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

FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, NW Washington, D.C. 20580 Plaintiff, v. CEPHALON, INC. 41 Moores Road Frazer, Pennsylvania 19355 Defendant.	Civil Action No. 08-cv-2141-RBS

PLAINTIFF FEDERAL TRADE COMMISSION'S MEMORANDUM IN OPPOSITION TO CEPHALON'S MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Regulations

Federal Statutes

Federal Legislative Materials

Federal Administrative Materials

Other Authorities

INTRODUCTION

The FTC's complaint tells a straightforward story of anticompetitive conduct: To preserve its monopoly in the sale of the sleep disorder drug modafinil, Cephalon used its monopoly profits to avoid competition by paying its four generic rivals to abandon their plans to compete. Cephalon had lodged patent infringement claims against the four companies, but did not expect to prevail and so carried out a scheme that would enable it to buy the protection that its patent would not provide. In the words of Cephalon's CEO, "We were able to get six more years of patent protection. That's $4 billion in sales that no one expected." (Compl. ¶ 4.)

Cephalon's motion to dismiss contends that its conduct is nothing more than the legitimate exercise of its patent rights. The crux of the disagreement between Cephalon and the FTC is whether, in an antitrust analysis of a patent settlement, the Court must disregard complaint allegations that a patent holder used its monopoly profits to achieve an exclusion the patent did not provide. The FTC's complaint charges that Cephalon maintained its monopoly not through the power of its patent, but by paying its four potential competitors. The complaint alleges facts – including the terms of Cephalon's agreements with its rivals, the circumstances under which these agreements were made, and the likelihood that the patent itself could not prevent generic entry – from which it can reasonably be inferred that the exclusionary effects of Cephalon's conduct are not attributable to its patent.

According to Cephalon, none of these facts matter. The mere possession of a patent, it contends, grants the holder the inexorable right to exclude any challenger until patent expiration – a right that may be exercised by splitting monopoly profits with potential entrants to induce them to abandon their patent challenges and refrain from competing. As the theory goes, the patent holder's right to purchase protection from competition is not tempered by the strength of its patent, so long as the infringement claim is not a sham. (Def.'s Mem. 2.) Indeed, the Court is

supposedly precluded – as a matter of law – from considering the patent holder's likelihood of success as viewed at the time of settlement. Instead, the Court must blindly accept the patent holder's construction of the patent claims and disregard complaint allegations that the patent was invalid or so narrow that it could not prevent generic entry on its own.

It makes no difference, under Cephalon's theory, that exclusion payments are most likely to be used to protect the weakest patents, those that are least likely to be valid or infringed. Nor does it matter that, as a result, the weakest patents – bolstered by payments – will have precisely the same ability to exclude competition until patent expiration as the strongest patents. Indeed, under Cephalon's end-of-patent-term rule, every patent can exclude every accused product from the market for the entire life of the patent without adjudication by any court.

The issue presented by Cephalon's motion to dismiss is whether to adopt this extreme view – that an untested patent confers on a monopolist a virtually absolute right to exclude through sharing monopoly profits, regardless of the strength of the patent. This Court should not do so. Cephalon's standard misconstrues the nature of patent rights and disregards the fundamental public interest in avoiding unwarranted patent monopolies. Neither the Supreme Court nor any court in this Circuit has endorsed Cephalon's expansive view of patent rights. And the facts of this case show why this Court should not follow other courts that have done so. Finally, Cephalon's arguments in support of its rule rest on purported facts that contradict the complaint and raise factual disputes that may not be resolved on a motion to dismiss. For these reasons, the motion to dismiss should be denied.

BACKGROUND

The Hatch-Waxman Act

Congress passed the Hatch-Waxman Act to make available more low-cost generic drugs, while fully protecting legitimate patent claims.[1] The Act allows for accelerated FDA approval of a generic drug through an Abbreviated New Drug Application (ANDA), upon a showing, among other things, that the new drug is "bioequivalent" to an approved drug. 21 U.S.C. § 355(j)(2)(A).

The Hatch-Waxman Act reflects a Congressional judgment that weak patents should not create unwarranted barriers to competition from generic drugs. It establishes certain rights and procedures that apply when a company seeks FDA approval to market a generic product before expiration of a patent relating to the counterpart brand-name drug. In such cases, the generic applicant must: (1) certify to the FDA that the patent in question is invalid or not infringed by the generic product (known as a "Paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the patent holder files suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed. 21 U.S.C. § 355(j)(2).

To encourage generic drug companies to challenge weak patents, the Hatch-Waxman Act awards the first generic companies to file an ANDA containing a Paragraph IV certification 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA. 21 U.S.C. § 355(j)(5)(B)(iv). As a result, a later ANDA filer cannot obtain FDA approval to enter the market until 180 days after the first filer begins selling its product, unless the first filer relinquishes or forfeits its claim to the exclusivity period. As the facts of this case

---

[1] *See, e.g.*, *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 690 (E.D. Pa. 2004).

reflect, multiple generic applicants may share the claim to the 180-day exclusivity period. (*See* Compl. ¶ 38.)

Competition Under the Hatch Waxman Act

This Congressional framework to encourage generic firms to challenge weak patents has resulted in enormous benefits to consumers.[2] Generic competitors typically enter the market at a steep discount to the brand price, and branded drugs consequently see a dramatic and immediate erosion of sales. (Compl. ¶¶ 19, 22, 23.) Apotex's challenge to patents on the branded anti-depression drug Paxil provides a compelling example. In March 2003, a district court ruled that Apotex did not infringe one of these patents.[3] Apotex launched its generic version of Paxil in September 2003 "at risk" – that is, while the district court ruling was on appeal and while other patent challenges were pending in this Court (concerning patents expiring as late as 2015). In April 2005, the Federal Circuit affirmed the judgment in favor of Apotex.[4] Early "at-risk" entry of generic Paxil saved consumers billions of dollars.

Although patent challenges have the potential for substantial consumer savings, the competitive dynamic between brand-name drugs and their generic equivalents creates an incentive for brand and generic manufacturers to conspire to avoid competition and share the

---

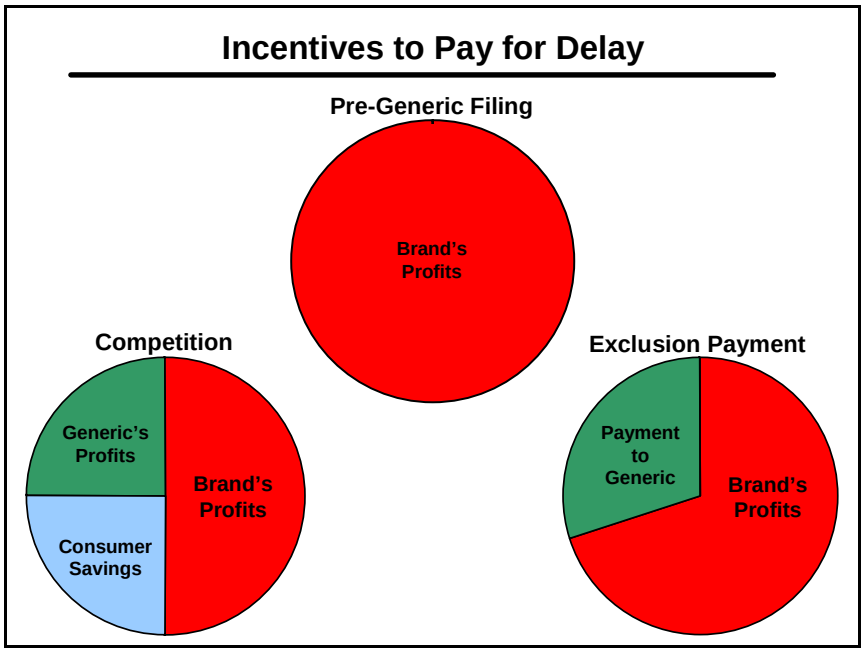
[2] Generic competition following successful patent challenges involving just four blockbuster drugs is estimated to have saved consumers more than $9 billion. *See Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the Sen. Commerce Comm.*, 107th Cong. 61, at 54-62 (2002) (prepared statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n), *available at* <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:90155.pdf>.

[3] *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003).

[4] *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005).

resulting profits. The reason is simple: In nearly any case in which generic entry is contemplated, the profits that the generic expects to make will be much less than the profits the brand stands to lose. This is because the generic firm sells at a significantly discounted price (Compl. ¶ 19); the difference between the brand's loss and the generic's gain is the consumer savings. Consequently, it will typically be more profitable for both parties if the brand-name company pays the generic company to settle the patent dispute and agree to defer entry.

As is illustrated below, by eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete:



Although both the brand and generic companies are better off with such settlements, consumers lose the possibility of earlier generic entry and the savings that would otherwise result.

In recognition of the threat that such agreements pose and to promote effective antitrust enforcement, Congress amended the Hatch-Waxman Act in 2003 to require brand-name companies and generic applicants to file patent settlement agreements with the FTC and the

Department of Justice.[5] As a Senate report explained, those amendments sought to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[6]

The Complaint Allegations

Provigil

Cephalon sells a prescription drug containing modafinil that it markets under the name Provigil. (Compl. ¶ 24.) Provigil is considered to be the "gold standard" for the treatment of excessive sleepiness in patients with certain sleep disorders. (¶¶ 26-27.) Provigil is Cephalon's largest-selling product, with U.S. Provigil sales of over $800 million in 2007. (¶¶ 28, 30.)

Cephalon's only unexpired patent relating to Provigil is a formulation patent that relates to the distribution of a specified size of particles of modafinil, the active pharmaceutical ingredient in Provigil. (¶ 33.) The patent covering the modafinil compound itself expired in 2001. (¶ 32.) Unlike the modafinil compound patent, Cephalon's particle size patent is narrow and does not block all generic competition to Provigil. (¶ 35.) A consultant advised Cephalon in 2002 that "all generic drug companies know . . . the [particle size patent] may be easily circumvented" by manufacturing their products to contain a distribution of modafinil particle sizes different than that covered by Cephalon's patent. (¶ 35.)

---

[5] Pub. L. No. 108-173, Title XI, Subtitle B, 117 Stat. 2066, 2461 (contained in 21 U.S.C. § 355, historical notes).

[6] S. Rep. No. 107-167, at 4 (2002), *available at* <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_reports&docid=f:sr167.pdf>.

The Threat of Generic Competition to Provigil

On December 24, 2002 – the first possible day the FDA could accept an ANDA for generic Provigil – four companies (hereinafter the "first filers") filed ANDAs that challenged Cephalon's patent. (¶ 36.) Each certified to the FDA that its version of generic Provigil did not infringe Cephalon's particle size patent, that the patent was invalid, or both. (¶ 36.) In March of 2003, Cephalon filed a patent infringement lawsuit against each of the first filers, triggering an automatic stay of final FDA approval of the first filers' generic versions of Provigil. (¶ 41.)

By late 2005, generic competition to Provigil appeared imminent to Cephalon, the generic firms, and Wall Street analysts who follow the industry. (¶ 48.) Each of the first filers expected to receive final FDA approval of their generic versions of Provigil by the time the regulatory stays expired in June 2006.[7] (¶¶ 41, 46.) Upon receiving final approval, each of the four first filers could lawfully launch generic Provigil while Cephalon's patent litigation was still pending, unless Cephalon obtained a preliminary injunction.[8] (¶ 47.) So-called "launching at risk," that is, at risk of liability for damages if the patent holder ultimately is able to prove infringement, occurs with some frequency in the pharmaceutical industry; indeed, one of the first filers has launched at risk more than 20 times. (¶ 47.) Meanwhile, Cephalon's plan to blunt the impact of generic competition to Provigil – by introducing a successor product called Nuvigil – was in jeopardy, because the FDA had not approved Nuvigil as of late 2005. (¶ 52.)

---

[7] Cephalon improperly contradicts the complaint when it asserts that the stay on FDA approval "would not have expired until December 24, 2006." (Def.'s Mem. 5 n.3.)

[8] *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990) (alleged infringer has legitimate right to compete where patentee fails to show likelihood of success in proving infringement).

Cephalon's Anticompetitive Scheme

Rather than seeking a preliminary injunction to block "at risk" generic entry and protect its Provigil monopoly, Cephalon set out to settle its patent litigation with the four first filers under terms that would eliminate potential generic competition for six years. (¶¶ 54-55, 59.) The first filers, however, were unwilling to accept significantly deferred entry absent substantial compensation from Cephalon. (¶ 55.) Cephalon therefore entered a series of settlement agreements under which it compensated each generic company – more than $200 million collectively – to abandon its patent challenge and forgo entry until April 2012. (¶¶ 3, 60-76.)

The Effects of Cephalon's Conduct

By sharing its monopoly profits with the first filers to secure the 2012 generic entry date in the settlement agreements, Cephalon eliminated the most direct and immediate threat to its monopoly. Absent the compensation Cephalon agreed to provide, generic competition to Provigil would have occurred prior to April 2012 because: (1) one or more of the first filers would have entered with its version of generic Provigil before conclusion of the patent litigation; (2) Cephalon would not have prevailed against each of the four first filers in the litigation; or (3) Cephalon would have agreed to settle the litigation on terms that did not compensate the first filers, but instead provided for generic entry earlier than April 2012. (¶ 83.)

In addition, the cumulative effect of the four settlements has been to create a barrier – by keeping intact the 180-day exclusivity period – to all other potential generic Provigil competitors, regardless of whether their products would infringe Cephalon's patent. (¶¶ 85-87.)

Thus, Cephalon has succeeded in excluding all potential generic competition to Provigil until April 2012, nearly six years after generic entry was likely to occur. Even then, consumers may realize few benefits from the entry of generic versions of Provigil because of Cephalon's

plan to switch sales from Provigil to its successor product, Nuvigil, which the FDA approved in June 2007. Cephalon has stated that it intends to delay Nuvigil's launch until around 2010, approximately two years before generic Provigil entry.[9] (¶ 80.)

ARGUMENT

A motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure may be granted only if the movant demonstrates that, after accepting the factual allegations in the complaint as true and drawing all reasonable inferences in the non-moving party's favor, the complaint fails to state a claim upon which relief can be granted. *See, e.g., Phillips v. County of Allegheny*, 515 F.3d 224, 231-33 (3d Cir. 2008). At this stage, the appropriate question is "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1969 n.8 (2007) (quotation omitted). In evaluating a Rule 12(b)(6) motion, the Court may consider the facts alleged in the pleadings, documents attached to or referred to in the complaint, and matters properly subject to judicial notice. *See, e.g., Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 425-26 (3d Cir. 1999).

Despite this clear standard, Cephalon repeatedly relies on propositions that either directly contradict the FTC's complaint or raise disputed matters outside the complaint that are not subject to judicial notice, in an effort to provide a rationale for the extreme legal rule that it asks the Court to adopt. As discussed in Section III, the court should disregard these assertions, as

---

[9] In its motion, Cephalon asserts that permitting the first filers to launch their products three years prior to patent expiration achieved "obvious benefits and efficiencies." (Def.'s Mem. 1.) At this stage, however, the Court must accept the FTC's allegation that generic entry in 2012 will likely provide few benefits to consumers because of Cephalon's plan to switch sales from Provigil to Nuvigil. (Compl. ¶¶ 55, 90.) *See, e.g., Mitel Corp. v. A&A Connections, Inc.*, No. 97-4205, 1998 WL 136529, at *4 (E.D. Pa. Mar. 20, 1998) (rejecting, on motion to dismiss, antitrust defendant's assertion that exclusive distribution network was procompetitive).

well as any inferences that Cephalon seeks to draw from them. *See, e.g., In re Warfarin Sodium Antitrust Litigation,* 214 F.3d 395, 398 (3d Cir. 2000).

I. Cephalon's Maintenance of Its Monopoly by Sharing Monopoly Profits with Potential Competitors Is Not the Mere Exercise of Legitimate Patent Rights

The offense of monopolization has two basic elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). As *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005), explains: "Unlawful maintenance of a monopoly is demonstrated by proof that a defendant has engaged in anticompetitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power."

The FTC's complaint alleges that Cephalon unlawfully maintained its monopoly by purchasing protection from competition that its patent did not afford. The complaint includes numerous allegations that, if proven, would permit the Court to conclude that Cephalon exceeded the protection provided by its patent, including: the terms Cephalon used to induce the first filers to delay their entry for six years (Compl. ¶¶ 56-58, 61-63, 65-67, 70, 73-75); the circumstances that made it so important for Cephalon to buy settlements with all of the first filers before June 2006 (¶¶ 1, 2, 28, 30, 39-40, 42-52, 56); the widely held view that Cephalon's narrow formulation patent was easily circumvented (¶¶ 32-37); as well as other facts to show that this weak patent was unlikely to prevent generic competition to Provigil (¶¶ 43-45).

Cephalon does not dispute that, in the absence of its particle size patent, the complaint states a valid claim of monopolization. According to Cephalon, however, the possession of a

patent gives the holder the right to share its monopoly profits with competitors to induce them to give up their challenges to the patent and refrain from competing. So long as the underlying infringement claim is not a sham, Cephalon argues, the Court is precluded as a matter of law from taking the strength of the patent into account in judging the effects of Cephalon's conduct. (Def.'s Mem. 23) ("allegations about the strength of the patent claims are not considered at all"). To be sure, there are a variety of ways for the antitrust analysis to account for Cephalon's patent, and courts and commentators have disagreed as to the appropriate approach.[10] But the Court does not face a choice among those variations here. The only issue here is whether to adopt Cephalon's end-of-patent-term rule.

The Court should not do so. As the leading antitrust treatise observes: "[Intellectual property] rights, like all property rights . . . do not include rights to violate the antitrust laws unless a more particularized warrant can be found in the IP statutes or sound policy analysis."[11] Neither patent law nor patent policy provides a basis for granting Cephalon's motion.

---

[10] *See, e.g.*, Herbert Hovenkamp et al., *The Interface Between Intellectual Property Law and Antitrust Law*, 87 Minn. L. Rev. 1719, 1759 (2003) (payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkanp, Janis, and Lemley*, 87 Minn. L. Rev. 1789, 1795-97 (2003) (burden on defendant to show likelihood of success in patent case); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 750 (2002) (exclusion payments should be permitted unless plaintiff shows patentee's infringement suit unlikely to succeed). For approaches of courts, see Section II.D, *infra*.

[11] Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law*, ¶ 2046c (2007 Supp.).

A. Mere possession of an untested patent does not shield Cephalon's conduct from antitrust scrutiny

The Supreme Court has emphasized the "careful balance" embodied in the patent system:

> From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989). As part of that careful balance, Congress granted valuable rights to patent holders. But Congress did not grant the holder of an untested patent an absolute, ironclad right to exclude competition until the expiration date of the patent. On the contrary, when a patent holder asks a court to enforce its patent against an alleged infringer, it must carry the burden of proving that the challenged product falls within the patent's claims as properly construed.[12] And while patent holders enjoy a statutory presumption of validity, it "does not constitute 'evidence' to be weighed against a challenger's evidence. It simply places the burden of persuasion on the party challenging validity."[13]

A patent holder's accusation of infringement thus creates no presumption that the challenged product actually infringes. Consequently, a patent holder seeking to exclude a rival from the market prior to adjudication of the merits must obtain a preliminary injunction. That patent holder cannot merely make a good faith assertion that the challenged product infringes, nor can it sit back and rely on the presumption of validity.[14] Instead, like other litigants, it must

---

[12] *See, e.g., Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004).

[13] Robert L. Harmon, *Patents in the Federal Circuit*, at 27 (4th ed. 1998). *See also, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

[14] *See, e.g., Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) (vacating grant of preliminary injunction and stating "'if [the defendant] raises a substantial

establish its right to relief by demonstrating, among other things, a likelihood of success on the merits.[15]

As the Supreme Court observed in *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969), "[t]he heart of [a patentee's] legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent." Thus, until a patentee obtains a court judgment, the patent's power to exclude competitors is tempered by the probability that the patentee will fail. To be sure, the parties can settle the patent dispute by agreeing to a patent license. In that case, the stronger the patentee's validity and infringement arguments, the more advantageous the terms it can negotiate.[16] When a patentee asserts its patent and threatens a lawsuit with the goal of excluding a competitor from the market, the strength of its patent may either convince the accused infringer to accede or convince a court to issue an injunction. In either case, the exclusion results from the patent.

According to Cephalon, however, a patentee with monopoly power need not rely on the strength of its patent to achieve exclusion and prevent competition. Instead, it can achieve what assertion of its patent alone does not, by sharing its monopoly profits with its rivals. Under Cephalon's end-of-patent-term rule, even a trivial patent (such as the patent Cephalon wants to use as a shield in this case) gives a patent holder the right to use its monopoly profits to buy

---

question concerning . . . validity, i.e., . . . [an] invalidity defense that the patentee cannot prove 'lacks substantial merit' then the patentee has not established a likelihood of success on the merits'") (citations omitted).

[15] *See, e.g., Polymer Techs, Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996).

[16] *See, e.g.*, Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. Econ. 77, 77-79 (1989) (a patentee will often settle a dispute by licensing the patent in exchange for royalty payments to avoid the threat of having its patent invalidated; the terms of the license depend, in part, on the probability of the patentee's prevailing in litigation) (attached at Exhibit 1).

protection from competition until patent expiration as long as the infringement allegation is not a sham. In other words, even if a patent holder cannot, based on the strength of its patent, convince a court to issue a preliminary injunction, it can, according to Cephalon, use a share of its monopoly profits to buy the equivalent of a permanent injunction. No principle of patent law supports the legal rule Cephalon asserts.

B. Protecting weak patents does not foster innovation or serve the public interest embodied in the patent system

Lacking any basis in patent law, Cephalon attempts to rely on patent policy to support its argument. Cephalon insists that its end-of-patent-term rule is essential to foster the innovation that the patent laws were designed to promote. But in fact, the rule it advocates undermines, rather than furthers, patent policy and disregards the important public interest in avoiding unwarranted patent monopolies.

By permitting patentees to buy off competition until patent expiration, Cephalon's rule grants weak patents – those that are likely invalid or narrow and easy to design around – the same exclusionary force as strong patents. It is the ability of the patentee to pay for exclusion that matters, not the value of the patented invention. Indeed, the incentive to pay a generic to abandon its patent challenge is likely to be greatest when the patent infringement claim is weak. But as the Supreme Court observed in *KSR International Co. v. Teleflex, Inc*., 127 S. Ct. 1727, 1746 (2007), were the patent system to protect trivial inventions with exclusive rights, "patents might stifle, rather than promote, the progress of useful arts." Indeed, "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress" by preventing the public from using ideas that would otherwise be freely available. *Id.* at 1741. *See also Graham v. John Deere Co.*, 383 U.S. 1, 5-11 (1966).

This concern has special force in the pharmaceutical industry. Often a branded-drug manufacturer obtains one or more patents in addition to the one covering the active ingredient compound, and many of these patents do not withstand judicial scrutiny.[17] Empirical studies have shown that when pharmaceutical patent infringement claims are tested in the courts, the alleged infringer prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the alleged infringers had a success rate of 70 percent.[18] An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.[19]

---

[17] *See, e.g.*, *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006) (affirming this Court's decision that product-by-process patent covering anti-depressant drug Paxil was invalid). *See also Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280, 2008 WL 2039065 (Fed. Cir. May 14, 2008) (patents covering blood-clotting drug Lovenox held unenforceable); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (patent covering high blood pressure drug Altace found invalid); *Daiichi Sankyo Co., Ltd. v. Apotex Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (patent covering method of treating ear infections with ofloxacin held invalid); *Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348 (Fed. Cir. 2007) (patent covering hypertension drug Norvasc held invalid); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (claims of patent related to extended release urinary incontinence drug Ditropan XL held invalid and not infringed).

[18] Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006) (attached as Exhibit 2). *See also* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-06 (1998) (study of all patent validity litigation from 1989-1996 found 46 percent of all patents litigated to judgment held invalid).

[19] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 19-20 (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

Cephalon claims, however, that exclusion payment settlements enable patentees to achieve certainty, which fosters innovation. (Def.'s Mem. 13.) But protecting weak patents does not foster innovation. *KSR*, 127 S. Ct. at 1746. And of course, a patent holder can achieve certainty without exclusion payments. *See infra* Section III.B (explaining that, until recent court decisions, Hatch-Waxman patent cases routinely settled without exclusion payments). Moreover, the Supreme Court has repeatedly made it clear – whether applying contract law, antitrust law, or declaratory judgment law in cases involving patents – that a patent holder's desire for certainty does not trump the public interest. "It is the public interest which is dominant in the patent system." *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944).

Because the public interest is dominant, a long line of cases has held that a licensee may later attack the validity of the patent under which it was licensed.[20] In *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969), the Court explained that this result is necessary to vindicate "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." Although the patentee may have relied on the license agreement, the

[20] *See, e.g., United States v. United States Gypsum Co.*, 333 U.S. 364, 387 (1948) ("In an antitrust suit instituted by a licensee against his licensor we have repeatedly held that the licensee may attack the validity of the patent under which he was licensed, because of the public interest in free competition, even though the licensee has agreed in his license not to do so." (*citing Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942))); *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394 (1947); *MacGregor v. Westinghouse Elec. & Mfg. Co.*, 329 U.S. 402 (1947).

private interests of the patent holder must give way, the Court held. Otherwise, "the public may continually be required to pay tribute to would-be monopolists without need or justification." *Id.*[21] In *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57-58 (1973), the Supreme Court ruled that the government, like patent licensees, could challenge the validity of a patent in the course of prosecuting an antitrust action "to vindicate the public interest in enjoining violations of the Sherman Act." Finally, applying declaratory judgment law in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 777 (2007), the Supreme Court held that a licensee need not stop paying royalties in order to seek a judicial determination that the underlying patent is invalid, unenforceable, or not infringed. Cephalon's rule, which would allow a patent holder to avoid scrutiny of an untested patent and protect its weakest patents simply by agreeing to split monopoly profits with patent challengers, would ill-serve the "important public interest" in competition and the use of "ideas which are in reality a part of the public domain." *Lear*, 395 U.S. at 670.

The rights accorded the patent holder are a tool to promote the public goals of the patent system, not an end in themselves. *See Graham*, 383 U.S. at 6. Cephalon's implicit premise that anything that maximizes the value of its patent is a legitimate use of that patent ignores the nature of the patent rights granted by Congress and the overriding public interest in the proper functioning of the patent system. As the Solicitor General has noted, "the Patent Act does not embody a policy of promoting the interests of patent holders at all costs."[22] Courts are not

---

[21] *See also Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349-50 (1971) (noting the Court's "consistent view" that a patentee "should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted").

[22] Brief for the United States as Amicus Curiae at 14, *Joblove v. Barr Labs, Inc.*, 127 U.S. 3001 (2007) (No. 06-830) ("U.S. *Tamoxifen* Br."), *available at*

entitled to set aside the careful balance struck by Congress. But this is what Cephalon's motion asks this Court to do.

C. The Supreme Court has not endorsed Cephalon's expansive view of patent rights

As the cases above reflect, Cephalon's claim that its end-of-patent-term rule "derives directly" from Supreme Court precedent (Def.'s Mem. 12, 28) is fundamentally inconsistent with the Court's approach to patent rights. Cephalon quotes language from the Supreme Court's decisions in *United States v. Masonite Corp.*, 316 U.S. 265 (1942), *United States v. Line Material Co.*, 333 U.S. 287 (1948), and *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963), to the effect that a patent holder may not extend its monopoly beyond the limits of what has been granted. But assertion of this principle simply begs the question – whether sharing monopoly profits to achieve exclusion falls *within* the exclusionary rights granted.

Indeed, *Masonite* says it does not. In that case, the Supreme Court condemned the patent holder's conduct under the antitrust laws even though Masonite did not restrain competition beyond the "scope of the patent" as Cephalon defines it – that is, "beyond the patent's expiration date." (Def.'s Mem. 10.) In that case, Masonite sued or threatened to sue its competitors for patent infringement. To resolve these disputes, Masonite licensed the competing firms to sell its product, but at a price that it set. The Supreme Court noted that a "patentee who employs such an agent to distribute his product certainly is not enlarging the scope of his patent privilege if it . . . operates only to secure to him the reward for his invention which Congress has provided." *Masonite*, 316 U.S. at 279. But a patent holder does more than secure a reward for his invention,

---

<http://www.usdoj.gov/osg/briefs/2006/2pet/6invit/2006-0830.pet.ami.inv.pdf>.

the Court held, when it pays its potential competitors a share of its monopoly profits to entice them to abandon their own products and patent challenges:

> Active and vigorous competition then tend[ed] to be impaired, not from any preference of the public for the patented product, but from the preference of the competitors for a mutual arrangement for price-fixing which promises more profit if the parties abandon rather than maintain competition.

Id. at 281.

This is the crux of the antitrust claim here. Like the licensing arrangement in *Masonite*, Cephalon's patent settlements served as a vehicle for sharing monopoly profits. By paying its potential generic rivals a share of these profits, the complaint alleges, Cephalon induced them to forgo their patent challenges and stay off the market until a date years in the future, without regard to the exclusionary force of Cephalon's particle size patent. The restraint on generic competition, therefore, flows not from the protections afforded by Cephalon's patent but rather from the sharing of Cephalon's monopoly profits. Thus, the conduct alleged here is the type the Supreme Court determined in *Masonite* fell beyond the "scope of the patent."

D. Courts in this Circuit and others have rejected Cephalon's expansive view of patent rights

The only court in this Circuit to face the precise question presented here declined to dismiss the antitrust complaint. In *In re K-Dur Antitrust Litigation*, 338 F. Supp. 2d 517, 531 (D.N.J. 2004), the defendants argued, as Cephalon does, that "[the brand company] had a valid patent, and thus was entitled to exclude generic competitors from the market until the patent expired." The *K-Dur* court acknowledged that defendants' argument had "a certain logical appeal," but on closer examination concluded that an exclusion payment settlement agreement "obvious[ly]"can be anticompetitive notwithstanding the existence of a patent:

> The patent regulatory regime creates incentives for generic manufacturers to challenge patents. . . . It would appear obvious that this incentive system can be distorted by cash payments made by a branded patent holder to generic manufacturers to discontinue patent validity or infringement challenges.

Id. at 531.[23]

Although Cephalon attempts to brush off this decision, it is fully consistent with the view expressed by the Sixth Circuit in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003). The Sixth Circuit dismissed the suggestion that an antitrust analysis of exclusion payments must simply accept the patentee's construction of the patent claims or treat payments to a potential competitor to stay out of the market during the pendency of patent infringement litigation as "merely an attempt to enforce patent rights."

> [I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.

Id. at 908.[24] *See also Andrx Pharms. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (on a motion to dismiss, it was reasonable to infer that substantial payments to an allegedly infringing generic rival were to obtain protection that the patent alone did not provide).

Moreover, the Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344

---

[23] The *K-Dur* court correctly noted that defendants' theory, in effect, required it to accept a hypothetical set of facts in which the patent litigation proceeded to conclusion with the brand company's patent being found valid and infringed. *K-Dur*, 338 F. Supp. 2d at 534 n.24. As these factual assertions contradicted the allegations in the complaint, the court refused to credit them.

[24] Cephalon's attempt to cast aside the *Cardizem* decision because it involved an interim agreement, rather than a final settlement, is unavailing. If, as Cephalon contends, a payment to buy off competition for the entire life of the patent is within the scope of the patent grant, then, *a fortiori*, a payment to buy off competition for only a portion of the patent life must also be protected.

F.3d 1294, 1312 (11th Cir. 2003), remanded an antitrust case for consideration of the protection afforded by a patent based on "the likelihood of [the patentee] obtaining such protections" at the time of the agreement. On remand, the district court assessed the merits of the parties' positions in the underlying patent case to evaluate the likelihood, at the time the agreement was entered, that the patent would prevent generic entry. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005). To assume that the patent protected its holder from generic competition until its expiration date without regard to the strength of the patent, the court observed, would "afford pioneer drug manufacturers an unbridled power to exclude" and would grant rights "beyond those granted by the Patent Act, and beyond the structure contained in the Hatch-Waxman Act." *Id*. at 1298. Concluding that the patentee was not likely to have obtained, based on the strength of the patent, the protection that the exclusion payments bought, the district court held that paying a generic to stay off the market was an unlawful restraint of trade. *Id*. at 1319.[25]

II. This Court Should Not Follow Decisions That Have Adopted Cephalon's End-of-Patent-Term Rule

Notwithstanding the decisions discussed above, Cephalon claims that its end-of-patent-term rule reflects the "prevailing legal standard." It relies on the majority opinion in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), and a district court *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (*Cipro III*), which accepted Cephalon's fundamental premise that, absent a sham allegation, the mere presence of a patent entitles the patent holder to purchase the equivalent of a permanent

[25] *See also In re Abbott Labs. Norvir Antitrust Litig.*, No. 04-1511, 2008 WL 2095516, at *5-8 (N.D. Cal. May 16, 2008) (denying summary judgment in pharmaceutical antitrust case and finding that patents did not defeat plaintiffs' monopolization claims).

injunction, thereby avoiding competition until patent expiration. And the Eleventh Circuit in *FTC v. Schering-Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005), appears to have adopted a similar standard, though, unlike *Tamoxifen*, it did not expressly foreclose an inquiry into the strength of the patent in assessing an exclusion payment settlement.[26]

The decisions on which Cephalon relies grant more protection than patent law or patent policy provide. Moreover, the *Schering* decision rests on a fundamental error of law, as it created a presumption of infringement, despite the fact that under the Patent Act a patent is presumptively *not* infringed.[27] Furthermore, courts in other antitrust cases have opted to consider the source of the exclusion – that is, whether it flows from the patent or from the sharing of monopoly profits. *See* Section I.D, *supra*. This Court should do the same, and decline to follow the Second Circuit's approach, both on the law and on the facts of this case.

A. The *Tamoxifen* decision is inconsistent with patent law and Supreme Court precedent and has been widely criticized

The *Tamoxifen* court's extreme view of a patent's exclusionary power has no basis in patent law or Supreme Court precedent. It disrupts the careful balance embodied in the patent system by overprotecting weak and narrow patents; it dismisses the means used to achieve

---

[26] *Schering*, 402 F.3d at 1076 ("underscor[ing] the need to evaluate the strength of the patent"). Others have interpreted *Schering* to require an assessment of the strength of the patent. *See* Brief for the United States as Amicus Curiae at 17-18, *FTC v. Schering-Plough*, 548 U.S. 919 (2006) (No. 05-273) ("Neither *Valley Drug* nor [*Schering*] holds. . . that evidence of invalidity or non-infringement available at the time of the settlement would be irrelevant in assessing the permissibility of a reverse payment."), *available at* <http://www.usdoj.gov/atr/cases/f216300/216358.pdf>. Cephalon has not argued that the complaint fails to state a claim under this standard.

[27] *Schering*, 402 F.3d at 1066-67 (stating that Schering's patent gave it "the legal right to exclude [the alleged infringers] from the market until *they proved* either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent") (emphasis added).

exclusion by allowing patent holders to purchase protection that their patents cannot provide; and it insufficiently protects the consumer interests in vigorous competition safeguarded by the antitrust laws. *See* Section I, *supra*. *See also Tamoxifen*, 466 F.3d at 228 (dissent, J. Pooler) ("The majority's requirement that an antitrust plaintiff show that a Hatch-Waxman lawsuit settled by agreement was a sham. . . is unjustified. A more searching inquiry and a less stringent standard are required to protect all interests.").

The *Tamoxifen* decision has been criticized by many outside the Second Circuit. For example, the Solicitor General, in an amicus brief to the Supreme Court, called the standard set forth in *Tamoxifen* "erroneous" and an "insufficiently stringent standard for scrutinizing patent settlements."[28] The Solicitor General did not urge the Court to review the decision because he concluded that it was not a good vehicle for the Court to resolve the question presented. But he disputed the *Tamoxifen* decision's premise that the general policy favoring settlement always prevails, "'even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents.'" U.S. *Tamoxifen* Brief at 14 (quoting *Tamoxifen*, 466 F.3d at 212). "The interests in consumer welfare protected by the antitrust laws," the Solicitor General observed, "militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a weak patent by dividing its monopoly profits with an alleged infringer." *Id.* at 11. Forty-one legal scholars, economics professors, and other academics, while not agreeing on the right standard, called the *Tamoxifen* standard "far outside the mainstream of judicial and academic analysis."[29]

---

[28] U.S. *Tamoxifen* Br., *supra* note 22, at 17.

[29] Brief Amici Curiae of 41 Professors of Economics, Business and Law in Support of Granting the Petition at 2, *Joblove v. Barr Labs, Inc.*, 127 S.Ct. 3001 (2007) (No. 06-830), *available at* <http://www.orangebookblog.com/Tamoxifen_20cert_20final_20brief.pdf>.

B. *Tamoxifen*'s premise – that an antitrust court may not, as a matter of law, evaluate the likelihood that a patent would prevent generic entry – is wrong

To grant Cephalon's motion to dismiss, this Court must agree with a key premise of the *Tamoxifen* decision: that the complaint allegations concerning the weakness of Cephalon's patent are irrelevant because the Court may not, as a matter of law, conduct any analysis of the strength of the patent or the likely outcome of the patent litigation. (Def.'s Mem. 21-23 (citing *Tamoxifen*, 466 F.3d at 203-04).) The FTC believes that a direct assessment of the likely outcome of the patent case typically is unnecessary to evaluate the antitrust implications of an exclusion payment settlement.[30] Indeed, the complaint here includes numerous allegations about the terms of Cephalon's agreements with its rivals, the circumstances under which these agreements were made, and the marketplace expectations concerning imminent generic entry that, if proven, would permit the Court to conclude – without separately weighing the merits of the patent case – that Cephalon exceeded the protection afforded by its patent. While the FTC does not believe it is necessary, however, for this Court to assess direct evidence of the weakness of Cephalon's patent claims as part of the antitrust case, it is prepared to offer such evidence if this Court believes such an inquiry would be useful.[31] The claim that this Court is legally precluded from such an inquiry is without merit.

---

[30] *See In re Schering-Plough Corp., et al.*, FTC Dkt No. 9297, 136 F.T.C. 956, 968, 992-99) (2003), *available at* <http://www.ftc.gov/os/decisions/docs/Volume136.pdf#page=961>, *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (2005).

[31] The complaint includes numerous allegations concerning the narrow scope of Cephalon's particle size patent (Compl. ¶ 35), the likelihood that the generic companies would launch "at-risk" prior to the conclusion of the litigation (¶¶ 47-51), or that the generics would prevail at trial. (¶¶ 41-45.)

First, as discussed above, it is well established that courts may assess the merits of a licensee's patent challenge, even well after the license agreement, because otherwise, "the public may continually be required to pay tribute to would-be monopolists without need or justification." *Lear*, 395 U.S. at 670. Second, in the Hatch-Waxman context, the district court on remand in *Terazosin* conducted precisely the inquiry Cephalon insists is impermissible, finding that the patent was unlikely to block generic entry. *Terazosin*, 352 F. Supp. 2d at 1304-07. Third, as the *Tamoxifen* dissent noted, "it is not outside the bounds of the district court's competence to predict" the likely outcome of the patent case, particularly when the court can examine the record that existed at the time of settlements. *Tamoxifen*, 466 F.3d at 229.[32] Finally, Cephalon's suggestion that any direct evaluation of the patent merits in an antitrust case would chill even legitimate settlements due to the risk of treble damages is unwarranted in this government enforcement action seeking only equitable relief.

C. The facts in this case illustrate why this Court should not adopt *Tamoxifen*'s approach

The *Tamoxifen* majority acknowledged that a rule protecting settlements in which branded and generic rivals agree to avoid competition and share the resulting profits would protect patents that are "fatally weak." *Tamoxifen*, 466 F.3d at 212. Indeed, *Tamoxifen* agreed with the district court's observation in *Cipro III* that "'the patents most likely to be the subject of

[32] *See also* U.S. *Tamoxifen* Br., *supra* note 22 at 17 (noting possibility of limited judicial inquiry, similar to those "commonplace" in preliminary injunction or class action settlement fairness proceedings).

exclusion payments would be precisely those patents that have the most questionable validity.'" *Id*. at 211 (quoting *Cipro III*, 363 F. Supp. 2d at 534).[33] But the Second Circuit dismissed this concern in the belief that such settlements could not be an effective strategy to protect weak patents. In the court's view, other challengers would come forward and it would be too expensive to pay them off. The facts alleged in this case, however, show that the court's optimism was misplaced.

First, the *Tamoxifen* court assumed that paying a generic rival to drop its patent challenge "would have no effect on other challengers of the patent." *Tamoxifen*, 466 F.3d at 211. But while the regulatory interpretation in effect at the time of the *Tamoxifen* and *Cipro* settlements led to loss of 180-day exclusivity upon settlement,[34] that is no longer the case. Cephalon's settlements with the four first filers secured the 180-day exclusivity barrier that keeps subsequent generic challengers from competing with generic Provigil products, without regard to whether they infringe Cephalon's patent. (Compl. ¶¶ 85-87.)

Second, the *Tamoxifen* majority believed that settling with the first generic applicant would increase incentives for other generic firms to mount a challenge. *Tamoxifen*, 466 F.3d at 211. But this belief rested on an assumption that the 180-day exclusivity period awarded to first filers would be passed along to the next generic challenger in line.[35] That has never been the

---

[33] *See also Tamoxifen*, 466 F.3d at 211 ("The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder.").

[34] *Tamoxifen*, 466 F.3d at 214 ("under procedures in effect at the time [of settlement]," the agreement between Zeneca, the branded drug firm, and Barr, the first generic filer, "appeared to ensure . . . that [Barr] was not eligible for the [180-day] exclusivity period.").

[35] *Tamoxifen*, 466 F.3d at 214 (stating that the settlement between Zeneca and Barr meant other potential generic manufacturers would be "spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a

law. Even if a later challenger to Cephalon's particle size patent obtained a court judgment that the patent is invalid or not infringed, it could not get FDA approval to sell its product until the first filers' exclusivity either expires or is forfeited. (Compl. ¶¶ 85-88.) Moreover, as the complaint alleges, the agreements here reduced the incentive to challenge Cephalon's patent because they include a "most favored nation" clause that allows for accelerated entry by each settling first filer in the event that another generic company enters the market. (¶ 58.)

Finally, the court assumed that it was not "realistic" to think that the branded-drug firm could pay off multiple generic challengers:

> There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt however, that this scenario is realistic."

Tamoxifen, 466 F.3d at 211-12 . But that is precisely what happened here. When multiple generic applicants seek to compete, the prospective profits of each will be substantially lower, since they do not enjoy any guaranteed exclusivity period. Consequently, the amount needed to buy off each potential competitor is far less. Cephalon had a weak patent – one that was narrow and of doubtful validity (¶¶ 41-45) – but it could and did pay off four generic rivals to ensure that they would not enter the market, which they were otherwise likely to do. (¶¶ 2-3.)

Thus, the facts of this case demonstrate that the anticompetitive implications the *Tamoxifen* court thought unrealistic are all too real. Because the complaint allegations here call into question fundamental premises of the Second Circuit's *Tamoxifen* decision, this Court should decline to follow the same approach.

---

subsequent infringement lawsuit").

III. Cephalon's Motion Improperly Relies on Factual Assertions That Contradict the FTC's Complaint and Raises Disputed Factual Issues Outside the Complaint

As noted above and as Cephalon concedes, at this stage the Court must accept the FTC's allegations as true and draw all reasonable inferences in the FTC's favor. *See, e.g.*, *Phillips*, 515 F.3d at 233; (Def.'s Mem. 8.). It is equally clear that the Court may not credit factual claims made by Cephalon as to matters outside the complaint. *See, e.g.*, *In re Warfarin*, 214 F.3d at 398 (reversing 12(b)(6) dismissal where "the [district] court impermissibly cited and relied on facts beyond the corners of the complaints").

Despite this clear standard, Cephalon's argument rests on propositions that contradict the FTC's complaint and raise factual disputes outside the complaint. First, Cephalon denies that exclusion payments raise any suspicion, as they "arise naturally" from the Hatch-Waxman Act. The complaint, however, tells a different story about why Cephalon paid the generic companies in this case. Second, Cephalon claims that it is "often impossible" to settle pharmaceutical patent litigation without payments to generic companies, pointing to "over optimism" on the part of generic alleged infringers. Again, this version of events is inconsistent with the complaint. Moreover, as evidence in this case will show, the general assertion that litigants in Hatch-Waxman patent litigation typically cannot settle without exclusion payments is not only disputed but incorrect. Indeed, before court decisions permitting such payments, parties routinely settled without them.

A. Cephalon's assertion that its exclusion payments were a "natural" by-product of the Hatch-Waxman Act contradicts the complaint

Cephalon asks this Court to believe that its payments to the first filers to forgo entry until 2012 merely "reflect[] incentives created by the [Hatch-Waxman] Act itself" (Def.'s Mem. 2), rather than a scheme to bolster a weak patent, as the complaint alleges. According to Cephalon,

the pre-entry litigation that Hatch-Waxman encourages means that generic companies have "dramatically increased leverage," because the branded-drug firm has no damage claim to use as a bargaining chip in settlement negotiations. *Id.* at 16. Consequently, Cephalon protests, "[t]here is . . . nothing nefarious about settlement payments to generics." *Id.*

Cephalon's argument contradicts the very thrust of the FTC's complaint, which alleges that Cephalon feared generic entry and used its monopoly profits to obtain protection from competition that its particle size patent would not provide. Indeed, the complaint alleges that Cephalon had to pay the generic companies as part of its settlements not because of the Hatch-Waxman Act, but because Cephalon's patent was weak. (Compl. ¶¶ 35-37, 41-45, 46-52, 55.) On a motion to dismiss, Cephalon may not offer its own explanation for its payments.

Moreover, Cephalon's suggestion that, under Hatch-Waxman, branded drug companies are worse off than other patent holders is particularly inapt in light of the FTC's allegations here that Cephalon intentionally made sure to settle its patent litigation before the first filers could begin competing with generic Provigil. (Compl. ¶ 48) (Cephalon expected generic entry in mid-2006), (¶¶ 52-54) (Cephalon set out to settle the patent litigation before generic entry occurred). Had Cephalon wished to avoid the supposed Hatch-Waxman handicap – the lack of a damages claim – it had only to wait until June 2006 when, according to the complaint, generic entry was likely.[36] (¶¶ 47-51.)

In addition to contradicting the complaint, Cephalon's arguments about the "natural" consequences of the Hatch-Waxman Act raise significant disputed issues of fact outside the

[36] Cephalon could also have chosen not to trigger a 30-month stay of FDA approval of generic versions of Provigil when it initiated the patent litigation in 2003, and thus shifted risk to the generic companies. *See, e.g., Pfizer, Inc. v. Shalala*, 182 F.3d 975, 979 (D.C. Cir. 1999) ("Nothing in the Act, however, precludes the owner of a pioneer drug from waiting longer than 45 days to sue for patent infringement" [and thus not triggering a 30-month stay]).

complaint. While the Court may take judicial notice of the Hatch-Waxman Act itself, Cephalon asks the Court to do much more: draw factual inferences in Cephalon's favor about the Act's effect on the leverage Cephalon had in its negotiation with the generic challengers. This is improper on a motion to dismiss.[37]

Nor can the fact that the *Tamoxifen* court accepted a Hatch-Waxman by-product argument on a motion to dismiss help Cephalon here. *Tamoxifen*, 466 F. 3d at 206-08 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) and *Schering*, 402 F.3d at 1074). A court may take judicial notice of the existence of another court's opinion, but not for the truth of the facts asserted therein. *Southern Cross Overseas Agencies*, 181 F.3d at 426. The FTC should have the chance to show through expert and other testimony that Cephalon is simply wrong about the "natural" consequences of the Hatch-Waxman Act.[38]

Finally, any reliance on an "asymmetry of risk" between branded and generic companies stemming from the substantial differential between the profits the brand stands to lose and the

---

[37] *See In re Warfarin*, 214 F.3d at 398 (stating that district court may not take judicial notice of "facts gleaned from counsel's argument"); Fed. R. Evid. 201(b) (a fact subject to judicial notice is "one not subject to reasonable dispute in that it is either generally known … or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned"). *See also Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 317 (3d Cir. 2007) (reversing 12(b)(6) dismissal and stating that "the [district court] erroneously assumed that monopoly is the 'natural consequence of the standard-setting process,' an unsupported factual finding that ignores the possibility of a standard comprised of nonproprietary technologies").

[38] Cephalon is also wrong that an exclusion payment settlement is no different than any other type of settlement, which necessarily includes "some consideration." (Def.'s Mem. 15 n.17) (citing *dicta* in *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). While all settlements include some form of consideration flowing between the parties, the type of consideration matters in antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or a compromise on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition. But if the consideration amounts to a sharing of profits achieved by avoiding competition, then that conduct is at the core of what the antitrust laws proscribe.

generic stands to gain (*see* Def.'s Mem. 19) cannot advance Cephalon's motion. Any monopolist – with or without a patent – has the incentive to protect its monopoly profits when faced with the threat of competition. That incentive cannot excuse Cephalon's exclusionary conduct.[39]

B. Cephalon's assertion that exclusion payments are necessary to settle Hatch-Waxman patent litigation contradicts the complaint

Cephalon's argument starts with a simple enough proposition: courts should promote settlement of litigation. (Def.'s Mem. 2, 18, 25, 26.) From there, however, Cephalon goes on to suggest that alleged generic infringers are overly optimistic in their view of the patent litigation merits; that this over-optimism creates a need for exclusion payment settlements; and indeed, that settlement of Hatch-Waxman litigation is "often impossible" without payments from the patent holder to the alleged infringer. Cephalon's assertion not only contradicts the allegations of the complaint, it is just wrong. *Id.* at 17-18.

The complaint alleges that Cephalon's particle size patent was unlikely to prevent generic competition and that the generic companies, Cephalon, and independent observers knew it (Compl. ¶¶ 45-51) – allegations plainly contradicted by Cephalon's suggestion that the generic challengers were "overly optimistic." The complaint also alleges that it was possible that "Cephalon would have agreed to settle its patent litigation on terms that did not compensate the First Filers, but instead provided for generic entry earlier than 2012." (¶ 83.) Cephalon essentially argues that the complaint is wrong, but on a motion to dismiss, the complaint's allegations and all reasonable inferences must be accepted.

---

[39] *See, e.g., LePage's Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) ("[A] defendant's assertion that it acted in furtherance of its economic interests does not constitute the type of business justification that is an acceptable defense to . . . monopolization.").

Moreover, the specific complaint allegations in this case are consistent with the observed ability generally of branded pharmaceutical companies to settle patent litigation without paying the alleged generic infringer. Beginning in 2000, the FTC brought several enforcement actions challenging exclusion payments in Hatch-Waxman patent litigation and until 2005,[40] these enforcement actions appear to have deterred exclusion payments. During this time, parties nonetheless routinely settled Hatch-Waxman patent cases – they simply did so without payments.[41] This history suggests that Cephalon's argument – that a judicial rule subjecting exclusion payment settlements to antitrust scrutiny will make it impossible to settle many cases – is unlikely to be borne out by the facts. In any event, it raises a disputed issue as to facts outside the complaint. The Court may not resolve this dispute now.

CONCLUSION

Advances in the pharmaceutical industry bring enormous benefits. The development of new drugs is risky and costly, and preserving incentives to undertake this task is critically important. Due regard for patent rights is thus a fundamental premise of the Hatch-Waxman Act framework. But shielding exclusion payment settlements by drug companies from antitrust scrutiny would grant monopolists the ability to buy more protection from competition than their Congressionally-granted patent rights provide and would retard – rather than foster – innovation. Drug companies, like Cephalon, will use this power not to preserve legitimate patent

[40] In 2005, the Eleventh Circuit issued the *Schering* decision and shortly thereafter, the Second Circuit issued the *Tamoxifen* decision.

[41] For example, in fiscal year 2004, 14 pharmaceutical patent settlements were filed with the FTC under the Medicare Modernization Act and none involved both a payment from the brand to the generic and an agreement to defer generic entry. *See* FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2004*, at 1-2, *available at* <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

monopolies, but rather to extinguish challenges to the weakest patents which would otherwise generate billions of dollars in consumers savings.

The Court should deny Cephalon's motion to dismiss.

Pursuant to Local Rule 7.1(f), the Federal Trade Commission respectfully requests oral argument on Cephalon's motion to dismiss.

Respectfully submitted,

/s/ Markus H. Meier
MARKUS H. MEIER
BRADLEY S. ALBERT
ELIZABETH R. HILDER
SARALISA C. BRAU
MARK J. WOODWARD
JEFFREY C. BANK
Attorneys for Plaintiff
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20580
Telephone: (202) 326-3759
Facsimile: (202) 326-3384
mmeier@ftc.gov

J. ROBERT ROBERTSON
Chief Trial Counsel

Dated: June 2, 2008