IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, Plaintiff, v. CEPHALON INC., Defendant.	:	CIVIL ACTION No. 08-cv-2141 MSG

ORDER

AND NOW, this ____day of _____, 2009, upon consideration of Defendant Cephalon, Inc.'s Motion to Dismiss the First Amended Complaint and any response thereto, it is hereby ORDERED that the Motion is GRANTED and the First Amended Complaint filed by Plaintiff Federal Trade Commission is DISMISSED WITH PREJUDICE.

BY THE COURT:

_____
Mitchell S. Goldberg, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, Plaintiff, v. CEPHALON INC., Defendant.	:	CIVIL ACTION No. 08-cv-2141 MSG

DEFENDANT CEPHALON, INC.'S MOTION TO DISMISS
THE FIRST AMENDED COMPLAINT

Pursuant to F.R.Civ.P. 12(b)(6), Defendant Cephalon, Inc. hereby moves to dismiss the First Amended Complaint filed by Plaintiff Federal Trade Commission (Docket No. 40). The grounds for this motion are set forth in the accompanying Memorandum.

Respectfully submitted,

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Dated: August 31, 2009

IN UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 08-cv-2141 (MSG)**
CEPHALON, INC.,	)	
Defendant.	)	

DEFENDANT CEPHALON, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

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TABLE OF ABBREVIATIONS AND DEFINED TERMS

AC	Plaintiff Federal Trade Commission's First Amended Complaint for Injunctive Relief, Docket No. 40 (Aug. 12, 2009)
ANDA	Abbreviated New Drug Application
Cephalon	Defendant Cephalon, Inc.
DOJ	U.S. Department of Justice
FDA	U.S. Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 et seq.
FTC	Plaintiff Federal Trade Commission
Generics	Defendants Barr Laboratories, Inc.; Mylan Laboratories, Inc.; Teva Pharmaceutical Industries, Ltd. together with its subsidiary Teva Pharmaceuticals USA, Inc.; and Ranbaxy Laboratories, Ltd., together with its subsidiary Ranbaxy Pharmaceuticals, Inc.
Hatch-Waxman	The Hatch-Waxman Act, Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified, in part, as amended at 21 U.S.C. § 355)
NDA	New Drug Application
PTO	U.S. Patent and Trademark Office
'516 Patent	U.S. Reissue Patent No. RE37,516

INTRODUCTION

In late 2005 and early 2006, Cephalon and the Generics separately settled vigorously disputed Hatch-Waxman patent litigation in which Cephalon sought to enforce its '516 patent, which covers Provigil®, a drug approved by the FDA for the treatment of narcolepsy (the "Provigil® Settlements" or "Settlements"). The Settlements reflect a series of compromises, reached after years of federal court litigation, pursuant to which each of the Generics is permitted to sell its competing products *three years before* the expiration of the '516 patent. Not content with this obviously pro-competitive result securing early generic entry and resolving complex and costly litigation, the FTC seeks in this action to undo the Settlements. Paradoxically, it characterizes the Settlements as agreements to *delay* competition, and alleges that contemporaneous business transactions between Cephalon and the Generics (such as supply, intellectual property, and product development agreements) were in fact disguised payments not to compete – a characterization that Cephalon emphatically disputes, but which is irrelevant to this motion to dismiss.

The FTC's position as to what the law should be has been soundly rejected by courts of appeal and district courts including, most notably, the Federal Circuit whose law should be applied to ensure a uniform body of patent law. As discussed below, under this prevailing standard, settlements within the "scope of the patent" – *i.e.*, settlements such as those at issue here that do not foreclose the sale of non-infringing products or restrict generic entry beyond the life of the patent – are not illegal. Provided a challenged settlement satisfies that standard, as the Settlements unquestionably do here, the courts will not separately evaluate the strength of the parties' respective positions in the underlying patent litigation, or evaluate their (or some third party's) subjective expectations about the outcome of that litigation. Nor will they impose liability because, hypothetically, a different settlement *might have been* reached under which no

payments were made from the innovator company to the generic. As the courts have also made clear, so-called "reverse payments" do not reflect anticompetitive purpose but instead are a natural consequence of the risks and rewards created by the Hatch-Waxman scheme itself.

The FTC has made no effort to conceal its desire to reverse the prevailing scope of the patent standard through Congressional action and by using this action in an effort to secure a split in the circuits which has so far eluded it. But, in fashioning that standard, the courts have carefully weighed the potential impact on competition of Hatch-Waxman settlements with the importance of respecting patent rights and the strong public policy supporting litigation settlements. The FTC's preference for a different standard – and it cannot offer a workable one – affords no basis for this Court to depart from its sister district courts and all the courts of appeals that have considered the issue.

Because the Settlements by their terms are well within the exclusionary scope of Cephalon's '516 Patent, they were clearly permitted under the law. Accordingly, the FTC's Amended Complaint (Docket No. 40) should be dismissed with prejudice.

BACKGROUND

A. Relevant Statutory and Regulatory Provisions

The Settlements resulted from, and must be viewed in light of, the particular legislative scheme embodied in the Hatch-Waxman Act. Hatch-Waxman provides incentives both for innovator companies to develop and market new and innovative drug treatments as well as, where consistent with innovator patent rights, for generic companies to introduce low cost versions of those branded drugs. *See Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988). Through Hatch-Waxman, Congress has attempted to balance these potentially conflicting goals. Among other things, it establishes different types of market exclusivities – *i.e.*, periods of time in which either innovators are free from generic competition

or in which the initial generic challenger(s) ("first-filer(s)") is free from competition from other generics. The Act also sets forth procedures for securing early determination of whether generics infringe innovators' patent rights.

NDAs. FDA approval is required before any drug can be introduced, or delivered for introduction, in interstate commerce. 21 U.S.C. §§ 331(d), 355(a) (2000). The FDA will not approve a New Drug Application ("NDA") until the applicant demonstrates that the drug is safe and effective for its intended use(s). *Id.* § 355(b)(1). Upon approval of an NDA, the NDA holder *must* identify to the FDA those patents covering the approved drug, which in turn lists them in a publication called *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." *Id.* at § 355(b)(1); 21 C.F.R. § 314.53(e) (2009).

ANDAs and Paragraph IV Certifications. In contrast to innovator manufacturers, generic manufacturers submit Abbreviated New Drug Applications ("ANDAs"). ANDAs need not independently demonstrate safety and efficacy, but rather must show that the proposed generic is "bioequivalent" to an approved branded drug. *See* 21 U.S.C. § 355(d), (j)(2)(A)(ii) & (iv). If the Orange Book lists patents covering the relevant branded drug, Hatch-Waxman establishes a mechanism for generics to challenge listed patents, and for patentees to enforce their patent rights, before product launch. *See* 35 U.S.C. § 271(e)(2) (2000). In particular, as part of the ANDA, the generic manufacturer must, for each unexpired patent included in the branded drug's Orange Book listing, either: (a) identify the patent and its expiration date (a "Paragraph III certification"); or (b) certify that each patent listed is either invalid or will not be infringed by the proposed generic (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III)-(IV).

A Paragraph III certification indicates that the generic does not seek FDA approval until the expiration of the patent. *Id.* at § 355(j)(2)(A)(vi)(III), (5)(B)(ii). A Paragraph IV

certification (such as the ones the Generics filed as to Provigil®), on the other hand, contests the validity or applicability of the patent. *Id.* at § 355(j)(2)(A)(vii)(IV). A Paragraph IV certification is itself an act of infringement, 35 U.S.C. § 271(e)(2), triggering the patent holder's right to enforce its patent immediately and enabling the generic applicant to challenge the patent without making potentially infringing sales that would expose it to damages. When making a Paragraph IV certification, the ANDA applicant must provide a "Paragraph IV notification" to the holders of each applicable patent, stating that an ANDA has been filed and setting forth a detailed statement of the basis for its claims of invalidity and/or noninfringement. *Id.* at § 355(j)(2)(B).

Litigation Stay. If the patent holder does not file an infringement suit within 45 days of receiving a Paragraph IV notification, the FDA may approve the ANDA once all the innovator drug's applicable FDA exclusivities have expired and the FDA determines that the proposed generic is bioequivalent to the approved innovator drug and is otherwise approvable. *Id.* at § 355(j)(5)(B)(iii). If, however, the patent holder files suit to enforce the patent within 45 days of receiving a Paragraph IV notification, FDA approval for that ANDA is automatically stayed for 30 months with certain exceptions,[1] or until the court hearing the infringement case determines that the patent is invalid, not infringed, or unenforceable, whichever is earlier (a "Paragraph IV litigation stay"). *Id.* During this time, the FDA may grant "tentative approval" for the ANDA, meaning the application is otherwise acceptable, but may not grant "final approval" until the stay and all other applicable FDA exclusivities have expired. *Id.* at §355(j)(5)(B)(iv)(II)(dd).

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[1] Where, as here, the active ingredient in the drug is deemed by the FDA a "New Chemical Entity," *infra* § B.2, the litigation stay lasts until seven-and-one-half years from approval (or 30 months from the date of receipt of the Paragraph IV notification, essentially whichever is longer). 21 U.S.C. § 355(j)(5)(F)(ii). In addition, another six months is added in cases where the FDA grants "pediatric exclusivity," *infra* § B.2. 21 U.S.C. § 355a(c)(1)(A)(i)(I).

180-Day Generic First-Filer Exclusivity. As an incentive for generic companies to mount patent challenges, the first ANDA holder to file a Paragraph IV certification is entitled to a 180-day generic exclusivity period, during which time the FDA will not approve any other ANDAs containing Paragraph IV certifications that list the same branded drug and patent. *Id.* at § 355(j)(5)(B)(iv)(I). If multiple applicants submit ANDAs with Paragraph IV certifications on the same day and no filer has submitted an ANDA with a Paragraph IV certification before that day, the FDA has treated each same-day applicant as a "first-filer." The 180-day exclusivity does not begin to run until one of the first filers markets the drug or until any generic applicant obtains a final, non-appealable judgment against the patent, whichever is sooner. *Id.* at § 355(j)(5)(B)(iv)(I), 355(j)(5)(D); *see* FDA, "Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day," 68 Fed. Reg. 45,252, 45,255 (Aug. 1, 2003). A first-filer retains its 180-day exclusivity if it is sued by a patentee and the parties subsequently settle and agree that the generic can begin marketing on a date certain.

B. Factual Background

1). *The '516 Patent and FDA Approval Of Provigil®*

In 1997, Cephalon obtained a patent on a particle size composition of modafinil, the active ingredient in Provigil®. AC ¶¶ 26, 35. Provigil® received FDA approval in December of the following year, indicated at the time for the treatment for excessive daytime sleepiness associated with narcolepsy. *Id.* ¶ 28. In 2002, Cephalon's particle size patent reissued as the '516 patent. *Id.* ¶ 35. The '516 patent expires in October 2014 (with pediatric exclusivity effectively extending Cephalon's exclusivity to April 2015). *Id.* ¶ 36.[2]

[2] *See* Provigil® Orange Book listing, *available at* http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=020717&Product_No=002&table1=OB_Rx (last accessed Aug. 26, 2009); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice on motion to dismiss of official FDA internet publications).

2). *The Underlying Infringement Litigation and the Settlements*

Because the FDA recognized Provigil® as a "New Chemical Entity,"[3] generic companies were not allowed to file ANDAs for Provigil® until December 24, 2002. *See id.* ¶ 38. On that day, each of the four Generics filed its ANDA for generic modafinil with a Paragraph IV certification. *See id.* On March 28, 2003, Cephalon timely filed patent infringement claims in the U.S. District Court for the District of New Jersey against each Generic, thereby triggering the statutory litigation stay. *See id.* ¶ 43.[4] The cases were consolidated. None of the Generics ever asserted that Cephalon's patent suit was not brought in good faith.[5]

By February 1, 2006, after two-and-a-half years of vigorous litigation, including full fact and expert discovery, Cephalon separately settled its patent infringement claims against each of the Generics. *See id.* ¶¶ 62, 66, 71, 74. Under each Settlement, Cephalon agreed to license the Generic to begin marketing a generic version of Provigil® in 2012, three years before the earliest date the Generics could have entered had Cephalon prevailed on its patent claims. *Id.* In addition, each settlement included an accelerated entry provision – permitting each Generic to launch even earlier if and when another generic manufacturer successfully entered the market. *Id.* ¶ 60.

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[3] *See* FDA drug approval summary for Provigil®, *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails (last accessed Aug. 26, 2009); *see Wellbutrin*, 281 F. Supp. 2d at 754 n.2 (judicial notice of FDA internet publications).

[4] *See* Complaint, *Cephalon, Inc. v. Mylan Pharms., Inc., et al.*, Civ. A. No. 03-1394, Doc. No. 1 (D.N.J. Mar. 28, 2003); *see also Travis v. Miller*, 226 F. Supp. 2d 663, 664-65 n.2 (E.D. Pa. 2002) (stating that, on motions to dismiss, courts may take judicial notice of public records such as court proceedings).

[5] Barr Laboratories' Answer, Affirmative Defenses, and Counterclaims, *Cephalon, Inc. v. Mylan Pharm., Inc.*, Civ. A. No. 03-1394, Doc. No. 3 (Apr. 30, 2003); Ranbaxy Laboratories, Ltd.'s First Amended Answer to Complaint and Counterclaims, *Cephalon, Inc. v. Mylan Pharms., Inc.*, Civ. A. No. 03-1394, Doc. No. 95 (Feb. 22, 2005); Teva Pharmaceuticals USA, Inc.'s First Answer to Complaint, *Cephalon, Inc. v. Mylan Pharms., Inc.*, Civ. A. No. 03-1394, Doc. No. 97 (Feb. 23, 2005); and Mylan Pharmaceuticals' Second Amended Answer to Complaint and Counterclaims for Patent Infringement, *Cephalon, Inc. v. Mylan Pharms., Inc.*, Civ. A. No. 03-1394, Doc. No. 99-1 (Feb. 25, 2005).

Cephalon and each of the Generics also entered into separate business transactions. For example, Cephalon obtained a non-exclusive, worldwide license to all of Teva's modafinil-related intellectual property rights. *See id.* ¶ 63. Cephalon also entered into a supply contract with a Teva subsidiary to purchase modafinil active pharmaceutical ingredient ("modafinil API"). *Id.* ¶ 64. In addition, Cephalon agreed to purchase modafinil API from Ranbaxy (*id.* ¶ 68) as well as from Chemagis, Ltd., a business partner of Barr's (*id.* ¶ 75). Cephalon further acquired licenses to or purchased patent rights relating to modafinil manufacturing processes and formulations from Ranbaxy, Barr, and Chemagis. *Id.* ¶¶ 69, 75, 77. Finally, Cephalon entered into business development collaboration agreements with both Mylan and an affiliate of Chemagis for the development of new pharmaceutical products. *Id.* ¶¶ 72, 77.

Contrary to the FTC's allegations, Cephalon vehemently denies that these transactions were merely "side-term inducements" intended to compensate the Generics for their "agreements not to compete." (*Id.* at ¶¶ 58-59.) Rather, the record will support that these were in fact legitimate business arrangements for which fair consideration was paid. While the Court must accept the FTC's allegations for the limited purpose of this motion, the FTC's characterization of the arrangements as "side-term inducements" cannot cure the legal insufficiency of its claims.

ARGUMENT

The FTC alleges that the Provigil® Settlements constitute unlawful exclusionary conduct that allowed Cephalon to maintain a monopoly in a product market narrowly defined to include only Provigil®. *Id.* ¶¶ 105-06.[6] According to the FTC, this alleged violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, constitutes an unfair method of competition under Section 5(a) of

[6] Cephalon accepts this alleged market definition for the purposes of this motion only.

the FTC Act, 15 U.S.C. § 45(a). *See* AC ¶ 106.[7] The FTC's Complaint can fairly be reduced to these principal allegations: (1) the Settlements included payments to the Generics in return for the Generics' agreement to "forego [generic] entry" until 2012, *e.g.*, AC ¶ 3; (2) a "cashless" settlement would have resulted in an even earlier generic entry date, *id.* ¶¶ 83, 85; (3) the litigants (and other parties) believed Cephalon's patent protection was weak, *id.* ¶¶ 37, 50-54; (4) Cephalon likely would have lost the patent case and/or a preliminary injunction motion, *id.* ¶¶ 83, 85; (5) the Settlements restricted the sale of actual or potential generic products other than the specific compositions at issue in the underlying litigation, *id.* ¶¶ 37, 79-81; and (6) the Settlements constrained the ability of other generics to enter the market, *id.* ¶¶ 87-89.

Similar challenges to Hatch-Waxman settlements by the FTC itself and by private plaintiffs advancing the same theories have been made and rejected many times, including by the only three courts of appeals to analyze the application of the antitrust laws to such settlements:

(1) the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro*"), 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied sub nom, Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009), whose law should be applied to ensure uniformity in the law of patent immunity, *see infra* § I(A)(4);

(2) the Eleventh Circuit in *Schering-Plough Corp. v. Federal Trade Comm'n* ("*Schering-Plough*"), 402 F.3d 1056, 1076 (11th Cir. 2005) (vacating an FTC order), *cert.*

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[7] Hatch-Waxman settlements have been challenged under Sections 1 and 2 of the Sherman Act, both directly and by the FTC through Section 5 of the FTC Act. *See*, *e.g.*, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (Section 1 claim); *Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005) (Section 1 allegations advanced under Section 5 of the FTC Act); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) (Section 1 and Section 2 claims); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (Section 1 claim). The courts have applied the same analysis under each of these provisions in rejecting each challenge. *See Tamoxifen*, 466 F.3d at 196-97, 201, 212 (applying same analysis to claims under both Sherman Act sections). The FTC cannot directly enforce the Sherman Act, but may challenge conduct that violates Sections 1 or 2 of the Sherman Act as "unfair methods of competition" under Section 5 of the FTC Act. *See* 15 U.S.C. §§ 4, 45.

denied, 126 S. Ct. 2929 (2006); and *Valley Drug Co. v. Geneva Pharm., Inc.* ("*Valley Drug*"), 344 F.3d 1294, 1312 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); and

(3) the Second Circuit in *In re Tamoxifen Citrate Antitrust Litig*. ("*Tamoxifen*"), 466 F.3d 187, 212-23 (2d Cir. 2006), *amending* 429 F.3d 370 (2d Cir. 2005), *cert. denied,* 127 S. Ct. 3001 (2007).

Each of those courts has adopted the "scope of the patent" test, under which settlements are lawful even if they contain "reverse payments," so long as they do not restrict competition beyond the scope of the patent's claims or beyond its term. These decisions recognize that Hatch-Waxman settlements require a balancing of the antitrust law's goal of promoting competition, the patent law's goal of fostering innovation, and the public policy supporting litigation settlements which courts have a duty to encourage. They also recognize that "reverse payments" flow from the risks and incentives created by Hatch-Waxman itself and do not reflect anticompetitive purpose or effect. Indeed, compared with litigation outcomes where the patentee would have prevailed, settlements allowing early generic entry (such as the settlements here) are highly pro-competitive. *See infra* § I(A).

Although the FTC briefly attempts to state a claim even under the scope of the patent test, *see infra* § II, its case depends principally on convincing the Court to reject that standard in favor of the FTC's own judicially-rejected policies. In particular, the Commission has made a variety of arguments against the prevailing standard, including (1) that there is supposedly a split in authority rather than a judicial consensus, *see infra* § I(B); (2) that application of the scope of the patent test here would involve an inappropriate "presumption" of infringement, *see infra* § I(C); (3) that the Court cannot apply the scope of the patent test on a motion to dismiss because the FTC makes allegations contrary to the test's rationale in its Amended Complaint, *see infra* §

I(D); and (4) that the scope of the patent test is somehow inconsistent with Supreme Court precedent, *see infra* § I(E). The Commission has proposed various, inconsistent alternative frameworks, but none are supported by authority and none are workable in practice, *see infra* § I(F).

Ultimately, the FTC's case is based not on what the law is, but rather on what the FTC believes the law should be. However, the Commission's litigation position here and its policy views on antitrust law are not entitled to any deference. *Appalachian States Low-Level Radioactive Waste Comm'n v. Pena*, 126 F.3d 193, 198-99 (3d Cir. 1997) ("No deference is due an agency's litigation position."); *United States v. Trident Seafood Corp.*, 60 F.3d 556, 559 (9th Cir. 1995) (same). The Sherman Act is a judicially administered statute, *State Oil Co. v. Khan*, 522 U.S. 3, 20-21 (1997) (noting "the accepted view that 'Congress expected the courts to give shape to the [Sherman Act]'s broad mandate by drawing on common-law tradition.'"), and thus this Court should follow the judicial consensus compelling dismissal.

I. The Court Should Adopt the Prevailing Scope of the Patent Standard for Assessing Hatch-Waxman Settlements

A. Every Court of Appeals to Assess Hatch-Waxman Settlements Has Adopted the Scope of the Patent Standard Based on Sound Considerations Including Promoting Innovation, Encouraging Settlements, and Declining to Engage in Second-Guessing

The Federal Circuit recently held that so long as Hatch-Waxman settlements do not restrain competition to any greater extent than the underlying patents, they do not violate the antitrust laws, even if the settlements include so-called "reverse payments" (that is, payments from the innovator company to the generic).[8] *See Cipro*, 544 F.3d at 1336 ("The essence of the

[8] Though not specifically using the phrase "reverse payments" in the Amended Complaint, the FTC has used this phrase in previous filings asserting the same theories as it advances here. *See* Brief of Respondent FTC at 45, 47, 54-56, *Schering-Plough*, 402 F.3d 1056 (No. 04-10688) (discussing propriety of reverse payments).

inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."). This holding accords with the Second and Eleventh Circuits. *Tamoxifen*, 466 F.3d at 212 (upholding dismissal of private challenges to Hatch-Waxman settlement, and stating that "[w]e generally agree … that 'simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection'"); *Schering-Plough*, 402 F.3d at 1064, 1076 (reversing FTC decision that had invalidated Hatch-Waxman settlements including "reverse payments" because restrictions were "no more broad than the patent's own exclusionary power"); *Valley Drug Co. v. Geneva Pharm., Inc.* ("*Valley Drug*"), 344 F.3d 1294, 1312 (11th Cir. 2003) ("reverse payment" settlement subject to antitrust scrutiny only if "found to have effects beyond the exclusionary effects of [defendant's] patent").

Under this standard, restrictions on the sale of generic products in Hatch-Waxman settlements (whether or not those settlements involve "reverse payments") are within the scope of the patent unless they: (1) delay entry of generic products beyond the patent's expiration date; or (2) restrict the sale of products not covered by the patent claims. *See, e.g., Cipro*, 544 F.3d at 1337 (rejecting FTC criticism of scope of the patent test, and holding district court correctly "equat[ed] the exclusionary power of the patent with the scope of the patent claims without consideration of the uncertainty of patent validity"); *Valley Drug*, 344 F.3d at 1305, 1310 (settlement of "genuine dispute" lawful so long as within exclusionary "potential" of patent); *Schering-Plough*, 402 F.3d at 1076 (applying *Valley Drug* in case involving disputed patent infringement); *Tamoxifen*, 466 F.3d at 213 (holding that agreement "did not extend the patent

monopoly by restraining the introduction or marketing of unrelated or non-infringing products"). No court of appeals has held to the contrary. *See infra* § I(B).[9]

The scope of the patent standard derives directly from Supreme Court precedent, which holds that a patentee is subject to antitrust liability *only* when it restrains competition *beyond* the confines of its lawful patent monopoly. *See United States v. Line Material Co.*, 333 U.S. 287, 305 (1948) ("Within the limits of the patentee's rights under his patent, monopoly of the process or product by him is authorized by the patent statutes."); *see also United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[T]he possession of a valid patent … does not give the patentee any exemption from the provisions of the Sherman Act *beyond the limits of the patent monopoly.*") (emphasis added; internal quotations omitted); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) ("The owner of a patent cannot *extend* his statutory grant by contract or agreement.") (emphasis added); *Tamoxifen*, 466 F.3d at 202 (citing *Singer*); *Schering-Plough*, 402 F.3d at 1067 (same); *Valley Drug*, 344 F.3d at 1312 (citing *Masonite*); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 248 (E.D.N.Y. 2003) (citing *Singer*).[10]

1). *The Scope of the Patent Standard Encourages Innovation and Promotes Settlements*

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[9] Although no court has so held, the Federal, Second, and Eleventh Circuits have suggested in *dicta* that a settlement would not be within the scope of a patent if the underlying suit was a "sham" or the patent at issue was procured by fraud. *Cipro*, 544 F.3d at 1336 ("[A]bsen[t] … evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment"); *Tamoxifen*, 466 F.3d at 213 ("[A]bsent an extension of the monopoly beyond the patent's scope … and absent fraud … the question is whether the underlying infringement lawsuit was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.'"). Neither circumstance is alleged by the FTC here.

[10] The scope of the patent test is also consistent with how district courts within the Third Circuit have analyzed the intersection between patent and antitrust law. *See, e.g., Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. 99-6299, 2000 WL 987865, at **2-3 (E.D. Pa. July 18, 2000) ("[A]ny allegation[s] of antitrust [liability] resulting from a patent must extend beyond the rights granted in the patent…." (citations omitted)); *United States v. CIBA GEIGY Corp.*, 508 F. Supp. 1118, 1150 (D.N.J. 1976) ("[W]here a patentee exercises his patent in an effort to expand his monopoly beyond that reasonably implicit in the patent grant, he may collide with the antitrust laws." (citing *Standard Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 28 (1912)).

The prevailing standard recognizes that Hatch-Waxman settlements, because they involve patent rights, cannot be analyzed under the antitrust laws as simple horizontal restraints of trade, *i.e.*, agreements among competitors to limit competition. As the Federal Circuit explained in *Cipro*, "a patent by its very nature is anticompetitive." 544 F.3d at 1333. To incentivize innovation, patents grant "the right to exclude" competitors from practicing the claimed invention. *Id.* Thus, while the antitrust laws generally prohibit anticompetitive conduct, "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." *Id.* The scope of the patent test thus emerged as a balance between the patent laws' goal of fostering innovation and antitrust laws' goal of prohibiting unreasonable restraints of trade. *See id.* ("The district court appreciated this underlying tension between the antitrust laws and the patent laws …. [T]he essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee."); *Tamoxifen*, 466 F.3d at 202 ("It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal."); *Valley Drug*, 344 F.3d at 1307 ("A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required….").

The scope of the patent test also reflects the need to balance competitive concerns with the long-standing judicial policy of encouraging litigation settlements, which provide important public and private efficiencies. *See Cipro*, 544 F.3d at 1333 ("[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation."); *Tamoxifen*, 466 F.3d at 202 (stating that courts "are bound to encourage" the settlement of litigation); *Schering-Plough*, 402 F.3d at 1072 (noting policy favoring settlement and noting that

"[p]atent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits"); *see generally Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and free competition …, settlement of litigation is more strongly favored by the law."); *D.R. by M.R. v. East Brunswick Bd. of Educ.*, 109 F.3d 896, 901 (3d Cir. 1997) ("Settlement agreements are encouraged as a matter of public policy because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by courts.").

In addition to the avoidance of "a litany of direct and indirect costs" of litigation, settlements play a particularly important role in the patent context because they foster innovation by enabling patentees to achieve certainty in their patent rights. As the Eleventh Circuit explained: "[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product." *Schering-Plough*, 402 F.3d at 1075; *see also Valley Drug*, 344 F.3d at 1308 ("By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation."). Thus, where there are "legitimately conflicting [patent] claims, … a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." *See Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

Courts adopting the prevailing scope of the patent standard also recognize that settlements in Hatch-Waxman cases may yield greater competition than if those cases had proceeded to judgment in favor of the patentees, by providing for entry prior to patent expiration. *See Schering-Plough*, 402 F.3d at 1074 ("If settlement negotiations fail and the patentee prevails in its suit, competition would be prevented to the same or an even greater extent because the

generic could not enter the market prior to the expiration of the patent."); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (expressing "doubt" that even agreement under which patentee pays generic to stay off market for remaining term of patent is anticompetitive, "since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent").

2). *Courts Adopting the Scope of the Patent Standard Have Appropriately Refused to Engage in* **Ex Post** *Review of the Merits of the Underlying Patent Claims and Defenses*

The courts have expressly rejected proposed standards that call for a judgment of the reasonableness of the settlement in light of the actual or perceived "strength" of the patent claims. *See*, *e.g.*, *Cipro*, 544 F.3d at 1336 ("[T]he court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."); *Tamoxifen*, 466 F.3d at 203 ("We cannot judge this … settlement on the basis of the likelihood *vel non* of success had [the matter] not settled…."); *Valley Drug*, 344 F.3d at 1308 (holding that even a subsequent judicial determination of invalidity of the patent at issue did not render a Hatch-Waxman settlement unlawful). As the Eleventh Circuit explained, "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast" the outcome. *Valley Drug*, 344 F.3d at 1308. Given this uncertainty, making a subsequent antitrust case turn on a reassessment of patent merits would chill settlements and thus dilute patent rights. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005), *aff'd* 544 F.3d 1323 (Fed. Cir. 2008) ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."), *cert. denied sub nom, Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009).

In the same vein, courts have refused to consider the litigants' own perceptions or predictions about the case. *See Tamoxifen*, 466 F.3d at 210 ("[W]e doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it."). As Judge Posner of the Seventh Circuit noted in a case in which he was sitting by designation:

> It is not "bad faith" . . . to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit.

Asahi Glass, 289 F. Supp. 2d at 993 (emphasis in original); *see also Christiansburg Garment Co. v. Equal Employment Opportunity Comm'n*, 434 U.S. 412, 422 (1978) ("[N]o matter how meritorious one's claim may appear at the outset, the course of litigation is rarely predictable.").

3). *"Reverse Payments" Are a Natural Consequence of the Risk-Shifting Aspects of the Hatch-Waxman Act*

The courts that have considered so-called "reverse payments" in the context of Hatch-Waxman settlements have observed that any "suspicion" about payments to generics "abates upon reflection" because those payments are merely a by-product of the incentives and risks created by Hatch-Waxman. *Cipro*, 544 F.3d at 1333 n.11; *Tamoxifen*, 466 F.3d at 208-09; *Schering-Plough*, 402 F.3d at 1074; *Valley Drug*, 344 F.3d at 1309. Therefore, even assuming the independent business arrangements at issue were "reverse payments" and not fair value transactions, they do not give rise to antitrust liability.[11]

Outside the Hatch-Waxman context, patent litigation usually involves circumstances where the potentially infringing product already has been sold, and the potential infringer

[11] Characterizing cash flowing from an innovator company to a generic as a "reverse payment" is a misnomer in the first instance because *any* patent settlement involves compensation to the alleged infringer (for example, in the form of reduced damages or lower royalty payments). *See Asahi Glass*, 289 F. Supp. 2d at 994 ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant") (emphasis in original); *see also Tamoxifen*, 466 F.3d at 207 n.20 ("It has been observed that even the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment ….").

therefore risks both substantial damages (indeed, treble damages) as well as significant lost investment if found liable. *See Cipro*, 261 F. Supp. 2d at 251. The potential infringer may mitigate that risk either by paying the patentee some amount of the profits earned or by agreeing to pay for a patent license. Conversely, the patentee may mitigate its risk of losing patent protection by accepting damages that are less than its actual lost profits, or granting a license for a fee less than it would have accepted had its patent protection not been in jeopardy. Thus, in non-Hatch-Waxman patent settlements, payments generally flow from the defendant to the plaintiff (although, as explained above, consideration also flows to the settling infringer).

When innovator drug companies sue generics under Hatch-Waxman, everything is different. The mere filing of a Paragraph IV certification is itself an act of infringement, 35 U.S.C. § 271(e)(2), and generic companies thus are able to challenge patents without marketing a drug and subjecting themselves to the risk damages for marketing an infringing product. *See Cipro*, 261 F. Supp. 2d at 252 ("[B]ecause of the generic manufacturer's entitlement under the Hatch-Waxman Amendments to institute patent litigation merely by filing [a Paragraph IV certification], the statutory scheme has the unintended consequence of altering the litigation risks of patent lawsuits."). Moreover, because a generic needs only to demonstrate that its drug is bioequivalent to the patented drug to obtain FDA approval, 21 U.S.C. § 355(j)(2)(A)(iv), it may have a relatively insubstantial investment at risk. On the other hand, the patentee faces the same type of risk it would face in the non-Hatch-Waxman context – potential loss of patent protection and loss of future profits, as well as substantial investment to obtain approval of an NDA – but (short of an at-risk launch by the generic) does not have the upside of a potential damages award (for sales lost because of the infringing product) to use as negotiation leverage. *See Valley Drug*, 344 F.3d at 1309 ("Appellees have not explained why a monetary payment as part of a patent

litigation settlement should be flatly prohibited as a *per se* violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with."). In fact, as a result of state generic drug substitution laws many of which mandate that pharmacies fill branded prescriptions with generic drugs, the risk of defeat to the patentee in the Hatch-Waxman context (losing most of its sales) is considerably greater than the risk to the patentee in other contexts (facing ordinary competition). *See* AC ¶¶ 20-22; *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 609 F. Supp. 2d 786, 811 n.23 (S.D. Ind. 2009) (providing examples of steep erosion of brand sales upon generic entry, *e.g.,* loss of approximately 80% of sales within three weeks).

There is, in short, nothing anticompetitive about settlement payments to generics. As the Federal Circuit stated, "[A] sizeable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed." *Cipro*, 544 F.3d at 1333 n.11. *See also Tamoxifen*, 466 F.3d at 206-07 (reverse payments are "particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them" and there is "no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent."); *Schering-Plough*, 402 F.3d at 1074 ("Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude."); *Cipro*, 261 F. Supp. 2d at 252 ("Accordingly, so-called reverse payments are a natural by-product of the Hatch-Waxman process."). *See also Asahi Glass*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) (concluding that *banning* reverse payment settlements "might well be thought anticompetitive," because it

would "reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement").

4). *This Court Should Apply* **Cipro** *in the Interest of Patent Law Uniformity*

This Court should apply the Federal Circuit's *Cipro* decision in order to ensure a uniform body of law concerning patent immunities. The Federal Circuit has stated that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). This case clearly involves such a patent immunity: the FTC challenges conduct in enforcing a patent (through settlement), and the scope of the patent standard establishes a patent immunity from the antitrust laws. *Cipro*, 544 F.3d at 1336 (scope of patent test flows from analysis of "right to exclude afforded by the patent" and recognition that "patent is an exception to the general rule against monopolies"); *Valley Drug*, 344 F.3d at 1308 (preserving "patent immunity" for "enforcing the exclusionary right through settlement"). In *Unitherm*, the Federal Circuit stated that even where questions of patent immunity arise by way of counterclaim and the cases therefore would be appealed to regional circuits, those courts should "apply Federal Circuit law or risk disturbing 'Congress's goal of ensuring patent-law uniformity' by applying [their] own law." *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1355 n.3 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006) (citations omitted); *see also Schinzing v. Mid-States Stainless, Inc.*, 415 F.3d 807, 811 (8th Cir. 2005) ("In examining this case, we adopt the Federal Circuit's precedent on substantive issues of patent law."); *In re Wellbutrin SR Antitrust Litig.*, No. Civ. A. 04-5525, 2006 WL 616292, at *11 (E.D. Pa. Mar. 9, 2006) (holding that "the controlling authority [as to sham litigation issue] is the Federal Circuit, whose decisions govern 'all antitrust claims

premised on the bringing of a patent infringement suit'") (quoting *Nobelpharma*, 141 F.3d at 1069).[12]

B. There Is No Circuit Split on Hatch-Waxman Settlements

Contrary to positions the FTC has taken in prior briefing here, the Sixth and District of Columbia Circuits are not at odds with the Federal, Second, and Eleventh Circuits; nor is the Eleventh Circuit scope of the patent standard different from that of the Federal and Second Circuits. Neither the Sixth nor the District of Columbia Circuit has considered a reverse payment *settlement* case, and the FTC itself has admitted that it would be "disingenuous" to suggest that the Eleventh Circuit has adopted a standard different from the Second and Federal Circuits. Moreover, any claim by the FTC that there is currently a circuit split would be inconsistent with the Commission's stated goal of *creating* one. *See Federal Trade Comm'n v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 30 (D.D.C. 2008) (transferring instant case to this Court, noting that"[T]he Commission is rather openly shopping for a circuit split … [b]ut it strikes the Court as both odd and unreasonable to do so at the expense of exposing a *single* defendant

[12] Now that the Federal Circuit has made clear that cases such as that at bar involve fundamental issues of patent immunity, *Cipro*, 544 F.3d at 1336, not only should Federal Circuit law apply, but the Federal Circuit likely has jurisdiction over any appeal here. The Federal Circuit's jurisdiction is exclusive as to claims that "arise under" the patent laws. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807-08 (1988) (jurisdictional test is whether plaintiffs' "right to relief necessarily depends on resolution of a substantial question of patent law"). This jurisdictional assessment is made based on the face of the complaint. *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 833 (2002). Here, the FTC's theory of liability depends on allegations that Cephalon has forfeited its patent immunity because the Settlements exceeded the scope of the '516 patent. *See* AC ¶¶ 5, 87, 88, 100, 147. The Amended Complaints therefore necessarily raise issues of patent law. *See Unitherm*, 375 F.3d at 1357 ("[T]he determination of which actions can cause a patentee ... to lose the general protection of patent law ... is clearly an issue unique to patent law - and therefore inappropriate for ... the regional circuits"); *Cipro*, 544 F.3d at 1335-36 (settlement was "within the exclusionary zone of the patent and therefore protected by patent law").

(engaged in a single course of conduct) to conflicting judgments in order to advance the agency's enforcement goals.") (emphasis in original).[13]

1). *The FTC's Reliance on Cases Involving Interim Agreements Is Misplaced and Inconsistent with Its Past Position*

The decisions in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *Andrx Pharms. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001),[14] and *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005) (*i.e.*, the *Valley Drug* remand decision) are not contrary to the scope of the patent test. These cases do not involve Hatch-Waxman settlements, but rather "interim agreements" in which a branded drug company paid a generic challenger to stay off the market while the patent suit continued. These agreements neither foster innovation nor resolve litigation, and thus – as courts recognize – are not subject to the same analysis. *See*, *e.g.*, *Schering-Plough*, 402 F.3d at 1066 n.14 ("We note that the case at bar is wholly different from [the *Valley Drug* remand decision]. The critical difference is that the agreements at issue in *Valley Drug* did not involve final settlements of patent litigation, and, moreover, the *Valley Drug* agreements did not permit the generic company to market its product before patent expiration. … Given these material distinctions, the same analysis cannot apply."); *In re K-Dur Antitrust Litig.*, No. 01-1652, slip op., 2009 WL 508869, at *24 (D.N.J. Feb. 6, 2009) (fmr. Judge Orlofsky, special master) (recommending adoption of scope of patent standard) ("Unlike the interim settlement in *Cardizem*, Schering's settlements in this case finally resolved its litigation with Upsher and ESI.").

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[13] The FTC's current Chairman has candidly acknowledged the FTC's strategy to attempt to create a circuit split in the hopes of persuading the Supreme Court to accept review. *See* Oral Statement of Commissioner Jon Leibowitz, Hearing of the Senate Judicial Committee (Jan. 17, 2007) at 3, *available at* http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf (last accessed August 26, 2009).

[14] The *Andrx* holding did not address whether the agreements violated the antitrust laws, but instead was focused on whether the plaintiff had sufficiently pleaded antitrust injury *assuming* there was a violation. 256 F.3d at 804, 812, 814.

In its joint *amicus* brief with the Solicitor General in opposition to *certiorari* in *Cardizem*, the FTC itself distinguished *Cardizem* (which involved an interim agreement) from *Tamoxifen, Cipro*, and *Schering-Plough* (which involved final settlements) in the same way:

> While final settlements of infringement claims may have anticompetitive effects, they may "facilitate innovation and investment in the patented technology by eliminating litigation risks and providing certainty over patent rights." The type of interim agreement at issue in [*Cardizem*], on the other hand, may have none of those effects, because it leaves questions of patent validity and infringement to be litigated.

Br. of United States as *Amicus Curiae*, *Andrx Pharms., Inc. v. Kroger Co.*, 125 S. Ct. 307 (2004) (No. 03-779) (FTC *Cardizem Amicus* Br.) (joined by the FTC), 2004 WL 1562075, at *17. The Commission advanced the same distinction in its *Schering-Plough* opinion: "The *Cardizem* case also can be distinguished on its facts…. Unlike the present case, *Cardizem* involved an interim [agreement] rather than a final settlement, so it would be more difficult to claim that the agreement was ancillary to an efficient disposition of the litigation." Opinion of the Commission, *In re Schering-Plough Corp.*, No. 9297 ("*FTC Schering-Plough*"), at 13 n.26, *available at* www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf (last accessed Aug. 26, 2009).

Finally, Cardizem is inapposite for the further reason that, as the Federal Circuit noted, the agreement there "clearly had anticompetitive effects outside the exclusion zone of the patent." *Cipro*, 544 F.3d at 1335. In particular, the generic agreed not to relinquish its 180-day exclusivity, and agreed not to market admittedly non-infringing versions of the drug. *Id.*; *see also* FTC *Cardizem Amicus* Br., at *12 ("The better reading of the Sixth Circuit's opinion is that *it does not* deem illegal *per se* every settlement agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product.") (emphasis added).

2). *The Eleventh Circuit Standard Is Not Different from the Second and Federal Circuits'*

a). Schering-Plough *States The Same Rule As The Other Circuits*

Notwithstanding its taking the exact opposite position in the *Schering-Plough* case itself, the FTC in prior briefing here has seized upon ambiguous *dictum* in the concluding paragraph of *Schering-Plough* to suggest that the Eleventh Circuit scope of the patent test – unlike the Federal and Second Circuit test – includes *ex post* evaluation of the patent merits. The decision does cryptically mention a "need to evaluate the strength of the patent." *Schering-Plough*, 402 F.3d at 1076. But in the context of an opinion holding that the settlements "fell well within the protections of the '743 patent" by reference to the patent's claims and expiration date, without any analysis of the validity or infringement arguments raised by the generics, *see* 402 F.3d at 1076, that hardly suggests the court meant to embrace a different approach. Indeed, in its unsuccessful effort to obtain Supreme Court review of *Schering-Plough*, the FTC itself asserted that the Eleventh Circuit approach "immunize[d]" settlements within the "*nominal scope*" of the patent without regard to a retrospective assessment of the underlying patent claims. Reply Br. for the Petitioner, *Federal Trade Comm'n v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2652617, at **2-3 (emphasis added); *see also id.* at *2 (concluding that "respondents' suggestion that a *post hoc* inquiry into the merits would satisfy the court of appeals, is disingenuous, because *Valley Drug* precludes a conclusion of liability on that basis"). Notably, in a brief just filed in Hatch-Waxman settlement litigation in the Northern District of Georgia, in which the FTC also expresses its revisionist view of Eleventh Circuit precedent, it candidly acknowledged its inconsistency. Brief of FTC at 2, *Federal Trade Comm'n v. Watson Pharms., Inc.*, No. 1:09-CV-00955 (N.D. Ga. Aug. 21, 2009) ("To be sure, the Commission has

expressed its concern to the Supreme Court and Congress that the Eleventh Circuit adopted [a standard that foreclosed inquiry into the strength of the patent]").

The Commission's interpretation of Eleventh Circuit precedent in its Supreme Court briefing was clearly correct, because *Valley Drug*, which the *Schering-Plough* court expressly followed, *see* 402 F.3d at 1065, held that even a judicial finding of patent invalidity *ex post* "is insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis." *Valley Drug*, 344 F.3d at 1309. The Federal Circuit read *Schering-Plough* and *Valley Drug* the same way: "[W]e agree with the Second and Eleventh Circuits and with the district court 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 of a settlement agreement involving a reverse payment." *Cipro*, 544 F.3d at 1336.

The Eleventh Circuit's most recent Hatch-Waxman settlement decision, *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), confirms that it measures a patent's exclusionary potential by the facial scope of its claims, not by the patentee's likelihood of success. The court applied *Valley Drug* to determine whether plaintiff had stated a claim, and answered the first question – the scope of the patent – by finding that, based on its claims, the patent covered the generic product. *Id.* at 1235 ("With regard to the first element [i.e., the scope of the patent], the allegations in Andrx's complaint demonstrated that the '320 patent was necessary to the manufacture and sale of controlled release naproxen medication."). The court did not discount or limit that scope based on an assessment of the patent merits, notwithstanding the plaintiff's allegation that the patent could not "be held to be valid upon adjudication." *Id.* at 1231-32.

b). *The* Valley Drug *Remand Decision Does Not Suggest a Different Rule*

Any reliance on the *Valley Drug* remand decision (decided before both *Schering-Plough* and *Elan*) to somehow suggest a different Eleventh Circuit rule is unavailable. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005). To be sure, in the unique circumstances of that case, the court considered whether the branded company could have obtained an injunction against entry by the generic into the market. But the case is clearly distinguishable as it did not involve a Hatch-Waxman settlement at all, but instead an interim agreement in which the generic agreed not to market pending appeal of a decision invalidating the patent. *Terazosin*, 352 F. Supp. 2d at 1294.[15]

The Eleventh Circuit itself in *Valley Drug* had stated that this unique appellate stay provision warranted different treatment than a final settlement allowing for earlier entry by generic companies. In particular, the Eleventh Circuit had addressed two separate agreements: (1) the Abbott-Zenith settlement allowing for generic entry in advance of the patent's expiration; and (2) the Abbott-Geneva interim agreement including the appellate-stay provision. *Valley Drug*, 344 F.3d at 1300. In analyzing the *settlement*, the Eleventh Circuit noted that the agreement "appears to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted Zenith to market its drug before the '207 patent expired." *Id.* at 1305. Not only did the court not consider the patentee's likelihood of success had the matter not settled, but it expressly observed that such inquiry "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." *Id*. at 1308.

[15] Other provisions of the same agreement as well as a separate final settlement which were at issue in the Eleventh Circuit appeal in *Valley Drug* were no longer part of the case when the district court issued its remand decision. *Terazosin*, 352 F. Supp. 2d at 1294.

In stark contrast, the court framed the question for the *interim* agreement as whether the patent would "have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal," and remanded to the district court to make that determination. *Id.* at 1305 & n.17. This distinction drawn by the Eleventh Circuit makes good sense, because the Geneva interim agreement did not resolve litigation or achieve certainty with respect to patent rights. In effect, the parties had simply stipulated to a private injunction pending appeal with no pro-competitive benefit, and in that unique circumstance, the court looked to whether the already invalidated patent could have secured that same exclusion.

The Eleventh Circuit in *Schering-Plough* subsequently distinguished *Terazosin* on the same basis. *Schering-Plough*, 402 F.3d at 1065 n.14 ("We note that the case at bar is wholly different from [the *Valley Drug* remand decision]. The critical difference is that the agreements at issue in [*Terazosin*] did not involve final settlements of patent litigation, and, moreover, the [*Terazosin*] agreements did not permit the generic company to market its product before patent expiration. … Given these material distinctions, the same analysis cannot apply.").

Accordingly, because no appellate stay provision or interim agreement is before the Court, *Terazosin* is irrelevant.[16]

3). *A Special Master Recently Recommended Adoption of the Prevailing Scope of the Patent Standard in the* **K-Dur** *Case*

In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517 (D.N.J. 2004), in which a district court denied a motion to dismiss a private antitrust suit arising from the settlements subsequently upheld in *Schering-Plough*, provides no support for the FTC's claim. According to the court, the complaint in *K-Dur* alleged a settlement that "grant[ed] rights to [the innovator company] in

[16] One court applying the scope of the patent test questioned whether *Terazosin* was correctly decided even in the limited context of an appellate-stay provision. *See Cipro*, 363 F. Supp. 2d at 526 ("It is not certain that the district court correctly interpreted the [*Valley Drug*] opinion.").

excess of what is granted by the patent." *Id.* at 532 (noting restrictions on non-infringing generic competitor drugs and bioequivalence research relating to the branded drug).

Moreover, the opinion is of limited precedential value, principally because it was decided before the Federal Circuit's decision in *Cipro*, the Second Circuit's decision in *Tamoxifen*, and the Eleventh Circuit's decision in *Schering-Plough*. The court drew upon the precedent available at the time: *Cardizem* (which, as stated above, is distinguishable) and the FTC's *Schering-Plough* decision and order (which the Eleventh Circuit later vacated because it was based on an "inflexible" legal theory that failed to account for the realities of Hatch-Waxman litigation, *see Schering-Plough*, 403 F.3d at 1075). *See K-Dur*, 338 F. Supp. 2d at 533 & n.21. Recently, recognizing that the *K-Dur* motion to dismiss decision "was issued … before the 11th Circuit's decision in *Schering-Plough* and before the decisions of the Second and Federal Circuits following the 11th Circuit approach," the special master in the case, Judge Orlofsky (former D.N.J. judge) recommended that the court adopt the prevailing scope of the patent standard for purposes of summary judgment. *In re K-Dur Antitrust Litig.*, No. Civ. A. 01-1652, slip op., 2009 WL 508869, at *26 (D.N.J. Feb. 6, 2009).[17]

C. The Scope of the Patent Test Applies Equally Where the Underlying Case Involved Noninfringement Defenses

Opponents of the scope of the patent test, including the FTC in prior briefing, have suggested that the test depends on the presumption of patent validity under 35 U.S.C. § 282, and that the Eleventh Circuit in *Schering-Plough* therefore erred in applying it to settlement of cases where infringement had been disputed. *Schering-Plough*, however, did not create a "presumption" of infringement or rely on any presumption of patent validity; it simply noted the truism that a party retains its patent rights until it loses them in patent litigation. *See* 402 F.3d at

[17] Plaintiffs' objections to Judge Orlofsky's recommendation are pending. *See HIP Health Plan of Fla., Inc. v. Schering-Plough, et al.*, C.A. No. 01-1652, Docket No. 737 (Mar. 20, 2009).

1066-67 ("By virtue of its '743 patent, Schering obtained the legal right to exclude [the generics] from the market until they proved either that the '743 patent was invalid or that their products … did not infringe ….") . The Eleventh Circuit was not justifying its decision by reference to evidentiary presumptions as to patent validity or infringement as they might have applied had the underlying patent case gone to trial. What the court *did* hold – without regard to evidentiary presumptions – is that the scope of the patent test applied whether the generic had claimed invalidity, non-infringement, or both. *Id.* at 1075-76 ("An exception [to the scope of the patent standard] cannot lie, as the Commission might think, when the issue turns on validity (*Valley Drug*) as opposed to infringement (the Schering agreements)."); *see also K-Dur*, 2009 WL 508869, at *25 (recommendation) (holding that scope of patent standard applies even where "disputed issues in the patent case involved infringement"). The Second Circuit, which reached the same result as *Schering-Plough*, similarly disclaimed any reliance on evidentiary presumptions: "[I]rrespective of whether there was a presumption [of patent validity] or where any such presumption lay at the time of settlement, we think that [patentee] was then entitled to protect its … patent monopoly through settlement." *Tamoxifen*, 466 F.3d at 209 n.22.

The broad rationale of the decisions recognizing the scope of the patent standard applies irrespective of the issues in the underlying patent litigation. The courts recognize that making the legality of settlement depend on *ex post* assessment of the merits of the underlying patent case – validity, infringement, or both – would chill settlements, limit patent rights, and run afoul of Judge Posner's broad pronouncement, quoted by the Federal Circuit, that where "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." *Cipro*, 544 F.3d at 1337 (quoting *Asahi*

Glass, 289 F. Supp. 2d at 992); *Tamoxifen*, 466 F.3d at 203 ("We cannot judge this … settlement on the basis of the likelihood *vel non* of success had [the matter] not settled …."); *Valley Drug*, 344 F.3d at 1308 (to same effect). Making the scope of the patent standard inapplicable where infringement is at issue would severely undercut this rationale, because (among other things) a plaintiff could automatically survive dismissal merely by *alleging* that the generic product did not infringe.

D. The FTC Cannot Plead Around the Prevailing Standard

The FTC previously contended that it can *plead* around the prevailing *legal* standard, first mischaracterizing the courts' general observations and legal reasoning about Hatch-Waxman settlements as somehow depending on "facts" peculiar to those cases; and then asserting that those rationales cannot be considered here because they are "contradicted" by or "outside" the Amended Complaint's allegations and not subject to judicial notice. In particular, the FTC alleges that "reverse payments" "are not a natural by-product of incentives created by the Hatch-Waxman Act," and that Hatch-Waxman patent cases could settle without reverse payments. AC ¶ 98. The FTC would foreclose this Court's consideration of the propositions, accepted by the Federal, Second, and Eleventh Circuits, that: (1) "reverse payments" *are* a "natural by-product" of Hatch-Waxman and therefore do not (as the FTC claims) signal "weak" patents or anticompetitive purpose; and (2) "reverse payments" may be necessary to settle some Hatch-Waxman cases because of the particular settlement dynamics created by the statute. *See Tamoxifen*, 466 F.3d at 206-07; *Schering-Plough*, 402 F.3d at 1074.[18]

[18] Cephalon does not claim that "reverse payments" are necessary to settle *all* Hatch-Waxman patent cases. Indeed, there were no "reverse payments" in this case. To the extent the FTC again relies on statistics about a number of unidentified settlements without "reverse payments," *see* AC ¶ 98, they are immaterial.

But courts *may*, and *do*, take judicial notice of precisely these types of "facts," which are not specific to the case but rather "have relevance to legal reasoning … whether in the formulation of a legal principle or ruling by a judge or court or in the enactment of a legislative body." *See* Fed. R. Evid. 201 advisory committee's note (distinguishing between "legislative facts" as defined above, of which courts may take judicial notice, and "adjudicative" facts, *i.e.*, the facts of a particular case, which are not subject to judicial notice); *Democratic Party of U.S. v. Nat'l Conservative Political Action Comm.*, 578 F. Supp. 797, 830 (E.D. Pa. 1983) (holding that absent admissible evidence supporting an "adjudicative finding," "the court … may guide its conclusions by reasonable exercise of its deductive powers," and on that basis finding that election funding statute unconstitutionally chilled speech), *aff'd in part and rev'd in part on other grounds sub nom Fed. Election Comm'n v. Nat'l Conservative Political Action Comm.*, 470 U.S. 480, 500 (1985); *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 309 (3d Cir. 2007) (relying on general observations about pro-competitive benefits of standard-setting in finding *per se* standard inapplicable).

Accordingly, Cephalon's reliance on both the cases applying the prevailing scope of the patent standard and their underlying rationales is perfectly appropriate. The FTC has it precisely backwards: far from *avoiding* dismissal under the scope of the patent test, allegations about patent "weakness" and the "possibility" of a "cashless" settlement are precisely the type of case-specific facts that the standard deems irrelevant as a matter of law. *See, e.g., Tamoxifen*, 466 F.3d at 210-11 (rejecting *ex post* assessments of patent merits); *Schering-Plough*, 402 F.3d at 1074-75 (rejecting rule basing liability on possibility of "compromise-without-payment").

E. The Scope of the Patent Test Derives from Supreme Court Precedent

Seeking to avoid the consensus of the courts of appeals, the Commission has sought to bolster its policy arguments by suggesting they derive directly from Supreme Court precedent.

This effort drew largely on sound-bites setting forth general principles that few would dispute, such as that the right to challenge patents is important to the public interest.

The cases on which the FTC has relied lend no support to the FTC's cornerstone policy proposition that antitrust liability for a patentee's conduct depends on the patent's "strength." Notably, *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), cited for the proposition that "weak" patents have less "exclusionary force" than "strong" patents, is not even an antitrust case. It merely discusses the patent law principle that inventions should not be patentable *at all* if they are "obvious" in light of prior art, *id.*, at 1741, and does not speak to the power of an *issued* patent to exclude others from practicing the claimed invention.[19]

United States v. Masonite Corp., 316 U.S. 265 (1942), likewise provides no support for the FTC's position. *Masonite* simply held that once a patentee sells a patented product, it is beyond the limits of its patent grant to then *conspire* with purchasers to *fix the resale price* of the product. *Id.* at 277-78. Like the prevailing scope of the patent standard, *Masonite* recognized that conduct by a patentee that merely excludes competition "within the limits of the [patent] monopoly" does not violate the antitrust laws. *Id*. Indeed, *Masonite* was affirmatively invoked by the Eleventh Circuit in *Valley Drug* as direct support for the scope of the patent standard. *See Valley Drug*, 344 F.3d at 1312 (citing *Masonite* for proposition that the "patent exception to antitrust liability … is limited by the terms of the patent and the statutory rights granted the patentee").

[19] To the extent the FTC attempts again to show that pharmaceutical patents tend to be "weak" through data on the percentage of successful challenges, such effort would be greatly skewed because it fails to account for patents that were not challenged in the first instance, or challenges resolved by agreement. In any event, suspect statistics about large groups of cases say nothing about the merits of this particular dispute at issue here.

United States v. Glaxo Group, Ltd., 410 U.S. 52 (1973), also supports the scope of the patent test. While the *Glaxo* Court recognized the government's standing to *directly* contest the validity of a patent as a remedy for *established* antitrust violations, it cautioned against subjecting a patentee to antitrust liability *based on* an *allegation* of patent invalidity. The Court stated, "[W]e do not recognize unlimited authority in the Government to attack a patent *by basing an antitrust claim on the simple assertion that the patent is invalid* … [n]or do we invest the Attorney General with a roving commission to question the validity of any patent lurking in the background of an antitrust case." *Id.* at 59 (emphasis added).

Finally, the FTC has argued that the scope of the patent test is inconsistent with the Supreme Court's decision in *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006) (applying four-part general permanent injunction standard to patent cases). It contends that because even a successful patentee is not automatically entitled to an injunction excluding competition, it somehow follows that a patentee that has not established its patent claims should not be allowed to exclude competition through settlement. But the argument compares apples to oranges. *eBay* is not an antitrust case or even a Hatch-Waxman case, and the general standard for obtaining a permanent injunction has no logical connection to the question whether Hatch-Waxman settlements violate the antitrust laws. Indeed, there is no reason to believe the parties in *eBay* could not have lawfully settled their claims. *See Standard Oil*, 283 U.S. at 171 (settlement of "legitimately conflicting [patent] claims . . . not precluded by the [Sherman] Act.").

The Supreme Court case most on point is one the FTC conspicuously has avoided in prior briefing: *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). In *Walker Process*, the Supreme Court considered the extent to which a patentee should be held liable under the Sherman Act for attempting to enforce patents against competitors. The Court

drew the critical distinction between patents *fraudulently* procured (enforcement of which could trigger antitrust liability) and patents that are merely found invalid (enforcement of which before the finding of invalidity does not give rise to antitrust liability). *Id*. at 177. Like the prevailing scope of the patent standard, the *Walker Process* holding reflects a balance of the competing interests of patent and antitrust law. *See id.* at 179-80 (Harlan, J., concurring) ("It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in the area between the differing policies of the patent and antitrust laws."). As Justice Harlan explained in his concurrence, subjecting a patentee to antitrust liability merely because a patent might be "voidable … might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits." *Id*. at 180.

Several courts articulating the prevailing scope of the patent standard specifically relied on *Walker Process*. *Cipro*, 544 F.3d at 1336 (citing *Walker Process* in concluding that the scope of the patent standard was "completely consistent" with Supreme Court precedent concerning the intersection of antitrust and patent law); *Valley Drug*, 344 F.3d at 1307-08 ("Justice Harlan's concurrence [in *Walker Process*] explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws… Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives."); *Cipro*, 363 F. Supp. 2d at 530 (subjecting patent settlements to antitrust liability based on an after-the-fact review of the patent merits "would overstep the bright-line rule adopted by the Supreme Court in

Walker Process, first elaborated upon by Justice Harlan in his concurrence and relied upon by the patent bar for the past forty years.").

F. The Inconsistent Alternative Standards Proposed or Invited by the FTC Are Flawed in Theory and Unworkable in Practice

The FTC's attempts to reduce its policy to practice are as flawed as the logic of the policy itself. The Amended Complaint and the Commission's prior briefing advance several, inconsistent alternative standards, each of which asks the Court either to condemn reverse payments outright or to measure the "exclusionary power" of the patent by considering the patent's actual or perceived strength. Each, however, is fundamentally flawed and completely unworkable.[20]

1). *The Settlements Are Not Outside the Exclusionary Scope of the '516 Patent Merely Because the Parties Theoretically Could Have Agreed on an Earlier Generic Entry Date*

The Amended Complaint alleges that the Provigil® Settlements "harm competition and consumer welfare" because, absent the alleged settlement payments, the parties "would have agreed to settle [their] patent litigation on terms that … provided for generic entry earlier than April 2012." AC ¶¶ 83, 85. These allegations reflect the FTC's hypothetical "entry-date-only" settlement theory of liability, which it has repeatedly and unsuccessfully advocated in other courts. Essentially, the theory contends that patents are only "probabilistic" (that is, they only confer on the patentee a right that may or may not be enforced in court depending on the strength of the patent). According to the FTC, a hypothetical settlement where no cash flows to the generic, and where the parties can bargain only about generic entry date, reflects the true "probability" that the patentee would have prevailed in the lawsuit and the true "exclusionary

[20] Any suggestion that the Court need not adopt a standard at all, but should simply reject the scope of the patent test, is ill-considered. A clear standard not only would be necessary for summary judgment and trial, but would impact the scope of discovery as well.

scope" of a patent, whereas a settlement that includes a reverse payment necessarily "delays" this hypothetical entry date, and therefore *must* be anticompetitive. The Eleventh Circuit in *Schering-Plough* specifically rejected this approach. 402 F.3d at 1074. Indeed, no court ever has adopted it. This Court should not be the first.

The FTC alleges no *facts* plausibly suggesting the parties here could have settled on different terms providing for earlier Generic entry. For that reason alone, its allegations should be discredited under *Bell Atlantic Co. v Twombly*, 550 U.S. 544, 557 (2007) (complaints must include sufficient factual allegations "plausibly suggesting" essential elements of claim); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (factual allegations in complaint must not "stop[] short of the line between possibility and plausibility of 'entitlement to relief'").

Even leaving that fatal defect aside, the FTC fundamental premise – that the hypothetical possibility of a different settlement is a basis for imposing antitrust liability – is quite mistaken. The FTC's "benchmark" theory wrongly assumes that cashless settlements necessarily reflect the parties' collective assessment of the "strength" of the patent case. But this theory ignores the very different risk profiles of the litigants. Because an ANDA applicant risks so little in the litigation, it is in a position to demand greater settlement concessions than the patent merits might dictate; and conversely, because the branded company risks so much, with so little to gain by way of damages, it may be in a position to concede more. The Second and Eleventh Circuits have observed that innovator companies may make settlement payments even when they are quite confident in their claims:

> [A] rule [prohibiting reverse payments would] fail to give sufficient consideration to the patent holder's incentive to settle the lawsuit without reference to the amount the generic manufacturer might earn in a competitive market, even when it is relatively confident of the validity of its patent – to insure against the possibility that its confidence is misplaced, or, put another way, that a reviewing court might (in its view) render an erroneous decision…. Whatever the degree of

> the patent holder's certainty, there is always some risk of loss that the patent holder might wish to insure against by settling.

Tamoxifen, 466 F.3d at 210 (upholding settlement in case where innovator made settlement payment to one generic and went on to prevail in patent challenges against others); *Valley Drug,* 344 F.3d at 1310 ("Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.").

The "entry-date-only" theory also proceeds from the faulty assumption that parties always can settle Hatch-Waxman cases without cash payments. However, in the real world, such settlements are often impossible because of the parties' dissimilar risks, rewards, and perceptions. Indeed, in many cases, the asymmetry of risk caused by Hatch-Waxman, *see supra* § I(A)(3), may mean that many cases cannot be settled "within the cashless, patent-term-splitting paradigm" the FTC suggests. *See* 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, 630 (2006):

> Over optimism, either by both parties or by the entrant alone, can produce a gap between the latest date at which the generic is willing to accept entry in order to settle litigation and the earliest date at which the innovator is willing to permit entry. A cash payment can bridge the gap.

See also Marc G. Schildkraut, "Patent-Splitting Settlements and the Reverse Payment Fallacy," 71 ANTITRUST L.J. 1033, 1034 (2004) ("The payment may be necessary, for instance, because the alleged infringer is unduly optimistic about its chances of prevailing in the litigation.").

Finally, the FTC's hypothetical "entry-date-only" settlement theory runs afoul of the basic antitrust principle that private parties have no affirmative obligation to enter into agreements that are the *most* pro-competitive. In *Cipro*, 363 F. Supp. 2d at 532, the court observed that "Requiring parties to a lawsuit either to litigate or negotiate a settlement in the

public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants 'to continue to litigate when they would prefer to settle' and 'to act as unwilling private attorneys general and to bear the various costs and risks of litigation.'" The court therefore found that "Bayer and Barr cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition beyond the scope of the '444 Patent." *Id.* at 536; *see also Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) (Sherman Act does not impose obligation on defendant to "alter its way of doing business whenever some other approach might yield greater competition"); *USM Corp. v. SPS Techns., Inc.*, 694 F.2d 505, 512-13 (7th Cir. 1982) (Posner, J.) (the antitrust laws do not create a positive duty to enhance competition); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975) (requiring businesses to enter into most procompetitive agreements possible would improperly make businesspeople "guarantors that the imaginations of lawyers could not conjure up some method of achieving the business purpose in question that would result in a somewhat lesser restriction of trade.

2). *The FTC's Proposed* **Ex Post** *Evaluation of the Patent Merits Would Chill Settlements and Is Unworkable*

The FTC devotes an entire section of its Amended Complaint to the proposition that the '516 patent was "unlikely to prevent generic competition to Provigil," *see* AC § V.B, thus inviting the Court to consider the reasonableness of the settlement terms as somehow measured by the relative merits of the parties' cases. Specifically, it alleges that "Cephalon bore the burden" of proving infringement, that (obviously, because the case settled before conclusion) "Cephalon had not met its burden," and that "Cephalon was … unlikely" to prevail. AC ¶ 47. This standard has not only been rejected by the courts for the reasons discussed above, *see supra*

§ I(A)(2), but also by the FTC itself and now the DOJ (the agency that initially proposed the *ex post* merits inquiry).

In prior litigation, the Commission repeatedly argued *against* the wisdom of such an assessment of the merits of the settled patent litigation. In its *Schering-Plough* opinion (later vacated by the Eleventh Circuit), the Commission acknowledged the "serious uncertainties that would confront parties who seek to settle patent litigation if the Commission undertook to examine the underlying merits itself later on, and gave them conclusive weight." *See* Supp. Br. for the Petitioner, *Federal Trade Comm'n v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2006 WL 1647529, at *4 ("A key drawback to [a *ex post* review] is that it places parties contemplating settlement in the predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal."); Reply Br. for the Petitioner Federal Trade Comm'n in Support of its Petition for Writ of *Certiorari*, *Federal Trade Comm'n v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2652617, at *5 n.4 (stating view that an "*ex post* inquiry into the patent merits was neither necessary nor helpful" and "ultimately [would] have a chilling effect on the efficient settlement of patent litigation.").

In addition to chilling settlements, requiring judges or juries to evaluate the lawfulness of settlements based on *ex post* assessments of the strength of the patent claims and defenses (or, even worse, private doubts of litigants) would pose enormous practical problems, including instructing the jury. One can imagine the confusion engendered by an instruction such as: "You should find the settlement violates the antitrust laws if you find by a preponderance of the evidence that the consideration paid by the patentee to the generic company was excessive

relative to the likelihood the patentee would have prevailed in the underlying suit."[21] Moreover, the efficacy of retrying the underlying patent case is highly doubtful. As the Commission itself has stated: "We question the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case." *FTC Schering-Plough*, at 33, *available at* www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf (last accessed August 26, 2009). Moreover, the DOJ – which previously advocated this approach – recently conceded it to be unworkable. *See* Br. for the U.S., *Arkansas Carpenters Health & Welfare Fund v. Bayer, AG*, No. 05-2851, 2852 (2009), 2009 WL 2429249 ("DOJ *Cipro* Br."), at 25-26 ("[A] mini-trial of the patent issue … could reduce parties' incentives to settle … [and] would align the infringement defendant with the infringement plaintiff in the antitrust case, reducing the accuracy of any validity determination.").

3). *Measuring the Settlement Against the Parties' Subjective Assessment of the Merits Is Unworkable*

The Amended Complaint also includes allegations concerning Cephalon's subjective expectations about the outcome of the suit, *see* AC ¶¶ 4, 51. These allegations signal that the FTC may advance, as yet another alternative, a standard based on the parties' subjective assessment of the patent case. The DOJ recently advocated this approach in a brief to the Second

[21] Similarly, instructing the jury to consider the "strength" or "weakness" of the patent would be impractical. How, for example, should jurors define a "strong" or a "weak" patent? Should the inquiry be purely qualitative, or should the fact-finder artificially quantify the likelihood that the patentee would have prevailed had the case been tried? Even if such an exercise were possible, does a 51 percent probability mean a patent is "strong" and a 49 percent probability mean a patent is "weak"? If not, should there be some other threshold below which a patent is too "weak" to support certain settlement terms? Should there be some amorphous sliding scale comparing the "weakness" of a patent to the amount of consideration given to the generic? Proponents of the merits-based standards have not meaningfully addressed these questions.

Circuit in *Cipro*. *See* DOJ *Cipro* Br.[22] The DOJ's approach, however, is as amorphous and unworkable as the objective *ex post* inquiry.

Specifically, the DOJ now proposes that any Hatch-Waxman settlement involving a so-called "reverse payment" to the alleged infringer should be treated as presumptively unlawful, with the burden on the defendants to show that "the agreed upon entry date and other terms of entry reasonably reflected their contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration." DOJ *Cipro* Br. at 21-27, 30-31.

The subjective approach naively assumes that each settling party had the same "evaluation" of the likelihood of success, and that those "odds" can readily translate into a corresponding settlement entry date. Yet, as previously noted, patent litigation is inherently uncertain, and there is no reason to presume that branded companies and generic litigants will assess the case in the same way, given their very different risk and reward profiles. *See supra* § I(A)(3).

The subjective assessment approach also presents troubling evidentiary issues because most case assessments would be protected by the attorney client privilege and/or work product doctrine. The prospect of having to waive privilege to defend a settlement, or alternatively having to risk treble damages to preserve the privilege, could both chill settlements and inhibit full and frank communications with counsel.

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[22] There were two appeals from the Eastern District of New York's decision in *Cipro*. The appeal of the indirect purchasers case went to the Federal Circuit because it included state law claims expressly raising issues of patent law. *Cipro*, 544 F.3d at 1330. The appeal of the direct purchasers case went to the Second Circuit over the objection of defendants, as based on the court's ruling that it did not raise patent law issues. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Nos. 05-2851 & 05-2852 (2d. Cir. Nov. 7, 2007) (order denying motion to transfer direct purchaser claims because they relied partially on theories involving no substantial question of patent law). The Second Circuit, however, recently requested briefing on whether it should transfer the remaining appeals to the Federal Circuit. *See Cipro*, Nos. 05-2851 & 05-2852, Apr. 29, 2009 Docket Entry (letter to DOJ regarding jurisdictional question).

Finally, even assuming these other problems could be overcome, subjective assessment does not present a workable standard that judges or juries could meaningfully apply, but instead leads to an amorphous and ultimately arbitrary inquiry. It is wholly unclear how a fact-finder meaningfully could determine whether an agreed-upon entry date "reasonably" reflected the parties' contemporaneous expectations about the litigation. In the recent DOJ filing regarding this proposed approach, the DOJ posed no workable solution, inconsistently eschewing the need for mathematical precision regarding expectations, but at the same time insisting that even common belief that the patent was "very likely" to be upheld would not justify a "reverse payment" settlement. *Id.* at 31.

II. Applying the Prevailing Standard, the Court Should Dismiss the Amended Complaint Because It Does Not Allege that the Settlement Restrictions Exceed the Scope of the '516 Patent

A. The Provigil® Settlements Do Not Include Products Outside the '516 Patent's Exclusionary Scope

The Commission attempts to avoid the prevailing standard by alleging that while the Generics agreed not to sell any generic version of Provigil® before 2012, the "patent lawsuit, in contrast, had the potential to restrict only sales of these companies' *current* [*i.e.*, proposed] versions of generic Provigil®, the products at issue in the litigation." *See* AC ¶ 81 (emphasis added).[23] Contrary to the FTC's allegation, the patent litigation did have the potential to restrict the Generics from selling not only the particular ANDA modafinil composition at issue, but also any generic product covered by Cephalon's construction of the '516 patent claims. *See Pfaff v. Wells Elecs.*, 5 F.3d 514, 518 (Fed. Cir. 1993) (prior court's interpretation of patent claims, if necessary to infringement finding, has preclusive effect in subsequent litigation between same

[23] The FTC further alleges that two of the Settlements also preclude the sale of "generic equivalents of successor products" of Provigil®. AC ¶ 80. The Amended Complaint, however, includes no allegations identifying the products or, more importantly, plausibly explaining why they would not fall within the scope of the '516 patent.

parties); *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1323 (Fed. Cir. 1987) (same); *Roche Palo Alto LLC v. Apotex, Inc.*, 526 F. Supp. 2d 985, 991 (N.D. Cal. 2007) (where generic company filed new ANDA after losing prior ANDA litigation, "issue preclusion would prevent [generic] from relitigating these claim construction issues"), *aff'd*, 531 F.3d 1372 (Fed. Cir. 2008), *cert denied*, 129 S. Ct. 1046 (2009).

Moreover, as the name suggests, the relevant issue under the "scope of the patent" test is the exclusionary potential of the patent, not the scope of the *lawsuit.* It is axiomatic that Cephalon has a right to exclude competition to the full breadth of the '516 patent's claims. *See, e.g., Cipro*, 544 F.3d at 1337 (district court correctly "equat[ed] the exclusionary power of the patent with the scope of the patent claims"); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) ("It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'").

The scope of the patent test, then, upholds as a lawful exercise of patent rights a settlement covering all generic products within Cephalon's good faith construction of the '516 patent claims, not just those products being litigated at the time. Any other result would invite the same *ex post* inquiry the scope of the patent test eschews, because there is no logical difference between later analyzing whether the generic product issue infringed and analyzing whether other generic products covered by the settlement infringed. *Valley Drug*, 344 F.3d at 1305, 1310 (declining to review merits of patent case so long as there was "genuine dispute"); *Schering-Plough*, 402 F.3d at 1075-76 (same, in case involving infringement dispute). Tellingly, the FTC does not challenge the *bona fides* of Cephalon's claim construction, or allege facts plausibly showing that any generic product subject to the settlement falls outside of that claim

construction. *See Twombly*, 550 U.S. at 557. Accordingly, the Settlements cannot be challenged on the basis that they encompass products beyond the scope of the '516 patent.

Permitting settlements to the full extent of good faith patent claim construction is also practical, and consistent with the duty of courts to promote settlements. Like many composition patents, the '516 patent covers a range of possible compositions of the drug.[24] If settlements were limited only to the specific composition submitted under a generic's ANDA, the generic potentially could modify that composition, submit a new ANDA, file a new Paragraph IV letter, and begin the litigation all over again. The patent holder wishing to settle an infringement suit would therefore face the Hobson's choice of (1) entering into a settlement covering only the current, specific ANDA product, leaving open the possibility of future infringement litigation over other ANDAs for the same drug, or (2) not settling at all. Adopting the FTC's position would compromise the very certainty that settlements are designed to provide, needlessly wasting judicial resources, and chilling settlements in contravention of the duty of courts to promote them. *See Tamoxifen*, 466 F.3d at 202.

The settlements here included only products within the exclusionary power of the '516 patent, and the FTC's Amended Complaint therefore should be dismissed.

B. The Alleged "Delay" in Subsequent Filer Entry Is Not Beyond the Patent's Scope and, in Any Event, Results from Hatch-Waxman

[24] Among other things, the '516 patent claims: "[a] pharmaceutical composition comprising a substantially homogeneous mixture of modafinil particles, wherein at least about 95% of the cumulative total of modafinil particles in said composition have a diameter of less than about 200 microns"; and also "[a] pharmaceutical composition in an oral dose form comprising: an amount of modafinil effective to alter a somnolent state of a mammal upon oral administration, said amount of modafinil being in the form of solid modafinil particles, said particles having a size distribution wherein at least about 95% of the cumulative total of said particles have a diameter of less than about 200 microns." *See* U.S. Patent RE37,516 (claims 1 & 7), *available at* www.uspto.gov. *See Ieradi v. Mylan Labs., Inc.*, 230 F.3d 594, 600 n.3 (3d Cir. 2000) (stating that courts may take judicial notice of facts that are "not subject to reasonable dispute [and are] capable of accurate and ready determination by resort to a source whose accuracy cannot be reasonably questioned"); *see also Messer v. HO Sports Co., Inc.*, Civ. A. No. 06-826, 2007 WL 3113334, at *6 (D. Or. Oct. 22, 2007) (taking judicial notice of substance of patent claims).

Finally, the FTC alleges that the Settlements have created a so-called "bottleneck." According to the Amended Complaint, because the first-filing Generics agreed not to launch until 2012, subsequent ANDA filers are blocked from getting FDA approval until after 2012 when the Generics will enjoy their 180-day exclusivity period. *See* AC ¶¶ 87-90. The Settlements, however, have not created any such "bottleneck," because under Hatch-Waxman, subsequent ANDA filers are able to trigger the Generics' first-filer exclusivity before 2012.

In particular, a subsequent ANDA filer such as Apotex can trigger the Generics' 180 days of marketing exclusivity by obtaining a "court decision" against the '516 patent. 21 U.S.C. § 355(j)(5)(B)(iv)(I); *see supra* § I(A). Indeed, Apotex is currently challenging the '516 patent through declaratory judgment claims, and if it succeeds, it can enter 180 days after the Generics enter. There is no "bottleneck." *See Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1951 (2009) ("bare assertions" are "not entitled to be assumed true").

The FTC likely based its allegations on prior Federal Circuit law that would have denied standing to Apotex to assert declaratory judgment claims. *Compare Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005) (no jurisdiction over declaratory judgment claim if subsequent ANDA filer not "in reasonable apprehension of suit" from patentee) *with Caraco Pharm. Labs, Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008) (jurisdiction if court judgment necessary to eliminate patent as barrier of regulatory approval). That would explain such allegations as that Cephalon took "further steps" to delay subsequent generic entry, "including settling or refusing to litigate with other generic companies that could trigger the exclusivity period." AC ¶ 90. But even under the prior regime where subsequent ANDA filers did not have a declaratory judgment remedy, any effect of the Settlements on subsequent ANDA filers was clearly the result of the Federal Circuit's standing requirements,

combined with Hatch-Waxman law that a first-filer retains its 180 days of exclusivity after settlement. *See* 21 U.S.C. § 355(j)(5)(D)(i)(V). Where an alleged anticompetitive effect results from operation of law, it cannot be attributed to the defendant's conduct. *See City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) ("[A]ny injury suffered by the City did not flow from the defendants' conduct, but, rather, from the realities of the regulated environment in which all three were actors."). Moreover, any allegation about effect on subsequent generic entry here proves too much, as the same effect results from any settlement in which a first filing generic retains exclusivity, whether the settlement includes "reverse payments" or not. At bottom, the critical question remains whether a "reverse payment" renders a Hatch-Waxman settlement outside the exclusionary scope of the patent, and the courts have decisively held that it does not.

Accordingly, there is no "bottleneck," and any prior effect on subsequent generic applicants is not actionable because it resulted only from operation of law.

CONCLUSION

Under the prevailing scope of the patent standard, adopted by the Federal, Second, and Eleventh Circuits, a complaint challenging the legality of a Hatch-Waxman patent settlement should be dismissed unless it alleges that the settlement either: (1) delays the entry of generic products beyond the patent's expiration date; or (2) restricts the sale of "unrelated or non-infringing" products. This standard is derived from Supreme Court precedent protecting the rights of patentees to restrict competition within the scope of the patent grant, and from the well-established judicial duty to encourage litigation settlements, particularly in the patent context. This Court should apply the prevailing standard rather than adopt the FTC's unsound policy views that have been repeatedly rejected by the courts. The standards the FTC proposes would turn precedent, public policy, and common sense squarely on their heads by asking courts to

second-guess how generic and branded drug manufacturers decide to settle commercial disputes. Because the Provigil® Settlements are well within Cephalon's patent rights, the Amended Complaint fails to state a claim and should be dismissed with prejudice.

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Dated: August 31, 2009

CERTIFICATE OF SERVICE

I certify that on the date set forth below the foregoing Defendant Cephalon, Inc.'s Motion to Dismiss the First Amended Complaint, Memorandum in support, and proposed Order were electronically filed pursuant to the Court's CM/ECF system, and that the documents are available for downloading and viewing from the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

s/ Frank R. Emmerich, Jr.
Frank R. Emmerich, Jr.

Date: August 31, 2009