

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

Federal Trade Commission,

Plaintiff,

v.

Cephalon, Inc.,

Defendants.

Case No. 08-cv-2141-RBS

ORAL ARGUMENT REQUESTED

**DEFENDANT CEPHALON, INC.'S REPLY BRIEF
IN SUPPORT OF ITS MOTION TO DISMISS**

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I. INTRODUCTION

The parties' briefs contrast starkly: Cephalon, Inc. ("Cephalon") moved to dismiss based on the prevailing standard that Hatch-Waxman settlements within the "scope of the patent" are lawful, as articulated in recent, directly applicable precedent, including decisions by two Courts of Appeals. The Federal Trade Commission (the "FTC" or the "Commission") opposes Cephalon's motion largely on the basis of what it contends antitrust policy should be. Indeed, the FTC does not cite a Hatch-Waxman settlement case until page 19 of its brief. Its arguments rest superficially on sound-bites and generalities from several Supreme Court cases, none of which support the FTC's policy position that settlements involving "weak" patents should give rise to antitrust liability, even if they do not exclude non-infringing products or extend beyond the patent term.

The Commission's position only decays further when it attempts to surmount the Hatch-Waxman decisions that run squarely against it. The Commission wrongly suggests that the Second and Eleventh Circuit standards are inconsistent, and mischaracterizes both *Tamoxifen*¹ and *Schering-Plough*² in an effort to undermine their persuasive force. Indeed, in attempting to develop a fresh spin on its previously-rejected arguments, the FTC backs itself into positions contrary to those it advanced in prior litigation. The FTC also seeks to plead around the Second and Eleventh Circuit standard by miscasting the legal reasoning behind those decisions as "facts" inconsistent with its Complaint. In another effort to avoid this clear precedent, the FTC relies on decisions involving *interim* agreements, which are inapposite (as it previously has acknowledged) because they achieve neither patent certainty nor settlement efficiencies.

¹ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

² *Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005).

Finally, although criticizing the “scope of the patent” test, the FTC proposes no workable alternative standard to assess the legality *vel non* of Hatch-Waxman settlements. After noting that a number of alternative standards have been proposed, it seeks to avoid the issue, suggesting that this Court need not choose one in order to deny Cephalon’s motion. The FTC also does not explain how any alternative could be implemented by this Court to allow it or a jury to speculate how the settled patent litigation otherwise would have ended, and then to measure the settlement against such speculation. Any such alternative not only would be unworkable but also would undermine the strong public policy in favor of encouraging settlements.

In short, nothing the Commission says or cites in its Opposition provides this Court with a basis to deviate from the prevailing standard. The courts applying that standard have carefully balanced competing antitrust, patent and settlement considerations under the Hatch-Waxman scheme, and have articulated a clear, workable, and fair standard – the “scope of the patent” test. That test should be applied here, and the Complaint should be dismissed.

II. ARGUMENT

A. The FTC’s Policy Views Find No Support In The Supreme Court Precedent It Cites

The FTC devotes much of its brief to espousing what it would like the law to be. In particular, the FTC urges that “reverse payment” settlements should be unlawful because they secure unwarranted protection from competition through the use of “weak” patents. But this same policy argument has been rejected by courts, in favor of the more compelling policies of securing certainty in patent rights, encouraging innovation, and promoting litigation settlements. Indeed, the Second Circuit has expressly stated that any small risk of extending so called “weak” patent monopolies is far outweighed by these important public policies: “[S]ettlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some

cases to the survival of monopolies created by what would otherwise be fatally weak patents.”
Tamoxifen, 466 F.3d at 212.

Recognizing that the prevailing law does not countenance discounting patent rights by a retrospective assessment of the patent’s “strength,” the Commission seeks to bolster its policy arguments by suggesting they derive directly from Supreme Court precedent. *See* Plaintiff FTC’s Mem. in Opposition to Cephalon’s Motion to Dismiss, Doc. No. 3, Civ. A. No. 08-2141-RBS (“Opp.”), at 12-19. This effort draws largely on sound-bites setting forth general principles that few would dispute – *e.g.*, that patents should not cover “trivial [*i.e.*, obvious] inventions,” *id.* at 14; that the right to challenge patents is “important ... [to] permitting full and free competition,” *id.* at 16; that the “public interest is dominant in the patent system,” *id.*; and that challenging patents is important “to vindicate the public interest,” *id.* at 17. These aphorisms, of course, do not answer the question of how to analyze Hatch-Waxman settlements, which involves reconciliation of antitrust, patent, and settlement principles.

None of the three Supreme Court cases on which the FTC principally relies supports its cornerstone policy proposition that antitrust liability for a patentee’s conduct depends on the patent’s “strength.” Notably, *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), which the FTC cites for the proposition that “weak” patents have less “exclusionary force” than “strong” patents, Opp. at 14, is not even an antitrust case. It merely discusses the patent law principle that inventions should not be patentable *at all* if they are “obvious” in light of prior art, 127 S. Ct. at 1741, and does not speak to the power of an *issued* patent to exclude others from practicing the claimed invention.³

³ The FTC’s position trivializes the significance of obtaining a patent in the first place, apparently assuming it is an all but ministerial task. Moreover, the Commission’s proffered data regarding the supposed “weakness” of pharmaceutical patents, *see* Opp. at 15, is greatly skewed because it fails to account for patents that were not challenged in the first instance, or challenges resolved by agreement.

Similarly, the FTC mistakenly relies on *United States v. Masonite Corp.*, 316 U.S. 265 (1942), which it cites for the proposition that “sharing monopoly profits to achieve exclusion” does not fall within the scope of a patent, Opp. at 18. In fact, the holding of *Masonite* is more limited and does not support the abstract principle the FTC would glean from it. The Court held that once a patentee sells a patented product, it is beyond the limits of its patent grant to then *conspire* with purchasers to *fix the resale price* of the product. 316 U.S. at 277-78. Like the prevailing standard, *Masonite* recognized that conduct by a patentee that merely excludes competition “within the limits of the [patent] monopoly” does not violate the antitrust laws. *Id.* Indeed, *Masonite* was affirmatively invoked by the Eleventh Circuit in *Valley Drug* as direct support for the “scope of the patent” standard. *See Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (citing *Masonite* for proposition that the “patent exception to antitrust liability ... is limited by the terms of the patent and the statutory rights granted the patentee”).

Finally, *United States v. Glaxo Group, Ltd.*, 410 U.S. 52 (1973), which the FTC cites in support of the vague notion that “protecting weak patents” is contrary to the public interest, Opp. at 17, in fact supports the “scope of the patent” test. While the *Glaxo* Court recognized the government’s standing to *directly* contest the validity of a patent as a remedy for *established* antitrust violations (which the FTC has not done), it cautioned against subjecting a patentee to antitrust liability *based on* an allegation of patent invalidity. The Court stated, “[W]e do not recognize unlimited authority in the Government to attack a patent *by basing an antitrust action on the simple assertion that the patent is invalid* ... [n]or do we invest the Attorney General with a roving commission to question the validity of any patent lurking in the background of an antitrust case.” *Id.* at 59 (emphasis added).

Glaxo relied on *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172 (1965), *see Glaxo*, 410 U.S. at 59, a case the FTC fails to cite though it is far more on point than those it does. In *Walker Process*, the Court considered the extent to which a patentee should be held liable under the Sherman Act for attempting to enforce patents against competitors. The Court drew the critical distinction between patents *fraudulently* procured (enforcement of which could trigger antitrust liability) and patents that are merely found invalid (enforcement of which prior to the finding of invalidity does not give rise to antitrust liability). *Walker Process*, 382 U.S. at 177. Like the prevailing Hatch-Waxman settlement standard, the *Walker Process* holding reflects a balance of the competing interests of patent and antitrust law. *See* 382 U.S. at 179-80 (Harlan, J., concurring) (“It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in the area between the differing policies of the patent and antitrust laws.”). As Justice Harlan explained in his concurrence, subjecting a patentee to antitrust liability merely because a patent might be “voidable ... might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits.” *Id.*

Indeed, two courts articulating the prevailing standard specifically relied on *Walker Process*. The district court in *Cipro III* stated that subjecting patent settlements to antitrust liability based on an after-the-fact review of the patent merits “would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, first elaborated upon by Justice Harlan in his concurrence and relied upon by the patent bar for the past forty years.” *In re Ciprofloxacin Antitrust Litig.*, 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005). Similarly, the Eleventh Circuit in *Valley Drug*, 344 F.3d at 1307, recognized: “Justice Harlan’s concurrence [in *Walker Process*] explained that the effect of antitrust liability on the incentives for innovation and disclosure

created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws.” The court continued: “Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives.” *Id.* at 1308.

Thus, the policy arguments that the FTC advances do not fairly rest on Supreme Court precedent. To the contrary, that precedent, including *Walker Process* in particular, supports the prevailing Hatch-Waxman settlement standard.

B. The FTC’s Efforts To Undercut Or Escape The Prevailing Standard Set Out In *Schering-Plough And Tamoxifen* Are Unavailing

Unable to cite to any Supreme Court precedent that undermines the decisions of the Second and Eleventh Circuits, the FTC instead seeks to temper the force of those decisions. In particular, the FTC: (1) suggests there is no consensus between the Second and Eleventh Circuits; (2) levels criticism that flows only from mischaracterization of the opinions; and (3) argues that the Court may not consider the decisions (or Cephalon’s arguments based on them) because it has pleaded “facts” contrary to their underlying rationale. None of these arguments is effective.

1. The Second And Eleventh Circuits Have Applied The Same, Clear Legal Standard To Hatch-Waxman Settlements

The FTC first tries to dilute the force of the prevailing standard by suggesting that there really is no accord between the Second and Eleventh Circuits’ approaches. Specifically, the FTC claims that, unlike *Tamoxifen, Schering-Plough* “did not expressly foreclose an inquiry into the strength of the patent” in an antitrust analysis of a “reverse payment” settlement and that “[o]thers have interpreted” *Schering-Plough* to require such an assessment. *Opp.* at 22 & n.26. However, the Commission itself argued (in its unsuccessful effort to obtain Supreme Court

review of *Schering-Plough*) that it was “*disingenuous*” to claim that the Eleventh Circuit had invited a *post hoc* merits assessment. Reply Br. for the Petitioner, *Federal Trade Comm’n v. Schering-Plough Corp.*, No. 05-273, at 2 (emphasis added), available at 2005 WL 2652617. Describing the contrast between the Eleventh Circuit’s holding and its own rejected approach, the FTC asserted that the “scope of the patent” test “immunize[d]” settlements within the “nominal scope” of the patent without regard to a retrospective assessment of the underlying patent claims. *Id.* at 2-3. It explained that the *Schering-Plough* decision – properly construed in light of the Eleventh Circuit’s prior holding in *Valley Drug* – did *not* call for a *post hoc* assessment of the patent merits: “Thus, respondents’ suggestion that a *post hoc* inquiry into the merits would satisfy the court of appeals, is disingenuous, because *Valley Drug* precludes a conclusion of liability on that basis.” *Id.* at 2.

The Commission’s previous position before the Supreme Court was clearly correct, as *Valley Drug*, which the *Schering-Plough* court expressly followed, see 402 F.3d at 1065, held that even a judicial finding of patent invalidity *post hoc* “is insufficient to render the patent’s potential exclusionary effects irrelevant to the antitrust analysis.” *Valley Drug*, 344 F.3d at 1309. The Second Circuit in *Tamoxifen* reached the identical conclusion: “We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca’s success had it not settled but rather pursued its appeal.” 466 F.3d at 203. Thus, the FTC is wrong to suggest now that there is any divergence between the “scope of the patent” test articulated and applied by the Second and Eleventh Circuit.

2. The FTC’s Criticisms Of *Schering-Plough* And *Tamoxifen* Depend On Mischaracterizations Of The Decisions

The FTC next tries to avoid the prevailing standard by arguing that the courts’ respective analyses rest on flawed premises that invalidate their conclusions. In particular, the FTC: (1)

claims that *Schering-Plough* was wrongly decided because it rests on “a fundamental error of law” – *i.e.*, the court incorrectly relied on a “presumption of [patent] infringement,” Opp. at 22 & n.27; and (2) claims that *Tamoxifen* was based on mistaken assumptions about the effect of the settlement on subsequent filers, Opp. at 25-27. Neither challenge succeeds.

a. *Schering-Plough* Does Not Rely On A “Presumption of Infringement” But Instead Holds That The “Scope Of The Patent” Test Applies Irrespective Of Whether Invalidity Or Non-Infringement Is Asserted

Although the FTC claims *Schering-Plough* was premised on a “presumption of infringement,” the language cited by the Commission merely reflects the court’s general observation that a party retains its patent rights until it loses them in patent infringement litigation. *Schering-Plough*, 402 F.3d at 1066-67 (“By virtue of its ‘743 patent, Schering obtained the legal right to exclude [the generics] from the market until they proved either that the ‘743 patent was invalid or that their products ... did not infringe ...”). The Eleventh Circuit was not justifying its decision by reference to evidentiary presumptions as to validity or infringement as they might have applied had the underlying patent case gone to trial. Indeed, the court did not discuss the likely outcome of the underlying patent case at all, because it viewed that inquiry as improper. *Schering-Plough*, 402 F.3d at 1065-66.

What the court *did* hold – without regard to evidentiary presumptions – is that the “scope of the patent” test applied whether the generic had claimed invalidity, non-infringement, or both. *Schering-Plough*, 402 F.3d at 1075-76 (“An exception [to the “scope of the patent” standard] cannot lie, as the Commission might think, when the issue turns on validity (*Valley Drug*) as opposed to infringement (the Schering agreements).”). The *Tamoxifen* court, which reached the same result as *Schering-Plough*, similarly disclaimed any reliance on evidentiary presumptions: “[I]rrespective of whether there was a presumption [of validity] or where any such presumption

lay at the time of settlement, we think that [patentee] was then entitled to protect its ... patent monopoly through settlement.” *Tamoxifen*, 466 F.3d at 209 n.22.

b. Tamoxifen Is Not “Fundamental[ly] Premise[d]” On Assumptions About The Effect Of The 180-Day Rule, But Instead Confirms That The Effect Alleged Here Does Not Render The Settlement Unlawful

The FTC next suggests that *Tamoxifen*’s holding was “fundamental[ly] premise[d]” on two assumptions about the operation of the 180-day first-filer exclusivity rule⁴ in that case: (1) the court’s reliance on the now-overruled FDA “successful defense” rule⁵; and (2) the court’s belief that subsequent generics would be incentivized to challenge the tamoxifen patent in order to secure 180 days of exclusivity for themselves. *Opp.* at 25-27. According to the FTC, its allegations here about the effect of the Provigil® Settlements on subsequent generic challengers – that they are unable to compete because the four settling generics (the “Generics”) retained their 180-day exclusivity, *id.* at 26, and that post-settlement they have little incentive to challenge the ‘516 patent, *id.* at 27 – “call into question fundamental premises of the Second Circuit’s ... decision.” *Id.* at 27. This argument fails for multiple reasons.

First, the courts in *Valley Drug* and *Schering-Plough* articulated the same “scope of the patent” test without relying on any assumptions about the operation of the 180-day rule or any other effect of the final settlements in those cases on subsequent generic challengers.

Second, the *Tamoxifen* court’s observations about the operation of 180-day rule were not essential “premises” of the decision. The Second Circuit (like the Eleventh) held that the “scope of the patent” standard reflected the proper balance of the conflicting antitrust, patent, and

⁴ 21 U.S.C. § 355(j)(5)(B)(iv)(I).

⁵ Following the settlement in *Tamoxifen*, the rule, under which a first filer could retain its exclusivity only by successfully defending a paragraph IV suit to conclusion, was held invalid. *See Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130-31 (D.D.C. 1997), *aff’d in part and rev’d in part on other grounds*, 140 F.3d 1060 (D.C. Cir. 1998).

settlement considerations presented by Hatch-Waxman settlement cases, and that neither the existence nor size of “reverse payments” was relevant. None of the court’s articulated rationales for that holding concerned either the 180-day rule or any effect on subsequent generics.⁶

The FTC focuses on passages it says reflect the court’s “belief” that “reverse payment” settlements “could not be an effective strategy to protect weak patents,” Opp. at 26. But while the *Tamoxifen* court may have been optimistic about the success of subsequent challenges to “weak” patents, that single aspect of its opinion hardly qualifies as an essential “premise.” To the contrary, the court candidly acknowledged that settlements would “lead[] in some cases to the survival of monopolies created by what would otherwise be fatally weak patents,” but held that settlement is nevertheless “encouraged for a variety of reasons.” 466 F.3d at 212.

Third, the *Tamoxifen* court considered and rejected allegations that the settlement was unlawful because the 180-day rule had anticompetitive effects on subsequent filers. 466 F.3d at 216-19. In particular, the *Tamoxifen* plaintiffs complained that Barr (the first-filer), after the settlement, had petitioned the FDA to restore its 180 days of exclusivity and that that conduct should be viewed as “circumstantial evidence demonstrating the anticompetitive consequences of

⁶ In particular, the court espoused the following principles supporting its holding:

- Courts should encourage settlement of patent litigation because that “longstanding principle” promotes judicial efficiency and certainty in patent rights. *Tamoxifen*, 466 F.3d at 202-03;
- Because “reverse payments” are “particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them[,]” there is no basis for condemning them when they are “employed to lift the uncertainty surrounding the validity and scope of the holder’s patent.” *Id.* at 206-07;
- The law should not prohibit even “reverse payments” that are allegedly in excess of the generic’s expected profits. Even if the payments in specific cases “betrays a fatal disbelief” in the patent strength (a conclusion the court disputed as a general matter), the court doubted the “wisdom of deeming a patent effectively invalid on the basis of a patent holder’s fear of losing it.” *Id.* at 210-11; and
- A rule restricting the ability to settle with cash payments to generics, in light of the generics’ superior bargaining position due to Hatch-Waxman, would improperly chill settlements by inhibiting even a confident patentee’s ability to “insure against the possibility that [the patentee’s] confidence is misplaced, or ... that a reviewing court might ... render an erroneous decision.” *Id.* at 210-11.

[the] agreement[] among the defendants.” *Id.* at 216 (alterations in original, internal quotations omitted). The court held that “even if we were to view Barr’s actions with regard to the 180-day exclusivity period as somehow constituting [such evidence], *it would not affect our conclusion* [that the settlement was lawful].” *Id.* at 218 (emphasis added). The court reasoned that “because we have concluded that the Settlement Agreement was not itself an unlawful conspiracy, Barr’s ‘block[ing of] [subsequent] generic entry’ would not be unlawful as ‘in furtherance of’ an unlawful conspiracy. There would have to *be* an unlawful conspiracy before Barr’s actions could contribute to it.” *Id.* (emphasis in original).

The Second Circuit’s conclusion – that effects on subsequent generic challengers cannot be used to challenge a Hatch-Waxman settlement – comports exactly with Cephalon’s previously-stated point that any impact on subsequent filers does not effect the legality of the Provigil[®] Settlements because it flows from the Hatch-Waxman scheme. *See* Cephalon’s Mem. of Points and Authorities in Support of its Motion to Dismiss, Doc. No. 1, Civ. A. No. 08-2141 (“Ceph. Br.”), at 26-27. The terms of the Provigil[®] Settlements do not speak at all to the Generics’ 180-day rights, and the FTC does not allege otherwise.⁷ Rather the alleged effects about which the FTC is complaining (*see* Compl. at ¶¶ 85-86) flow from the operation of Hatch-Waxman itself (under which a settling defendant who maintains its paragraph IV certification keeps its 180 days of exclusivity), and/or the Generics’ unilateral decisions not to waive their 180 days. *Cf. City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998)

⁷ The court in *Tamoxifen* emphasized repeatedly that the question was not merely one of effect but rather whether the agreement’s *terms* required the action that caused that effect. *See, e.g., Tamoxifen*, 466 F.3d at 215 (“Thus the *stated terms* of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca’s patent.”) (emphasis added); *see also id.* at 200 (“[I]f the plaintiffs plausibly alleged that the defendants entered into an *agreement to manipulate* the 180-day exclusivity period to the defendants’ joint benefit, and if they were able to prove based on the facts alleged that they suffered antitrust injury as a result of that agreement then that ... would likely be sufficient to state an antitrust violation.”) (emphasis added).

(dismissing on antitrust injury grounds because “any injury suffered by the City did not flow from defendants’ conduct, but, rather, from the realities of the regulated environment ...”).⁸

3. The FTC Cannot Plead Around The Prevailing Standard

In yet another effort to avoid the prevailing *legal* standard, the FTC in effect contends that it can *plead* around it. The FTC does this by miscasting the rationales underlying the standard – advanced by the courts on the basis of their general observations and legal reasoning – as depending instead on “facts” peculiar to those cases. The Commission then argues that those rationales cannot be considered here because they are “contradicted” by or “outside” the Complaint’s allegations and not subject to judicial notice.⁹ Opp. at 9-10, 28-31. The FTC thereby seeks to foreclose consideration of the propositions that: (1) “reverse payments” are a “natural by-product” of Hatch-Waxman and therefore do not (as the FTC claims) signal “weak” patents or anticompetitive purpose; and (2) “reverse payments” may be necessary to settle some Hatch-Waxman cases because of the particular settlement dynamics created by the statute. *See Tamoxifen*, 466 F.3d at 206-07; *Schering-Plough*, 402 F.3d at 1074.¹⁰

⁸ Indeed, in dissenting in part from the Commission’s Order authorizing this suit, Commissioner Leibowitz attributed the effects at issue to the Generics’ unilateral conduct and not to the Provigil[®] Settlements:

I also would have named as a defendant any generic company that took these [alleged] pay-offs and now refuses to relinquish their 180-day exclusivity, *thus blocking generic entry* into the Provigil market that otherwise could occur in 2008.

Statement of Commissioner Jon Leibowitz, *In re Cephalon, Inc.* (No. 061-0182) (concurring in part, dissenting in part), available at <http://www.ftc.gov/os/caselist/0610182/080213comment.pdf> (last accessed June 12, 2008) (emphasis added).

⁹ In particular, the FTC relies on its allegations that Cephalon paid the Generics, not because of Hatch-Waxman dynamics, but because it believed it had a “weak” patent, Opp. at 29, and that it was “possible” Cephalon would have agreed to a cashless settlement, *id.* at 31.

¹⁰ Contrary to the Opposition, Cephalon did not assert that “reverse payments” are necessary to settle *all* Hatch-Waxman patent litigation. *See* Opp. at 31 (“Cephalon’s assertion that exclusion payments are necessary to settle Hatch-Waxman patent litigation contradicts the complaint.”). In light of Cephalon position that there were *no* “reverse payments” *in this case* (*see* Ceph. Br. at 8), it is difficult to imagine how the FTC could construe Cephalon’s brief as advocating that position. Thus, the FTC’s statistics about a number of unidentified settlements without “reverse payments,” Opp. at 32, are immaterial.

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

Thus, it is futile to suggest that by relying on the rationales for the "scope of the patent" test, Cephalon is "contradicting" the Complaint or asking the Court to take judicial notice of "disputed facts" outside the pleadings. *See* Opp. at 30 (urging Court not to accept *Tamoxifen* rationale because "a court may take judicial notice of the existence of another court's opinion, but not for the truth of the facts asserted therein."). Indeed, the FTC's argument has it exactly backwards: the allegations about patent "weakness" and the "possibility" of a cashless settlement which it contends avoid the prevailing standard are precisely the type of case-specific facts that the standard deems irrelevant as a matter of law. *See, e.g., Tamoxifen*, 466 F.3d at 210-11 (rejecting *post hoc* assessments of patent merits); *Schering-Plough*, 402 F.3d at 1075 (rejecting

rule basing liability on possibility of “compromise-without-payment”); Ceph. Br. at 17-22.¹¹

The only “facts” that could possibly state a claim under the “scope of the patent” test are that the patent was procured by fraud, that the patent claims were sham, that the settlement excluded indisputably non-infringing products, or that the settlement extended beyond patent life. No such facts are alleged here.¹²

C. The FTC’s Reliance On Cases Involving Interim Agreements Is Misplaced And Inconsistent With Its Past Position

The FTC’s reliance on the Sixth Circuit’s decision in *Cardizem*, the Southern District of Florida’s remand decision in *Valley Drug* and *dicta* in the D.C. Circuit’s decision in *Andrx* is misplaced. Opp. at 20-21, citing *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005); *Andrx Pharms. Inc. v. Biovail Corp. Int’l*, 256 F.3d 799 (D.C. Cir. 2001). These cases cannot be contrary to the prevailing standard for the essential reason that they do not involve Hatch-Waxman settlements at all. Rather, they involve “interim agreements” in which the branded company paid the generic challenger to stay off the market while the patent suit continued. Simply put, interim agreements do not resolve patent disputes and thus two primary considerations that are balanced against antitrust concerns – *i.e.*, promoting innovation by preserving patent rights, and promoting efficiency by encouraging litigation settlements – are not

¹¹ The FTC urges that the risk-shifting aspects of Hatch-Waxman (and the resulting “asymmetry of risk” between the innovator and the generic) cannot “excuse” Cephalon’s conduct because “any monopolist – with or without a patent – has the incentive to protect its monopoly profits from the threat of competition.” Opp. at 30-31. This, however, mischaracterizes Cephalon’s argument. Cephalon does not assume “reverse payments” are anticompetitive and offer the statutory dynamics as “business justification,” *see* Opp. at 31 n.39. Rather, Cephalon argues, and the courts articulating the “scope of the patent” test reason, that “asymmetries of risk” explain why “reverse payments” do not signal unreasonably exclusionary conduct in the first instance. *See Schering-Plough*, 402 F.3d at 1074 (“Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of the settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generics] gained considerable leverage in patent litigation: the exposure to liability amounted to its litigation costs ...”) (internal citation omitted).

¹² In its opening brief, Cephalon argued that the FTC failed in its vague efforts to allege the Settlements exceeded the “scope of the patent” by restricting non-infringing products. *See* Ceph. Br. at 23-26. In its opposition, the FTC offers no response.

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

The FTC claims that “Cephalon’s attempt to cast aside the *Cardizem* decision because it involved an interim agreement, rather than a final settlement, is unavailing.” Opp. at 20 n.24. The FTC’s mechanistic argument is that Cephalon must be wrong because if, as it contends, an agreement to exclude competition for the entire patent life would be lawful, then *a fortiori* an agreement that covers only a portion of the patent life must be lawful. *Id.* This contention ignores the distinction between full settlements and interim agreements – a distinction previously acknowledged by the FTC itself. In its joint *amicus* brief with the Solicitor General in opposition to *certiorari* in *Cardizem*, the FTC distinguished *Cardizem* from *Tamoxifen*, *Cipro*, and *Schering-Plough* in the same way Cephalon does here:

In contrast to the agreements in this case and in *Valley Drug*, all of the decisions [then] pending in the lower courts cited by the petitioner [including *Tamoxifen*, *Cipro*, and *Schering-Plough*] involve final settlements that conclusively resolve the parties’ patent dispute. *The distinction is important* because the calculus of competitive costs and benefits is substantially different for interim settlements and final settlements.

Br. of United States as *Amicus Curiae*, *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779, at 17 (emphasis added) (joined by the FTC), *available at* 2004 WL 1562075. The Commission also distinguished *Cardizem* in its *Schering-Plough* opinion: “The *Cardizem* case also can be distinguished on its facts. . . . Unlike the present case, *Cardizem* involved an interim [agreement] rather than a final settlement, so it would be more difficult to claim that the agreement was

ancillary to an efficient disposition of the litigation.” Opinion of the Commission, *In re Schering-Plough Corp.*, No. 9297 (“Comm’n Op.”), at 13, n.26.¹³

The lone decision the FTC cites that arguably is at odds with the Second and Eleventh Circuits is *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004), the follow-on private suit arising from the same settlements that were subsequently upheld by the Eleventh Circuit in *Schering-Plough*. While the *K-Dur* court denied a motion to dismiss a complaint challenging a Hatch-Waxman settlement, the opinion, however, is of limited precedential value, principally because it preceded both *Tamoxifen* and *Schering-Plough*.¹⁴ The court drew upon the precedent available at the time: *Cardizem* (which, as the FTC previously conceded, is distinguishable) and the FTC’s own *Schering-Plough* decision and order (which the Eleventh Circuit later vacated because it was based on an “inflexible” legal theory that failed to account for the realities of Hatch-Waxman litigation¹⁵). *See K-Dur*, 338 F. Supp. 2d at 533 & n.21.

Finally, to the extent the *K-Dur* court also relied on an early ruling in the *Cipro* litigation, that discussion involved a jurisdictional issue not raised here. In *K-Dur*, defendants appeared to concede that plaintiffs could challenge a Hatch-Waxman settlement by alleging that the underlying patent was invalid,¹⁶ but argued that the complaint should be dismissed because plaintiffs did not so allege. *K-Dur*, 338 F. Supp. 2d at 530-31. The court disagreed, relying on *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001), in

¹³ Available at www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf (last accessed June 19, 2008).

¹⁴ Indeed, the court’s opinion never examines the two chief considerations underlying the prevailing standard, ensuring patent certainty and promoting litigation settlements. Moreover, the opinion never discusses the relationship between “reverse payments” and the risk-shifting aspects of Hatch-Waxman.

¹⁵ *See Schering-Plough*, 403 F.3d at 1075.

¹⁶ Cephalon does not make this concession here because, under the prevailing standard, even an actual subsequent finding of invalidity has no relevance to antitrust assessment of Hatch-Waxman settlements, so *a fortiori* allegations of invalidity would not state a claim. *See Valley Drug*, 344 F.3d at 1308 (settlement lawful despite subsequent judgment of invalidity); Ceph. Br. at 21-23.

which the court – in deciding only whether plaintiffs’ state law claims were pre-empted by patent law – held that the claims did not “arise under” federal law because a claim of invalidity was not an essential element of each theory of recovery, 166 F. Supp. 2d at 750-51. When the *Cipro* court subsequently considered the *legality* of the agreements, it adopted the “scope of the patent” test. *Cipro III*, 363 F. Supp. 2d at 535. Thus, all the “precedent” on which the 2004 *K-Dur* decision relied has lost its force, and *K-Dur* does not supply any justification for departure from the now prevailing standard.

D. The FTC Proposes No Workable Standard For Evaluating Hatch-Waxman Settlements By *Post Hoc* Assessment Of The Patent Merits

The FTC does not propose a workable standard by which an antitrust court could account for the “strength” or “weakness” of the underlying patent case in evaluating Hatch-Waxman settlements. The FTC observes that commentators have disagreed on the “appropriate approach,” and avoids proposing one itself. *See* Opp. at 11 & n.10 (“But the Court does not face a choice among those variations here. The only issue here is whether to adopt Cephalon’s ... rule,” *i.e.*, the prevailing Second and Eleventh Circuit standard). The FTC’s avoidance of this critical issue is both telling and inappropriate. The Court obviously must apply a precise standard if it sustains the Complaint and the case is to proceed.¹⁷

Any standard that depends on the amorphous concept of *post hoc* evaluation of patent “strength” is both impractical and unsound. How, for example, should a judge or jury define a “weak” patent? Should the determination be purely qualitative? Should the fact-finder instead determine the likelihood that the patentee would have prevailed had the case been tried? Even if such an exercise were possible, does a 51 percent probability mean a patent is “strong” and a 49

¹⁷ A precise standard not only would be necessary for summary judgment and trial, but could impact the scope of discovery as well.

percent probability mean a patent is “weak”? If not, should there be some other threshold below which a patent is too “weak” to support certain settlement terms? Should there be some sliding scale comparing the “weakness” of a patent to the amount of consideration given to the generic? None of these inquiries are either feasible or appropriate, which is why the courts applying the prevailing standard have eschewed *post hoc* inquiry. If the parties themselves were unable to predict the outcome of the case because patent litigation is inherently uncertain, *Valley Drug*, 344 F.3d at 1308 (“Patent litigation is too complex and the results too uncertain for parties to accurately forecast” the outcome), a judge or jury cannot meaningfully do so retrospectively. Moreover, any standard that required such second-guessing to determine whether settlements were permissible would significantly chill the patent litigants’ interest in settling, and thereby undermine the important public policy encouraging patent litigants to resolve their differences amicably. *See, e.g., Tamoxifen*, 466 F.3d at 212 n.26; *Cipro III*, 363 F. Supp. 2d at 529-30.

The FTC nonetheless suggests, without explaining *how*, that a “direct” assessment of the patent merits would be workable. Opp. at 24-25 (quoting the *Tamoxifen* dissent for the proposition that “it is not outside the bounds of the district court’s competence to predict’ the likely outcome of a patent case”). But the Commission has repeatedly argued *against* the wisdom of such an assessment in prior litigation. In its *Schering-Plough* opinion, the Commission acknowledged the “serious uncertainties that would confront parties who seek to settle patent litigation if the Commission undertook to examine the underlying merits itself later on, and gave them conclusive weight.” Comm’n Op. at 35 (*see supra* n. 13); *see also* Supp. Br. for the Petitioner, *Federal Trade Comm’n v. Schering-Plough Corp.*, No. 05-273, at 4 (“A key drawback to [a *post hoc* review] is that it places parties contemplating settlement in the

predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal.”) *available at* 2006 WL 1647529.¹⁸

The FTC also proposes reliance on indirect evidence. *See, e.g.*, Opp. at 24 (“[T]he 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 protections afforded by its patent.”). But where courts (and the FTC itself) have criticized *ex post* assessment of patent merits from *direct* evidence as unduly speculative, reliance on *indirect* evidence would only exacerbate the problem. As “[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast” the outcome, *Valley Drug*, 344 F.3d at 1308, drawing upon speculation from industry consultants and analysts (*see* Compl. at ¶¶ 35, 51) and Cephalon’s *contingency* planning (*id.* at ¶ 52) is surely an even more unreliable approach to measuring the “strength” of a patent. *See, e.g.*, *Tamoxifen*, 466 F.3d at 210 (“[W]e doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder’s fear of losing it.”). Similarly, in light of the dynamics of Hatch-Waxman litigation, the mere presence (or even size) of payments to generics does not signal patent “weakness” (Opp. at 2, 14). *E.g.*, *Valley Drug*, 344 F.3d at 1310 (“Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”); *Tamoxifen*, 466 F.3d at 210 (quoting *Valley Drug*); *see also* Ceph. Br. at 21-23. Finally, the chilling effect would be even greater if parties wishing to settle their patent disputes

¹⁸ The Commission’s suggestion here that *ex post* review would not chill settlements because it seeks only equitable relief, Opp. at 25, is undermined by the observations to the contrary cited above in *Schering-Plough*, a case where it also sought only equitable relief. Moreover, the FTC cannot seriously maintain that there should be one standard in FTC enforcement actions and another in private damages litigation.

knew they could be subject to antitrust liability based on an amorphous after-the-fact analysis of indirect evidence.

Accordingly, the only workable and analytically sound standard for judging Hatch-Waxman settlements is the “scope of the patent” test already adopted by the Second and Eleventh Circuits.

III. CONCLUSION

The FTC (1) lacks judicial support for its policy views, (2) cannot undermine the decisions under which the Provigil[®] Settlements are plainly lawful, and (3) fails to offer a workable alternative to the “scope of the patent” test. Moreover, its proffered views, if adopted by this Court, would significantly undermine the strong public policy in favor of encouraging amicable resolution of patent litigation. For these reasons, and those articulated in Cephalon’s opening brief, this Court should follow the prevailing standard and dismiss the FTC’s Complaint with prejudice.

Respectfully submitted,

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Attorneys for Cephalon, Inc.

Dated: June 20, 2008

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

<p>FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, N.W. Washington, D.C. 20508</p> <p>Plaintiff,</p> <p>v.</p> <p>CEPHALON, INC. 41 Moores Road Frazer, Pennsylvania 19355</p> <p>Defendant.</p>	<p>Civil Action No. 08-cv-2141 (RBS)</p>
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CERTIFICATE OF SERVICE

I, David E. Edwards hereby certify that on June 20, 2008, Defendant Cephalon, Inc.'s Reply Brief In Support of its Motion to Dismiss has been filed electronically and served via electronic mail on the following counsel, and is now available for viewing and downloading from the Court's Electronic Case Filing System.

<p>Markus H. Meier, Esquire FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, N.W. Washington, D.C. 20580</p> <p>Counsel for Plaintiff, Federal Trade Commission</p>	<p>James C. Burling, Esquire WILMER CUTLER PICKERING HALE AND DORR LLP 60 State Street Boston, MA 02109</p> <p>Counsel for Defendant. Cephalon, Inc.</p>
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/s/ David E. Edwards
Attorney for Defendant,
Cephalon, Inc.

**IN THE UNITED 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 MOTION TO COMPEL

Plaintiff Federal Trade Commission, by undersigned counsel, respectfully moves the Court, pursuant to Rules 36 and 37 of the Federal Rules of Civil Procedure, to grant its motion to strike defendant Cephalon's objections and: (1) compel Cephalon to respond to the pending set of document requests; (2) deem admitted the Commission's First Requests for Admission or, at a minimum, compel Cephalon to supply responses; and (3) award the Commission's reasonable expenses in bringing this motion. In support of this motion, the Court is referred to the accompanying memorandum. A proposed order is also attached.

Pursuant to Fed. R. Civ. P. 37(a)(1) and LCvR 26.1(f), the undersigned counsel certifies that counsel conferred in good faith on December 3, 2008 and attempted to resolve this discovery issue, but were unable to do so.

Oral argument is requested.

Dated: December 5, 2008

Respectfully submitted,

/s/ Markus H. Meier

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**IN THE UNITED DISTRICT COURT
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Plaintiff,

v.

CEPHALON, INC.
41 Moores Road
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Defendant.

Civil Action No. 08-cv-2141-RBS

[PROPOSED] ORDER

Having considered Plaintiff's Motion to Compel in this action, its memorandum of points and authorities in support thereof, and all documents filed in support thereof or opposition thereto, the Court hereby ORDERS that:

The Plaintiff's Motion to Compel is GRANTED

It is hereby further ORDERED that:

1. Defendant Cephalon produce documents responsive to Plaintiff Federal Trade Commission's First Request for Documents (i.e., Nos. 1,2, and 3) within ten (10) days of this Order;
2. Plaintiff Federal Trade Commission's First Request for Admissions are deemed admitted in their entirety (i.e., Nos. 1-23);

3. Plaintiff Federal Trade Commission file an affidavit setting forth reasonable expenses incurred in connection with its Motion to Compel within ten (10) days of this Order; and
4. Defendant Cephalon file a response to the FTC's reasonable expenses within five (5) days of receipt.

SO ORDERED this _____ day of _____, 2008.

R. Barclay Surrick
United States District Judge

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

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, NW
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Plaintiff,

v.

CEPHALON, INC.
41 Moores Road
Frazer, Pennsylvania 19355

Defendant.

Civil Action No. 08-cv-2141-RBS

CERTIFICATE OF SERVICE

I hereby certify that on December 5, 2008, Plaintiff Federal Trade Commission's Motion to Compel was filed electronically and served via ECF notification on counsel listed below, and is available for viewing and downloading on the ECF system.

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Respectfully submitted,

By: /s/ Saralisa C. Brau
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**IN THE UNITED 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 SUPPORT OF ITS MOTION TO COMPEL**

This action seeks injunctive relief that would open the door to generic competition to the sleep-disorder drug Provigil, thereby saving consumers millions of dollars each day. In light of the time-sensitive nature of this matter, the Federal Trade Commission ("FTC" or "Commission") served initial discovery on Cephalon on September 18, 2008 in the form of a set of 23 Requests for Admission ("RFAs") and a set of three document requests. No stay of discovery blocks the progress of this action.

Nonetheless, Cephalon has failed to respond. It has sought to delay discovery by serving blanket objections (among others) on October 20, 2008 claiming that its pending motion to dismiss and the absence of a scheduling order render discovery "premature." Cephalon's objections find no support in the Federal Rules of Civil Procedure or case law. Discovery commenced on May 12, 2008, when the parties met their requirements under Rule 26(f) of the

Federal Rules of Civil Procedure. No authority provides for an “automatic” stay of discovery pending a motion to dismiss.

Cephalon’s improper objections deprive the FTC of the discovery to which it is entitled and delay the resolution of this case to the detriment of consumers. The FTC therefore moves to strike Cephalon’s objections and: (1) compel Cephalon to respond to the discovery requests; (2) deem admitted the Commission’s RFAs or, at a minimum, compel Cephalon to supply responses; and (3) award the Commission’s reasonable expenses in bringing this motion. Fed. R. Civ. P. 36, 37.

I. Under the Federal Rules of Civil Procedure, Discovery Began on May 12, 2008

The Federal Rules of Civil Procedure provide that discovery commences when – as here – the parties have conferred and submitted to the court the proposed discovery plan required by Rule 26(f). Fed. R. Civ. P. 26(d)(1), 26(f). Once parties satisfy their obligations under Rule 26(f), they are “allowed to use the discovery devices when and how they choose.” 8 Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* § 2047 (2d ed. 2008). In this case, the parties satisfied the requirements of Rule 26(f) by conferring on April 28, 2008 and submitting a written discovery report to the Court on May 12, 2008. Discovery in this case therefore commenced on May 12, 2008, at which point the FTC was free to serve discovery on Cephalon. The FTC’s set of 23 RFAs and set of three document requests were timely, relevant, and susceptible to a substantive response.¹ (Exs. 1, 2). Because Cephalon never moved to stay discovery, the FTC is entitled to a response to its discovery requests.

¹ See Section III, *infra*, for a more detailed discussion of the FTC’s requests.

II. Cephalon's Primary Objection – That Discovery Is Premature – Is Inconsistent with the Federal Rules and with the Case Law

The Court should grant the Commission's motion to compel because Cephalon's primary objection to discovery is improper. Discovery has commenced but Cephalon has not moved for – and the Court has not ordered – a protective order staying discovery. Cephalon nonetheless objects to all discovery as “premature” and has refused to respond to any discovery requests. (Exs. 3, 4). In effect, by objecting to all discovery as “premature,” Cephalon seeks to invoke the benefits of a protective order staying discovery without bearing the high burden of proving it.² The Court should not countenance Cephalon's blunt attempts to evade its burden of proof. Moreover, Cephalon's objection rests on the false premise that the mere absence of a scheduling order or filing of a motion to dismiss constitutes a permissible basis to refuse to comply with proper discovery requests. This is not so.

The absence of a scheduling order does not render discovery premature. Courts have rejected the notion that discovery is “premature” in cases – such as this one – where discovery is served after the parties have met the requirements of Rule 26(f) of the Federal Rules of Civil Procedure by conferring and filing a written discovery report with the court. *See, e.g., Old Dominion Elec. Coop. v. Ragnar Benson, Inc.*, No. 3:05CV034-JRS, 2005 U.S. Dist. LEXIS 9842, at *2-3 (E.D. Va. May 23, 2005) (finding defendant's objection that plaintiff's discovery was served “prematurely” to be “simply unacceptable” where defendant had not alleged that plaintiff served discovery requests prior to Rule 26(f) conference).

²To obtain an order to stay discovery, the movant “must make a strong showing of ‘good cause’ by demonstrating a particular need for protection.” *Coca-Cola Bottling Co. v. Grol*, No. 92-7061, 1993 U.S. Dist. LEXIS 3734, at *9 (E.D. Pa. Mar. 3, 1993) (quoting *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986)).

Nor does the filing of a motion to dismiss “automatically” stay discovery or otherwise render it premature. *E.g., Coca-Cola Bottling Co. v. Grol*, No. 92-7061, 1993 U.S. Dist. LEXIS 3734, at *5-6 (E.D. Pa. Mar. 3, 1993) (“A court should not automatically stay discovery pending a motion to dismiss under Rule 12(b).”); *Gray v. First Winthrop Corp.*, 133 F.R.D. 39, 40 (N.D. Cal. 1990) (rejecting the proposition that a motion to dismiss justifies a stay of discovery because it “goes against the purpose of the federal discovery rules” and is “directly at odds with the need for expeditious resolution of litigation.”). No provision of the Federal Rules of Civil Procedure supports Cephalon’s position.³ Indeed, “had the drafters of the Federal Rules of Civil Procedure wanted an automatic stay of discovery pending a motion to dismiss, they could have so provided.” *Coca-Cola Bottling Co.*, 1993 U.S. Dist. LEXIS 3734, at *6. Instead, motions to stay are often disfavored because delayed or prolonged discovery “can create case management problems which impede the court’s responsibility to expedite discovery and cause unnecessary litigation expenses and problems.” *Id.*

III. Cephalon’s Other Objections Also Lack Merit

Cephalon’s other objections are also unavailing because Cephalon cannot meet its burden to show specific support for its objections.

As an initial matter, once a party objects to discovery, “the party seeking discovery must demonstrate the relevancy of the information sought.” *Creely v. Genesis Health Ventures, Inc.*, No. 04-CV-0679, 2005 U.S. Dist. LEXIS 240, at *3 (E.D. Pa. Jan. 10, 2005) (Surrick, J.) The FTC’s requests are squarely relevant to its claims and satisfy the liberal standards for relevancy

³*See Old Dominion Elec. Coop. v. Ragnar Benson, Inc.*, No. 3:05CV034-JRS, 2005 U.S. Dist. LEXIS 9842, at *3 (E.D. Va. May 23, 2005) (finding “[no] authority establishing a maturity standard for when discovery may begin once the parties have conferred [as required by Rule 26(f) of the Federal Rules of Civil Procedure]”).

articulated in the federal rules. *See* Fed. R. Civ. P. 26(b)(1); *see also* *Creely*, 2005 U.S. Dist. LEXIS 240, at *3-4 (granting a motion to compel and noting that “[t]he court should and ordinarily does interpret ‘relevant’ very broadly to mean matters that are relevant to anything that is or may become an issue in the litigation.”) (quoting *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n.12 (1978)).

The FTC alleges that Cephalon’s patent litigation settlements unlawfully restrained competition to the detriment of consumers by inducing its generic competitors to delay entry. The RFAs are relevant to the FTC’s claim because they help determine the date when generic competitors were first permitted to compete with Provigil and, consequently, when Cephalon first faced the threat of generic competition for its flagship product.⁴ This date goes to the heart of the conduct at issue in this case: we allege that it was this threat of impending generic competition in mid-2006 that spurred Cephalon to settle with all four of its potential generic competitors and pay the generics to delay entry by six years – to 2012. The RFDs are also relevant to the FTC’s claims because they update existing investigative document requests concerning core issues in this case, including the terms of the settlement agreements, the scope and strength of the patents at issue, and competition for the sale of modafinil products.⁵ (Ex. 5).

Once the moving party demonstrates the relevance of its requests, the resisting party “must show specifically” the support for its objection. *In re Automotive Refinishing Paint Antitrust Litig.*, MDL No. 1426, 2006 U.S. Dist. LEXIS 34129, at *6 (E.D. Pa. May 26, 2006)

⁴The RFAs area also relevant because they seek to limit issues at trial relating to the FTC’s jurisdiction over Cephalon under Section 5 of the FTC Act. RFA Nos. 1, 2; *Creely*, 2005 U.S. Dist. LEXIS 240, at *6-7 (the purpose of Rule 36(a) of the Federal Rules of Civil Procedure is to “obtain[] admissions for the record of facts already known’ by the seeker” in order to “assist[s] in limiting issues for a trial.”) (citations omitted).

⁵*E.g.*, RFA Nos. 8, 14.

(Surrick, J.) (citing *Josephs v. Harris Corp.*, 677 F.2d 985 at 992 (3d Cir. 1982)); *Creely*, 2005 U.S. Dist. LEXIS 240, at *3 (quoting *Josephs*, 677 F.2d at 992). “A party’s statement ‘that the discovery sought is overly broad, burdensome, oppressive, vague or irrelevant is not adequate to voice a successful objection.’” *Creely*, 2005 U.S. Dist. LEXIS 240, at *3 (quoting *Josephs*, 677 F.2d at 992). Cephalon’s piecemeal objections concerning relevance,⁶ vagueness,⁷ privilege,⁸ confidentiality,⁹ burden,¹⁰ and breadth¹¹ are insufficient for this reason. Cephalon has not borne its burden to show specific support for its objections, nor will it be able to do so in light of the Commission’s narrowly tailored discovery requests, each of which is susceptible to production, admission, denial, qualified admission or an inability to admit or deny.

For example, Cephalon objected to over half of the RFA definitions as “vague and ambiguous,” even though they were defined by reference to statute. RFA Definition Nos. 2 (“30 month stay”), 10 (“Orphan Drug Exclusivity”), 12 (“Pediatric Exclusivity”), and 14 (“Tentative Approval”). Cephalon also asserted meritless objections to numerous well-known industry terms.¹² Cephalon’s privilege claims also have not been substantiated and consequently do not meet the strict standards set forth in Rule 26(b)(5) of the Federal Rules of Civil Procedure. The

⁶Cephalon Specific Objection to RFD No. 3.

⁷Cephalon RFA General Objection Nos. 3-8 (objecting to RFA Definition Nos. 1, 2, 6, 10, 12, 14); Cephalon Specific Objections to RFA Nos. 8, 14, 22, 23; Cephalon Specific Objections to RFD Nos. 1, 3.

⁸Cephalon’s RFD General Objections No. 6.

⁹Cephalon’s RFD General Objections No. 3; Cephalon’s RFD Specific Objection No. 1.

¹⁰Cephalon RFA Specific Objection to No. 23.

¹¹Cephalon RFA General Objections No. 3(objecting to RFA Definition No. 1)

¹²*E.g.*, RFA Nos. 1 (“Cephalon”), 8 (“exclusivity”), and 14 (“additional 6 months exclusivity”).

remaining objections relating to confidentiality, burden and breadth likewise lack any specific support.

IV. The Court Should Deem Admitted the Commission's RFAs or, at a Minimum, Compel Cephalon to Provide a Substantive Response

"[C]ourts have substantial discretion under Rule 36 to determine the adequacy of the responding party's responses to requests for admissions, and if they determine that an answer does not comply with the requirements of Rule 36, they can order either that the matter is admitted or require the responding party to serve an amended answer." *O'Connor v. AM General Corp.*, No. 85-6679, 1992 U.S. Dist. LEXIS 19681, at * 7 (E.D. Pa. Dec. 7, 1992). The Commission's RFAs should be deemed admitted in their entirety because Cephalon's invalid objections to each and every one of the 23 RFAs is functionally equivalent to a complete failure to answer. *See Kelvin Cryosystems, Inc. v. Lightnin*, No. 05-4880, 2007 U.S. App. LEXIS 25315 (3d Cir. Oct. 29, 2007) (affirming grant of summary judgment based on deemed admission and noting that district court did not err or abuse its discretion in deeming admitted RFAs where the opposing party served "untimely answers" or failed to answer altogether) (not precedential); *see also Southern Ry. Co. v. Crosby*, 201 F.2d 878, 880 (4th Cir. 1953) ("A refusal to admit without specific denial or detailed reasons why the respondent cannot truthfully admit or deny, is the equivalent of an admission.").

At a minimum, the Court should order Cephalon to amend its response and provide substantive answers. The FTC's RFAs are straightforward and are deserving of a straightforward answer – not evasive objections. *See Guinan v. A.I. duPont Hosp. For Children*, No. 08-228, 2008 U.S. Dist. LEXIS 27798, at *6 (E.D. Pa. April 7, 2008) (referred to Sitariski, M. J., by Surrick, J.) (granting in part motion to compel substantive answers to RFAs); *Kutner Buick, Inc.*

v. Crum & Foster Corp., No. 95-CV-1268, 1995 U.S. Dist. LEXIS 12524, at *4, 11 (E.D. Pa. Aug. 24, 1995) (ordering defendant to amend its answers and “supply responses due plaintiffs” in a case where defendant objected to “each and every request for admission”).

V. Timely Discovery Is Particularly Important in This Case Seeking Injunctive Relief for Consumers

This action seeks injunctive relief that would save consumers millions of dollars each day by allowing generic drug competition. But the potential for effective injunctive relief diminishes the longer the case remains unresolved: as long as the case continues, Cephalon will continue to benefit from the lack of generic competition and charge its monopoly price for its drug. Prompt discovery and resolution of this case is therefore critical to protect consumers harmed by Cephalon’s ongoing scheme to monopolize the sale of Provigil. This public interest in preserving an effective remedy for consumers of modafinil outweighs any minimal burden on Cephalon should discovery proceed. *See Yakus v. U.S.*, 321 U.S. 414, 441 (1944) (“Courts of equity may, and frequently do, go much farther both to give and withhold relief in furtherance of the public interest than they are accustomed to go when only private interests are involved”) (citations omitted); *In re Plastics Additives Antitrust Litigation*, No. 03-2038, 2004 WL 2743591, at *8 (E.D. Pa. Nov. 29, 2004) (“Public interest considerations weigh against granting a stay of merit-based discovery. The public’s interest in vigorously enforcing national anti-trust laws through the expeditious resolution of a private antitrust litigation is particularly great.”)

VI. Conclusion

For the reasons stated above, the FTC therefore respectfully asks the Court to compel the discovery requested in the Commission’s First Request for Documents and First Request for

Admissions. The FTC also respectfully requests that the Court award the FTC its reasonable expenses under Fed. R. Civ. P. 37(a)(5). We request oral argument on this matter.

Dated: December 5, 2008

Respectfully submitted,

/s/ Markus H. Meier
J. ROBERT ROBERTSON
MARKUS H. MEIER
SARALISA C. BRAU
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

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

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

**PLAINTIFF FEDERAL TRADE COMMISSION'S FIRST REQUESTS
FOR ADMISSIONS DIRECTED TO DEFENDANT CEPHALON, INC.**

Pursuant to Federal Rules of Civil Procedure ("FRCP") 26 and 36 and Local Rule 26.1, Defendant Cephalon, Inc. must respond under oath to the following requests for admissions within 30 days of service in accordance with the following definitions and instructions. Requests not timely answered may be deemed admitted by the court, pursuant to FRCP 36(a)(6).

DEFINITIONS

1. "Cephalon," "You," "Your," or "the Company" refers to Cephalon, Inc., Cephalon (UK) Limited, their domestic and foreign parents, predecessors, divisions, and wholly or partially owned subsidiaries, affiliates, partnerships, and joint ventures; and all directors, officers, employees, consultants, agents and representatives of the foregoing. The terms "subsidiary," "affiliate," and "joint venture" refer to any person in which there is partial (25 percent or more) or total ownership or control by Cephalon.

2. “30-Month Stay” means the 30-month period triggered by a brand’s patent infringement lawsuit against a generic that enjoins the FDA from approving an ANDA with a Paragraph IV Certification, as defined at 21 U.S.C. § 355(j)(5)(B)(iii) and 21 U.S.C. § 355(j)(5)(F)(ii).
3. “ANDA” means an Abbreviated New Drug Application, as defined at 21 U.S.C. § 355(j), *et seq.*
4. “Barr” means Barr Laboratories, Inc. as well as its current and former parents, subsidiaries, affiliates, predecessors, and successors.
5. “FDA” means the United States Food and Drug Administration.
6. “Final Approval” means that no obstacles in the FDA block the launch of a drug product, as defined at 21 C.F.R. § 314.105.
7. “Mylan” means Mylan Pharmaceuticals, Inc., as well as its current and former parents, subsidiaries, affiliates, predecessors, and successors.
8. “New Chemical Entity Exclusivity” means the five-year period of exclusivity conferred on new drug applications for products containing new chemical entities never previously approved by FDA, as defined at 21 U.S.C. § 355(j)(5)(F)(ii), *et seq.*
9. “FDA Orange Book” means the list of Approved Drug Products with Therapeutic Equivalence Evaluations, as defined at 21 U.S.C. §§ 355(b)(1), (c)(2) and 21 C.F.R. §§ 314.3, 53(b).
10. “Orphan Drug Exclusivity” means the seven-year period of market exclusivity guaranteed to the developer of an orphan product by the FDA following the approval of that product for that indication, as defined at Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.).

11. "Paragraph IV Certification" means a certification by a generic company that its generic product would not infringe the brand's patent or that the brand's patent is invalid, as defined at 21 U.S.C. § 355(j)(2)(A)(vii)(I) to (IV).
12. "Pediatric Exclusivity" means the six months of marketing exclusivity guaranteed to drug manufacturers that conduct certain pediatric studies, as defined in 21 U.S.C. § 355a(c)(1).
13. "Ranbaxy" means Ranbaxy Laboratories, Inc., as well as its current and former parents, subsidiaries, affiliates, predecessors, and successors.
14. "Tentative Approval" means that the FDA's scientific review of the ANDA is complete and that the ANDA is normally approvable, but it cannot receive Final Approval because some exclusivity or stay of approval remains intact, as defined at 21 U.S.C. § 355(j)(5)(B).
15. "Teva" means Teva Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., as well as its current and former parents, subsidiaries, affiliates, predecessors, and successors.

INSTRUCTIONS

Your answer to each request to admit shall specifically admit or deny the matter or set forth in detail the reasons why you cannot truthfully admit or deny the matter. When in good faith you must qualify an answer or deny only part of the matter of which an admission is requested, you should specify so much of it as is true and qualify or deny the remainder. You should not give lack of information or lack of knowledge as a reason for failure to admit or deny unless you affirmatively state that you have made reasonably inquiry and that the information known or readily obtainable is insufficient to enable you to admit or deny. If an objection is made, the reasons therefore should be stated. Pursuant to Rule 36 of the Federal Rules of Civil Procedure, you may not object on the ground that you believe that a matter of which an admission has been requested presents a genuine issue for trial. Unless otherwise indicated, this

Request seeks information concerning the time period 2002 through the present. Submit your response to the offices of the Federal Trade Commission, Saralisa Brau c/o Jason Peterson, 601 New Jersey Avenue, NW, Washington, DC 20001. Please contact Saralisa Brau with any questions at (202) 326-2774.

REQUESTS FOR ADMISSIONS

Admit that:

1. Cephalon is a "corporation" as defined in Section 4 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 44.
2. Cephalon's sales of Provigil in the United States are activities "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.
3. A United States patent covering pharmaceutical compositions comprising modafinil in the form of particles of a defined size first issued in 1997 and re-issued in 2002 as U.S. Reissue Patent No. RE37,516 ("the '516 patent").
4. Cephalon listed the '516 patent in the FDA's Orange Book as claiming Provigil and methods of using Provigil for improved wakefulness in patients with excessive daytime sleepiness associated with narcolepsy.
5. The '516 patent expires on October 6, 2014.
6. Cephalon submitted an application for Pediatric Exclusivity for Provigil on December 21, 2005.
7. Cephalon obtained Pediatric Exclusivity for Provigil on March 21, 2006.
8. Pediatric exclusivity for Provigil provides Cephalon with an additional six months of exclusivity beyond the expiration of its '516 patent, to April 6, 2015.
9. Cephalon obtained Final Approval to market Provigil on December 24, 1998.

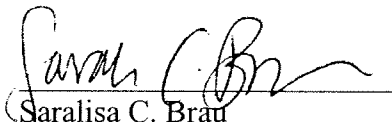
10. Cephalon obtained New Chemical Entity exclusivity for Provigil on December 24, 1998.
11. Cephalon's New Chemical Entity exclusivity for Provigil expired on December 24, 2003.
12. Cephalon obtained Orphan Drug Exclusivity for Provigil on December 24, 1998.
13. Cephalon's Orphan Drug Exclusivity for Provigil expired on December 24, 2005.
14. Pediatric Exclusivity provided Cephalon with an additional six months of exclusivity for Provigil beyond the expiration of the Orphan Drug Exclusivity, to June 24, 2006.
15. On December 24, 2002, four generic companies -- Teva, Ranbaxy, Mylan, and Barr (collectively, the "First Filers") -- submitted ANDA applications with Paragraph IV Certifications to the FDA to market generic versions of Provigil.
16. On March 8, 2003, Cephalon sued Teva, Ranbaxy, Mylan, and Barr for infringement of the '516 patent under 35 U.S.C. § 271(e)(2)(A) in the United States District Court for the District of New Jersey.
17. Each of the First Filers obtained Tentative Approval of its respective generic version of Provigil before the end of calendar year 2005.
18. Cephalon's patent infringement lawsuit triggered a 30-Month Stay that enjoined the FDA from granting Final Approval to the First Filers' generic versions of Provigil.
19. Cephalon's 30-Month Stay began to run on December 24, 2003.
20. At the time of Cephalon's patent litigation settlements with the First Filers, the earliest date on which FDA regulations permitted a First Filer to obtain Final Approval for generic Provigil was June 24, 2006.
21. Upon receiving Final Approval, FDA regulations permit a generic company to begin commercial sale of its drug product.

22. Before Cephalon settled the patent litigation with the First Filers, Cephalon planned for one or more First Filers to begin commercial sale of a generic version of Provigil on or about June 24, 2006.
23. Before Cephalon settled the patent litigation with the First Filers, no contemporaneous documents that Cephalon submitted to the FTC in connection with FTC File No. 0610182, the investigation that preceded this action, planned for potential generic Provigil entry on a date other than on or about June 24, 2006.

Respectfully submitted,

Dated: September 18, 2008

J. Robert Robertson
Lore Unt
Office of the Director


Saralisa C. Brau
*Health Care Services and
Products Division*

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
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Counsel for Plaintiff
Federal Trade Commission

**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 FIRST REQUEST FOR THE
PRODUCTION OF DOCUMENTS FROM DEFENDANT CEPHALON, INC.**

Pursuant to Federal Rules of Civil Procedure 26(b) and 34, Defendant Cephalon, Inc. shall produce one set of the documents described below within 30 days of service of this Request at the offices of the Federal Trade Commission, Saralisa Brau c/o Jason Peterson, 601 New Jersey Avenue, NW, Washington, DC 20001.

DEFINITIONS

1. "Cephalon," "You," "Your," or "the Company" refers to Cephalon, Inc., Cephalon (UK) Limited, their domestic and foreign parents, predecessors, divisions, and wholly or partially owned subsidiaries, affiliates, partnerships, and joint ventures; and all directors, officers, employees, consultants, agents and representatives of the foregoing. The terms "subsidiary," "affiliate," and "joint venture" refer to any person in which there is partial (25 percent or more) or total ownership or control by Cephalon.
2. "Access Letter" means the letter from Michael Kades (FTC) to James Burling (WilmerHale) dated July 11, 2006 requesting that Cephalon voluntarily submit certain documents and information in connection with FTC File No. 061-0182, the investigation that led to the issuance of a complaint in this litigation.
3. "Civil Investigative Demand" means the narrative requests dated April 26, 2007 issued by the Commission to Cephalon in connection with FTC File No. 061-0182, the investigation that led to the issuance of a complaint in this litigation.

4. “Document” means all written, recorded, or graphic materials of every kind, prepared by any person, that are in the Company’s possession, custody, or control. The term “document” includes the complete original document (or a copy thereof if the original is not available), all drafts, whether or not they resulted in a final document, and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on the original. Documents covered by this subpoena include, but are not limited to, the following: Electronically Stored Information; letters; memoranda; all papers filed with a court in litigation and relating to litigation settlement; reports; contracts, including patent license agreements; studies; plans; notes; entries in calendars; expense reports; publications, including the publication entitled “Datamonitor”; facsimiles; tabulations; ledgers and other records of financial matters or commercial transactions; audio and video tapes; recorded voice mail messages and computer printouts.
5. “Electronically Stored Information” refers to any portion of data found only on a computer or other device capable of storing electronic data, where such data is capable of being manipulated as an entry. “Electronically Stored Information” includes, but is not limited to, e-mail, spreadsheets, databases, word processing Documents, images, presentations, application files, executable files, log files, and all other files present on any type of device capable of storing electronic data. Devices capable of storing Electronically Stored Information include, but are not limited to: servers, desktop computers, portable computers, handheld computers, flash memory devices, wireless communication devices, pagers, workstations, minicomputers, mainframes, and any other forms of online or offline storage, whether on or off company premises.
6. “Investigative Discovery Requests” means the Access Letter, the Subpoena, and the Civil Investigative Demand.
7. “Relating to” is used in the broadest possible sense and means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in connection with, dealing with, discussing, describing, embodying, evidencing, identifying, pertaining to, referring to, reflecting, reporting, stating, or summarizing.
8. “Subpoena” means the subpoena duces tecum dated March 13, 2007 issued by the Commission to Cephalon in connection with FTC File No. 061-0182, the investigation that led to the issuance of a complaint in this litigation.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in these Requests covers any and all Documents prepared, created, sent, or received during, and all Documents relating to, the period from January 1, 2002, to present. These Requests are continuing in nature and require the production of all Documents written or obtained by You up to sixty (60) days prior to the time of the final response to this request.

2. Documents requested are those in actual or constructive possession, custody, or control of the Company, and its representatives, attorneys, and other agents, including but not limited to, consultants, accountants, lawyers, or any other persons retained, consulted by, or working on behalf or under the direction of the Company, wherever they may be located.
3. Documents shall be accompanied at the time of their submission by an index that identifies: (i) the name of each person from whom responsive Documents are submitted (e.g., files of "John Doe", Vice President of Company); and (ii) the corresponding consecutive document control number(s) used to identify that person's Documents.
4. Produce all Documents in complete, unredacted form, unless privileged. Submit Documents as stored by the Company or individual. Mark, in a color other than black or with a raised label, each page of each Document with a corporate identification and consecutive Bates numbers, except that bound pamphlets or books with numbered pages may be marked with corporate identification and a single Bates number. Provide a translation of non-English Documents into English; submit the foreign language Document, with the English translation attached.
5. The Company is encouraged to discuss the form and method of production of responsive documents with the Commission representative identified in the final paragraph of these Instructions, or with the representative's designee. The Company shall be permitted to use the form and method of production of responsive documents identified below. Any other form or method must be specifically approved in writing by the Commission representative in advance of any submission.
 - A. You may submit copies of original hard copy documents as either hard copies or electronic copies in lieu of original documents, provided that such copies are accompanied by an affidavit stating that the copies are true, correct and complete copies of the original documents. However, if the coloring of any document communicates any substantive information, or if black-and-white photocopying of any document (e.g., a chart or graph) makes any substantive information contained in the document unintelligible, You must submit the original document or a like-colored photocopy.
 1. Hard copies. Submit copies in sturdy cartons not larger than 1.5 cubic feet. Number and mark each box with corporate identification. Produce all documents as they are kept in the ordinary course of business (e.g., produce documents that in their original condition were stapled, clipped, or otherwise fastened in the same form).
 2. Electronic copies. You may submit original hard-copy documents as single-page TIFF images, named for the

Bates number of the document, and accompanied by OCR and a Concordance/Opticon load file denoting the appropriate document breaks (document delimitation). OCR may be produced in corresponding files, either by page or by document, or can be produced in ASCII format suitable for loading into Concordance.

B. Electronically Stored Information. Documents, information or data stored in an electronic format in the ordinary course of business must be submitted in electronic format. Metadata associated with Electronically Stored Information must be produced. You may produce Electronically Stored Information in the following forms and formats, provided that such copies are true, correct and complete copies of the original documents:

1. Microsoft Excel and Access files must be submitted in native format.
2. TIFF files. Submit files as single-page, 300 DPI - Group IV TIFF files, with a corresponding file containing the extracted text from the document. Name each file, comprised of both images and text, for the Bates number of the document. Include a Concordance/Opticon load file that preserves all document breaks (document delimitation). Include metadata and other information about the documents in delimited ASCII format. Produce Microsoft PowerPoint presentations in "Notes Pages" format. "Notes Pages" includes a small version of the slide that appears at the top of the page with any notes appearing directly below.
 - i. Include the following metadata fields for electronic files other than email: creation date/time; modified date/time; last accessed date/time; size; location or "path file name"; and custodian.
 - ii. Include the following metadata fields for emails: to; from; CC; BCC; subject; date and time sent; attachment (range or begin attach, end attach); file name of attachments; and custodian.
3. Native format. Electronically stored documents, excluding e-mail other than Microsoft Outlook, may be produced natively. Please discuss logistics of native

production with the Commission representative identified in the final paragraph of these Instructions.

4. Data productions as ASCII text files. You may submit database files, with prior approval, as delimited ASCII text files, with field names as the first record, or as fixed-length flat files with appropriate record layout. For ASCII text files, provide field-level documentation and ensure that delimiters and quote characters do not appear in the data. All database files should include or be accompanied with the definitions of the field names, codes, and abbreviations used in the database and, upon request from the FTC, the instructions for using the database. The FTC may require that a sample of the data be sent for testing. File and record structures must conform to the following requirements:
 - i. File structures. The FTC will accept sequential files only. Convert all other file structures into sequential format.
 - ii. Record structures. The FTC will accept fixed-length records only. Include all data in the record as it would appear in printed format: viz, numbers unpacked, and decimal points and signs printed.
5. Submit electronic files and images in any combination of the following forms:
 - i. For any production over 10 gigabytes, use IDE and EIDE hard disk drives, formatted in Microsoft Windows-compatible, uncompressed data.
 - ii. For productions under 10 gigabytes, CD-R CD-ROMs formatted to ISO 9660 specifications, DVD-ROM for Windows-compatible personal computers, and USB 2.0 Flash Drives are also acceptable storage formats.
6. All documents produced in electronic format shall be scanned for and free of viruses. The FTC will return any infected media for replacement.

6. You are to produce entire Documents including all attachments, cover letters, memoranda, and appendices, as well as the file, folder tabs, and labels appended to or containing any Documents. Copies which differ in any respect from an original (because, by way of example only, handwritten or printed notations have been added) should be produced separately. Each Document requested herein must be produced in its entirety and without deletion, abbreviation, redaction, expurgation, or excisions, regardless of whether You consider the entire Document to be relevant or responsive to these Requests. If You have redacted any portion of a Document, stamp the word “redacted” where the redacted material originally appeared, on each page of the Document which You have redacted. Privileged redactions must be included in a privilege log prepared pursuant to Paragraph 7; any non-privileged redactions must also be included in a log describing the basis for redaction, prepared pursuant to Paragraph 8.
7. If any privilege is claimed as a ground for not producing a Document or tangible thing, provide a privilege log describing the basis for the claim of privilege and all information necessary for the FTC to assess the claim of privilege. Separately, for each Document and attachment withheld or redacted, the log shall include the following: (i) specific grounds for the claim of privilege; (ii) the title of the Document or attachment; (iii) the date of the Document or attachment; (iv) the author of the Document or attachment; (v) the addressees and recipients of the Document or attachment or any copy thereof (including persons “cc’d,” or “bcc’d,” or “blind cc’d”); (vi) a description of the subject matter of the Document or attachment in sufficient detail to assess the claim of privilege; (vii) the Bates range or page length of the Document or attachment; and (viii) the Requests to which the Document or attachment are responsive. Additionally, for each Document withheld under a claim of attorney work product immunity, state whether the Document was produced in anticipation of litigation or for trial, and, if so, identify the anticipated litigation or trial upon which the assertion is based. Any attachment to a Document withheld under a claim of privilege or immunity shall be produced unless the attachment is also subject to a claim of privilege or immunity, and the basis for such claim is described in a privilege log.
8. If any Documents are redacted on a basis other than privilege, provide the information and reason for redacting that Document per Paragraph 7.
9. Whenever necessary to bring within the scope of a Request a response that might otherwise be construed to be outside its scope, the following constructions should be applied:
 - A. Construing the terms “and” and “or” in the disjunctive or conjunctive, as necessary, to make the Request more inclusive;
 - B. Construing the singular form of any word to include the plural and the plural form to include the singular;

- C. Construing the past tense of the verb to include the present tense and the present tense to include the past tense;
 - D. Construing the masculine form to include the feminine form; and
 - E. Construing the term “Date” to mean the exact day, month, and year if ascertainable; if not, the closest approximation that can be made by means of relationship to other events, locations, or matters.
10. These Instructions exclude any Documents that You have previously produced to the Commission in the course of FTC File No. 0610182, the investigation that led to the issuance of a complaint in this litigation.
 11. Written responses to these Requests, as well as all responsive Documents, should be submitted within the time frame prescribed by Fed. R. Civ. P. 34, unless otherwise agreed. You should comply with these Requests by submitting all responsive Documents and written responses to Jason Peterson, Federal Trade Commission, Bureau of Competition, 601 New Jersey Avenue, N.W., Room 7159, Washington, D.C. 20001.
 12. Please contact Saralisa Brau at (202) 326-2774 with any questions.

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DOCUMENT REQUESTS

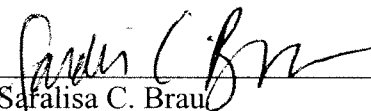
In accordance with the above Definitions and Instructions, submit the following documents:

1. All Documents and written responses specified in the Investigative Discovery Requests.
2. All Documents upon which Cephalon relied for the information contained in the written responses to the Access Letter and Civil Investigative Demand.
3. All Documents responsive to the Investigative Discovery Requests that were prepared, created, sent, or received during the period from your receipt of each Investigative Recovery Request to the present.

Respectfully submitted,

Dated: September 18, 2008

J. Robert Robertson
Lore Unt
Office of the Director


Safalisa C. Brau
*Health Care Services and
Products Division*

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Telephone: (202) 326-3759
Facsimile: (202) 326-3384
sbrau@ftc.gov
Counsel for Plaintiff
Federal Trade Commission

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

Federal Trade Commission,

Plaintiff,

v.

Cephalon, Inc.,

Defendant.

Case No. 08-cv-2141-RBS

**DEFENDANT, CEPHALON, INC.'S
OBJECTIONS TO PLAINTIFF FEDERAL TRADE COMMISSION'S
FIRST REQUESTS FOR ADMISSIONS**

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure and Local Rule 26.1, Defendant Cephalon, Inc. ("Cephalon") hereby objects to the Plaintiff Federal Trade Commission's First Requests for Admissions ("the Requests") as follows:

GENERAL OBJECTIONS

1. Cephalon objects to the Requests in their entirety on the ground that they are premature in light of Cephalon's pending Motion to Dismiss, filed on May 2, 2008. A decision on the motion could obviate the need for discovery altogether or substantially narrow its scope.

2. Cephalon objects to the Requests in their entirety as premature because the Court has not yet entered a scheduling order governing discovery in this case, including when service of discovery requests may commence. Cephalon objects to any discovery prior to a conference with

the Court pursuant to Local Rule of Civil Procedure 16.1 and Section 3:01 of the Civil Justice Expense and Delay Reduction Plan.

3. Cephalon objects to Definition No. 1 (“Cephalon,” “You,” “Your,” or “the Company”) as vague, ambiguous, and overly broad.
4. Cephalon objects to Definition No. 2 (“30-Month Stay”) as vague and ambiguous.
5. Cephalon objects to Definition No. 6 (“Final Approval”) as vague and ambiguous.
6. Cephalon objects to Definition No. 10 (“Orphan Drug Exclusivity”) as vague and ambiguous.
7. Cephalon objects to Definition No. 12 (“Pediatric Exclusivity”) as vague and ambiguous.
8. Cephalon objects to Definition No. 14 (“Tentative Approval”) as vague and ambiguous.

SPECIFIC OBJECTIONS

In addition to its General Objections, which are incorporated in each response below, Cephalon further objects to the Requests as follows:

REQUEST NO. 1:

Cephalon is a “corporation” as defined in Section 4 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 44.

Objection(s) To Request No. 1:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 2:

Cephalon’s sales of Provigil in the United States are activities “in or affecting commerce” within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

Objection(s) To Request No. 2:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 3:

A United States patent covering pharmaceutical compositions comprising modafinil in the form of particles of a defined size first issued in 1997 and re-issued in 2002 as U.S. Reissue Patent No. RE37,516 (“the ‘516 patent”).

Objection(s) To Request No. 3:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 4:

Cephalon listed the ‘516 patent in the FDA’s Orange Book as claiming Provigil and methods of using Provigil for improved wakefulness in patients with excessive daytime sleepiness associated with narcolepsy.

Objection(s) To Request No. 4:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 5:

The ‘516 patent expires on October 6, 2014.

Objection(s) To Request No. 5:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 6:

Cephalon submitted an application for Pediatric Exclusivity for Provigil on December 21, 2005.

Objection(s) To Request No. 6:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 7:

Cephalon obtained Pediatric Exclusivity for Provigil on March 21, 2006.

Objection(s) To Request No. 7:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 8:

Pediatric exclusivity for Provigil provides Cephalon with an additional six months of exclusivity beyond the expiration of its '516 patent, to April 6, 2015.

Objection(s) To Request No. 8:

Cephalon objects to Request No. 8 on the ground that the term "exclusivity" is vague and ambiguous.

REQUEST NO. 9:

Cephalon obtained Final Approval to market Provigil on December 24, 1998.

Objection(s) To Request No. 9:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 10:

Cephalon obtained New Chemical Entity exclusivity for Provigil on December 24, 1998.

Objection(s) To Request No. 10:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 11:

Cephalon's New Chemical Entity exclusivity for Provigil expired on December 24, 2003.

Objection(s) To Request No. 11:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 12:

Cephalon obtained Orphan Drug Exclusivity for Provigil on December 24, 1998.

Objection(s) To Request No. 12:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 13:

Cephalon's Orphan Drug Exclusivity for Provigil expired on December 24, 2005.

Objection(s) To Request No. 13:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 14:

Pediatric Exclusivity provided Cephalon with an additional six months of exclusivity for Provigil beyond the expiration of the Orphan Drug Exclusivity, to June 24, 2006.

Objection(s) To Request No. 14:

Cephalon objects to Request No. 14 because the phrase "additional six months of exclusivity" is vague and ambiguous.

REQUEST NO. 15:

On December 24, 2002, four generic companies -- Teva, Ranbaxy, Mylan, and Barr (collectively, the "First Filers") -- submitted ANDA applications with Paragraph IV Certifications to the FDA to market generic versions of Provigil.

Objection(s) To Request No. 15:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 16:

On March 8, 2003, Cephalon sued Teva, Ranbaxy, Mylan, and Barr for infringement of the '516 patent under 35 U.S.C. § 271(e)(2)(A) in the United States District Court for the District of New Jersey.

Objection(s) To Request No. 16:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 17:

Each of the First Filers obtained Tentative Approval of its respective generic version of Provigil before the end of calendar year 2005.

Objection(s) To Request No. 17:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 18:

Cephalon's patent infringement lawsuit triggered a 30-Month Stay that enjoined the FDA from granting Final Approval to the First Filers' generic versions of Provigil.

Objection(s) To Request No. 18:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 19:

Cephalon's 30-Month Stay began to run on December 24, 2003.

Objection(s) To Request No. 19:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 20:

At the time of Cephalon's patent litigation settlements with the First Filers, the earliest date on which FDA regulations permitted a First Filer to obtain Final Approval for generic Provigil was June 24, 2006.

Objection(s) To Request No. 20:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 21:

Upon receiving Final Approval, FDA regulations permit a generic company to begin commercial sale of its drug product.

Objection(s) To Request No. 21:

Cephalon has no additional objections beyond those set forth in the General Objections.

REQUEST NO. 22:

Before Cephalon settled the patent litigation with the First Filers, Cephalon planned for one or more First Filers to begin commercial sale of a generic version of Provigil on or about June 24, 2006.

Objection(s) To Request No. 22:

Cephalon objects to Request No. 22 because the term “planned” is vague and ambiguous.

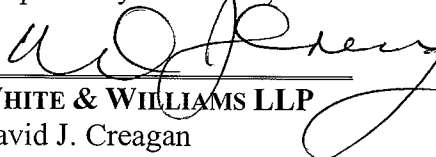
REQUEST NO. 23:

Before Cephalon settled the patent litigation with the First Filers, no contemporaneous documents that Cephalon submitted to the FTC in connection with FTC File No. 0610182, the investigation that preceded this action, planned for potential generic Provigil entry on a date other than on or about June 24, 2006.

Objection(s) To Request No. 23:

Cephalon objects to Request No. 23 because it is overly burdensome and because the terms “contemporaneous documents” and “planned” are vague and ambiguous.

Respectfully submitted,



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Dated: October 20, 2008

Counsel for Cephalon, Inc.

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

<p>FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, N.W. Washington, D.C. 20508</p> <p style="text-align: center;">Plaintiff,</p> <p>v.</p> <p>CEPHALON, INC. 41 Moores Road Frazer, Pennsylvania 19355</p> <p style="text-align: center;">Defendant.</p>	<p>Civil Action No. 08-CV-2141 (RBS)</p>
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CERTIFICATE OF SERVICE

I, David J. Creagan hereby certify that on October 20, 2008, Defendant Cephalon, Inc.'s Objections to Plaintiff Federal Trade Commission's First Requests for Admissions were served by electronic mail and by First-Class Mail, postage prepaid, on the following counsel:

<p>Saralisa C. Brau, Esquire c/o Jason Peterson, Esquire FEDERAL TRADE COMMISSION Bureau of Competition 601 New Jersey Avenue, N.W., Room 7159 Washington, D.C. 20001 sbrau@ftc.gov</p> <p>Counsel for Plaintiff, Federal Trade Commission</p>	<p>James C. Burling, Esquire Michelle D. Miller, Esquire Peter A. Spaeth, Esquire Mark A. Ford, Esquire WILMER CUTLER PICKERING HALE AND DORR LLP 60 State Street Boston, MA 02109 james.burling@wilmerhale.com</p> <p>Counsel for Defendant, Cephalon, Inc.</p>
---	---

By: /s/ David J. Creagan
Attorney for Defendant,
Cephalon, Inc.

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

Federal Trade Commission,

Plaintiff,

v.

Cephalon, Inc.,

Defendant.

Case No. 08-cv-2141-RBS

**DEFENDANT, CEPHALON, INC.'S OBJECTIONS
TO PLAINTIFF FEDERAL TRADE COMMISSION'S FIRST REQUEST FOR THE
PRODUCTION OF DOCUMENTS**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and Local Rule 26.1, Defendant Cephalon, Inc. ("Cephalon"), hereby objects to the Plaintiff Federal Trade Commission's First Request for the Production of Documents ("the Request") as follows:

GENERAL OBJECTIONS

1. Cephalon objects to the Request in its entirety on the ground that it is premature in light of Cephalon's pending Motion to Dismiss, filed on May 2, 2008. A decision on the motion could obviate the need for discovery altogether or substantially narrow its scope. Accordingly, responding now subjects Cephalon to unnecessary burden and expense.
2. Cephalon objects to the Request in its entirety on the ground that it is premature because the Court has not yet entered a scheduling order governing discovery in this case,

including when service of document requests may commence. Cephalon objects to any discovery prior to a conference with the Court pursuant to Local Rule of Civil Procedure 16.1 and Section 3:01 of the Civil Justice Expense and Delay Reduction Plan.

3. Cephalon objects to the Request in its entirety on the ground that it seeks production of trade secrets or other confidential or proprietary scientific, technical, financial, strategic, commercial, or personal information or documents of Cephalon or third parties (“Confidential Materials”) before the Court has entered a protective order.

4. Cephalon objects to Definition No. 1 (“Cephalon,” “You,” “Your,” or “the Company”) on the ground that it is overly broad.

5. Cephalon objects to the Instructions to the extent that they purport to impose upon Cephalon any obligation not required by the Federal Rules of Civil Procedure or the Local Rules of this Court including, without limitation, Instructions Nos. 2, 4, 5, 7, and 8, which purport to impose obligations upon Cephalon beyond those contained in Federal Rules of Civil Procedure, including without limitation Rules 26 and 34(b).

6. Cephalon objects to the Request to the extent that it calls for the disclosure or production of documents or information protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege, protection or immunity. The inadvertent production by Cephalon of any document containing information protected from disclosure by the attorney-client privilege, work product doctrine, or any other applicable privilege, shall not constitute a waiver by Cephalon of any such protection.

SPECIFIC OBJECTIONS

In addition to its General Objections, which are incorporated in each response below, Cephalon further objects to the FTC's specific requests as follows:

REQUEST NO. 1:

All Documents and written responses specified in the Investigative Discovery Requests.

OBJECTION TO REQUEST NO. 1

Cephalon objects to Request No. 1 to the extent that the specifications in the Investigative Discovery Requests are vague, ambiguous, and overly broad. Cephalon further objects to Request No. 1 on the ground that it seeks documents that may be protected by the Stipulated Protective Order entered by the district court in *Cephalon, Inc. v. Mylan Pharmaceuticals, Inc., et al.*, Case No. 03-CV-1394 (JCL) (D.N.J.).

REQUEST NO. 2:

All Documents upon which Cephalon relied for the information contained in the written responses to the Access Letter and Civil Investigative Demand.

OBJECTION TO REQUEST NO. 2

Cephalon has no additional objections beyond those set forth in the General Objections.

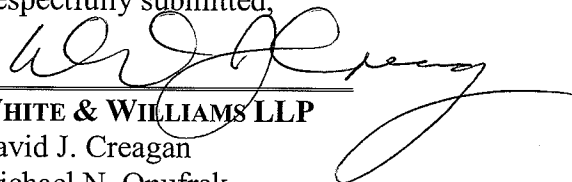
REQUEST NO. 3:

All Documents responsive to the Investigative Discovery Requests that were prepared, created, sent, or received during the period from your receipt of each Investigation [Discovery] Request to the present.

OBJECTION TO REQUEST NO. 3

Cephalon objects to Request No. 3 to the extent that the specifications in the Investigative Discovery Requests are vague, ambiguous, and overly broad. Cephalon further objects to Request No. 3 because it seeks documents not relevant to any of the parties' claims or defenses.

Respectfully submitted,



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F: 617-526-5000

Dated: October 20, 2008

Counsel for Cephalon, Inc.

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

<p>FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, N.W. Washington, D.C. 20508</p> <p>Plaintiff,</p> <p>v.</p> <p>CEPHALON, INC. 41 Moores Road Frazer, Pennsylvania 19355</p> <p>Defendant.</p>	<p>Civil Action No. 08-CV-2141 (RBS)</p>
--	--

CERTIFICATE OF SERVICE

I, David J. Creagan hereby certify that on October 20, 2008, Defendant Cephalon, Inc.'s Objections to Plaintiff Federal Trade Commission's First Request for the Production of Documents were served by electronic mail and by First-Class Mail, postage prepaid, on the following counsel:

<p>Saralisa C. Brau, Esquire c/o Jason Peterson, Esquire FEDERAL TRADE COMMISSION Bureau of Competition 601 New Jersey Avenue, N.W., Room 7159 Washington, D.C. 20001 sbrau@ftc.gov</p> <p>Counsel for Plaintiff, Federal Trade Commission</p>	<p>James C. Burling, Esquire Michelle D. Miller, Esquire Peter A. Spaeth, Esquire Mark A. Ford, Esquire WILMER CUTLER PICKERING HALE AND DORR LLP 60 State Street Boston, MA 02109 james.burling@wilmerhale.com</p> <p>Counsel for Defendant, Cephalon, Inc.</p>
---	---

By: /s/ David J. Creagan
Attorney for Defendant,
Cephalon, Inc.



SUBPOENA DUCES TECUM

<p>1. TO</p> <p>Cephalon, Inc. 41 Moores Rd. Frazer, PA 19355 Attn: General Counsel</p>	<p>2. FROM</p> <p style="text-align: center;">UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION</p>
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This subpoena requires you to appear and testify at the request of the Federal Trade Commission at a hearing [or deposition] in the proceeding described in Item 6.

<p>3. LOCATION OF HEARING</p> <p>Federal Trade Commission 601 New Jersey Ave., NW Room NJ-7207 Washington, DC 20001</p>	<p>4. YOUR APPEARANCE WILL BE BEFORE</p> <p>No appearance required.</p>
<p>5. DATE AND TIME OF HEARING OR DEPOSITION</p> <p>Return date is 30 days from date subpoena is issued.</p>	

6. SUBJECT OF INVESTIGATION

Cephalon, Inc.; FTC File No. 0610182

7. RECORDS YOU MUST BRING WITH YOU

See attached Definitions, Instructions, and Specifications.

<p>8. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN</p> <p>Markus H. Meier, Records Custodian Philip M. Eisenstat, Deputy Records Custodian</p>	<p>9. COMMISSION COUNSEL</p> <p>Philip M. Eisenstat, Saralisa C. Brau, Jeffrey Bank, Mark Woodward</p>
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<p>DATE ISSUED</p> <p style="font-size: 1.2em;">3/15/2007</p>	<p>COMMISSIONER'S SIGNATURE</p>
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GENERAL INSTRUCTIONS

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this subpoena be filed within 20 days after service or, if the return date is less than 20 days after service, prior to the return date. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission. Send one copy to the Commission Counsel named in Item 9.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

**SUBPOENA DUCES TECUM
TO CEPHALON, INC.**

DEFINITIONS

1. "Cephalon," "You," "Your," or "the Company" refers to Cephalon, Inc., Cephalon (UK) Limited, their domestic and foreign parents, predecessors, divisions, and wholly or partially owned subsidiaries, affiliates, partnerships, and joint ventures; and all directors, officers, employees, consultants, agents and representatives of the foregoing. The terms "subsidiary," "affiliate," and "joint venture" refer to any person in which there is partial (25 percent or more) or total ownership or control by Cephalon.
2. "Access Letter" means the letter from Michael Kades (FTC) to James Burling (WilmerHale) dated July 11, 2006 requesting that Cephalon voluntarily submit certain documents and information.
3. "ANDA" means Abbreviated New Drug Application, as defined in Title I of the Drug Price Competition and Patent Term Restoration Act of 1984.
4. "API" means Active Pharmaceutical Ingredient.
5. "Barr Agreements" means any agreement or Side Agreement between Barr Laboratories, Inc. or any of its domestic or foreign parents or affiliates (collectively, "Barr"), Perrigo, Chemagis and/or Cephalon related to the patent litigation settlement for Provigil and/or Actiq, including, but not limited to, the following agreements between Barr and Cephalon, all dated February 1, 2006, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: the Provigil Settlement Agreement, the Actiq Settlement Agreement, the Actiq Supplemental License and Supply Agreement, the Supply, Purchase and License Agreement between Cephalon and Chemagis, the letter agreement between Paul M. Bisaro (President and COO of Barr) to Boaz Laor (President of Chemagis Ltd.) concerning modafinil sales to Cephalon, and the Collaboration Agreement between Cephalon and Perrigo.
6. "Carlsbad/Watson Agreements" means any agreement or Side Agreements between Carlsbad Technology, Inc. ("Carlsbad") or Watson Pharmaceuticals, Inc. ("Watson"), and any of their domestic or foreign parents or affiliates, and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the following agreements dated August 2, 2006, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: the Provigil Settlement and License Agreement by and among Carlsbad, Watson and Cephalon, and the Oral Transmucosal Fentanyl Citrate Sales Agent Agreement by and between Watson and Cephalon.
7. "Chemagis" means Chemagis, Ltd. and any of its domestic or foreign parents or affiliates.

8. “Communication” is used in the broadest possible sense and means every conceivable manner or means of disclosure, transfer, or exchange of oral, written, or electronic information between one or more persons or entities.

9. “Document” means all written, recorded, or graphic materials of every kind, prepared by any person, that are in the Company’s possession, custody, or control. The term “document” includes the complete original document (or a copy thereof if the original is not available), all drafts, whether or not they resulted in a final document, and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on the original. Documents covered by this subpoena include, but are not limited to, the following: Electronically Stored Information; letters; memoranda; all papers filed with a court in litigation and relating to litigation settlement; reports; contracts, including patent license agreements; studies; plans; notes; entries in calendars; publications, including the publication entitled “Datamonitor”; facsimiles; tabulations; ledgers and other records of financial matters or commercial transactions; audio and video tapes; recorded voice mail messages and computer printouts.

10. “Electronically Stored Information” refers to any portion of data found only on a computer or other device capable of storing electronic data, where such data is capable of being manipulated as an entry. “Electronically Stored Information” includes, but is not limited to, e-mail, spreadsheets, databases, word processing Documents, images, presentations, application files, executable files, log files, and all other files present on any type of device capable of storing electronic data. Devices capable of storing Electronically Stored Information include, but are not limited to: servers, desktop computers, portable computers, handheld computers, flash memory devices, wireless communication devices, pagers, workstations, minicomputers, mainframes, and any other forms of online or offline storage, whether on or off company premises.

11. “Generic Agreements” means the Barr Agreements, Carlsbad/Watson Agreements, Mylan Agreements, Ranbaxy Agreements and/or Teva Agreements.

12. “Medicare Modernization Act” means Section 1112(a) of Subtitle B of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

13. “Modafinil API Supply Requirements” means your Company’s forecasts of the quantity of modafinil API that You estimate consuming on an annual or quarterly basis, including but not limited to volume allocated for the manufacture of any modafinil Product, to build or maintain inventory levels, to allow for manufacturing lead time, and any other purposes for which Your marketing or manufacturing departments may forecast volume requirements.

14. “Modafinil Product” refers to both the commercialized version of a drug containing modafinil or r-modafinil, as well as any pre-commercialized, proposed, or anticipated versions of such a drug.

15. “Mylan Agreements” means any agreement or Side Agreement between Mylan Pharmaceuticals, Inc. or any of its domestic or foreign parents or affiliates (collectively,

“Mylan”) and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the following agreements between Mylan and Cephalon, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: the Provigil Settlement Agreement, the Transdermal Fentanyl Patch Option and Exclusivity Agreement, and the Transdermal Fentanyl Patch Collaboration Agreement, all dated January 9, 2006, the Modafinil License Agreement dated March 23, 2006, the Collaboration, License and Supply Agreement dated October 26, 2006, and the Letter Agreements dated May 31, 2006 and January 31, 2007.

16. “Narrative Response” means Cephalon’s submission to the FTC dated February 23, 2007 responding to certain specifications in the Access Letter.

17. “Perrigo” means Perrigo Company and Perrigo Israel Pharmaceuticals, Ltd. and any of its domestic or foreign parents or affiliates.

18. “Ranbaxy Agreements” means any agreement or side-agreement between Ranbaxy Laboratories, Inc. or any of its domestic or foreign parents or affiliates (collectively, “Ranbaxy”) and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the following agreements between Ranbaxy and Cephalon, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: the Provigil Settlement Agreement dated December 12, 2005, the Modafinil License Agreement dated May 23, 2006, and the API Supply Agreement dated January 11, 2007.

19. “Relating to” is used in the broadest possible sense and means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in connection with, dealing with, discussing, describing, embodying, evidencing, identifying, pertaining to, referring to, reflecting, reporting, stating, or summarizing.

20. “Side Agreement” means any agreement entered into between Cephalon and any party to the Generic Agreements, either (i) within 30 days of the signing of the agreement(s) settling the Provigil patent litigation or (ii) that is in any way related to the negotiation of the agreement(s) settling the Provigil patent litigation.

21. “Teva Agreements” means any agreement or Side Agreement between Teva Pharmaceutical Industries, Inc., Teva Pharmaceuticals USA, Inc., and any of their domestic or foreign parents or affiliates (collectively, “Teva”) and Cephalon related to patent litigation settlement for Provigil, including, but not limited to, the following agreements that were entered into between Teva and Cephalon, which were filed with the Federal Trade Commission pursuant to the Medicare Modernization Act, and any subsequent additions, amendments or modifications thereto: (i) the Settlement Agreement between Teva and Cephalon dated December 8, 2005, (ii) the four agreements between Cephalon (UK) Limited and Teva UK Limited dated August 7, 2006, consisting of an Agreement, a Safety Data Exchange Agreement, a Quality Technical Agreement, and a Side Letter to the Distribution Agreement; and (iii) the API Supply Agreement between Cephalon and Teva dated November 7, 2006.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in this subpoena covers any and all Documents prepared, created, sent, or received during, and all Documents relating to, the period from January 1, 2002, to present. This subpoena is continuing in nature and requires the production of all documents written or obtained by You up to sixty (60) days prior to the time of the final response to this request.
2. Documents requested are those in actual or constructive possession, custody, or control of the Company, and its representatives, attorneys, and other agents, including but not limited to, consultants, accountants, lawyers, or any other persons retained, consulted by, or working on behalf or under the direction of the Company, wherever they may be located.
3. Documents shall be accompanied at the time of their submission by an index that identifies: (i) the name of each person from whom responsive Documents are submitted (e.g., files of "John Doe, Vice President"); and (ii) the corresponding consecutive document control number(s) used to identify that person's Documents.
4. Produce all Documents in complete, unredacted form, unless privileged. Submit Documents as stored by the Company or individual. Mark, in a color other than black or with a raised label, each page of each Document with a corporate identification and consecutive Bates numbers, except that bound pamphlets or books with numbered pages may be marked with corporate identification and a single Bates number. Provide a translation of non-English Documents into English; submit the foreign language Document, with the English translation attached.
5. The Company is encouraged to discuss the form and method of production of responsive documents with the Commission representative identified in paragraph 10, or with the representative's designee. The Company shall be permitted to use the form and method of production of responsive documents identified below. Any other form or method must be specifically approved in writing by the Commission representative in advance of any submission.
 - A. You may submit copies of original hard copy Documents as either hard copies or electronic copies in lieu of original Documents, provided that such copies are accompanied by an affidavit of an officer of the Company stating that the copies are true, correct, and complete copies of the original Documents.
 - (1). Hard copies. Provide color photocopies where the original Document is in color. Submit copies in sturdy cartons not larger than 1.5 cubic feet. Number and mark each box with corporate identification. Produce all Documents as they are kept in the ordinary course of business (e.g., produce Documents that in their

original condition were stapled, clipped, or otherwise fastened in the same form).

- (2). Electronic copies. You may submit original hard copy Documents as fully text-searchable electronic copies in single-page, 300 DPI (dots per inch) - Group IV TIFF (tagged image file format) files, named for the Bates number of the Document, and accompanied by a Summation image load file (*.dii), which denotes the appropriate information to allow the loading of the images into Summation with all Document breaks (Document delimitation) preserved, and a corresponding text file containing the optical character recognition (OCR) for either each page or each Document.
- B. Electronically Stored Information. You may produce Electronically Stored Information in the following forms and formats, provided that such copies are true, correct, and complete copies of the original Documents:
- (1). Microsoft Excel and Access files. Submit in native format. Documents provided in native format shall be accompanied by a Summation Class III DII file containing document control numbers for each file submitted.
 - (2). TIFF files. Submit files as single-page, 300 DPI - Group IV TIFF files, with a corresponding file containing the extracted text from the Document. Name each file, comprised of both images and text, for the Bates number of the Document. Include a Summation DII file that denotes the appropriate information and allows the loading of the images into Summation, while preserving all Document breaks (Document delimitation). Include metadata and other information about the Documents in delimited ASCII format. Produce Microsoft PowerPoint presentations in "Notes Pages" format. "Notes Pages" includes a small version of the slide that appears at the top of the page with any notes appearing directly below.
 - (i). Include the following metadata fields for electronic files other than email: creation date/time; modified date/time; last accessed date/time; size; location or "path"; file name; and custodian.
 - (ii). Include the following metadata fields for emails: to; from; CC; BCC; subject; date and time sent; attachment (range or begin attach, end attach); file name of attachments; and custodian.

- (3). Native format. Submit files, accompanied by a Summation Class III DII file containing Document control numbers for each Document. Provide any Documents that are originally stored in .ZIP format, or any other compressed format, as extracted, uncompressed files. Microsoft Outlook files may be produced as Outlook .PST files. Each .PST file should contain e-mails from only one custodian, and should be accompanied by a Summation Class III DII file containing a Bates number and Message ID for each e-mail. Please note that any .MSG files located on a file system should be treated as an electronic Document and not as an e-mail. All other e-mail formats must be produced in TIFF or PDF formats. Any PDF files produced must be searchable and include all metadata and attachments.
- C. Data productions as ASCII text files. You may submit database files as delimited ASCII text files, with field names as the first record, or as fixed-length flat files with appropriate record layout. For ASCII text files, provide field-level Documentation and ensure that delimiters and quote characters do not appear in the data. All database files should include or be accompanied with the definitions of the field names, codes, and abbreviations used in the database and, upon request from the FTC, the instructions for using the database. The FTC may require that a sample of the data be sent for testing. File and record structures must conform to the following requirements:
 - (1). File structures. The FTC will accept sequential files only. Convert all other file structures into sequential format.
 - (2). Record structures. The FTC will accept fixed-length records only. Include all data in the record as it would appear in printed format: viz, numbers unpacked, and decimal points and signs printed.
- D. Submit Electronic Files and images in any combination of the following forms:
 - (1). For any production over 10 gigabytes, use IDE and EIDE hard disk drives, formatted in Microsoft Windows-compatible, uncompressed data.
 - (2). For productions under 10 gigabytes, CD-R CD-ROMs formatted to ISO 9660 specifications, DVD-ROM for Windows-compatible personal computers, and USB 2.0 Flash Drives are also acceptable storage formats.

- E. All documents produced in electronic format shall be scanned for and free of viruses. The FTC will return any infected media for replacement.

6. You are to produce entire Documents including all attachments, cover letters, memoranda, and appendices, as well as the file, folder tabs, and labels appended to or containing any Documents. Copies which differ in any respect from an original (because, by way of example only, handwritten or printed notations have been added) should be produced separately. Each Document requested herein must be produced in its entirety and without deletion, abbreviation, redaction, expurgation, or excisions, regardless of whether You consider the entire Document to be relevant or responsive to these Requests. If You have redacted any portion of a Document, stamp the word "redacted" where the redacted material originally appeared, on each page of the Document which You have redacted. Privileged redactions must be included in a privilege log prepared pursuant to Paragraph 7; any non-privileged redactions must also be included in a log describing the basis for redaction, prepared pursuant to Paragraph 8.

7. If any privilege is claimed as a ground for not producing a Document or tangible thing, provide a privilege log describing the basis for the claim of privilege and all information necessary for the FTC to assess the claim of privilege. Separately, for each Document and attachment withheld or redacted, the log shall include the following: (i) specific grounds for the claim of privilege; (ii) the title of the Document or attachment; (iii) the date of the Document or attachment; (iv) the author of the Document or attachment; (v) the addressees and recipients of the Document or attachment or any copy thereof (including persons "cc'd," or "bcc'd," or "blind cc'd"); (vi) a description of the subject matter of the Document or attachment in sufficient detail to assess the claim of privilege; (vii) the Bates range or page length of the Document or attachment; and (viii) the Requests to which the Document or attachment are responsive. Additionally, for each Document withheld under a claim of attorney work product immunity, state whether the Document was produced in anticipation of litigation or for trial, and, if so, identify the anticipated litigation or trial upon which the assertion is based. Any attachment to a Document withheld under a claim of privilege or immunity shall be produced unless the attachment is also subject to a claim of privilege or immunity, and the basis for such claim is described in a privilege log.

8. If any Documents are redacted on a basis other than privilege, provide the information and reason for redacting that Document per instruction 7.

9. Whenever necessary to bring within the scope of a Request a response that might otherwise be construed to be outside its scope, the following constructions should be applied:

- A. Construing the terms "and" and "or" in the disjunctive or conjunctive, as necessary, to make the Request more inclusive;
- B. Construing the singular form of any word to include the plural and the plural form to include the singular;

- C. Construing the past tense of the verb to include the present tense and the present tense to include the past tense;
- D. Construing the masculine form to include the feminine form; and
- E. Construing the term "Date" to mean the exact day, month, and year if ascertainable; if not, the closest approximation that can be made by means of relationship to other events, locations, or matters.

10. You are not required to re-submit documents previously produced in response to the Access Letter.

11. You are required to submit all documents specified in the subpoena on or before the formal return date together with the attached executed affidavit stating that the attached submission constitutes full compliance with the subpoena. You should comply with this subpoena by submitting all responsive documents on or before the return date, which is 30 days from the date the subpoena is issued, to Kelly Vaughan, Federal Trade Commission, Bureau of Competition, 601 New Jersey Avenue, N.W., Room 6148, Washington, D.C. 20001. Please contact Saralisa Brau at (202) 326-2774 or Philip Eisenstat at (202) 326-2769 with any questions.

SPECIFICATIONS

In accordance with the above Definitions and Instructions, submit the following documents:

1. All Documents specified in the Access Letter.
2. All Documents upon which You relied for the information contained in Your Narrative Response.
3. All Documents relating to the Generic Agreements and the terms contained therein, including but not limited to Documents related to the negotiations of such agreement(s); discussions, communications, analyses, evaluations, and notes regarding such agreements; and drafts of the agreements (whether or not incorporated in the executed agreement).
4. All Documents (including forecasts) discussing the marketing or sale of any Modafinil Product, including but not limited to: analyst reports, business plans, marketing plans, strategic plans, short term and long range strategies and objectives, collaboration plans, budgets and financial projections, sales forecasts, revenue forecasts, and presentations to management committees, executive committees, and boards of directors.
5. All Documents relating to any decision to reduce, eliminate, or increase promotional support for Provigil, including but not limited to sampling and detailing.

6. All Documents constituting or relating to any manufacturing forecasts or manufacturing plans for any Modafinil Product, including but not limited to any adjustments to such forecasts and the basis for such adjustments.

7. All Documents relating to the actual or potential marketing of an authorized generic version of Provigil.

8. All Documents relating to the projected, anticipated, or actual effect that a generic Provigil may have or have had on the sales, revenues, prices or profits of Provigil.

9. All Documents constituting or relating to any communication relating to the sale of any Modafinil Product between or among any parties to the Generic Agreements or any other company that has filed an ANDA referencing Provigil.

10. Submit one copy of each organization chart and personnel directory in effect since January 1, 2004 for the company as a whole and for each of the company's facilities or divisions involved in any activity relating to any Modafinil Product.

11. All Documents constituting or relating to communications with the Food and Drug Administration concerning any Modafinil Product or the qualification of any manufacturers or suppliers of modafinil API.

12. Submit one unredacted copy of each of the following Documents, issued by any party, relating to any patent infringement litigation concerning Provigil or a generic version of Provigil:

- A. All complaints and counterclaims and answers, replies or responses thereto, and any amendments or supplements to the foregoing;
- B. All motions and briefs and oppositions, replies and other responsive pleadings thereto, including any memoranda, exhibits, or other Documents filed in support of such pleadings;
- C. All expert reports, including drafts, and supporting Documents and exhibits;
- D. Transcripts of all depositions, including exhibits to the depositions;
- E. Transcripts of all court hearings;
- F. All document requests issued by any party and all documents produced by You in response to such requests;
- G. All privilege logs produced by any party; and
- H. All interrogatories issued by any party and all answers thereto issued by any party.

13. All Documents relating to the patent prosecution history of U.S. Patent No. 4,927,855, U.S. Patent No. 5,618,845, and U.S. Reissue Patent No. RE37,516, including but not limited to the references cited.

14. All Documents relating to the prosecution history of all continuations, continuations-in-part, divisionals, and reissues of all patent applications and patents that claim priority to Application Number 08/319,124, the application from which U.S. Patent No. 5,618,845 issued, including but not limited to abandoned applications and foreign counterparts.

15. All Documents that express an opinion as to the validity, invalidity, enforceability, unenforceability, infringement or non-infringement of U.S. Patent No. 4,927,855, U.S. Patent No. 5,618,845, and U.S. Reissue Patent No. RE37,516, including but not limited to freedom to practice opinions.

16. All Documents constituting or relating to any communication involving any intellectual property that does, could, or is claimed to apply to the manufacture, sale, and composition of a Modafinil Product, including but not limited to threat to sue letters.

17. All Documents relating to Cephalon's general practices, procedures, strategies, methods, process, requirements, criteria, factors or standards for licensing intellectual property, both as licensor or licensee.

18. All Documents relating to Cephalon's licensing of Teva's intellectual property in the Teva Agreements, including but not limited to, due diligence, analyses, forecasts, budgets, financial projections, internal evaluations, business plans, marketing plans, strategic plans, short term and long range strategies and objectives, any presentations to management committees, executive committees, and boards of directors.

19. All Documents relating to Cephalon's licensing of Ranbaxy's intellectual property in the Ranbaxy Agreements, including but not limited to, due diligence, analyses, forecasts, budgets, financial projections, internal evaluations, business plans, marketing plans, strategic plans, short term and long range strategies and objectives, any presentations to management committees, executive committees, and boards of directors.

20. All Documents relating to Cephalon's licensing of Barr's intellectual property in the Barr Agreements, including but not limited to, due diligence, analyses, forecasts, budgets, financial projections, internal evaluations, business plans, marketing plans, strategic plans, short term and long range strategies and objectives, any presentations to management committees, executive committees, and boards of directors.

21. All Documents relating to Cephalon's general practices, procedures, strategies, methods, process, requirements, criteria, factors or standards for contracting for the supply of API.

22. All Documents constituting or relating to communications or proposals about any actual or potential sale of modafinil API between or among Cephalon, any manufacturer or supplier of modafinil API, and any company that has filed an ANDA referencing Provigil.
23. All Documents relating to the negotiation of any actual or potential agreement for Cephalon to purchase modafinil API and the terms contained therein, including but not limited to discussions, communications, analyses, evaluations, and notes regarding such agreements, and drafts of the agreements.
24. All contracts or agreements relating to Cephalon's purchase of modafinil API.
25. All Documents relating to annual or quarterly forecasts for Cephalon's Modafinil API Supply Requirements, including but not limited to any adjustments to such forecasts and the basis for such adjustments.
26. Documents sufficient to show, on an annual basis, the quantity of modafinil API manufactured at each of Cephalon's production facilities at Mitry-Mory, France.
27. All Documents constituting or relating to communications about the performance of any modafinil API supplier or manufacturer under the terms of any agreement to supply modafinil API to Cephalon.
28. All Documents constituting or relating to communications about the qualification of new modafinil API suppliers, including but not limited to the timeliness of such qualification.
29. All Documents relating to any decision to add a new modafinil API supplier, terminate an existing modafinil API supplier, change the quantities of modafinil API purchased from any supplier, or improve Cephalon's production facilities for modafinil API.
30. All Documents discussing any party's profitability under the terms of any modafinil API supply agreement, including but not limited to forecasts, evaluations, projections, and budget documents.
31. Submit one copy of all supply agreements for finished Provigil product or agreements providing Cephalon an option to purchase finished Provigil product.
32. All Documents relating to Cephalon's general practices, procedures, strategies, methods, process, requirements, criteria, factors or standards for entering into codevelopment or collaboration programs.
33. All Documents constituting or relating to communications with any party relating to the actual or potential development of a naltrexone transdermal patch or a transdermal fentanyl patch.

34. All Documents relating to the actual or potential development of a naltrexone transdermal patch or a transdermal fentanyl patch, including but not limited to, due diligence, analyses, forecasts, budgets, financial projections, internal evaluations, business plans, marketing plans, strategic plans, short term and long range strategies and objectives, any presentations to management committees, executive committees, and boards of directors.

35. All Documents constituting or relating to communications with any party relating to the possible license or use of CEP-1347 data in connection with the treatment of Parkinson's disease.

36. All Documents relating to the possible use of lestaurtinib/CEP-701 in a topical drug delivery formulation or to treat psoriasis, including but not limited to communications with any party regarding possible collaboration or co-development of lestaurtinib/CEP-701.

37. Provide a copy of the Company's accounting policies and procedures.

38. Provide a copy of each financial statement, budget, profit and loss statement, cost center report, profitability report, balance sheet, account reconciliation, and other financial report regularly prepared by or for the Company on any periodic basis, including but not limited to statements and reports for the Company as a whole, and for each of the Company's manufacturing facilities, sales offices, and distribution facilities that relate to the manufacture and sale of any modafinil Product or modafinil API. If available, these reports should be provided in an electronic spreadsheet format acceptable to the Commission.

39. Provide a copy of the Company's document retention policy and any Documents related to the retention of Documents in connection with the Access Letter or the FTC's review of the Generic Agreements.

40. All Documents discussing competition for the sale of any Modafinil Products.

SUBPOENA DUCES TECUM TO CEPHALON, INC., ET AL.

CERTIFICATION

This response to the Subpoena Duces Tecum issued by the Federal Trade Commission, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Federal Trade Commission. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required data, the information is, to the best of my knowledge, true, correct, and complete in accordance with the statute and rules.

Where copies rather than original documents have been submitted, the copies are true, correct, and complete. If the Commission uses such copies in any court or administrative proceeding, the Company will not object based on the Commission not offering the original document.

I declare under penalty of perjury that the foregoing is true and correct.

TYPE OR PRINT NAME AND TITLE

(Signature)

Subscribed and sworn to before me at the City of _____,

State of _____, this _____ day of _____, 2007.

(Notary Public)

My Commission expires: _____

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY
PROCESS IN A NONPUBLIC INVESTIGATION

File No. 0610182

Nature and Scope of Investigation:

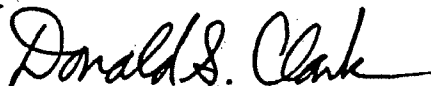
To determine whether Cephalon, Inc., Teva Pharmaceutical Industries, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. *et. seq.*, and supplements thereto.

By direction of the Commission.



Donald S. Clark
Secretary

ISSUED: August 30, 2006

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

Federal Trade Commission,

Plaintiff,

v.

Cephalon, Inc.,

Defendant.

Case No. 08-cv-2141-RBS

**DEFENDANT CEPHALON INC.'S OPPOSITION TO
THE FEDERAL TRADE COMMISSION'S MOTION TO COMPEL**

Cephalon, Inc. ("Cephalon") respectfully submits that it should not be required to respond to the FTC's discovery requests until the Court rules on the pending Motion to Dismiss.¹ If the Court applies the prevailing legal standard articulated by the Second, Eleventh, and most recently the Federal Circuit,² the FTC's Complaint will be dismissed in its entirety, and the need for burdensome, extensive discovery would be avoided. Moreover, before any discovery proceeds, judicial economy dictates that it should be coordinated with discovery in the related cases. That is best done after decisions on all the motions to dismiss,³ when the scope of any surviving claims will be clear. In far less complex circumstances, courts in this District and elsewhere have determined that discovery should commence only after the resolution of dispositive motions to dismiss.

¹ See Cephalon's Motion to Dismiss, Doc. No. 1 (May 2, 2008).

² See Defendant Cephalon Inc.'s Notice of New Federal Circuit Authority Affirming "Scope of Patent" Standard, Doc. No. 8 (Oct. 24, 2008).

³ See also Cephalon's Motion to Dismiss and the Strike (Apotex), Civ. A. No. 06-1797, Doc. No. 31 (Sept. 29, 2006); Cephalon's Motion to Dismiss (Direct Purchasers), Civ. A. No. 06-1797, Doc. No. 44 (Nov. 3, 2006); Cephalon's Motion to Dismiss (End Payors), Civ. A. No. 06-1797, Doc. No. 45 (Nov. 3, 2006).

Cephalon's objections to the FTC's discovery requests reflect a position it has taken consistently throughout the litigation challenging the Provigil[®] Settlements. Even before the FTC served its discovery requests, Cephalon had presented that position in the parties' Rule 26(f) Report and in response to the Commission's motion for a scheduling conference. *See* Fed. R. Civ. P. 26(f)(2) Report to the Court at 2 & ¶¶ 2-3, Doc. No. 2 (May 12, 2008); Cephalon, Inc.'s Response to Federal Trade Commission's Request for Scheduling Conference, Doc. No. 7 (June 25, 2008). Moreover, the identical issue already had been briefed in the context of Apotex's motion to compel discovery, which it filed in response to nearly identical objections by Cephalon to discovery requests in that case. *See* Defendants' Opposition to Apotex's Motion to Compel, Doc. No. 65, Civ. A. No. 06-1797 (Dec. 18, 2006).⁴

The FTC's protestation that there is an urgent public need to begin discovery rings hollow after its own delay in filing this action (two years after the underlying settlements were filed with the agency), and because the claimed harm to consumers is the subject of private treble damages actions. Equally meritless are the FTC's suggestions that Cephalon must move for a stay or protective order rather than interposing objections to the FTC's discovery requests, and that the Court should deem its Requests for Admission ("RFAs") admitted.

For these and others reasons set out below, the Commission's Motion should be denied.

A. Cephalon's Motion to Dismiss, If Granted, Would Eliminate the Burden and Expense of Discovery Entirely

Cephalon's Motion to Dismiss proceeds from a simple premise: the Second, Eleventh, and Federal Circuits have held that Hatch-Waxman settlements, even those involving so-called "reverse payments," do not violate the antitrust laws so long as they do not exceed the scope of

⁴ *See also* Report of Parties' Planning Meeting (Apotex) at 2-3, Doc. No. 18, Civ. A. No. 06-1797-RBS (Aug. 29, 2006); Rule 26(f) Report of Parties (class plaintiffs) at 15-18, Doc. No. 41, Civ. A. No. 06-1797-RBS (Oct. 27, 2006).

the patent at issue.⁵ If the Court applies these holdings, the FTC's case will be dismissed in its entirety, along with most, if not all, of the claims of the various private plaintiffs. The burden and expense of discovery and the need to coordinate will be avoided; and even if the Court does not dismiss the cases outright, in all likelihood its decision would narrow the scope of discovery significantly.

Under these circumstances, it is clearly appropriate to wait for a decision on the Motion to Dismiss before proceeding to discovery. *See Weisman v. Mediq, Inc.*, Civ. A. No. 95-1831, 1995 U.S. Dist. LEXIS 5900, at *5 (E.D. Pa. May 3, 1995) (deferring discovery appropriate “[w]here a pending motion to dismiss may dispose of the entire action and where discovery is not needed to rule on such motion”); *Norfolk S. Ry. Co. v. Power Source Supply, Inc.*, Civ. A. No. 06-58, 2007 U.S. Dist. LEXIS 15306, at * 4 (E.D. Pa. Mar. 5, 2007) (“[W]here, as here, an objection to the Court’s jurisdiction made under Rule 12 might compel the dismissal of an entire action, the Court finds that considerations of fairness and efficiency suggest the prudence of limiting discovery to those facts necessary to resolve the motion.”); *see also Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1367 (11th Cir. 1997) (“Facial challenges to the legal sufficiency of a claim or defense, such as a motion to dismiss based on failure to state a claim for relief, should, however, be resolved before discovery begins.”); *Institut Pasteur v. Chiron Corp.*, 315 F. Supp. 2d 33, 37 (D.D.C. 2004) (“It is well settled that discovery is generally considered inappropriate while a motion that would be thoroughly dispositive of the claim in the Complaint is pending.”).

Ignoring these authorities and the force of their reasoning, the Commission fixates on the truism that filing a motion to dismiss does not “automatically” stay discovery. *See Plaintiff*

⁵ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (“*Cipro*”); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. Federal Trade Comm’n*, 402 F.3d 1056 (11th Cir. 2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

Federal Trade Commission's Mem. in Support of Its Motion to Compel ("Motion"), at 4, Doc. 11-4 (Dec. 5, 2008). This "straw man" substantially mischaracterizes Cephalon's position, and the cases cited by the FTC are not on point. *Coca-Cola Bottling Co. v. Grol*, Civ. A. No. 92-7061, 1993 U.S. Dist. LEXIS 3734 (E.D. Pa. Mar. 3, 1993), Motion at 4, holds only that deferring discovery is "rarely appropriate *where resolution of the motion to dismiss will not dispose of the entire case.*" *Id.* at *6-7 (emphasis added). The court specifically acknowledged the appropriateness of considering whether the pending motion to dismiss would "entirely eliminate" the need for discovery. *Id.*⁶ *Old Dominion Elec. Coop. v. Ragnar Benson, Inc.*, Civ. A. No. 05-34, 2005 U.S. Dist. LEXIS 9842 (E.D. Va. May 23, 2005), Motion at 3-4, is simply inapposite, as the court there denied a "prematurity" objection to discovery that was based on the service of discovery requests a week before entry of the scheduling order, not on the pendency of a motion to dismiss. *Id.* at *2.

The FTC is equally mistaken in suggesting that the public will be greatly harmed if discovery awaits a decision on the Motion to Dismiss. The pace at which the Commission has proceeded (including commencing this action two years after Cephalon filed the Provigil[®] Settlements with the agency) belies any claim of urgency.⁷ Moreover, while the Commission seeks injunctive relief only, the private plaintiffs seek damages to compensate them for the alleged "delay" in generic modafinil entry resulting from the settlements, and if they prevail appropriate damages will be awarded.

⁶ The court allowed discovery to proceed where only one of multiple defendants moved to dismiss and the third-party discovery at issue was relevant to the case against the remaining defendants. *Coca-Cola*, 1993 U.S. Dist. LEXIS 3734, at *6-8.

⁷ The settlements were filed with the Commission and the Department of Justice for review pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, Title XI, §§ 1111-18, 117 Stat. 2066, 2461-64 (Dec. 8, 2003) (contained in 21 U.S.C. § 355, *notes*).

B. Cephalon's Objections Are Procedurally Appropriate

The FTC argues that Cephalon violated some unspecified rule by interposing prematurity objections (among others) instead of moving to stay discovery or for a protective order. Motion at 1-3. The FTC cites no authority supporting its position, instead decreeing that Cephalon's position "find[s] no support in the Federal Rules ... or case law," Motion at 1. The FTC is wrong. In *In re Sulfuric Acid Antitrust Litig.*, 231 F.R.D. 331, 337 (N.D. Ill. 2005), where an antitrust plaintiff similarly challenged the sufficiency of a defendant's objection to discovery because of its pending motion to dismiss, the court ruled for the defendant: "[a party] has the option of providing appropriate written objections and leaving it to the party seeking discovery to file a motion to compel.... Either method brings the disputed matter before the court." *See also Acuity Specialty Group, Inc. v. Paulshock*, Civ. A. No. 06-780, 2006 U.S. Dist. LEXIS 67862, at *5 n.4 (M.D. Pa. Aug. 10, 2006) ("Defendant objected [to discovery], essentially arguing that responding to them may be a waste of time and resources if the Court were to grant its Motion to Dismiss ... We directed that ... Defendant's responses ... would not be due until the Court ruled on Defendant's pending Motion to Dismiss.").

C. Cephalon's Other Objections Are Well Taken, and Are Not Properly Challenged By This Motion

The Commission's challenge to Cephalon's remaining objections (which Cephalon asserted to preserve its rights, not to avoid responding) proceeds from the mistaken assumption that objections served in response to discovery requests need to set forth detailed arguments in support. *See* Motion at 4-7 (stating that "Cephalon has not [borne] its burden to show specific support for its objections"). The Commission goes so far as to argue that Cephalon's general and routine objection to the document requests "to the extent that [they call] for the disclosure or production of documents or information protected by the attorney-client privilege" is invalid because Cephalon did not produce a completed privilege log pursuant to Fed. R. Civ. P. 26(b)(5)

along with the initial written objections. *See* Motion at 6 (“Cephalon’s privilege claims also have not been substantiated and consequently do not meet the strict standards set forth in Rule 26(b)(5) of the Federal Rules of Civil Procedure.”).

This position is, of course, contrary to the Federal Rules, which require only a concise statement of the ground for objection. *See, e.g.*, Fed. R. Civ. P. 36(a)(5) (“The grounds for objecting to a request must be stated.”). As the very cases the Commission cites demonstrate, arguments supporting the objections stated in written responses are made in motion practice. *See In re Automotive Refinishing Paint Antitrust Litig.*, MDL No. 1426, 2006 U.S. Dist. LEXIS 34129, at *30 (E.D. Pa. May 26, 2006) (assessing adequacy of arguments raised in opposition to motion to compel); *Creely v. Genesis Health Ventures, Inc.*, No. 04-679, 2005 U.S. Dist. LEXIS 240, at *3 (E.D. Pa. Jan. 10, 2005) (same).

Except for urging relevance – not a principal objection advanced by Cephalon – the Commission has not addressed Cephalon’s specific objections on the merits, either through the mandatory meet and confer process, *see* L. R. Civ. P. 26.1(f),⁸ or by argument setting out its position with respect to each request as required by L. R. Civ. P. 26.1(b).⁹ Instead, in a single paragraph, the FTC simply decrees – rather than articulates why – that certain of the objections are improper because they relate to statutory or “well known” industry terms, and summarily dismisses Cephalon’s privilege claims as “not substantiated.” Motion at 6-7.

⁸ The Commission did not raise any of these specific objections during its brief meet and confer with Cephalon. Accordingly, it has burdened the Court with issues that may have been resolved by clarification or correction of the requests. *See Crown Cork & Seal Co., Inc. v. Chemed Corp.*, 101 F.R.D. 105, 106-07 (E.D. Pa. 1984) (“Discovery disputes should not be referred to the court unless such serious differences exist ... that further efforts at negotiation are pointless....”); *see also Evans v. American Honda Motors Co.*, Civ. A. No. 00-2061, 2003 U.S. Dist. LEXIS 22189, at *4 (E.D. Pa. Nov. 26, 2003) (“Local Rule 26.1 is to impose a substantial obligation on the parties to make strong efforts to resolve discovery disputes before rushing to the Court for intervention....”).

⁹ *Coleman v. Blockbuster, Inc.*, 238 F.R.D. 167, 170 (E.D. Pa. 2006) (“Local Rule 26.1(b) is clearly designed to force parties to bring into sharp focus the particular discovery disputes that they want a court to resolve.”). The Commission thus leaves it to the Court to “wade through a morass of paperwork that bogs down judicial resources.” *Id.*

In fact, Cephalon's objections are well-taken. Many of the FTC's requests are stated imprecisely. For example, RFA No. 23 asks Cephalon about the content of "contemporaneous" documents. Putting aside the lack of clarity regarding what the documents must be contemporaneous with, the term "contemporaneous" is inherently vague, *see United States v. Caseres*, 533 F.3d 1064, 1073 (9th Cir. 2008) ("[W]e have previously noted that 'what is 'contemporaneous' is in the eye of the beholder....'").

Similarly, a number of the Commission's purported definitions of statutory terms inaccurately summarize key provisions of Hatch-Waxman, resulting in requests that assume as true highly disputed legal contentions. For example, the Commission defined the Hatch-Waxman litigation stay as a "30-month period," RFA Def. No. 2, despite Cephalon's correct and consistent position that the litigation stay here, resulting from the application of the several relevant statutory provisions, was considerably longer than 30 months. *See, e.g.*, Defendant Cephalon's Memorandum of Points and Authorities in Support of its Motion to Dismiss at 4-5 & n.3, Doc. No. 1; *see also* RFA Def. No. 10 (defining Orphan Drug Exclusivity as a seven-year period despite Cephalon's argument that Hatch-Waxman offers a longer period in the case of Provigil[®]).

The Commission's blanket and superficial challenge to Cephalon's specific objections is thus both procedurally and substantively defective and should be rejected.

D. The Circumstances Hardly Warrant the Extreme Remedy of Deeming Requests Admitted

The Commission compounds its flawed challenges to Cephalon's objections by asking the Court to deem all the RFAs admitted. This draconian remedy is clearly unwarranted even if the Court felt it procedurally appropriate at this juncture to consider individual requests and reject specific objections. As this Court previously has stated, where objections to requests for

admission are not sustained, the remedy is to order the objecting party to answer. *Creely*, 2005 U.S. Dist. LEXIS 240, at *4. The two cases the Commission cites, Motion at 7, are inapposite. In *Kelvin Crycosystems, Inc. v. Lightnin*, 252 Fed. Appx. 469 (3d Cir. 2007) (not precedential), Motion at 7, the court upheld the trial court's decision to deem requests admitted only after the defendant "ignored multiple court orders ... missed filing deadlines, and failed to provide satisfactory justification for its repeated delays." *Id.* at 473. In *Southern Ry. Co. v. Crosby*, 201 F.2d 878 (4th Cir. 1953), Motion at 7, the court upheld a decision to deem a request admitted after the defendant gave a blatantly "evasive" answer (and refused to respond even when given another chance at trial). *Id.* at 880. Obviously no such extreme circumstances are present here.

* * *

For the foregoing reasons, the Court should deny the FTC's Motion to Compel.

RESPECTFULLY SUBMITTED,

/s/ David J. Creagan

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Counsel for Cephalon, Inc.

Dated: December 19, 2008

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

Federal Trade Commission, Plaintiff, v. Cephalon, Inc., Defendant.	Case No. 08-cv-2141-RBS
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CERTIFICATE OF SERVICE

I, David J. Creagan, hereby certify that on December 19, 2008, Defendant Cephalon, Inc.'s Opposition to the Federal Trade Commission's Motion to Compel has been filed electronically and served via electronic mail on the following counsel, and is now available for viewing and downloading from the Court's Electronic Case Filing System.

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By: /s/ David J. Creagan
Attorney for Defendant,
Cephalon, Inc.

**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
REPLY IN SUPPORT OF ITS MOTION TO COMPEL**

In its opposition, Cephalon continues to press the wrong-headed view that it need not provide discovery materials until the Court decides its motion to dismiss. Not surprisingly, Cephalon cannot support this view. The cases it cites are all easily distinguished, and the procedural rules unambiguously require Cephalon to respond to discovery requests in the absence of a stay – something Cephalon has neither sought nor been granted. Despite its repeated attempts to confuse the issues and shift the burden to the Commission, the law clearly requires Cephalon – as the party resisting production – to show why discovery should not be allowed. Cephalon has failed to carry its burden.

Cephalon's efforts to stall discovery should be stopped for another reason as well. There is a strong public interest in resolving government antitrust enforcement actions expeditiously. The injunctive relief sought here by the Commission would allow generic competition to Cephalon's Provigil, saving consumers millions of dollars every day. Given what is at stake for

consumers, discovery should proceed so that if this Court denies Cephalon's motion to dismiss, the parties will be prepared to move forward without undue delay.

1. Cephalon Has No Basis for Its Refusal to Respond to Proper Discovery

Cephalon's "prematurity" objection to the Commission's discovery requests is without merit. Discovery in this case began on May 12, 2008, when the parties met their obligations under Rule 26(f) of the Federal Rules of Civil Procedure, and it continues unless and until this Court issues a stay. *Old Dominion Electric Cooperative v. Ragnar Benson, Inc.*, 2005 U.S. Dist. LEXIS 9842, at *2-3 (E.D. Va. May 23, 2005).¹ If Cephalon wants discovery stayed, it bears the burden of persuading this Court to issue a stay. *In re Automotive Refinishing Paint Antitrust Litigation*, 2006 U.S. Dist. LEXIS 34129, at *6 (E.D. Pa. May 26, 2006) (Surrick, J.) ("The party resisting production bears the burden of persuasion."); *Creely v. Genesis Health Ventures, Inc.*, 2005 U.S. Dist. LEXIS 240, at *3 (E.D. Pa. Jan. 10, 2005) (Surrick, J.). For whatever reason, Cephalon has simply ignored that burden, deciding instead to unilaterally act as if a stay had already been granted.

The cases Cephalon relies on to justify this self-help do not support its position, as those cases all arise in factually distinct circumstances, primarily involving motions for a stay or protective order. *Weisman v. Mediq, Inc.*, Civ. A. No. 95-1831, 1995 U.S. Dist. LEXIS 5900 (E.D.Pa. May 3, 1995) (granting motion for stay); *Norfolk S. Ry. Co. v. Power Source Supply, Inc.*, Civ. A. No. 06-58, 2009 U.S. Dist. LEXIS 15306 (E.D.Pa. Mar. 5, 2007) (same); *Institut Pasteur v. Chiron Corp.*, 315 F.Supp. 2d 33 (D.D.C. 2004) (same); *Chudasama v. Mazda Motor*

¹ Cephalon's attempt to distinguish *Old Dominion*, Opp. at 4, is unpersuasive. That court held that discovery served after the Rule 26(f) conference was not premature, and required a response. That the party resisting discovery in that case had not filed a motion to dismiss is irrelevant. Filing a motion to dismiss does not suspend a party's obligation to proceed with discovery.

Corp., 123 F.3d 1353 (11th Cir. 1997) (defendant repeatedly asked the court to rule on its objections, during argument and in a separate filing, and later sought a protective order); *Acuity Specialty Group, Inc. v. Paulshock*, 2006 U.S. Dist. LEXIS 67862 (M.D. Pa. Aug. 10, 2006) (court defers responses to discovery requests, in response to request from defendant). Each of these cases demonstrate that the appropriate course of action when seeking to delay discovery is to persuade the court to issue a stay.

Likewise, the *Sulfuric Acid* case Cephalon cites does not justify its position. The court there denied plaintiff's motion to compel, but based on the late filing of that motion rather than on the substance of any objection raised by the defendant. The court found that "by consciously deciding not to file a motion to compel, the plaintiffs acquiesced in what was functionally a stay." *In re Sulfuric Acid Antitrust Litigation*, 231 F.R.D. 331, 337 (N.D. Ill. 2005). The Commission here has wasted no time in filing its motion to compel, it has in no way acquiesced in Cephalon's attempts to effectively grant itself a stay, and Cephalon has not even attempted to persuade the Court that it is entitled to a stay. Given these facts, Cephalon's continued refusal to provide any discovery is completely inappropriate.

2. Public Equities Favor Proceeding with Discovery in this Enforcement Action

Cephalon ignores more than just its own burden of persuasion in seeking to delay discovery. Incorrectly suggesting that private damages actions will be sufficient to compensate consumers, Cephalon attempts to downplay the substantial public equities that favor moving

forward with this important law enforcement action.² Opp. at 4. And, it makes no effort to show that the discovery sought would impose a burden outweighing these substantial equities.

Indeed, Congress has explicitly recognized the primacy of government antitrust enforcement – even when there are similar private actions – by exempting from the requirements of the multidistrict litigation statute “any action in which the United States is a complainant arising under the antitrust laws.” 28 U.S.C. § 1407(g). As the district court explained in *United States v. Dentsply International, Inc.*, 190 F.R.D. 140, 145 (D.Del. 1999), this exemption represents a clear public policy choice in favor of promptly resolving government antitrust actions to protect the nation’s consumers from competitive harm:

This antitrust exemption is not capricious, but rather based on congressional recognition of the primacy of antitrust enforcement actions brought by the United States, and that such actions are of special urgency and serve a different purpose than private damages suits because they seek to enjoin ongoing anticompetitive conduct.

As in *Dentsply*, the Commission’s enforcement action here has a “special urgency” and serves a “different purpose” than the private actions against Cephalon. While private damages actions may be able to compensate certain consumers for paying inflated prices for Provigil, they offer nothing for patients suffering continuing harm who stop taking their medication because they can no longer afford it – an increasingly common occurrence as healthcare costs skyrocket in a troubled economy.³ Cephalon makes no attempt to show that the discovery sought here will impose a burden outweighing these strong interests in moving the Commission’s case forward.

² Cephalon also seems to think the Commission should have moved more quickly to file suit in this matter, mentioning twice in three pages the time that elapsed between when it filed its settlement agreements with the Commission and when the Commission filed its action. Opp. at 2, 4. Investigations, however, take time. Is Cephalon seriously advocating that the Commission adopt a “shoot first, ask questions later” approach when initiating a lawsuit?

³ See, e.g., Stephanie Saul, *In Sour Economy, Some Scale Back on Medications*, N.Y. Times, October 22, 2008, at A1.

3. Cephalon's Other Objections Are Insufficient to Excuse its Failure to Respond

As with its primary “prematurity” objection, Cephalon has failed to carry its burden to substantiate the other boilerplate objections it has raised, once again seeking to shift that burden to the Commission. *See, e.g.*, Opp. at 6 (Commission “has not addressed Cephalon’s specific objections on the merits”); Opp. at 7 (Commission’s challenges to Cephalon’s objections are “defective”). The law is clear, however, that once the Commission established the relevance of the materials it is seeking (something Cephalon does not dispute in its opposition), the burden shifts to the party opposing discovery – in this case, Cephalon – to show why the discovery should not be permitted. *Creely*, 2005 U.S. Dist. LEXIS 240, at *3. *Creely* also makes clear that this burden cannot be met with blanket statements that a request “is overly broad, burdensome, oppressive, vague, or irrelevant.” *Id.* (internal quotation marks omitted).

Indeed, Cephalon understands that “arguments supporting the objections stated in written responses are made in motion practice.” Opp. at 6. Yet here we are in motion practice, and Cephalon has only attempted to support three of its specific objections. Opp. at 7. Even in these few attempts, Cephalon fails.

- Cephalon addresses its objection to the term “contemporaneous” by claiming the word is “inherently vague,” citing *United States v. Caseres*, 353 F.3d 1064, 1073 (9th Cir. 2008) as its only support. Far from supporting some inherent vagueness, the quoted language about contemporaneous being “in the eye of the beholder” refers to a specific issue – the lack of a bright line test for what constitutes a search contemporaneous with an arrest.
- Cephalon also addresses two terms defined by the Commission – “30-Month Stay” and “Orphan Drug Exclusivity” – which it objected to as “vague and ambiguous.” It claims that the “purported definitions of statutory terms inaccurately summarize key provisions

of Hatch-Waxman, resulting in requests that assume as true highly disputed legal contentions.” Opp. at 7. This argument demonstrates that, rather than finding the terms vague and ambiguous, Cephalon simply disagrees with the Commission’s definitions. In that case, the proper course is to admit or deny the fact as defined, and explain any issue it has with the definition.

Finally, having consistently failed to carry its own burden, Cephalon seeks to muddy the waters by suggesting – with no support – that the Commission somehow should have done more to resolve this issue, either in the meet and confer process or in meeting its obligations under Rule 26.1(b). Opp. at 6. These insinuations are without merit,⁴ and in no way justify Cephalon’s attempt to claim for itself a discovery stay that it has neither requested nor proven is warranted.

⁴ The Commission fully complied with L. R. Civ. P. 26.1(b), which requires that each discovery motion “identify and set forth, verbatim, the relevant parts of the interrogatory, request, answer, response, objection, notice, subpoena, or depositions.” The Commission attached the full text of its requests, along with Cephalon’s responses, as exhibits to the present motion, and addressed Cephalon’s objections in the supporting memorandum. As for the meet and confer, it is unclear why counsel for Cephalon now thinks these issues could be resolved between the parties. During the actual meet and confer in this matter, counsel for Cephalon repeated its consistent position that discovery prior to the resolution of its motion to dismiss would be premature. This statement, coming as it did after Cephalon repeatedly invoked this prematurity argument in refusing to offer alternatives to the Commission’s pre-trial and discovery proposals in the 26(f)(2) report, led us to believe that Cephalon was not interested in resolving discovery issues until it loses its motion to dismiss.

Conclusion

The Commission respectfully asks the Court to compel the discovery requested in the Commission's First Request for Documents and First Request for Admissions.

Dated: December 30, 2008

Respectfully submitted,

/s/ Markus H. Meier

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CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2008, Plaintiff Federal Trade Commission's Reply in Support of Its Motion to Compel was filed electronically and served via ECF notification on counsel listed below, and is available for viewing and downloading on the ECF system.

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Respectfully submitted,

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