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**

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

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I. INTRODUCTION

Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1066, 1072-73, 1075 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006), the law governing in this Circuit, holds that even where "reverse payments" are present, competitive restrictions in a patent settlement that are no more broad than the patent's own "exclusionary potential" are not illegal. The *Schering-Plough* approach to patent settlements, which has been adopted by every court that has subsequently considered the issue, has been termed the "scope of the patent test." The FTC's Opposition instead attributes this uniformly-adopted test to Defendants, re-labeling it "Defendants' end-of-patent-term standard." Opp'n 2.

Aware that the Second Amended Complaint (SAC) cannot survive application of the scope of the patent test, the FTC urges an unprecedented interpretation of *Schering-Plough* rooted in the claim that *Schering-Plough* did *not* adopt the test. Instead, according to the FTC, *Schering-Plough* permits the FTC to "offer direct evidence of the patent merits in this case." Opp'n 25 n.23.

Of course, the FTC's reading of *Schering-Plough* would turn Eleventh Circuit precedent on its head. The FTC's position stands in stark contrast not only to its own characterization of *Schering-Plough* over the past four years but also to the careful readings of the case conducted by *every* court since it was decided. The

FTC may rail against *Schering-Plough*, but it is still binding authority in this Circuit. The SAC should be dismissed with prejudice.

II. ARGUMENT

A. *Schering-Plough* Governs This Case and Mandates Dismissal.

The Eleventh Circuit in *Schering-Plough* held that courts testing Hatch-Waxman settlements under the antitrust laws must examine: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." 402 F.3d at 1066. As long as the settlement terms are within the "exclusionary potential of the patent," there can be no antitrust liability. *Id.* *See also Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003); *Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1235 (11th Cir. 2005); Defs.' Mot. to Dismiss 10-15 ("Defs.' Mot."). Here, the SAC does not allege that the settlement terms contain restrictions on any product other than generic AndroGel®; the SAC also does not allege that the settlements contain restrictions going past the patent's expiration. Under the "scope of the patent" test, therefore, the SAC must be dismissed. *See* Opp'n 2 ("The primary issue presented by defendants' motions is whether Eleventh Circuit precedent requires this Court to apply this end-of-patent-term standard to the arrangements challenged here.").

B. The FTC's Attempt to Recast Eleventh Circuit Precedent Must Be Rejected.

The FTC now attempts to rehabilitate the SAC by seeking a new interpretation of *Schering-Plough* from this Court: according to the FTC, *Schering-Plough* did not adopt the scope of the patent test, and instead permits an inquiry into the merits of the patent case. Opp'n 14. This is a road to reversible error, given that Defendants' interpretation is supported by all other circuit courts to have interpreted *Schering-Plough*, by the FTC's own prior interpretation of the precedent, and by a careful reading of the Eleventh Circuit precedent itself.

1. *Schering-Plough* Does Not Require an Evaluation of the Patent Merits Before Assessing Antitrust Claims.

The FTC draws from one sentence of dicta in *Schering-Plough* to construct an argument that in this Circuit, there is a "need to evaluate the strength of the patent." Opp'n 3, 15 (citing *Schering-Plough*, 402 F.3d at 1076). In delineating the scope of the exclusionary potential of Schering's patent, however, the Eleventh Circuit looked to the patent's term and noted that the settlements extended only to the allegedly infringing products. *Schering-Plough*, 402 F.3d at 1067-68, 1070. Thus, "[i]n the context of both the opinion as a whole and the controlling precedent of *Valley Drug*, this admonition is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's

validity." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), *aff'd*, 544 F.3d 1323 (Fed. Cir. 2008), *cert denied*, 129 S. Ct. 2828 (2009); *see also id.* 544 F.3d at 1336-37 n.12 ("*Cipro*") ("Although certain statements by the Eleventh Circuit have been interpreted to mean that it advocated consideration of the validity of the patent, the district court correctly noted that the Eleventh Circuit did not consider or rely on evidence of patent invalidity in either *Valley Drug* or *Schering-Plough*.") (citation omitted).

2. Every Court Has Rejected the FTC's Reading of *Schering-Plough*.

The FTC's anomalous interpretation of *Schering-Plough* finds no support in the caselaw. The Federal Circuit has explicitly stated that "the Eleventh Circuit did not consider or rely on evidence of patent invalidity in either *Valley Drug* or *Schering-Plough*." *Cipro*, 544 F.3d at 1336 n.12. Like the Federal Circuit, the Second Circuit adopted the reasoning of *Schering-Plough* to buttress its own holding that "the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007). *See also In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *25 (D.N.J. Feb. 6, 2009) (stating that "the weight of authority counsels against adopting . . . a

presumption" that reverse payments indicate patent invalidity or infringement) (citing *Schering-Plough*, 402 F.3d at 1066); *Coordination Proceeding Cipro Cases I and II*, No. JCCP4154, Dkt. No. 31, at 10 (Cal. Sup. Ct. Aug. 21, 2009) (attached as Ex. B) ("The federal cases dealing generally with Hatch Waxman settlements, and specifically with this agreement, have uniformly held that settlements within the scope of the patent do not violate antitrust laws."). The leading antitrust treatise agrees that reverse payments within the scope of the patent are lawful in the Eleventh Circuit. *See* Herbert Hovenkamp et al., IP AND ANTITRUST § 7.4(e)(3) (2001).

3. The FTC's New Reading of Eleventh Circuit Precedent Conflicts With Its Own Prior Interpretation.

The FTC attempts to take Defendants to task for suggesting that *Schering-Plough* holds "that the mere possession of a patent conveys the inexorable right to exclude any challenger until the end of the patent term." Opp'n 2. But as the FTC acknowledges, that is precisely how the FTC's Chairman and other top-level staff have characterized *Schering-Plough*. Opp'n 14; *see also* Defs.' Mot. 1, 6-8. It is also how the FTC itself characterized *Schering-Plough* when seeking Supreme Court review of the decision: in light of the rulings in *Schering-Plough* and *Valley Drug*, the FTC concluded that "it appears that the [Eleventh Circuit] would recognize only limited exceptions to its rule that settlements within the *outer,*

nominal bounds of patent claims are presumed lawful." Pet. for Writ of Cert., *F.T.C. v. Schering-Plough Corp*., 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2105243, at *15 ("FTC Cert. Pet.") (emphasis supplied); *see also* Reply Br. for the Pet'r, *F.T.C. v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2652617, at *2-*3 ("[*Schering-Plough*] goes beyond *Valley Drug* and completes the barrier against antitrust liability for patent settlements"; together, the two cases "effectively immunize all payments to delay generic competition, provided the delay does not extend beyond the nominal scope of an untested patent, unless the patent claim is an obvious 'sham,' or the patentee 'knew' that its claim was without merit") ("FTC Cert. Pet. Reply Br.") (citation omitted).

4. Both *Valley Drug* and *Andrx* Support the Scope of the Patent Test.

The FTC also urges a strained reading of *Valley Drug* and *Andrx*. Opp'n 14-15. In *Valley Drug*, however, with respect to a final settlement of patent litigation, the Eleventh Circuit equated the "potential exclusionary effect" of the patent with its nominal scope. *See Valley Drug*, 344 F.3d at 1305 ("The effect of the Zenith Agreement on the production of Zenith's infringing . . . product appears to be no broader than the potential exclusionary effect of [Abbott's] patent, and was actually narrower to the extent it permitted Zenith to market its drug before [Abbott's] patent expired."). The FTC's reliance on language relating only to the

interim agreement in *Valley Drug* (Opp'n 14)—which did not end the underlying patent litigation—is thus inapposite. Because the remand court considered only this interim agreement, its decision and reasoning are inapplicable to this Court's consideration of the AndroGel® settlements. *See In re Terazosin Hydrochloride Antitrust Litig*., 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

Similarly, in *Andrx*—decided after *Schering-Plough*—in assessing the sufficiency of the complaint the Eleventh Circuit considered only whether the generic product could be manufactured or sold without violating the patent's nominal claims. Defs.' Mot. 16; *see also Andrx*, 421 F.3d at 1235 (asking whether the patent was "necessary to the manufacture and sale of a controlled release naproxen medication"; stating that if allegation that generic challenger agreed never to enter with its generic product were true, "this dynamic would exceed the scope of exclusion intended by the . . . patent").

C. Eleventh Circuit Precedent Does Not Permit a Trial on the Patent Merits.

As part of its attack on the scope of the patent rule, the FTC claims that, because the Eleventh Circuit never "expressly foreclosed an inquiry into the strength of the patent" or declared such evidence "irrelevant," it left the door wide open for the FTC and other plaintiffs to "construe Eleventh Circuit precedent to permit an inquiry into" the merits of Solvay's patent. Opp'n 13, 15. Specifically,

the FTC contends that it states a claim because the SAC "contains a variety of allegations about the strength of Solvay's patent, including that Solvay was unlikely to preclude generic entry by enforcing its patent." Opp'n 16. The FTC's approach—flatly contrary to the case law—would eviscerate *Schering-Plough*, effectively requiring parties to conduct the potentially complex and lengthy trials on patent validity and infringement that final settlements make unnecessary.

1. The FTC's Allegations Regarding Patent Invalidity and Infringement Are Irrelevant.

In hopes that the Court will reject the scope of the patent rule and read *Schering-Plough*, *Valley Drug*, and *Andrx* as permitting an inquiry into the patent merits, the FTC makes two arguments attacking Solvay's patent: one of patent invalidity and another of patent infringement. *See* Opp'n 9 (arguing that Solvay "was not likely" to win the underlying patent cases, and that "Solvay was not likely to meet its burden of proving that Watson and Par/Paddock infringed the formulation patent"). However, neither of these arguments is relevant under the Eleventh Circuit precedent.

Schering-Plough foreclosed inquiries into the validity of the underlying patent when the Eleventh Circuit invoked the well-established principle that "[a] patent shall be *presumed* valid." 402 F.3d at 1066-67 (emphasis supplied; internal quotation marks omitted). As the FTC explained to the Supreme Court, the

Schering-Plough panel "based its reasoning upon the statutory presumption of patent validity and upon a[n] . . . extension of that presumption to the patent issues most relevant [in the case]." FTC Cert. Pet., 2005 WL 2105243, at *14 (citation omitted). The panel "ruled that the 'exclusionary power' of the patent at issue . . . encompassed a right to exclude [the generics] from the market 'until they proved either that the . . . patent was invalid or that their products did not infringe Schering's patent.'" *Id.; see also* Hovenkamp, IP AND ANTITRUST § 7.4(e)(3) ("Because [the Eleventh Circuit] presumed that a patent that had not yet been invalidated was necessarily valid . . . the court found no expansion beyond the proper legal scope of the patent.").

Schering-Plough reaffirmed the well-established principle that evidence of noninfringement is not relevant to determining the exclusionary potential of a patent. *See Schering-Plough*, 402 F.3d at 1075-76 ("An exception cannot lie, as the [FTC] might think, when the issue turns on validity . . . as opposed to infringement. . . ."). The *Valley Drug* court also held that a finding of patent invalidity could not be a basis of liability unless the settlement went beyond the exclusionary potential of the patent. *Valley Drug*, 344 F.3d at 1309.

When evaluating whether a patent settlement or license is lawful, a court only need determine if that agreement is "reasonably within the patent grant, *i.e.*,

that it relates to subject matter within the scope of the patent claims." *Virginia Panel Corp. v. MAC Panel Co*., 133 F.3d 860, 869 (Fed. Cir. 1997) (holding that patentee's practices "did not constitute patent misuse because they did not broaden the scope of its patent, either in terms of covered subject matter or temporally") (citing *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F. 2d 700, 709 (Fed. Cir. 1992), *overruled on other grounds*).[1]

2. Reopening the Patent Merits to Evaluate Antitrust Challenges Would Chill Patent Settlements.

The FTC's proposal to permit an inquiry into the patent merits would undoubtedly result in fewer patent settlements. Nowhere does the FTC explain why, if its view of the law is correct, any patent holder would enter into a settlement of a Hatch-Waxman patent suit only to risk treble damages liability in subsequent antitrust litigation. "Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right

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[1] *See also Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004) ("In the cases in which the restriction is reasonably within the patent grant, the patent misuse defense can never succeed."); *U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179, 1197 (Fed. Cir. 2005) (examining only the breadth of the patent grant); *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997) (citing rule; remanding and instructing district court to determine whether patentee's restriction "impermissibly broadened the 'physical or temporal scope' of the patent grant").

through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent." *Valley Drug*, 344 F.3d at 1309.

This is exactly why the FTC told the Supreme Court that "*ex post* inquiry into the patent merits [is] neither necessary nor helpful." FTC Cert. Pet. Reply Br. at *5 n.4. The FTC explained that such inquiries were "inherent[ly] unreliab[le]" and "ultimately [would] have a chilling effect on the efficient settlement of patent litigation." *Id.* (internal quotation marks omitted)*; see also id*. at *2-*3 ("*Valley Drug* held that a plaintiff cannot rely on a *post hoc* inquiry into the merits.").

The FTC inexplicably suggests that in California, Defendants "conceded" that this Court must weigh the patent merits in assessing the sufficiency of the complaint. Opp'n 25. But Defendants were characterizing the thrust of the FTC's complaint, not advancing their own view of the law, as is apparent from the fact that the Defendants filed a motion to dismiss in California in April explaining the holding of *Schering-Plough* exactly as they do here. Defs.' Joint Mot. to Dismiss Pls.' First Am. Compl. at 1 ("*Schering-Plough* held that a non-sham final resolution of a good-faith patent dispute does not violate the antitrust laws as long as the settlement is within the exclusionary scope of the patent."). At oral argument on the Motion to Transfer, the FTC's Counsel in fact conceded that the case had been brought in California to avoid *Schering-Plough*, and to change the

rule of law that *Schering-Plough* establishes. Ex. A at 34 ("Just to be fair, Your Honor, I certainly am not preferring to go to the Eleventh Circuit or Atlanta. I think our brief makes that pretty clear. . . . There are two reasons one brings these cases, Your Honor. One is—and there is all this interest in changing the law. And laws are made through litigation often in this country. . . . Sometimes laws are made by Courts.").

D. The FTC's Rationales for Ignoring Eleventh Circuit Precedent Must Be Disregarded.

As a last resort, the FTC argues that the scope of the patent test adopted by this Circuit is "inconsistent with" or "disrupts" Supreme Court precedent. Opp'n 16-26. This Court may reject the FTC's arguments for several reasons.

First, the FTC previously cited several of these Supreme Court cases before the Eleventh Circuit and lost. *See, e.g.,* Resp't Br. *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005), (No. 04-10688), 2004 WL 3557972, at *42 (quoting *United States v. Masonite Corp.*, 316 U.S. 265, 279 (1942), and arguing that "Courts have long held . . . that a settlement may be unlawful if the patent holder obtains 'protection from competition which the patent law, unaided by restrictive agreements, does not afford'").

Second, none of the Supreme Court cases cited by the FTC is instructive here. Defendants note that the Federal Circuit, in adopting the *Schering-Plough*

analysis, explicitly stated that the scope of the patent test is "completely consistent with Supreme Court precedent," *Cipro*, 544 F.3d at 1336, and that the Supreme Court itself, having had three opportunities to weigh in on the merits of the exclusionary potential rule, has declined to do so.[2] As for the Supreme Court cases relied upon by the FTC, the majority have nothing to do with patent settlements at all, but rather set out general principles of patent or antitrust law.[3] The remaining cases involved a patent holder's unlawful expansion of the scope of its patent through questionable claims or patent pools. *See United States v. New Wrinkle*, 342 U.S. 371, 380 (1952) (patent pooling and price fixing in wrinkle finish industry); *United States v. Masonite Corp.*, 316 U.S. 265, 279 (1942) (hardboard price fixing agreement whereby patentee enlarged scope of patent privilege).

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[2] *See* Den. of Cert., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 129 S. Ct. 2828 (2009); Den. of Cert., *In re Tamoxifen Citrate Antitrust Litig.*, 127 S. Ct. 3001 (2007); Den. of Cert., *Schering-Plough Corp. v. FTC*, 548 U.S. 919 (2006).

[3] *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) (resolving whether court must construe claims of patent; lacking any reference to settlement); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427-28 (2007) (holding patent invalid as obvious); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-94 (2006) (deciding whether test for injunctive relief was properly applied by lower courts); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 168 (1989) (addressing preemption question unrelated to patent settlements); *United States v. Univis Lens Co.*, 316 U.S. 241, 254 (1942) (defining the scope of an injunction); *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 671-72 (1944) (allowing Section 4 Clayton Act damages claim); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (allowing licensee to attack validity of patent).

Furthermore, while the Supreme Court has allowed government challenges to the validity in patent pooling agreements outside of the pharmaceutical industry, *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 53-55 (1973); *United States v. United States Gypsum Co.*, 333 U.S. 364, 387 (1948), it has qualified that right: "we do not recognize unlimited authority in the Government to attack a patent by basing an antitrust claim on the simple assertion that the patent is invalid. . . . Nor do we invest the Attorney General with a roving commission to question the validity of any patent lurking in the background of an antitrust case." *Glaxo*, 410 U.S. at 59; Opp'n 24. *Glaxo* and *Gypsum* stand for the proposition that the Government may challenge the validity of patents where an antitrust violation has already been found, which is certainly not the case here. *See Glaxo*, 410 U.S. at 57 (*Gypsum* permits the Government to challenge patents "relied upon to justify anticompetitive conduct *otherwise violative of the law*") (emphasis added); *see also id.* 53, 59 (issue presented was "whether the Government may challenge the validity of patents involved in *illegal* restraints of trade"; finding that district courts may "entertain and decide antitrust suits brought by the Government and, *where a violation is found*, to fashion effective relief") (emphases added).

Third, the FTC's policy justifications, including its suggestion that patent settlements containing "reverse payments" are "presumptively unlawful" (Opp'n

3-4, 11-12, 30-31), were squarely rejected when the Eleventh Circuit adopted the scope of the patent rule and overturned the FTC's administrative decision. *Schering-Plough,* 402 F.3d at 1072-76 (explaining why prohibiting reverse payment settlements would have anticompetitive effects). Explicit attacks on *Schering-Plough* launched by certain policy-makers and the Department of Justice's Antitrust Division in amicus briefs cannot serve as a basis for overruling binding precedent. *E.g.,* Opp'n 29 (citing Amicus Briefs of Rep. Henry Waxman in support of FTC's Petition to Overturn *Schering-Plough* and of Antitrust Division).

III. CONCLUSION

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

Respectfully submitted, this 11th day of September, 2009.

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CERTIFICATE OF COMPLIANCE

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

Respectfully submitted this 11th day of September, 2009.

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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of September, 2009, a copy of the foregoing **REPLY MEMORANDUM 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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