No. 10-12729-DD

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FEDERAL TRADE COMMISSION,

Plaintiff-Appellant,

v.

WATSON PHARMACEUTICALS, INC. et al.,

***Defendants-Appellees*.**

On Appeal from the United States District Court for the Northern District of Georgia, Atlanta Division, Case No. 1:09-cv-955-TWT

BRIEF FOR APPELLEES UNIMED PHARMACEUTICALS, LLC, ABBOTT PRODUCTS, INC., AND WATSON PHARMACEUTICALS, INC.

Jeffrey I. Weinberger
Rohit K. Singla
Adam R. Lawton (of counsel)
MUNGER, TOLLES & OLSON LLP
355 S. Grand Ave., 35th Floor
Los Angeles, CA 90071
(213) 683-9100

Mark W. Ryan
John Roberti
MAYER BROWN LLP
1909 K Street N.W.
Washington, D.C. 20006
(202) 263-3000

Counsel for Unimed Pharmaceuticals, LLC and Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc.

Steven C. Sunshine
Paul M. Eckles (of counsel)
Julia K. York
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Ave., N.W.
Washington, DC 20005
(202) 371-7000

Counsel for Watson Pharmaceuticals, Inc.

(Additional Counsel Listed on Inside Cover)

Teresa T. Bonder
Matthew D. Kent
ALSTON & BIRD LLP
1201 West Peachtree Street
Atlanta, GA 30309
(404) 881-7000

Counsel for Unimed Pharmaceuticals, LLC and Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc.

David A. Rabin
Jason W. Eakes
MORRIS, MANNING & MARTIN, LLP
3343 Peachtree Road, N.E.
Suite 1600 Atlanta Financial Center
Atlanta, GA 30326
(404) 233-7000

Counsel for Watson Pharmaceuticals, Inc.

Certificate of Interested Persons and Corporate Disclosure Statement

No. 10-12729-DD

Federal Trade Commission v. Watson Pharmaceuticals, Inc. et al.

Pursuant to Circuit Rules 26.1-1 and 26.1-2, this is to certify that the following is a complete list of all attorneys, persons, and entities known to the undersigned that have an interest in the outcome of this appeal:

Abbott Health Products, Inc.

Abbott Laboratories (NYSE: ABT), parent company of Abbott Pharma US Holdings, Inc.

Abbott Laboratories International Co.

Abbott Pharma US Holdings, Inc., parent company of Abbott Products, Inc.

Abbott Point of Care Inc.

Abbott Products, Inc., Appellee, and parent company of Unimed Pharmaceuticals, LLC

Abbott Products US Holdings, Inc.

Abbott Universal Ltd.

Albert, Bradley S., Attorney, FTC

Alston & Bird, LLP

Bonder, Teresa T., Attorney, Alston & Bird, LLP

Daly, John F., Deputy General Counsel, FTC

DeMille-Wagman, Lawrence, Attorney, FTC

Eakes, Jason W., Attorney, Morris, Manning, & Martin LLP

Eckles, Paul M., Attorney, Skadden, Arps, Slate, Meagher & Flom LLP

Federal Trade Commission, Appellant

Feinstein, Richard, Director, Bureau of Competition, FTC

Gidley, J. Mark, Attorney, White & Case LLP

Grannon, Eric, Attorney, White & Case LLP

Greenberg Traurig, LLP

Hilder, Elizabeth R., Attorney, FTC

Kelly, Christopher J., Attorney, Mayer Brown LLP

Kent, Matthew, Alston & Bird, L.L.P.

Laboratoires Besins Iscovesco

Lawton, Adam R., Attorney, Munger, Tolles, & Olson LLP

Liebes, Cynthia A., Attorney, FTC

Mayer Brown LLP

Meier, Markus H., Attorney, FTC

Morris, Manning & Martin LLP

Munger, Tolles, & Olson LLP

Paddock Laboratories, Inc. (Privately Held), Appellee

Par Pharmaceutical Companies, Inc. (NYSE: PRX), Appellee

Rabin, David A., Attorney, Morris, Manning, & Martin LLP

Raptis, Maria A., Attorney, Skadden, Arps, Slate, Meagher & Flom LLP

Robertson, John R., Attorney, FTC

Roberti, John, Attorney, Mayer Brown LLP

Ryan, Mark William, Attorney, Mayer Brown LLP

Singla, Rohit K., Attorney, Munger, Tolles & Olson LLP

Skadden, Arps, Slate, Meagher & Flom LLP

Solvay S.A. (NYSE Euronext: SOLB)

Solvay Pharmaceuticals, Inc., Appellee,

Sunshine, Steven C., Attorney, Skadden, Arps, Slate, Meagher & Flom LLP

Thrash, Jr., Thomas W., U.S. District Court Judge

Tom, Willard K., General Counsel, FTC

Trigg, Mark G., Greenberg, Traurig, LLP

Unimed Pharmaceuticals, LLC, a subsidiary of Abbott Products, Inc.

Unt, Lore A., Attorney, FTC

Valentine, Rebecca, Attorney, Mayer Brown LLP

Watson Pharma, Inc., a subsidiary of Watson Pharmaceuticals, Inc.

Watson Pharmaceuticals, Inc. (NYSE: WPI), Appellee

Weinberger, Jeffrey, Attorney, Munger, Tolles & Olsen LLP

White & Case LLP

Woodward, Mark J., Attorney, FTC

York, Julia K., Attorney, Skadden, Arps, Slate, Meagher & Flom LLP

Dated: November 10, 2010 Checked by Rohit K. Singla

Rohit K. Singla
MUNGER, TOLLES & OLSON LLP
355 S. Grand Ave., 35th Floor
Los Angeles, CA 90071
(213) 683-9100
Counsel for Unimed Pharmaceuticals, LLC and Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc.

Checked by Julia K. York

Julia K. York
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, DC 20005
(202) 371-7000
Counsel for Watson Pharmaceuticals, Inc.

STATEMENT REGARDING ORAL ARGUMENT

Appellees agree with the FTC that oral argument is likely to assist the Court in resolving the issues presented in this case.

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

FEDERAL STATUTES

TABLE OF AUTHORITIES
(continued)

Page

FEDERAL RULES

FEDERAL REGULATIONS

ADMINISTRATIVE DECISIONS

OTHER AUTHORITIES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

STATEMENT OF JURISDICTION

The district court had jurisdiction over this action pursuant to 15 U.S.C. § 53(a) and 28 U.S.C. §§ 1331, 1337(a), and 1345. This Court has jurisdiction under 28 U.S.C. § 1291 because this is an appeal from a final judgment of the district court. The district court dismissed the Federal Trade Commission's complaint on February 22, 2010 (R.E. Doc. 153), and entered judgment on April 21, 2010 (R.E. Doc. 156). The FTC filed its notice of appeal on June 10, 2010 (R.E. Doc. 158), which is timely under Fed. R. App. P. 4(a)(1)(B).

By letter dated July 22, 2010, the Clerk of this Court questioned whether this Court has appellate jurisdiction given the district court's failure to address a counterclaim raised by Par/Paddock in their Answer to the FTC's First Amended Complaint. All parties jointly responded by letter docketed August 5, 2010, stating their shared view that this Court has appellate jurisdiction for two reasons: First, due to the FTC's subsequent filing of a Second Amended Complaint and Par/Paddock's decision not to reassert their counterclaim in response to the Second Amended Complaint, the counterclaim to the First Amended Complaint was no longer pending under *General Mills, Inc. v. Kraft Foods Global, Inc.*, 487 F.3d 1368, 1377 (Fed. Cir.), *clarified on reh'g*, 495 F.3d 1378, 1381 (Fed. Cir. 2007). Second, even assuming the counterclaim were still pending, the parties stipulated to its dismissal with prejudice on August 3, 2010, which was approved by the

district court on August 4, 2010 (by minute entry). In *Finn v. Prudential-Bache Securities, Inc.*, 821 F.2d 581 (11th Cir. 1987), this Court held that a similar after-the-fact dismissal was sufficient to cure any potential defect in appellate jurisdiction. *Id.* at 585.

By letter of the Clerk of this Court dated September 21, 2010, this Court responded that it appeared to have appellate jurisdiction but that final determination of appellate jurisdiction would be made by the merits panel. For the reasons detailed in the parties' letter dated August 5, 2010, appellees believe this Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

Whether the district court correctly applied the "exclusionary potential of the patent" test from the controlling *Valley Drug*, *Schering*, and *Andrx* precedents of this Court, under which patent settlements that are not alleged to contain any provisions that exceed the exclusionary potential of the underlying patent are not subject to antitrust scrutiny.

STATEMENT OF THE CASE

The well-established law of this Circuit is clear: patent settlements do not violate the antitrust laws unless they contain provisions that exceed the exclusionary potential of the underlying patent, *i.e.*, provide the patentee relief that it could not have obtained had it prevailed in its patent suit. The district court

properly dismissed the FTC's Second Amended Complaint because the FTC did not — and cannot — allege that the patent litigation settlements at issue contained any provision that exceeded the exclusionary potential of the patent. Indeed, there is *no dispute* that (1) if Solvay had won the underlying patent litigation, Watson and Par/Paddock would not receive FDA approval to market the generic AndroGel products for which they applied until the '894 patent expires in 2020; and (2) the patent settlements provide licenses for generic AndroGel five years before the patent expires. Thus, the settlements provide the patentees less relief than they would have obtained if they prevailed in the underlying litigation.

Every court to consider patent-settlement antitrust issues since this Court's seminal *Valley Drug* and *Schering* decisions — including the Second and Federal Circuits, and numerous district courts — has followed this Court's analysis. The FTC's decision to originally file outside this Circuit, despite the case's intimate connection to the Northern District of Georgia, may not be surprising given the FTC's longstanding public disagreement with this Court's precedents on the antitrust analysis of patent litigation settlements.

Now, the FTC is essentially arguing on appeal for reversal of this Court's *Valley Drug*, *Schering*, and *Andrx* precedents. The FTC argues that patent settlements that include any consideration to the generic should be presumed anticompetitive if the court concludes that the generic had a greater-than-50%

chance of prevailing in the patent case. (FTC Br. at 22, 32.) Recognizing that its new and untested proposed rule is in stark conflict with controlling precedent of this Court (as the FTC has itself previously admitted), the FTC then devotes a significant portion of its brief to arguing for *en banc* reversal of *Valley Drug*, *Schering*, and *Andrx*.

A. Factual Background

1. Unimed successfully developed the pioneer drug AndroGel and obtained a patent on it.

AndroGel is a prescription drug that is used to treat symptoms of low testosterone, a condition known as hypogonadism. (FTC Br. at 3; Second Am. Compl. ("SAC"), R.E. Doc. 114 ¶¶ 1, 31-33.) It was developed and first brought to market through the cooperative efforts of Besins Healthcare, S.A. and Unimed Pharmaceuticals, Inc. Unimed was later acquired by Solvay Pharmaceuticals, Inc.[1] (SAC, R.E. Doc. 114 ¶¶ 16, 32.) AndroGel has been on the market in the United States since February 2000, when the FDA approved Unimed's New Drug Application. (*Id.* ¶ 33.) Since its launch, AndroGel has been a tremendously successful product, generating hundreds of millions of dollars in annual sales in recent years. (*Id.* ¶¶ 34-35.)

In August 2000, Unimed and Besins applied for a patent on the AndroGel formulation and on methods of using that formulation to treat the symptoms and

[1] Solvay was in turn acquired by Abbott Laboratories in 2010.

achieve the physiological effects for which it is designed. The Patent and Trademark Office (the "USPTO") granted the patent application and issued U.S. Patent No. 6,503,894 (the "'894 patent") in January 2003. (*Id.* ¶¶ 39, 42-43.) The '894 patent describes the AndroGel formulation in detail and has 42 separate claims covering that and similar formulations and methods of using them. The protection of the '894 patent will not expire until August 2020. *See* 35 U.S.C. § 154(a)(2) (patents generally expire 20 years from the priority date). (SAC, R.E. Doc. 114 ¶ 43.)

2. Watson and Paddock sought approval under the Hatch-Waxman regulatory scheme for a generic version of AndroGel, leading Solvay to file a Hatch-Waxman patent suit.

The approval of generic drugs and the resolution of patent disputes between pioneer (or "brand-name") and generic drug companies is governed by the Hatch-Waxman regulatory regime. *See generally* 21 U.S.C. § 355(j).

ANDAs. Hatch-Waxman permits generic companies to submit so-called Abbreviated New Drug Applications ("ANDAs") for FDA approval of their products, without the expensive clinical trial data normally required to establish a drug's safety and efficacy. Rather, ANDA applicants are permitted to rely on the pioneer drug company's proprietary clinical trial data. In return, brand-name companies are given the right to seek early resolution of any patent claims, before the generic even markets an infringing product.

In May 2003, a subsidiary of Watson Pharmaceuticals, Inc. submitted an ANDA seeking FDA approval to market a bioequivalent, generic version of AndroGel. (SAC, R.E. Doc. 114 ¶ 44.) Paddock Laboratories, Inc. filed its own ANDA soon thereafter. Given the closeness in time between the issuance of the '894 patent and Watson's and Paddock's filing of their ANDAs (*id.* ¶¶ 42, 44), there can be no doubt that Watson and Paddock had begun development of their respective generic AndroGel products well before they realized the '894 patent had been issued.

Paragraph IV Certifications. Because Unimed provided public notice that the '894 patent covers AndroGel (by listing the patent in the FDA's "Orange Book," *see* 21 C.F.R. § 314.53), the Hatch-Waxman regulatory regime precluded Watson and Paddock from receiving final (or "effective") FDA approval to market their generic versions before the '894 patent's expiration in 2020 unless their ANDAs were accompanied by so-called "paragraph IV certifications." These are statements alleging that the '894 patent is invalid or unenforceable, that the generic versions would not infringe the '894 patent, or both. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Watson and Paddock each submitted a paragraph IV certification.

Hatch-Waxman Patent Infringement Lawsuits. The filing of a paragraph IV certification is deemed a constructive act of patent infringement under Hatch-

Waxman and thus gives the pioneer drug company the ability to immediately bring a patent infringement lawsuit against the ANDA filer. 35 U.S.C. § 271(e)(2)(A). Such a lawsuit prevents FDA approval from becoming final for 30 months after the lawsuit is filed or until the ANDA filer prevails in litigation, whichever occurs sooner. 21 U.S.C. § 355(j)(5)(B)(iii). If the pioneer drug company prevails, then the district court *must* issue an order preventing the FDA approval from becoming final before the patent expires. *Id.* § 355(j)(5)(B)(iii)(II)(bb); 35 U.S.C. § 271(e)(4)(A).

In accordance with this regulatory regime, Unimed and Besins filed patent infringement lawsuits against Watson and Paddock in August 2003 in the United States District Court for the Northern District of Georgia, where Unimed was headquartered. The Honorable Thomas W. Thrash, Jr., of that court presided over the patent infringement cases. (Docket no. 1, *Unimed Pharms., Inc. v. Watson Pharms., Inc.* ("*Watson*"), No. 03-cv-2501 (N.D. Ga.); docket no. 1, *Unimed Pharms., Inc. v. Paddock Labs., Inc.* ("*Paddock*"), No. 03-cv-2503 (N.D. Ga.).[2]) The Hatch-Waxman 30-month stay of final approval of Watson's ANDA expired in January 2006. (SAC, R.E. Doc. 114 ¶¶ 47, 52.)

[2] The Court may take judicial notice of the existence of docket entries in the patent infringement cases. *See United States v. Jones*, 29 F.3d 1549, 1553 (11th Cir. 1994).

Upon receiving final FDA approval in January 2006, Watson could legally have launched its generic drug even though the infringement lawsuit against it had not been resolved — a so-called "at-risk launch." (*Id.* ¶ 52.) But if Watson then ultimately were to have lost the infringement action, it would have been liable for significant damages. Notably, Watson did not launch its generic drug "at risk" in January 2006 or at any time thereafter. And Paddock could not have launched its generic drug until 180 days after Watson had done so.

180-Day Exclusivity. As the first filer of an ANDA for a generic version of AndroGel, Watson was entitled to 180 days of marketing exclusivity for generic AndroGel. Hatch-Waxman provides this 180-day exclusivity period to the first ANDA filer. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Only after Watson had used its 180-day exclusivity rights could Paddock's (or any other company's) ANDA for generic AndroGel receive final FDA approval.

3. Watson and Par/Paddock argued that they did not infringe the patent because of a supposed drafting error on Solvay's part.

The discovery phase of the patent infringement lawsuits against Unimed and Besins closed in July 2005, after multiple extensions and almost two years after the suits were filed. (Docket no. 57, *Paddock*.) By this time, the parties had taken nearly 40 depositions, and 350,000 pages of documents had been produced by Solvay and Unimed alone.

Watson and Par/Paddock[3] did not dispute that their formulations used the same ingredients as the formulation described in Solvay's patent. Rather, the principal dispute concerning infringement was the interpretation of an ambiguity created by a supposed drafting error in Solvay's patent claims, or, if the claims were found unambiguous, the correction of that error. One of the ingredients in AndroGel is a dilute solution of sodium hydroxide. This is explained in the specification (the technical discussion) of the '894 patent, and many of the patent's claims require a certain proportion of "sodium hydroxide." Watson and Par/Paddock argued, however, that the term "sodium hydroxide" in the '894 patent claims must have meant *solid* sodium hydroxide rather than the dilute solution actually used in AndroGel.

Solvay had a more than reasonable response. First, Solvay argued that the court should construe "sodium hydroxide" to mean the dilute solution used in the AndroGel formulation. Not only is the only reference to sodium hydroxide in the patent specification to a dilute solution, but if the '894 patent's claims referred to solid sodium hydroxide, then the claims would have excluded AndroGel and the other formulations described in the patent. *Cf. Vitronics Corp. v. Conceptronic,*

[3] During the litigation, Paddock partnered with Par Pharmaceutical Companies, Inc., a larger generic drug company. Paddock gave Par the exclusive right to distribute Paddock's generic version of AndroGel in exchange for Par's helping to fund Paddock's litigation costs. (SAC, R.E. Doc. 114 ¶¶ 2, 46.)

Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) (a claim construction that excludes the preferred embodiment "is rarely, if ever correct and would require highly persuasive evidentiary support"). It is also undisputed that using solid sodium hydroxide would be caustic to human skin and unsuitable for use as a topical drug. (*See* Order, R.E. Doc. 153, at 18-20 (summarizing arguments).) Second, Solvay also argued that if "sodium hydroxide" meant solid sodium hydroxide and there was a drafting error, then the court could correct that error.

Between July and November 2005, the parties filed claim-construction briefs, and Watson and Paddock each filed partial summary judgment motions addressing two narrow issues. (Docket nos. 89, 91, 117, 144, *Watson*; docket nos. 59, 60, 80, 90, *Paddock*.) Neither Watson nor Par filed motions for summary judgment of noninfringement, lack of novelty, or obviousness. Moreover, the summary judgment motions and claim construction briefs that Watson and Par/Paddock did file would not have been case-dispositive even if the motions had all been granted.

4. The patent suits were settled to allow Watson and Par/Paddock to introduce their products on an accelerated schedule free of patent liability.

In September 2006, before the district court construed the claims of the '894 patent or decided any of the summary judgment motions, the parties settled both cases. (Docket no. 174, *Watson*; docket no. 131, *Paddock*.) On September 14 and

15, 2006, respectively, the district court entered a Stipulation of Dismissal in the case against Watson and a Consent Judgment and Order of Permanent Injunction in the case against Par/Paddock.

Given that the patent cases were litigated in the Northern District of Georgia, these settlements were negotiated and executed in reliance on this Court's opinions in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), and *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), as well as the Second Circuit's opinion in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), which interpreted and applied those decisions. Each settlement, as discussed below, fully complies with the standards adopted in *Schering*, *Valley Drug*, and *Tamoxifen*.

Under the terms of both settlements, the parties agreed to dismiss the patent cases, Watson and Par/Paddock agreed to respect Solvay's patent, and Watson and Par/Paddock were each authorized to launch their respective generic testosterone gels in August 2015, five years before the '894 patent will expire. (SAC, R.E. Doc. 114 ¶ 65.)

The FTC pointedly does *not* allege any of the circumstances that courts have suggested can cause a patent settlement to exceed the exclusionary potential of a patent:

- The FTC does not allege that either of the patent lawsuits was a sham, objectively baseless, or brought in bad faith.
- The FTC does not allege that the '894 patent was procured by fraud.
- The FTC does not allege that any of the settlements affected any party's ability to market products other than those described in the ANDAs or that Unimed alleged were covered by the '894 patent.
- The FTC does not allege that any of the settlements had the potential to prevent Watson or Par/Paddock from marketing generic testosterone gel after the '894 patent expired or if it was ever found invalid or unenforceable by a court of final appeal.
- The FTC does not allege that Watson's settlement allowed it, the first ANDA filer, to retain any 180-day generic marketing exclusivity or otherwise manipulate 180-day exclusivity rights to block other potential generic entrants.
- The FTC does not allege that any of the settlements operated as a so-called "interim" agreement under which the generic agreed not to market its product while the underlying patent litigation continued, without doing anything to actually settle the litigation. *Cf. In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902-03, 907-09 (6th Cir. 2003) (interim agreement held unlawful); *In re Terazosin*

Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1290-91, 1308 (S.D. Fla. 2005) (same).

Rather than allege that any aspect of the settlements could affect competition beyond the rights accruing to Solvay under the patent, the FTC focuses on the terms of business deals negotiated separately but concurrently with the defendants' settlements. Specifically, Watson agreed that its sales force would promote AndroGel to urologists to further develop the market. In return, Solvay agreed to pay Watson a portion of the net profits generated by the sale of AndroGel to urologists. (SAC, R.E. Doc. 114 ¶ 66.) The FTC alleges that Solvay expected that Watson's portion of the profits under this contract would amount to approximately $20-30 million annually. (*Id.* ¶¶ 66, 82.) Par also agreed that its sales force would promote AndroGel to primary care physicians from 2006 until 2012, and Solvay agreed to pay Par $10 million annually for its promotion services. (*Id.* ¶¶ 74, 77.) Paddock agreed that it would provide backup manufacturing capacity for AndroGel from 2006 until 2012, and Solvay agreed to pay Paddock $2 million annually for this backup capacity. (*Id.*)

Although the FTC alleges that Solvay overpaid for these services, the FTC does not deny that Solvay received legitimate benefits from these arrangements and that they imposed real costs on Watson, Par, and Paddock. Nor does the FTC deny that these separate business arrangements involved relatively small sums

compared to the over $400 million (and growing) annual domestic sales generated by AndroGel. (*Id.* ¶ 34.)

B. Procedural History

1. The FTC filed this suit after two years of discovery and investigation of the settlements.

In late 2006, shortly following the settlement of the patent lawsuits, the FTC began an investigation in which it sought to determine whether Solvay, Watson, Paddock, and Par had committed antitrust violations by entering into the settlement agreements and business arrangements. This investigation continued for over two years, with the FTC receiving millions of pages of documents from the defendants and deposition testimony from almost two dozen witnesses.

On January 27, 2009, with the benefit of this extensive discovery, the FTC filed the initial complaint in this case in the United States District Court for the Central District of California challenging the two patent settlements under the antitrust laws. The defendants moved to transfer the case to the Northern District of Georgia, where the underlying patent cases had been litigated. The California district court agreed to transfer the case pursuant to 28 U.S.C. § 1404(a). (R.E. Doc. 71.) Upon transfer to Georgia, this case, as well as coordinated cases brought by private plaintiffs, were assigned to Judge Thrash — the same judge who presided over the underlying patent lawsuits between Solvay, Watson, and Par/Paddock.

The FTC has amended its complaint twice: once on February 12, 2009, in California prior to transfer, and once on May 28, 2009, after being transferred to the Northern District of Georgia. The FTC's Second Amended Complaint — the operative complaint in this appeal — makes three claims: (1) that the settlement agreement between Solvay and Watson is an unfair method of competition; (2) that the settlement agreement among Solvay, Paddock, and Par is an unfair method of competition; and (3) that Solvay engaged in unfair methods of competition by eliminating the threat of generic competition to AndroGel and thereby monopolizing the market. The FTC requested declaratory relief that each defendant had violated section 5(a) of the FTC Act, as well as injunctive relief preventing the defendants from engaging in unspecified "similar" and "related" conduct.

2. The FTC's arguments in opposition to dismissal

Each defendant moved to dismiss the Second Amended Complaint, arguing that this Court's precedents — principally *Schering* and *Valley Drug* — bar the FTC's claims because those precedents preclude antitrust scrutiny for agreements that finally settle non-sham patent litigation, so long as the terms of the settlement remain within the scope of the exclusionary potential of the patent, *i.e.*, do not provide for exclusion going beyond the patent's term or operate to exclude clearly

noninfringing products, regardless of whether consideration flowed to the alleged infringer. (R.E. Docs. 130, 131.)

In opposing this motion, the FTC argued that parties to patent litigation should not be permitted to settle patent litigation with payments to the alleged infringers in exchange for a delay in generic entry. The focus of the FTC's argument was that patent settlements should not have alleged infringers agreeing to stay off the market in exchange for consideration until the "end of the patent term" (something that did not even occur here given the five-year-early entry granted to Watson and Par/Paddock under the settlements).

The FTC urged the district court to reinterpret the "exclusionary potential of the patent" language from *Schering* and *Valley Drug* to permit consideration of the alleged "weakness" of the '894 patent as part of the antitrust analysis. Yet the FTC's novel reading of this Court's precedents was premised not on the actual holdings or outcomes of those cases, but on a half-sentence statement from *Schering* noting that the FTC had erred by failing to consider the "strength" of Schering's patent. (Opp. to Mot. to Dismiss, R.E. Doc. 137, at 14-16.) By the FTC's own admission, however, it has until now itself read those precedents as acknowledging that the exclusionary potential of a patent grants patentees broad rights to settle *bona fide* patent disputes, regardless of the ultimate validity of the patent and regardless of settlement payments to infringers. (*Id.* at 2-3.) As the

FTC told the district court, "the FTC has expressed its concern to the Supreme Court and Congress that the Eleventh Circuit has adopted an expansive view of the exclusionary scope of patents." (*Id.* at 14.) The FTC also admitted that the same approach has been adopted by the Second Circuit in *Tamoxifen*, 466 F.3d 187, and by the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* ("*Cipro IV*"), 544 F.3d 1323 (Fed. Cir. 2008). (Opp. to Mot. to Dismiss, R.E. Doc. 137, at 28.)

Under its new reading of the Court's precedents, the FTC suggested that where payments are made, antitrust plaintiffs should be able to "test the strength of the patent." Despite the lack of explanation as to how that would be done or what effect the "strength" would have on the antitrust analysis, the FTC argued that if an inquiry into the "strength" of the patent were allowed, then its allegations that Solvay was unlikely to have prevailed in the underlying patent litigation sufficed to state a claim. (*Id.* at 16.)

3. The district court decision on review

On February 22, 2010, the district court dismissed the FTC's claims, relying on *Schering* and *Valley Drug* and rejecting the FTC's invitation to "reinterpret" those cases. (Order, R.E. Doc. 153.) As the district court recognized, evaluation of an antitrust challenge to a Hatch-Waxman settlement requires consideration of "(1) the scope of the exclusionary potential of the patent; (2) the extent to which

the agreements exceed that scope; and (3) the resulting anticompetitive effects." (*Id.* at 12 (quoting *Schering*, 402 F.3d at 1066) (internal quotation mark omitted).)

Because the settlement agreements "do not exclude any product other than generic AndroGel" and "provide[] for five years less exclusion than the '894 patent," the district court found that the settlements do not exceed the scope of the patent's exclusionary potential under this Court's precedents. (*Id.* at 12-13.) The court found the FTC's statements regarding the likely winner of the underlying patent case to be irrelevant under *Valley Drug* unless the patent litigation was so lacking in merit as to have been a sham — something the FTC did not allege. (*Id.* at 13-15 & n.2.) Since the FTC "d[id] not allege that the settlements exceed the scope of the '894 patent," the district court ruled that under *Valley Drug* "it does not matter if the Defendants settled their patent disputes with reverse payments," *i.e.*, with settlement consideration paid to the generics. (*Id.* at 16.) The FTC's complaint was dismissed in its entirety.[4] The FTC did not seek leave to amend. This appeal followed. (R.E. Docs. 156, 157, 158.)

[4] The district court denied related motions to dismiss claims brought by private plaintiffs to the extent those plaintiffs alleged sham litigation. Those claims are still pending below.

C. Standard of Review

This Court reviews de novo the district court's dismissal of a complaint for failure to state a claim on which relief can be granted. *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1288 (11th Cir. 2010).

In reviewing a motion to dismiss, this Court evaluates whether the complaint is sufficient as a matter of law. While the Court must "accept well-pled facts as true" and draw "reasonable inferences in Plaintiff's favor," *Sinaltrainal v. Coca-Cola Co.*, 578 F.3d 1252, 1260 (11th Cir. 2009) (citing *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)), the Court need not "accept a plaintiff's legal conclusions" or its "'unwarranted deductions of fact,'" *id.* (quoting *Aldana v. Del Monte Fresh Produce, N.A., Inc.*, 416 F.3d 1242, 1248 (11th Cir. 2005)).

Moreover, the "mere possibility the defendant acted unlawfully is insufficient" to save a complaint from a motion to dismiss. *Id.* at 1261. Rather, to survive a motion to dismiss, a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Am. Dental Ass'n*, 605 F.3d at 1289 (quoting *Bell Atl. Corp. v. Twombly*, 520 U.S. 544, 570 (2007)). That is, the plaintiff must plead enough facts to "nudge[] [its] claims across the line from conceivable to plausible." *Id.* (quoting *Twombly*, 520 U.S. at 570). The requirement of plausibility supersedes — and is more stringent than — the "any set of facts" standard previously used by some courts. *See Canyon*

County v. Syngenta Seeds, Inc., 519 F.3d 969, 974-75 & n.8 (9th Cir. 2008) (a complaint that does not meet the now-abrogated "any set of facts" standard necessarily cannot meet *Twombly*'s "plausibility" standard).

SUMMARY OF ARGUMENT

The law regarding the antitrust analysis of patent settlements is now well established. Since this Court's seminal decision in *Valley Drug*, every court in every jurisdiction to consider the issue has reached the same conclusion: parties are not subject to antitrust liability for a final settlement of *bona fide* patent litigation unless the settlement terms exceed the exclusionary potential of the patent. In other words, in settling a good-faith claim of patent infringement, a patentee can demand that an accused infringer respect its patent and agree not to market its product just as if the patentee had won.

It does not matter if the settlement includes payments to the accused infringer. Nor does it matter that an antitrust plaintiff later alleges that the patentee might have lost. Rather, the standard adopted in this Court's precedents permits even hotly disputed cases to be settled. Otherwise, parties could never settle patent litigation for fear of treble-damage antitrust liability predicated on a later court's estimate of who would have won the patent case. So long as the parties do not exceed the patent's exclusionary potential by agreeing to provisions that, for example, preclude the sale of products indisputably outside the patent's claims,

that manipulate the regulatory regime to block other companies from entering the market, or that otherwise exceed the relief that victory in the patent case could have provided, their settlements will not be subject to antitrust scrutiny.

This Court reaffirmed these principles in the *Schering* and *Andrx* decisions. The Second Circuit and the Federal Circuit, along with a number of district courts, have all reached the same conclusions. And the FTC cites no precedent from *any* jurisdiction to the contrary. Nor does the FTC allege that the settlements at issue have any provisions that exceed the exclusionary potential of Solvay's patent. All the FTC alleges is that the patent defendants, Watson and Par/Paddock, had "evidence and arguments" for noninfringement. But of course almost every accused infringer will try to make a case for noninfringement. That is plainly not what "exceed[ing] the exclusionary potential of the patent" means.

The FTC effectively seeks nullification of this Court's precedents *sub silentio* through a supposed "reinterpretation" of *Valley Drug* and *Schering* that equates the patent's "exclusionary potential" with an evaluation of the patent's merits. The FTC now manufactures for the first time a "rule that an exclusion payment is unlawful if, viewing the situation objectively as at the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." (FTC Br. at 15.) The FTC's new rule would effectively overrule *Valley Drug* and *Schering* by focusing antitrust

analysis on the existence of settlement payments. Importantly, the FTC's new rule would also require a retrial of the patent merits inside the antitrust case.

The FTC has made no bones about its long-term strategy of seeking reversal of *Valley Drug*, *Schering*, and their progeny. The FTC originally filed this litigation in California, presumably in an effort to obtain a Circuit split. Now that the FTC finds itself involuntarily back in the Eleventh Circuit, it has little choice but to argue that *Valley Drug* and *Schering* do not mean what they say. But the FTC's own representations to Congress, to the Supreme Court, and to other courts show that the FTC itself agrees that *Valley Drug* and *Schering* mean what the district court in this case read them to mean. That is why the FTC devotes much of its brief to seeking, in the alternative, *en banc* reversal of these precedents. There is no basis, however, for *en banc* review here. Every other court to consider the issue has followed this Court's lead for a reason: this Court's precedents are correct as a matter of law and as a matter of policy.

ARGUMENT

A. The District Court Did No More Than Apply Well-Established Circuit Precedent.

1. The law of this Circuit is clear: only settlement provisions beyond a patent's exclusionary potential draw antitrust scrutiny.

The antitrust analysis of patent settlements, like the ones at issue here, is now quite well established, particularly in this Circuit. Settlement payments (what the FTC calls "reverse" or "exclusion" payments) do not affect the antitrust

analysis. Nor does a patent settlement give rise to antitrust liability based on *ex post* argument about who might have won the underlying patent case. Patent settlements are subject to antitrust scrutiny only to the extent that they contain provisions that exceed the exclusionary potential of the patent at issue, *i.e.*, contain provisions that would have been unavailable to the patentee even had it prevailed on its patent claims.

a. *This Circuit's precedents establish that settlement payments and the odds that the patentee would have won are irrelevant.*

This Court's seminal decision in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), held that there is nothing anticompetitive about an alleged patent infringer agreeing to stay off the market as part of the settlement of a *bona fide* patent dispute. The entire point of a patent, after all, is to "grant[] its owner the lawful right to exclude others." *Id.* at 1304. Such a settlement merely acknowledges that exclusionary right, which is granted, moreover, for a *procompetitive* purpose: "to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions." *Id.*

The Court thus rejected any antitrust scrutiny — whether a *per se* or a rule of reason analysis — for patent settlements within the "scope of the exclusionary potential of the patent." *Id.* at 1311 n.27 ("[T]he patent laws prevent antitrust liability for such exclusionary effects."). Only provisions that "have effects

beyond the exclusionary" potential of the patent are subject to antitrust analysis. *Id.* at 1312 (emphasis added). The *Valley Drug* analysis was reaffirmed by this Court in an appeal involving the FTC, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005), and again in *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir. 2005).

Irrelevance of Settlement Payments. This Court has flatly rejected the relevance of settlement payments to the accused infringer in the antitrust analysis of settlements of Hatch-Waxman patent litigation: "If [the patentee] had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit." *Valley Drug*, 344 F.3d at 1309. In *Schering*, the FTC argued (just as it does here) that in the absence of consideration from the pioneer manufacturer, the generics would have negotiated an earlier entry date. Again, the Court rejected the relevance of settlement consideration to the antitrust analysis: "We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement." *Schering*, 402 F.3d at 1075.

Irrelevance of Odds That the Patentee Might Have Lost. The *Valley Drug* plaintiffs also argued that the patent at issue had no exclusionary potential because the patent was ultimately held invalid by a district court and by the Federal Circuit. This Court rejected the relevance of the patent's "mere invalidity." *Valley*

Drug, 344 F.3d at 1307-08. The merits of the patent dispute were relevant to the antitrust analysis only if the patent had been "procured by fraud" or the settling parties "knew the patent was invalid" or "such similar allegations." *Id.* at 1307 n.19. The Court cited the Supreme Court's analysis in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), regarding the deference that antitrust analysis must give to validly issued patents. *See Valley Drug*, 344 F.3d at 1307 (citing *Walker Process*, 382 U.S. at 177). The Court quoted at length Justice Harlan's conclusion that predicating antitrust liability on whether a patent is "voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions . . . because of fear of the vexations or punitive consequences of treble-damage suits." *Id.* (quoting *Walker Process*, 382 U.S. at 180 (Harlan, J., concurring)).

The Court followed the same approach in *Schering*. The exclusionary potential of Schering's patent encompassed the "legal right to exclude [the alleged infringers] from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe." *Schering*, 402 F.3d at 1066-67. The precise odds of the patentee prevailing were not part of the calculus, as long as the litigation was not a sham. *Id.*; *see also id.* at 1068 ("Although the FTC alleges that Schering's settlement agreements are veiled attempts to disguise a *quid pro quo* arrangement aimed at preserving Schering's monopoly . . . there has been no

allegation that . . . the resulting infringement suits against Upsher and ESI were 'shams.'"). Therefore, "mere invalidity" — much less a mere *risk* of invalidity — is not enough to create antitrust liability.

The Exclusionary Potential of the Patent. The Court has clearly explained the kinds of provisions that can exceed the exclusionary potential of the patent: settlement terms that the patentee could not have obtained had it prevailed in its patent infringement lawsuit. In *Valley Drug*, for example, the Court identified the following provisions in one of the agreements at issue: (1) a provision blocking a generic from introducing other competing products regardless of whether they could be considered in good faith to infringe the patent; (2) the generic's promise to maintain its 180-day Hatch-Waxman exclusivity rights while not coming to market, thereby creating a "bottleneck" for other companies seeking to enter the market;[5] and (3) the generic's interim agreement to stay off the market while the

[5] These types of provisions no longer create a bottleneck for later entrants because the law now provides that subsequent ANDA filers can generally bring declaratory judgment actions to trigger an acceleration of a first ANDA filer's exclusivity if the subsequent ANDA filer prevails in litigation. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282-85 (Fed. Cir. 2008). In addition, Hatch-Waxman was amended in December 2003 to provide that the 180-day exclusivity can be lost when the first filer fails to come to market within certain time periods. *See id.* at 1283 n.2. Accordingly, settlements in which the first ANDA filer maintains its 180-day exclusivity are no longer a cause for antitrust concern.

patent litigation and appeal between the parties continued.[6] *See Valley Drug*, 344 F.3d at 1311-12; *cf. Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("The appropriate criterion is whether [the patent holder's] restriction is reasonably within the patent grant, or whether the patentee has ventured beyond the patent grant . . . . Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the inquiry.").

The Court remanded in *Valley Drug* for further analysis of these provisions to determine if they exceeded the patent's exclusionary potential. *Valley Drug*, 344 F.3d at 1312. The Court was particularly concerned that the agreement at issue did not actually settle any litigation, but was instead an agreement by the generic to remain off the market *while the litigation continued* (a so-called "interim agreement").[7] *See id.* at 1310 ("Another possibly suspicious characteristic of the payments to Geneva is their structure (*i.e.*, tying their duration to the length of the litigation), which . . . may have given Geneva an incentive to delay resolution of the infringement suit.").

---

[6] Even these kinds of provisions may be immune from scrutiny under the ancillary restraints doctrine. *See, e.g.*, *Schering*, 402 F.3d at 1072-73.

[7] On remand, the district court found the agreement to be illegal precisely because the generic's agreement to stay off the market while the litigation continued was something that the patentee was highly unlikely to have obtained in the litigation. The court relied heavily on the fact that such an interim agreement was not actually a patent settlement. *See Terazosin*, 352 F. Supp. 2d at 1308-09.

By contrast, a second agreement with another generic was found legal and was not subject to further challenge on remand. That agreement finally settled a patent dispute, with the generic obtaining the right to come to market after a few years and the patentee agreeing to pay the generic $24 million per year. *Id.* at 1300. This kind of settlement has come to be described as a "patent term split" settlement because the parties agreed to "split" the remaining term of the patent: for some number of years the infringer agrees not to market its product and for the remaining term the patentee licenses the infringer to enter the market. This Court concluded that the terms of that settlement were "at the heart of the patent right" that had been granted to the patentee and was thus immune from liability — even though the patent later proved to be invalid. *Id.* at 1306. The Court explained that the effect of that settlement "appear[ed] to be no broader than the potential exclusionary effect of the . . . patent, and was actually narrower to the extent it permitted [the generic] to market its drug before the . . . patent expired." *Id.* at 1305.

The Court applied the same analysis a third time in *Andrx*. That case involved a patent settlement in which the generic agreed to respect the pioneer's patent and the pioneer agreed to pay the generic a substantial sum. Critically, however, the settlement allowed the generic to retain its 180-day marketing exclusivity, even though it allegedly had "no intention of marketing its generic

drug and therefore would never trigger the running of the 180-day exclusivity period." *Andrx*, 421 F.3d at 1231. As a result, the settlement allegedly had the effect of "preventing *any* generic competition in the controlled release naproxen market." *Id.* (emphasis added). This Court held that an antitrust challenge to the patent settlement could proceed — but *only* because the 180-day exclusivity provision, coupled with the generic's intent never to use it, created a "bottleneck" to other entrants and thus may have exceeded the exclusionary potential of the patent.[8] *Id.* at 1231, 1235.

b. *Other courts have uniformly followed Valley Drug and Schering.*

A broad and uniform consensus has developed on these issues over the past seven years. Without exception, every court since *Valley Drug* to consider an antitrust challenge to a Hatch-Waxman patent settlement — including the Second Circuit, the Federal Circuit, and numerous district judges (including Judge Posner, sitting by designation) — has agreed with this Court that (1) patent settlements give rise to antitrust liability only to the extent that any provision exceeds the potential of the patent; (2) settlement payments to accused infringers are irrelevant; and (3) the patentee's odds of success are irrelevant (as long as the case was not a

[8] The FTC has acknowledged that the *Andrx* decision "is premised on . . . allegations that the patentee and generic entrant conspired to use the generic's 180-day exclusivity period to block other competitors." Reply Brief for the Petitioner ("FTC *Schering* Reply Brief"), *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2652617, at *9 n.6.

sham). *See Tamoxifen*, 466 F.3d 187 (upholding dismissal on the pleadings of an antitrust challenge to a patent settlement entered into *after* the patent was held invalid because the settlement was within the patent's potential since the patent might have been upheld on appeal); *Cipro IV*, 544 F.3d at 1323, 1327, 1336-37 (agreeing that "in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis" and need not "conduct a limited evaluation of the merits of the patent claims"); *Ark. Carpenters Health & Welfare Fund v. Bayer AG* ("*Cipro V*"), 604 F.3d 98, 105 (2d Cir. 2010) ("[T]he right to enter into reverse exclusionary payment agreements falls within the terms of the exclusionary grant conferred by the branded manufacturer's patent."); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) (Posner, J.) (dismissing challenge to patent settlement on the pleadings even though generic likely did not infringe patent); *In re K-Dur Antitrust Litig.*, 2009 WL 508869, at *24 (D.N.J. Feb. 6, 2009) (following analysis of *Valley Drug*), *adopted by* 2010 WL 1172995 (D.N.J. Mar. 25, 2010); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 528 (E.D. Pa. 2010) (permitting antitrust challenge to proceed past the pleadings because settlements at issue allegedly manipulated 180-day exclusivity rights, creating a bottleneck to future generic entrants); *Coordination Proceeding Cipro Cases I & II*, 2009 WL 2700124, at 2, 5 (Cal. Super. Ct. Aug. 21, 2009)

(settlement with payment to alleged infringers does not violate the Cartwright Act — California's Sherman Act analogue — where settlement terms do not exceed the patent's exclusionary potential).

Courts since *Valley Drug* have thus *uniformly* rejected — often on the pleadings — antitrust challenges to the kinds of patent settlements at issue here. The FTC does not address this uniform line of decisions except to assert that they are all "erroneous." (FTC Br. at 43 n.28.) The *only* decisions that have permitted antitrust challenges to patent settlements to proceed are those, like *Andrx*, that involved either allegations of sham litigation or the kinds of provisions identified in *Valley Drug* as potentially exceeding the exclusionary potential of a patent.[9]

[9] Parties bringing antitrust challenges to patent settlements often cite *Cardizem* as if it stands for a different rule. *Cardizem*, however, concerned an agreement that was clearly beyond the exclusionary potential of the patent at issue. The court relied on (1) the agreement not being a final settlement of litigation but instead an "interim" agreement that had the effect of prolonging the litigation; (2) the "dispositive" fact that the generic had agreed not to relinquish or transfer its 180-day Hatch-Waxman exclusivity, which was a "bottleneck" to the entry of any other generic competitor; and (3) a restraint on all competing products regardless of whether they might be covered by the patent at issue. *See Cardizem*, 332 F.3d at 907-08 & n.13; *see also, e.g.*, *Tamoxifen*, 466 F.3d at 213-15 (noting that "[i]n *Cardizem*, . . . the settlement included periodic payments . . . during the pendency of the lawsuit" and created "a 'bottleneck'" to further generics); *Cipro IV*, 544 F.3d at 1335 (distinguishing *Cardizem* as concerning an "agreement by the generic manufacturer to not relinquish its 180-day exclusivity period" and to "not market non-infringing versions of the generic drug"). The United States — in a brief joined by the FTC — has also interpreted *Cardizem* this way. *See* Brief for the United States as Amicus Curiae at 13, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779), 2004 WL 1562075 (*Cardizem* is "better read . . . as

2. The FTC has not alleged any term that exceeded the exclusionary potential of Solvay's patent.

The FTC's Second Amended Complaint does not allege that any provision of the Solvay-Watson or Solvay-Par/Paddock settlements exceeds the exclusionary potential of Solvay's patent. There is no allegation that the settlements limit the marketing of formulations other than the ones specified in Watson's and Par/Paddock's ANDAs, *i.e.*, the ones that Solvay alleged infringed its patent. Unlike in *Valley Drug*, there is no allegation here that either agreement was not a final settlement of patent litigation; nor is there any allegation that the agreements continued or prolonged either patent case. The FTC has not alleged sham litigation or that the patent was procured by fraud. And there is no allegation that Watson maintained any 180-day exclusivity rights, whether or not to create a bottleneck to further entrants. *See supra* pp. 11-13. The absence of those allegations is all that is needed to decide this appeal under this Court's law discussed above. The FTC pointedly has not cited any case from any jurisdiction that has found patent settlements like those at issue here to be subject to any antitrust scrutiny.

The FTC argues on appeal that its complaint alleged that Watson and Par's products were not within the exclusionary potential of Solvay's patent. (FTC Br. at 11, 38.) Setting aside for now that the FTC urges an incorrect reading of the

---

limited to the particular agreement before the court," which "extend[ed] beyond the legitimate scope of the patent claims").

term "exclusionary potential" of the patent, *see infra* pp. 34-35, 41-42, that is pointedly *not* what the FTC alleged, nor what it argued to the district court below. The actual allegation in the FTC's Second Amended Complaint — coming after two years of discovery and two rounds of re-pleading — was merely that "Watson and Par/Paddock . . . assembled evidence that their generic products did not infringe the patent because their products contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent." (FTC Br. at 12 n.11 (quoting SAC, R.E. Doc. 114 ¶ 87).)

All the FTC alleged, in other words, is that Watson and Par/Paddock had evidence and arguments for noninfringement, not that Solvay lacked a basis to allege infringement. No one has disputed that Watson and Par/Paddock's products use a formulation with similar ingredients to those described in Solvay's patent specification. Rather, the principal dispute was the interpretation of the ambiguity created by — or, alternatively, the correction of — the supposed "drafting error" in the patent's claims, as explained above. *See supra* pp. 8-10. Solvay had good arguments and evidence in support of its claims, and the district judge, who had presided over the underlying patent litigation, was well aware of the infringement dispute. (Order, R.E. Doc. 153, at 18-21.)

In rejecting the FTC's attempt to sneak the merits of the patent dispute into the antitrust analysis, the district court correctly concluded that this rather technical

infringement dispute was irrelevant to the question whether the patent settlements were beyond the exclusionary potential of Solvay's patent. Infringement, after all, is disputed in most every patent case. That an alleged infringer defends against an infringement claim cannot mean that a settlement that keeps the alleged infringer off the market then exceeds "the exclusionary potential of the patent." Here, for example, the FTC admits that Solvay "might have achieved exclusion" had it "continued to pursue" the patent litigation. (FTC Br. at 17.) That is enough for the settlement here to be within the exclusionary *potential* of the patent: it is undisputed that the patent had the potential to keep the generics off the market until 2020, five years longer than the settlement. Antitrust liability cannot hinge on the precise odds of the various outcomes. Otherwise, settling parties would face the threat of treble-damage antitrust liability until the patent case — that they had tried to settle and put behind them — was relitigated years later inside an antitrust action. It would also mean that many (maybe most) patent settlements, even outside the Hatch-Waxman context, would be deemed anticompetitive as long as infringement was disputed. That makes no sense and it is not the law.

In *Schering*, the fact that infringement was "fierce[ly]" disputed in the underlying patent case did not affect the analysis. *Schering*, 402 F.3d at 1072. To the contrary, this Court rejected the FTC's suggestion that the nature of the patent dispute (*i.e.*, infringement or invalidity or both) affects the appropriate antitrust

analysis: "An exception cannot lie, as the [FTC] might think, when the issue turns on validity . . . as opposed to infringement." *Id.* at 1075-76. The *Schering* settlements were within the patent's exclusionary potential because (1) the patent gave Schering "the lawful right to exclude infringing products from the market until" the patent's expiration and (2) Schering had good-faith arguments for infringement. *Id.* at 1067. That infringement was disputed was of no moment. *Id.* The *Schering* Court cited with approval Judge Posner's conclusion in the *Asahi Glass* case that disputes about the patent litigation merits can result in a settlement exceeding the exclusionary potential of the patent — in other words, "transcend[] the confines of the patent" — only if the patent litigation was a sham. *Id.* (citing *Asahi Glass*, 289 F. Supp. 2d at 991); *see also Valley Drug*, 344 F.3d 1306-08 & n.19; *K-Dur*, 2009 WL 508869, at *25 ("[I]t is inappropriate to conduct an *ex post* inquiry into infringement issues that were resolved by the parties' settlement.").

This understanding of this Court's precedents should not be controversial. It is precisely how the FTC interpreted *Schering* in seeking Supreme Court review of the decision:

> In assessing the exclusionary potential of the '743 patent, the [*Schering*] court [assumed] . . . the patent provided Schering with "the legal right to exclude Upsher and ESI from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent," and noted that there was no allegation that the patent claim was a "sham."

Petition for Writ of Certiorari at 11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2105243 (omissions in original) (citation omitted) (quoting *Schering*, 402 F.3d at 1066-68).

The district court's opinion at issue here was thus a straightforward application of the well-settled law of this Circuit.

B. The FTC's Proposed Rule Seeks to Overturn This Court's Precedents.

The FTC's brief does not seriously argue that the settlements here are subject to antitrust scrutiny under this Court's existing precedents. Rather, now that the FTC finds itself involuntarily in the Eleventh Circuit, the FTC argues either that *Valley Drug* and *Schering* do not mean what they say or that this Court should nullify those decisions.

The FTC has made no secret over the past six years that it wishes to have this entire line of precedent overturned. For example, Commissioner Rosch has publicly stated, "I believe that *Schering* and *Tamoxifen* are bad law and should be reversed."[10] The FTC has therefore embarked on an explicit strategy of seeking to create a split among the Circuits. In testimony before Congress, then-Commissioner (now Chairman) Leibowitz admitted that it was "public knowledge"

[10] FTC Litigation at the Antitrust/Intellectual Property Interface 3 (Apr. 26, 2007) (remarks of J. Thomas Rosch, Comm'r, FTC), *available at* http://www.ftc.gov/speeches/rosch/070426si_pharma.pdf ("The Commission is hopeful that the Supreme Court will review and reverse *Tamoxifen* in a fashion that will discredit *Schering*.").

that the FTC's "litigation strategy" in these cases is to "bring a case that will create a clearer split in the circuits" and lead to Supreme Court review.[11] *See also FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 30 (D.D.C. 2008) ("[T]he Commission is rather openly shopping for a circuit split on the issue of reverse-payment Hatch-Waxman settlements.").

Although the FTC has had no success so far, its professed desire for a Circuit split may well explain its decision to file this case in California in a district with little relationship to the underlying facts, even though the patent litigation was pending in this Circuit. Indeed, the FTC all but conceded below that the case had been brought in California to avoid this Court's precedents and to try to create a circuit split: "Just to be fair, Your Honor, *I certainly am not preferring to go to the Eleventh Circuit* or to Atlanta. . . . There are two reasons one brings these cases, Your Honor. One is . . . *this interest in changing the law*." (Reply Memo. in Support of Mot. to Dismiss, R.E. Doc. 139 Ex. A, at 34 (emphases added).) But there is no basis in law or policy to revisit this Court's precedents, which have been followed by every other court to consider the issue over the past seven years.

[11] Oral Statement of FTC Commissioner Jon Leibowitz, Hearing of the House Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce 3 (May 2, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070502reversepayments.pdf.

1. The FTC's new proposed legal rule is contrary to this Court's precedents.

The FTC suggests the Court's precedents "permit" an entirely new rule: "an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." (FTC Br. at 15.) In other words, the FTC is urging this Court to reinterpret *Valley Drug* and *Schering* to outlaw settlement payments to infringers if a judge or jury in an antitrust case concludes years later that the patentee had a less-than-50% chance of prevailing in the underlying patent case.[12] The FTC essentially argues that the antitrust analysis of these patent settlements requires a full-blown patent litigation to be nested inside the antitrust case. This is supposedly the result of a "more nuanced reading of Eleventh Circuit precedent." (FTC Br. at 21.)

[12] The FTC alternatively proposes that the *en banc* Court reverse *Valley Drug*, *Schering*, and *Andrx* and hold that any patent settlement with consideration flowing to an alleged infringer is presumptively illegal. (FTC Br. at 43-56 & n.29.) Such a rule has not been adopted by any court, as far as we are aware. *See K-Dur*, 2009 WL 508869, at *24-25 (concluding, after survey of case law, that "[p]laintiffs have not cited — nor am I aware of — any case that has applied this legal framework"). The FTC argues that the Department of Justice advocated a similar rule in seeking *en banc* review of the *Cipro V* decision in the Second Circuit. (FTC Br. at 43-44.) But the Second Circuit has declined to accept the government's argument for this rule, refusing to revisit its prior decisions in *Tamoxifen* and *Cipro V*. *See Ark. Carpenters Health & Welfare Fund v. Bayer AG* ("*Cipro VI*"), --- F.3d ----, 2010 WL 3464382 (2d Cir. Sept. 7, 2010).

The FTC has created its proposed legal rule out of whole cloth. The rule finds no support whatsoever in the Court's precedents, and the FTC cites no case that has adopted such a rule — and we know of none. Nor do we believe that either the FTC or the DOJ has espoused this rule in any of their prior briefs to the courts. The FTC has not even applied such a rule in its own administrative proceedings. *See, e.g.*, *In re Schering-Plough Corp.*, 136 F.T.C. 956, 998 (2003). To the contrary, when the *Schering* case was before the FTC, the Commission concluded that analyzing the "underlying merits" would be inappropriate because it would create "serious uncertainties" for "parties who seek to settle patent litigation."[13] *Id.* Settling parties would not know if they were subject to antitrust liability until years down the road.

[13] The government has continuously shifted its position on the relevance of the patent merits. In *Schering*, as noted, the FTC argued strenuously that the merits of the patent dispute *should not* be considered in the antitrust analysis. But in *Tamoxifen* — where the patent had been held unenforceable before the settlement — the United States argued that the courts *should* "take into account the relative likelihood of success of the parties' claims, viewed ex ante." Brief for the United States as Amicus Curiae at 12, *Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007) (No. 06-830), *denying cert. to Tamoxifen*, 466 F.3d 187, 2007 WL 1511527. Then in *Cipro* — where the patent was never found invalid and was ultimately upheld — the FTC and the DOJ argued that the court *should not* consider likelihood that the patentee would have prevailed: "[t]hat Bayer might have won its patent litigation had it not paid Barr to settle does not alter" the antitrust analysis. Corrected Brief of Amicus Curiae FTC at 25-26, *Cipro IV*, 544 F.3d 1323 (No. 2008-1097), 2008 WL 644394; *see also* Brief for the United States at 24, *Cipro V*, 604 F.3d 98 (No. 05-2851-cv), 2009 WL 2429249 ("It is neither necessary nor appropriate to determine whether the patent holder would likely have prevailed in the patent infringement litigation in determining liability for a Hatch-Waxman reverse

More importantly, this Court in both *Valley Drug* and *Schering* went out of its way to explain that the antitrust analysis cannot turn on an *ex post* estimate of who would have won the underlying patent case. *See supra* pp. 24-26. Until now, this has been the FTC's own interpretation of *Valley Drug*. The FTC argued to the Supreme Court, for example, that "*Valley Drug* held that a plaintiff cannot rely on a *post hoc* inquiry into the merits." FTC *Schering* Reply Brief, *supra* note 8, at *2-3.

The Court has similarly explained that settlement payments to an infringer are not a basis for increased antitrust scrutiny. *See supra* p. 24. "We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement." *Schering*, 402 F.3d at 1075. The Court explained that the FTC's (continuing) effort to outlaw settlement payments is "[d]irectly contrary to our opinion in *Valley Drug*." *Id.* at 1075 n.26; *see also Valley Drug*, 344 F.3d at 1309-11.

2. The FTC's effort to misconstrue *Schering* has been rejected by courts, commentators, and the FTC itself.

The only authority the FTC cites to support its proposed rule are mischaracterizations of a few passing comments in *Schering.* The FTC points to

---

payment settlement . . . ."). Now, where a court has yet to pass on the validity of Solvay's patent, the FTC turns around and argues that the antitrust analysis *should* turn on whether Solvay had a greater-than-50% chance of prevailing in the underlying lawsuits.

the *Schering* Court's conclusion that "*Valley Drug* . . . underscores the need to evaluate the strength of the patent" in antitrust challenges to patent settlements. *Schering*, 402 F.3d at 1076, *quoted in* FTC Br. at 26. But even the FTC cannot argue that this statement has anything to do with outlawing settlement payments to infringers — the focus of the FTC's proposed rule. Moreover, by "strength of the patent," the Court was referring to the *Valley Drug* analysis of a patent's exclusionary potential, *i.e.*, the rights granted to patentees by the patent laws. Nothing suggests the Court was referring to the precise odds that any party would prevail.

Similarly, the FTC cites the *Schering* Court's comment that the FTC had admitted "that it could not prove that [the generics] could have entered the market on their own prior to the . . . patent's expiration" and that that "reinforces the validity and strength of the patent." *Id.* at 1068, *quoted in* FTC Br. at 26. But again, the Court was noting that because the generics' products were within the reasonably asserted scope of Schering's patent, as the FTC could not dispute, the generics did not have the unfettered right to enter the market. Therefore, the strength of the patent, *i.e.*, its *exclusionary potential*, had to be considered. "Strength of the patent" refers to "exclusionary potential" — not the odds that the patent would be found valid and infringed.

The Court nowhere suggested that the rule established in *Valley Drug* and *Schering* applies only if a jury later concludes that the patentee had a greater-than-50% chance of winning its patent case. To the contrary, the Court has taken precisely the opposite approach: "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages." *Valley Drug*, 344 F.3d at 1308; *see also Schering*, 402 F.3d at 1067 (patent merits may cause a settlement to transcend the patent's exclusionary potential only where the patentee "*knows* [the patent] is *almost certainly* invalid" (emphases added) (quoting *Asahi Glass*, 289 F. Supp. 2d at 991)).

The FTC's misreading of *Schering* has been rejected again and again by other courts and commentators. *See, e.g.*, *Cipro IV*, 544 F.3d at 1336 n.12 ("Although certain statements by the Eleventh Circuit have been interpreted [by the government] 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*." (citations omitted)); *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro III*"), 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005) ("In 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 . . . ."); *Tamoxifen*, 466 F.3d at 210-11 (citing *Schering* and concluding that "the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid"); Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *IP and Antitrust* § 7.4(e)(3) (2001) ("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.").

Indeed, even the FTC has *itself* admitted in testimony before Congress that the reading of *Schering* it is proposing now is incorrect: "Other courts have understood [*Schering*] to require only an inquiry into the nominal reach of the patent, and not (as some have suggested) a direct assessment of the likelihood that the patent holder could successfully effect exclusion through patent litigation."[14] A year earlier, the FTC's current Chairman testified that *Schering* held that settlements with payments to infringers "are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham."[15]

---

[14] Prepared Statement of the FTC Before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution 15-16 (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

[15] Hearing Before the Senate Special Committee on Aging 14, 109th Cong. (Jul. 20, 2006) (statement of Hon. Jon Leibowitz), *available at* http://www.aging.senate.gov/events/hr161jl.pdf.

Finally, in its petition for certiorari in *Schering*, the FTC argued that this Circuit's law permits patent settlements to exclude products from the market if they *might* lie within the patent's claims — regardless of the odds a court would have actually found infringement: *Schering* and *Valley Drug* "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 *Schering* Reply Brief, *supra* note 8, at *2-3 (citation omitted).[16]

[16] The FTC also argues that *United States v. Glaxo Group, Ltd.*, 410 U.S. 52 (1973), and *United States v. United States Gypsum Co.*, 333 U.S. 364 (1948), hold that the government can "challenge the validity of a patent" asserted as a defense in an antitrust case. (FTC Br. at 31.) But these cases hold that the government can challenge a patent where the patent's *continuing validity* is a defense to an antitrust claim. That is not the situation here. The legality of patent settlements does not turn on the patent's *current* status. *See Valley Drug*, 344 F.3d at 1306-07 (Zenith settlement found legal even though patent had subsequently been invalidated); *Tamoxifen*, 466 F.3d at 205 (patent settlement permitted even after patent held invalid by trial court). Even if the FTC were to prove that Solvay's patent is invalid (an effort the FTC did not purport to undertake before the district court), that would not be relevant to the antitrust analysis here. Patent settlements are to be judged as of the time they were entered into. *Valley Drug*, 344 F.3d at 1306-07. To the extent the FTC hopes to rely upon cases concerning "worthless" patents (*see, e.g.*, FTC Br. at 30, 35-36), these cases are inapposite because the FTC has not made such allegations here.

3. Neither of the FTC's proposed legal rules would serve a procompetitive purpose.

a. *The FTC's fixation on settlement payments is misguided because such payments are neither surprising nor suspicious.*

At the core of the FTC's position is the view that litigants should face antitrust liability — and thus treble damages — for settling patent disputes with consideration flowing the "wrong way," *i.e.*, to the alleged infringer. The FTC refuses to acknowledge, however, that Hatch-Waxman reverses the risks and rewards of patent litigation, as this Court has repeatedly explained.

In a typical patent case, the patentee has a damage claim against the accused infringer. But "the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement." *Schering*, 402 F.3d at 1074. The patentee thus has no damages claim to compromise, even though it may face ruinous economic consequences should it lose. The infringer by contrast has no potential damages liability to worry about. *See Valley Drug*, 344 F.3d at 1309. Even the potential for an erroneous judgment can create a massive economic risk for a patentee who is confident in its patent position. *Id.* at 1310. There is, in other words, a stark "asymmetr[y] of risk." *Id.*

As a result of this dynamic, generic defendants "gain[] considerable leverage in patent litigation." *Schering*, 402 F.3d at 1074. This "redistribut[ion of] the

relative risk assessments . . . explains the flow of settlement funds and their magnitude." *Id.* Generic companies in Hatch-Waxman patent litigation can demand substantial concessions that may not reflect either the merits of the litigation or the settlement that might have been reached outside of the Hatch-Waxman context. *See, e.g.*, *Tamoxifen*, 466 F.3d at 206-07 (agreeing that Hatch-Waxman litigation provides generics substantial negotiating leverage and naturally results in settlement payments to the alleged infringer). These dynamics can justify even very large payments by the patentee to accused infringers without raising antitrust suspicions. *See Valley Drug*, 344 F.3d at 1310 (citing payments in the *Cipro* litigation of approximately $450 million).

The FTC's lead counsel on appeal, Willard Tom, also agrees that the idiosyncratic dynamics of Hatch-Waxman gives generics tremendous leverage: "the Hatch-Waxman context both incentivizes an ANDA filing even by a generic infringer with a very weak case and puts enormous settlement leverage in the hands of such an infringer." 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, 619-21 (2006). Settlement payments to the infringer are thus not surprising even where the patentee is very confident of success. Settlement payments may also be used to "bridge th[e] gap" of the parties' conflicting views of the patent merits. *See id.* at 630.

This Court has also explained that the FTC's approach would condemn not just Hatch-Waxman pharmaceutical settlements, but many routine patent settlements because any settlement can be characterized as providing compensation to both parties. The Court quoted Judge Posner's view with approval:

> If any settlement agreement can be characterized as involving "compensation" to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden "reverse payment," we shall have no more patent settlements.

Schering, 402 F.3d at 1073-74 (quoting *Asahi Glass*, 289 F. Supp. 2d at 994). There is thus no meaningful limit to the FTC's proposed rule.

b. *Outlawing settlement payments to alleged infringers would discourage settlement and thus have undesirable consequences for both innovation and challenges to patents.*

The Hatch-Waxman Act represents congressional policy to encourage generic companies to challenge patents, and the FTC admits that patent-split settlements "may bring consumer benefits." (FTC Br. at 51.) This Court has also held that settlements, including the settlement of Hatch-Waxman patent lawsuits, provide substantial benefits: "There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation." *Schering*, 402 F.3d at 1075.

Yet, as this Court has recognized, the FTC's effort to outlaw settlement payments might undermine each of those goals and thus produce *anticompetitive* results:

> A prohibition on reverse-payment settlements would "reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."

Id. (quoting *Asahi Glass*, 289 F. Supp. 2d at 994). The value of patents, and the resulting levels of investment in innovation, may well be reduced because patentees could not be confident that they could protect legitimate innovations through settlement. There is a broad recognition of this point. *See, e.g.*, *Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements" would prolong lawsuits, "heighten the uncertainty surrounding patents and might delay innovation."); *Asahi Glass*, 289 F. Supp. 2d at 994 ("A ban on reverse-payment settlements . . . might well be thought anticompetitive.").

Similarly, generic companies, denied the ability to exit costly litigation through settlement, may well opt to forgo future ANDA filings and paragraph IV challenges to pharmaceutical patents. Generic drug companies file a large number of ANDA applications each year and large numbers of paragraph IV patent

challenges.[17] Litigating each of these patent cases to completion costs millions of dollars, with no guarantee at all of success. The investment in ANDA filings and patent challenges thus depends on the ability to settle the litigation, often by shaving years off the patent term. A rule that removes, or unnecessarily restricts, a generic manufacturer's settlement options at the risk of treble damages might well lessen consumer welfare by discouraging the filing of paragraph IV ANDAs and investment in development of generic drugs.[18] Nor should generic manufacturers be required to litigate infringement cases through to judgment in every instance, turning them into "'unwilling private attorneys general.'" *Cipro III*, 363 F. Supp. 2d at 532; *see also id*. ("Although plaintiffs would no doubt argue that litigation is to be preferred in these drug patent cases, . . . there is no support for the view that Hatch-Waxman intended to thwart settlements.").

And these are not idle fears. The FTC admits that "in some cases, a settlement without payment may not be achievable." (FTC Br. at 52 n.39; *see also*

---

[17] In 2008, the FDA received over 800 ANDAs. Generic Pharm. Ass'n, *Celebrating the Past, Defining the Future* 20 (2009), *available at* http://www.gphaonline.com/sites/default/files/gpha-low-res.pdf.

[18] *See* Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements* 4 (Aug. 10, 2010), *available at* http://www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf ("[P]atent settlements with reverse payments may actually accelerate generic competition for numerous drugs."); *id.* at 7 ("[R]estricting generic manufacturers' ability to settle lengthy, expensive patent litigation will reduce generic companies' incentives to bring such patent challenges in the first place . . . .").

Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study 9 (2010)[19] (FTC is not "assuming that all settlements with payments would 'become' settlements without payments if the former were banned. Some would; others might involve litigation of the patent.").) Without the ability to negotiate other business arrangements in some instances, negotiations solely focused on the patent term split become a zero-sum game in which settlement is not possible if the parties have divergent valuations of the litigation.[20]

In the FTC's view, however, the inability of some litigants to settle without risking massive antitrust liability is just the price that has to be paid because the FTC has decided we are better off "with a 'roll of the dice' on litigation." (FTC Br. at 52 n.39.) The FTC suggests this is a minor concern because 70% of the settlements it has seen in Hatch-Waxman cases "did not involve exclusion-payments and delayed entry." (*Id.* at 51.) But this statistic suggests, at most, that settlement consideration is flowing to the generic only in the 30% of cases where it

[19] http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[20] *See* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 394-97 (2010); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 Geo. L.J. 1303, 1336-37 (2010) (citing Robert H. Gertner, *Asymmetric Information, Uncertainty, and Selection Bias in Litigation*, 1993 U. Chi. L. Sch. Roundtable 75, 76; George Loewenstein & Don A. Moore, *When Ignorance Is Bliss: Information Exchange and Inefficiency in Bargaining*, 33 J. Legal Stud. 37, 53 (2004)); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, 49 Antitrust Bull. 655, 660-61 (2004).

is necessary to reach a settlement.[21] Outlawing all those patent settlements would have a substantial impact.

More fundamentally, although the FTC pays lip service to respecting the legitimate rights of patent holders (FTC Br. at 35), the FTC's proposed approach gives no weight to the long-term, procompetitive innovation that the patent system is designed to incentivize. Ensuring that patents are respected, that patentees can bring litigation that they are confident they can settle, and that patentees can respond to the leverage that alleged infringers gain under Hatch-Waxman are factors critical to continued innovation. The FTC claims that patent settlements with "exclusion payments" cost consumers $3.5 billion annually. (*Id.*) Not only is that just 1.5% of what the FTC estimates is spent annually on prescription drugs (*id.* at 35 n.24), but more importantly, the FTC is missing the larger issue. The real worry is ensuring that future innovation — the real driver of our prosperity — is not hampered:

> [T]he undercutting of the reward for innovation is a much more serious matter than is the loss of an opportunity for price reductions. As noted above, Judge Easterbrook reminded us that an antitrust policy that reduces prices today, even by a substantial amount, at the expense of a

[21] The FTC's statistic also ignores how many cases are *not* being settled for fear of antitrust scrutiny and how many more patent challenges would be brought overall under an "exclusionary potential" approach (with a definite ability to settle) than would be brought under the FTC's desired approach.

> small annual reduction in the rate at which innovation occurs "would be a calamity."

Bernard & Tom, *supra*, at 623 (quoting Frank H. Easterbrook, *Ignorance and Antitrust*, *in* ANTITRUST, INNOVATION, AND COMPETITIVENESS 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992)). This is even more true in the pharmaceutical industry where, as perhaps nowhere else, patents drive life-saving and beneficial innovation.[22] There is no reason to think that saving 1.5% of the nation's spending on prescription drugs is worth diminishing the level of investment and innovation in the industry. It is estimated that for each new drug to reach the market, the pharmaceutical industry spends more than $800 million, testing perhaps 10,000 compounds for each one that makes it to market. *See id.*

[22] The FTC cites its own "study" as showing that a large portion of pharmaceutical patents litigated to conclusion are found invalid or not infringed. (FTC Br. at 37, 55.) Even if the FTC's own statistics — constructed in support of its litigation position in these cases — are given any consideration, the FTC ignores that most disputes are settled. The statistics reflect only the small subset of cases that the parties are unable to settle. Thus, if anything, the FTC's statistics suggest that the cases that do *not* settle are those in which the generics are likely to prevail. In other words, the FTC's statistics suggest that the cases that do *not* settle involve so-called "weak" patents, not that settlements with payments to infringers involve "weak" patents. That makes logical sense: generic companies challenging the "weakest" patents are unlikely to accept compensation in lieu of entry into a lucrative market. Moreover, there is persuasive evidence that the patents involved in these settlements were not "weak." In the *Cipro* case, for example, nearly $400 million was paid to the generics, but the patents were later upheld both in litigation and by the USPTO in reexamination. *See Cipro IV*, 544 F.3d at 1329, 1331; *Cipro III*, 363 F. Supp. 2d at 519-20; *see also Andrx*, 421 F.3d at 1332 n.4 (patent upheld after "reverse" payment settlement); *Tamoxifen*, 466 F.3d at 195-96 (same).

The FTC's analysis gives no weight to the importance of incentivizing such enormous investments.

c. *An ex post estimate of the patentee's chances of success is too unpredictable a basis for antitrust liability.*

The FTC's proposal to focus the antitrust analysis on an *ex post* analysis of the precise chances that the patentee would have prevailed is equally misguided. Indeed, this is precisely what the FTC told the Supreme Court when appealing from the *Schering* decision: "*ex post* inquiry into the patent merits [is] neither necessary nor helpful." FTC *Schering* Reply Brief, *supra* note 8, at *5 n.4. When the *Schering* matter was before the FTC, the FTC rejected the very *post hoc* merits analysis of patent disputes that it now insists the district court should have undertaken here: it is not "necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements." *Schering*, 136 F.T.C. at 998. The FTC opined that only in "an extreme case," *e.g.*, when either the patent claim or the paragraph IV certification was "objectively a sham," could such an inquiry be helpful. *Id.* at 996.

First, the FTC's *ex post* inquiry would force the settling parties to litigate in its entirety the very patent case they were trying to settle. In other words, parties would be unable to avoid litigating the merits of their patent dispute.

Second, and more importantly, the practical difficulties of this approach cannot be overstated. This "Russian dolls" approach, where "the antitrust case opens up to reveal that a full-scale intellectual property litigation hides inside," is "extraordinarily resource-intensive." Willard K. Tom & Alexis J. Gilman, *U.S. and E.C. Antitrust Approaches to Patent Uncertainty*, 34 Law & Pol'y Int'l Bus. 859, 871-72 (2003). In one case that the FTC litigated in this way, *62 weeks* were spent on just a subset of patent merits issues. *See id.* at 872.

Finally, this kind of analysis is inherently unreliable. This Court has cautioned that predicating liability on predictions of the outcome of patent litigation would stifle most patent settlements because parties can never be confident that they have "correctly" predicted the outcome of their patent litigation, much less that they have correctly predicated how some future court years later will evaluate the patent case:

> Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.

Valley Drug, 344 F.3d at 1308. The reality is that even district judges cannot predict how the Federal Circuit will rule on an issue of patent law, as reflected by

the very high reversal rates in patent appeals.[23] The difficulty of predicting patent outcomes is only increased by the clear-and-convincing standard that governs patent invalidity. The antitrust court would, for example, have to determine not whether the patent was more likely obvious or not, but whether there was a greater-than-50% chance that the accused infringer would have established by clear and convincing evidence that the patent was obvious.

The FTC has itself admitted that "Russian doll" inquiries into the patent merits are "inherent[ly] unreliab[le]." FTC *Schering* Reply Brief, *supra* note 8, at *5 n.4; *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro II*"), 261 F. Supp. 2d 188, 200 (E.D.N.Y. 2003) ("[A] legal theory dependent on predicting the outcome of a specific lawsuit is unduly speculative."). Not only are litigation outcomes inherently impossible to predict, but as a former assistant attorney general for antitrust noted, "evaluating the underlying IP rights [is] a task

[23] *See, e.g.*, Judge James F. Holderman & Halley Guren, *The Patent Litigation Predicament in the United States*, 2007 U. Ill. J.L. Tech. & Pol'y 1, 2 (discussing studies that showed the Federal Circuit's reversal rate for claim construction — an issue that was hotly contested in the AndroGel patent litigation — to be between 33% and 50%); U.S. Court of Appeals for the Federal Circuit, *Affirmance and Reversal Rates for District Court Patent Infringement Appeals*, http://www.cafc.uscourts.gov/images/stories/the-court/statistics/Caseload_Patent_Infringement_Affirmance_and_Reversal_Rates_2001-2010.pdf (showing that over 40% of appeals from district court decisions in patent infringement cases result in reversal or vacatur at least in part).

that is outside our core expertise as antitrust enforcers."[24] Former FTC Commissioner Thomas Leary, the author of the Commission's *Schering* decision, similarly indicated that "[t]he FTC does not claim to have any particular expertise in the resolution of patent disputes."[25]

Even outside the context of patent litigation, the Supreme Court and numerous other courts have held that liability cannot turn on an analysis of how some other case would have come out because "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) (denying standing to party when injury depended on speculative prediction of the outcome of unresolved litigation); *see also, e.g.*, *Pony v. County of Los Angeles*, 433 F.3d 1138, 1146 (9th Cir. 2006) (denying standing to a lawyer whose damages claim rested alternatively on the hypothetical outcome of litigation that never went to trial and on a settlement under terms other than the ones actually reached — a scenario that the court considered "inherently 'conjectural or hypothetical'").

[24] R. Hewitt Pate, Antitrust and Intellectual Property, Address Before the Am. Intellectual Prop. Law Ass'n 2003 Mid-Winter Institute (Jan. 24, 2003), http://www.usdoj.gov/atr/public/speeches/200701.htm (last visited Nov. 10, 2010).

[25] Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II, http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.shtm (last visited Nov. 10, 2010).

The end result, as the FTC has itself argued, is that predicating antitrust liability on the patent merits would "ultimately have a chilling effect on the efficient settlement of patent litigation." FTC *Schering* Reply Brief, *supra* note 8, at *5 n.4. Despite the FTC's apparent (and unexplained) change of heart now, that is the same conclusion this Court has reached: "This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose." *Valley Drug*, 344 F.3d at 1308; *see also* Bernard & Tom, *supra*, at 632 (endorsing the sham standard set forth by Judge Posner in *Asahi Glass* as "likely to do less harm than any alternative of which we are aware").

There is thus no practical or theoretical justification for what the FTC is now proposing: that litigants settling patent litigation face treble-damage liability for incorrectly guessing which party some future court will think would have prevailed in their patent case.

CONCLUSION

For the foregoing reasons, the district court's judgment should be affirmed.

Dated: November 10, 2010

Respectfully submitted,

Mark W. Ryan
John Roberti
MAYER BROWN LLP
1909 K Street N.W.
Washington, D.C. 20006
(202) 263-3000

Teresa T. Bonder
Matthew D. Kent
ALSTON & BIRD LLP
1201 West Peachtree Street
Atlanta, GA 30309
(404) 881-7000

Jeffrey I. Weinberger
Rohit K. Singla (CA Bar No. 213057)
Adam R. Lawton (of counsel)
MUNGER, TOLLES & OLSON LLP
355 S. Grand Ave., 35th Floor
Los Angeles, CA 90071
(213) 683-9100

Counsel for Unimed Pharmaceuticals, LLC and Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc.

David A. Rabin
Jason W. Eakes
MORRIS, MANNING & MARTIN, LLP
3343 Peachtree Road, N.E.
Suite 1600 Atlanta Financial Center
Atlanta, GA 30326
(404) 233-7000

Steven C. Sunshine
(DC Bar No. 450078)
Paul M. Eckles (of counsel)
Julia K. York
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Ave., N.W.
Washington, DC 20005
(202) 371-7000

Counsel for Watson Pharmaceuticals, Inc.

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because it contains 13,818 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure and this Court's Rule 32-4.

Dated: November 10, 2010

Adam R. Lawton
Munger, Tolles & Olson LLP
355 S. Grand Ave., 35th Floor
Los Angeles, CA 90071
(213) 683-9100

CERTIFICATE OF SERVICE

I hereby certify that, on November 10, 2010, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the Court's EDF system. I further certify that one paper copy was sent via first-class mail to each of the following:

Bradley S. Albert
Lawrence DeMille-Wagman
Markus H. Meier
John R. Robertson
Mark J. Woodward
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580-0002

David A. Rabin
Jason W. Eakes
Morris, Manning & Martin, LLP
3343 Peachtree Road, NE
Suite 1600
Atlanta, GA 30326-1429

Cindy A. Liebes
Federal Trade Commission
225 Peachtree Street, NE
Suite 1500
Atlanta, GA 30303-1729

Eric Grannon
J. Mark Gidley
White & Case LLP
701 13th Street, N.W.
Washington, DC 20005-3807

Lore A. Unt
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, DC 20580

Mark G. Trigg
Greenberg Traurig, LLP
The Forum
3290 Northside Parkway
Suite 400
Atlanta, GA 30327-2268

Steven C. Sunshine
Maria A. Raptis
Julia K. York
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Ave., N.W.
Washington, D.C. 20005

Dated: November 10, 2010

Adam R. Lawton
Munger, Tolles & Olson LLP
355 S. Grand Ave., 35th Floor
Los Angeles, CA 90071
(213) 683-9100