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

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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

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

[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

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[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).

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 Provig

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[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.)

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[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

[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

[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 gpti upcr tir cha Il(insnt tr th[Paten(anre8 Ts it from)5(of gem)5.4(p7(eAnng).So lovinasng thundeflynngor)]TJ

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.

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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.

[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).

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[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." (

private interests of the patent holder must give way, the Court held. Otherwise, "the public may

[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

<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.

[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).

[26] *Schering*, 402 F.3d at 1076 ("underscor[ing] the need to evaluate the strength of the

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 (thfor theat-.00009 Tw[(prevailsion presentDld)]TJ-17.355 -3al_0ition saf)3.

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[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>.

[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

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).

[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 eligib*T*

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.

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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]).

[37] *See In re Warfarin*

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.

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[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,

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