 2105243.

The Eleventh Circuit first addressed reverse-payment settlements in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). Reversing a finding of *per se* illegality, the court recognized that patents confer a "lawful right to exclude others," *id.* at 1304, and the plaintiffs had not alleged that the patent "was procured by fraud, that [the patentee] knew the patent was invalid,

[or] that there was no objective basis to believe that the patent was valid." *Id.* at 1306 n.19.[10] The court held that so long as the settlements' terms remained within the exclusionary rights claimed under the patent, "traditional antitrust analysis" would not apply. *Id.* at 1312-13 & n.29. The "reverse payments" themselves worked no exclusion because "[t]he failure to produce the competing . . . drug, rather than the payment of money, is the exclusionary effect." *Id.* at 1309.

A few months later, in reaching its *Schering-Plough* decision, the FTC ignored *Valley Drug*'s holding as to reverse payments and enjoined a patent holder's settlements with two generic challengers as unreasonable restraints of trade under Section 5 of the FTC Act. *See In re Schering-Plough*, 136 F.T.C. 956 (2003). Vacating the FTC's decision, the Eleventh Circuit held that the settlements could yield no anticompetitive effects so long as the exclusion they produced were "no more broad than the patent's own exclusionary power." 402 F.3d at 1064. Thus, the presence of a reverse payment "should not dictate the availability of a settlement remedy." *Id*. at 1075. That the generic manufacturers had claimed not to infringe the patent did not matter: without an allegation that "the infringement suits . . . were 'shams,'" *id*. at 1068, the patentee should be in no "worse position,

[10] Even though the patent was later declared invalid in a separate challenge, *Valley Drug*, 344 F.3d at 1301, the Eleventh Circuit held that "the appropriate antitrust analysis" must be measured as of the time of settlement. *Id*. at 1307.

by virtue of the patent right, to negotiate and settle surrounding lawsuits" on terms entirely "within the patent's exclusionary power." *Id*. at 1072.

In *Andrx Pharmaceuticals, Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1235 (11th Cir. 2005), the Eleventh Circuit reaffirmed that patent infringement settlements are lawful as long as they do not exceed the scope of the exclusionary potential of the patent. Having found that the underlying infringement litigation was not a sham, the court held that an antitrust claim challenging the settlement of that litigation required proof of (1) the scope of the patent's exclusionary potential; (2) the extent to which the settlement agreement exceeded that scope; and (3) the resulting anticompetitive effects in the relevant market. *Id.* (citing *Schering-Plough*, 402 F.3d at 1066). Significantly, in *Andrx,* unlike *Schering-Plough* and *Valley Drug*, the complaint alleged that the combination of a licensing agreement and the generic defendant's agreement never to launch its ANDA product manipulated the generic manufacturer's 180-day exclusivity period to block other competitors from entering. This, the court held, "would exceed the scope of exclusion intended by the [patent in suit]." *Andrx*, 421 F.3d at 1235. Consequently, the court reversed judgment on the pleadings for the defendants as to the settlement agreement. *Id.* at 1237; *see* Pet'rs Reply Br. at 9 n.6, *Schering-Plough*, 548 U.S. 919 (No. 05-273), 2005 WL 2652617 (brief of FTC noting that

Andrx "is premised on the acceptance (at the dismissal stage) of allegations that the patentee and generic entrant conspired to use the generic's 180-day exclusivity period to block other competitors from ever marketing a generic version of the drug in question") (internal quotation marks omitted). The manipulation of the 180-day exclusivity that distinguished *Andrx* from *Schering-Plough* and *Valley Drug* is notably absent here where Watson explicitly agreed to abandon its 180-day exclusivity period as part of its settlement with Solvay.

Taken together, *Valley Drug*, *Schering-Plough*, and *Andrx* make clear that under binding Eleventh Circuit law a settlement of a Hatch-Waxman patent suit does not violate the antitrust laws unless (1) the settlement delays generic entry beyond the end of the patent life or extends the patent's scope by restraining unrelated or non-infringing products; (2) the underlying patent was obtained through fraud on the Patent & Trademark Office; or (3) the patent litigation was a sham. *See Schering-Plough*, 402 F.3d at 1068, 1072-73; *Valley Drug*, 344 F.3d at 1306-07 nn.18-19, 1312; *Andrx,* 421 F.3d at 1234-35. If each of these questions is answered in the negative, then no further inquiry is appropriate because patents "[b]y their nature . . . create an environment of exclusion." *Schering-Plough*, 402 F.3d at 1065-66; *accord Valley Drug*, 344 F.3d at 1311 n.27.

That this robust body of law bars suits like the present one in the Eleventh

Circuit is not lost on the FTC.[11] Indeed, when seeking certiorari in *Schering-Plough*, the FTC conceded that "the combined effect of the court of appeals' decisions [in *Schering-Plough*] and in *Valley Drug* precludes meaningful Commission review of patent settlements." Reply Brief for Petitioner at 9, *Schering-Plough*, 548 U.S. 919 (No. 05-273), 2005 WL 2652617.

Nor does the Eleventh Circuit stand alone on this issue. Both the Second and Federal Circuits, the only other circuits to have ruled on the antitrust analysis of final patent settlements, have rejected as a matter of law antitrust claims challenging settlements of bona fide patent litigation that do not impose exclusions beyond the scope of the patent at issue. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335-36 (Fed. Cir. 2008), *cert. denied*, 2009 WL 1738658 (U.S. June 22, 2009); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007).[12] No circuit

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[11] *See* Hearing Before the S. Special Comm. On Aging, 109th Cong. (2006) (statement of Jon Leibowitz) describing *Schering-Plough* as holding that reverse payment settlements "are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham"), *available at* http://www.aging.senate.gov/events/hr161jl.pdf; FTC Litigation at the Antitrust/Intellectual Property Interface, at 3 (Apr. 26, 2007) (remarks of J. Thomas Rosch, Comm'r, FTC), *available at* http://www.ftc.gov/speeches/rosch/070426si_pharma.pdf ("Under *Schering* at least, the viability of many, if not all, challenges to patent abuses turns on whether or not 'the exclusionary effects of the agreement fall within the scope of the patent's protection.'").

[12] *See also In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *27-

addressing final patent settlements has held to the contrary.

The FTC evidently believes that the Eleventh Circuit, and the Second and Federal Circuits, have decided the issue presented in this case wrongly. *See supra* pp. 5-8. It was, presumably, the FTC's recognition of Eleventh Circuit precedent and the FTC's desire to create a circuit split that led the FTC to file this case in the Central District of California. Because the Ninth Circuit has yet to rule on the issue, the FTC hoped by filing there to avoid binding precedent that doomed its claim, and simultaneously to generate a circuit split.[13]

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*30 (D.N.J. Feb. 6, 2009) (report and recommendation of special master) (applying "an analysis consistent with the approach that has been adopted by the Second, Eleventh and Federal Circuits" in analyzing a Hatch-Waxman settlement involving an alleged reverse payment, and recommending summary judgment for defendants); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003) (Posner, J., by designation) ("[W]hether [the theory opposing reverse-payment patent settlements] is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent"; moreover, if "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation."); Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 619 (2005-2006) ("Accordingly, it may be that antitrust can do no better in handling the settlement issue than the 'sham' standard suggested by Judge Posner in *Asahi Glass* . . . .") (quoting *Asahi Glass,* 289 F. Supp. 2d at 993).

[13] Notably, however, as Defendants stated in their motion to dismiss before Judge Pfaelzer, the FTC's claims would have failed in the Ninth Circuit as well. *See Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1216 (9th Cir. 1997) (holding that when "a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws") (internal quotation marks omitted); *United States v. Westinghouse Elec.*

But the fact remains that under binding Eleventh Circuit law, the SAC's allegations, even if true, do not state a claim under the antitrust laws.

1. The FTC Does Not Allege That the AndroGel® Settlements Have Anticompetitive Effects Beyond the Scope of the '894 Patent's Claims

As noted above, a Hatch-Waxman settlement may be found to violate the antitrust laws if it imposes an exclusion greater than that contained in the patent at issue. Here, however, there is no such allegation.

In *Andrx*, where the Eleventh Circuit addressed an antitrust challenge to a Hatch-Waxman settlement at the pleadings stage, the Eleventh Circuit determined the "scope of the exclusionary potential of the patent" by reference to the patent's claims. *Andrx*, 421 F.3d at 1235-36; *accord Schering-Plough*, 402 F.3d at 1066, 1073. The Eleventh Circuit looked only to the patent's nominal scope, *despite* the complaint's express claim that the patent holder knew the patent to be invalid when the infringement suits were initiated. *Andrx*, 421 F.3d at 1235 (citing Andrx's First Am. Compl. ¶¶ 22-23, 33-35); *see also* First Am. Compl. ¶ 35, *Andrx Pharms., Inc. v. Elan Corp. PLC*, No. 1:00-cv-03481, Dkt. No. 3 (S.D. Fla. filed Mar. 28,

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Corp., 648 F.2d 642, 647 (9th Cir. 1981) (holding that no "antitrust violation may be found where a patent holder does precisely that which the patent laws authorize"); *Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979) (holding that claim against patent settlement failed because plaintiff had not shown that the patent holder "had any intent to use its patent as a tool to extend its property rights beyond the claims of the [] patent").

2001).

Here, the SAC alleges that Solvay and Besins applied for a U.S. patent "relating to AndroGel®" that claimed a particular pharmaceutical gel formulation containing testosterone and other specified ingredients in certain amounts (SAC ¶ 39), that the patent was issued as the '894 Patent (SAC ¶ 42), and that the Generics had filed ANDAs for approval to market "a generic version of AndroGel®." (SAC ¶ 44.) As in *Andrx*, then, the SAC's allegations demonstrate that the '894 Patent is necessary to the manufacture and sale of AndroGel®, and that Solvay and Besins, as the patent holders, had the right to exclude competitors from manufacturing or selling generic versions of AndroGel®.[14] Moreover, as in *Andrx* the Court need not consider the SAC's allegations that the '894 Patent itself was "unlikely to prevent generic entry" when determining the scope of the exclusionary potential of the patent. (SAC ¶ 3.)

The SAC does not allege that the settlements restrain trade in any non-

[14] Indeed, had Solvay prevailed in its patent suits against Watson and Paddock, it would have obtained injunctions against copying AndroGel® "until after the expiration of the '894 Patent" in 2021. Am. Compl. at 6, *Unimed Pharms., Inc. v. Watson Pharms., Inc.*, No. 1:03-cv-2501, Dkt. No. 3 (N.D. Ga. Aug. 22, 2003); Am. Compl. at 6, *Unimed Pharms., Inc. v. Paddock Labs., Inc.*, No. 1:03-cv-2503, Dkt. No. 4 (N.D. Ga. Aug. 22, 2003). The settlements challenged here in fact permit Watson and Par/Paddock to enter in 2015, five-and-a-half years before the patent expires. Notably, other courts have upheld alleged reverse-payment Hatch-Waxman settlements that lasted until the very expiration of the patent. *See, e.g.*, *In re Ciprofloxacin*, 544 F.3d at 1328-29; *In re Tamoxifen*, 466 F.3d at 193-94.

infringing products. According to the SAC, the settlements restricted Watson and Par/Paddock only from "marketing generic AndroGel®." (SAC ¶¶ 65, 76.) *See also Andrx*, 421 F.3d at 1235 (generic product is within the exclusionary scope of the patent if the patent is "necessary to the manufacture and sale" of the drug). By excluding these generic copies, the settlements restrain trade only in the products covered by the '894 Patent, and thus do not create any anticompetitive effects outside the '894 Patent's exclusionary zone. Thus, Defendants have established that the settlements are within the scope of Solvay's Patent, regardless of whether the patent suits focused on validity or infringement. *See Schering-Plough*, 402 F.3d at 1075 ("An exception cannot lie, as the [FTC] might think, when the issue turns on validity . . . as opposed to infringement . . . ."). The SAC also does not allege that the settlements extend the patent rights beyond the Patent's expiration in 2020, since the settlements allow entry in 2015. (SAC ¶¶ 43, 76.)

Finally, in contrast to the complaint in *Andrx*, the SAC also does not allege any agreement to manipulate Watson's 180-day marketing exclusivity so as to prevent subsequent generic entry—nor could it, since Watson relinquished its marketing exclusivity as part of the settlement.

2. The SAC Does Not Allege That Unimed Obtained the Androgel® Patent Through Fraud

To avoid *Schering-Plough* and the inevitable dismissal of its complaint, the FTC might have attempted to allege that the '894 Patent was obtained through fraud, if the facts had supported such an allegation. To show fraud in the procurement of a patent, a plaintiff must demonstrate that: (1) the patentee obtained a patent by knowingly and willfully misrepresenting the facts to the PTO; (2) the patentee obtained a patent with independent and clear evidence of an intent to deceive; and (3) the patent would not have issued but for the misrepresentation or omission. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-72 (Fed. Cir. 1998). The allegations of fraud must be pleaded with specificity. Fed. R. Civ. P. 9(b); *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed. Cir. 2005), *rev'd on other grounds*, 549 U.S. 118 (2007).

But the FTC does not, and cannot, allege that the '894 Patent was procured by fraud. Nowhere does the FTC allege that Solvay or Unimed made any false material statement to the Patent and Trademark Office, much less that either firm did so fraudulently. The FTC does allege that during the course of the patent litigation Watson claimed that Solvay and Besins "did not disclose their 1995 commercial supply agreement to the patent examiner" (SAC ¶ 89), but the FTC does not claim that such an omission would have amounted to fraud—an argument Watson itself never advanced in the underlying patent litigation.

3. The FTC Does Not Allege That Unimed Lacked an Objective Basis for Its Infringement Suits Against the Generics' ANDA Products

The FTC also fails to allege that Solvay engaged in sham enforcement of the '894 Patent. A lawsuit is a "sham" only if "(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 (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993)). The "existence of probable cause to bring a lawsuit is sufficient to thwart a claim that litigation was objectively baseless." *See Prof'l Real Estate Investors*, 508 U.S. at 60 n.5 & 62; *Andrx*, 421 F.3d at 1234.

The SAC nowhere alleges that the patent suits were objectively baseless, nor does it suggest that Solvay believed its suits to lack merit. The SAC falls far short of pleading that "no reasonable litigant could [have] realistically expect[ed] success on the merits." *Prof'l Real Estate Investors*, 508 U.S. at 60. Nor does the SAC allege a subjective bad faith, in other words that Unimed wrongfully brought the underlying patent lawsuit knowing it would lose. *See id.*; *C.R. Bard, Inc. v. M3*

Sys. Inc., 157 F.3d 1340, 1368-69 (Fed. Cir. 1998); *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1560 n.12 (11th Cir. 1992).

B. The Eleventh Circuit's Framework for Analyzing Hatch-Waxman Settlements Applies to FTC Act Claims

The FTC's decision to drop its express reliance on Section 1 of the Sherman Act (in Counts I and II) and Section 2 of the Sherman Act (Count III) in favor of proceeding exclusively under Section 5 of the FTC Act in no way lessens the force of *Schering-Plough* as binding precedent. (*Compare* FAC ¶ 109 *with* SAC ¶ 108.) This is because *Schering-Plough* itself was a Section 5 case. *In re Schering-Plough*, 136 F.T.C. at 961; *see also id*. at 1057 n.107 ("The counts plead a violation of Section 5 of the Federal Trade Commission Act, but the standards for applying Section 5 are, for the most part, co-extensive with the Sherman Act."); *see also Schering-Plough*, 402 F.3d at 1063. The SAC's allegations that Defendants' agreements constituted "unfair method[s] of competition" (Counts I and II) and that Solvay "has willfully maintained its monopoly and excluded competition through its anticompetitive conduct" (SAC ¶ 111, Count III) must therefore similarly be measured under this Circuit's established standard.

This conclusion is consistent with settled law that, when conduct implicates both Section 1 of the Sherman Act and Section 5 of the FTC Act, the analysis under both statutes is the same. *See Cal. Dental Ass'n v. F.T.C.*, 526 U.S. 756, 762

n.3 (1999) ("The FTC Act's prohibition of unfair competition and deceptive acts or practices . . . overlaps the scope of § 1 of the Sherman Act . . . aimed at prohibiting restraint of trade . . . ."); *Polygram Holding, Inc. v. F.T.C.*, 416 F.3d 29, 32-33 (D.C. Cir. 2005) (stating that the Commission "correctly" concluded that the analysis under Section 1 of the Sherman Act and Section 5 of the FTC Act is the same); *N. Tex. Specialty Physicians v. F.T.C.*, 528 F.3d 346, 354-55 (5th Cir. 2008) (discussing the FTC's own analysis that "the definition of 'unfair methods of competition' under the FTC Act . . . is the same as the definition of a 'contract combination . . . or conspiracy, in restraint of trade. . . .' under Section 1 of the Sherman Act"), *cert. denied*, 129 S. Ct. 1313 (2009).

C. Leave to Amend Should Be Denied

The FTC's SAC should be dismissed without leave to amend because the FTC cannot allege other facts to cure its prior failures to state a claim under the antitrust laws. A district court should not allow an amendment where doing so would be an exercise in futility. *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001) (per curiam). Likewise, a court should not allow a party to amend its complaint where that party has repeatedly failed to cure deficiencies by amendments previously allowed. *Id.* at 1163-64.

The FTC has had the benefit of a two-year investigation and two

opportunities to amend its Complaint. The Court allowed the FTC a second opportunity to amend so that the FTC could set forth its best effort to state a claim under Eleventh Circuit law. *Meijer Inc. v. Unimed Pharms., Inc.*, No. 1:09-cv-958 (Dkt # 95) (N.D. Ga. May 1, 2009). Any defects in the FTC's FAC should have been cured by the SAC.

Yet the FTC's SAC still fails to allege—and indeed cannot allege—that (1) the settlements extend beyond the '894 Patent's term or encompass non-infringing products, (2) the '894 Patent was procured by fraud or (3) Solvay enforced the enforced '894 Patent through sham litigation. The SAC is therefore devoid of any allegations that the settlements exceed the exclusionary scope of the '894 Patent's protections. *See In re Tamoxifen*, 466 F.3d at 220-21 (district court did not abuse discretion in denying leave to amend where "in the absence of any plausible allegation that [the patentee's] patent infringement lawsuit was baseless or that the Settlement Agreement otherwise restrained competition beyond the scope of the tamoxifen patent, [plaintiffs'] complaint would fail to state a claim on which relief can be granted").

III. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court enter an order dismissing all of the FTC's claims with prejudice.

Respectfully submitted, this 20th day of July, 2009.

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

FEDERAL TRADE COMMISSION, Plaintiff, v. WATSON PHARMACEUTICALS, INC. PAR PHARMACEUTICAL COMPANIES, INC. PADDOCK LABORATORIES, INC., and SOLVAY PHARMACEUTICALS, INC., Defendants.	**Case No. 1:09-cv-955-TWT**

CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1D, counsel hereby certifies that the foregoing motion and memorandum of law has been prepared in accordance with Local Rule 5.1 using Times New Roman 14 point font.

Respectfully submitted this 20th day of July 2009.

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of July, 2009, a copy of the foregoing **DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT** was served using the CM/ECF system on the following parties:

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