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

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

CEPHALON, INC.
41 Moores Road
Frazer, Pennsylvania 19355

Defendant.

Civil Action No. 2:08-cv-2141-MSG

Plaintiff Federal Trade Commission's
First Amended Complaint for Injunctive Relief

Plaintiff, the Federal Trade Commission, by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), for a permanent injunction against defendant Cephalon, Inc. to undo and prevent its unfair methods of competition in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

I. Nature of the Case

1. This case challenges the course of anticompetitive conduct by Cephalon to prevent lower-cost generic competition to one of its key products, a branded prescription drug known as Provigil. With U.S. sales of Provigil – over $920 million in 2008 – accounting for over 46 percent of Cephalon's total sales, the prospect of generic competition was a major threat to the company. Cephalon knew that generic entry would decimate its sales and that any delay in such entry would be highly profitable for Cephalon, but very costly for consumers.

2. By late 2005, generic competition to Provigil appeared imminent. Several years earlier, on the first day permitted by regulation, four companies had raced to submit applications with the U.S. Food and Drug Administration to market generic versions of Provigil. Each of the generic companies had designed around, or challenged the validity of, the only then-remaining patent that covered Provigil, a narrow formulation patent relating to the size of the particles used in the product. Cephalon, like the generic drug companies and the investment community, expected that one or more of the companies would launch a generic version of Provigil in 2006.

3. Faced with this threat to its Provigil monopoly, Cephalon bought off all four of its potential competitors. Cephalon handsomely compensated each generic company – more than $200 million collectively – to abandon its patent challenge and agree to forgo entry until April 2012. Furthermore, by securing these agreements with all four companies to forgo entry, Cephalon blocked competition by any other potential generic entrant as well. Cephalon obtained this result not through the strength of its patent, but by paying its potential competitors to accept the April 2012 entry date.

4. As Cephalon's CEO observed shortly after entering these agreements: "We were able to get six more years of patent protection. That's $4 billion in sales that no one expected." However, Cephalon achieved this unexpected windfall at the expense of consumers. Its anticompetitive scheme to thwart generic competition has denied, and continues to deny, patients the opportunity to purchase lower-cost generic versions of Provigil, forcing patients and other purchasers to pay hundreds of millions of dollars a year more for Provigil.

II. Jurisdiction and Venue

5. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

6. This Court has personal jurisdiction over Cephalon pursuant to 15 U.S.C. § 53(b), and because Cephalon has the requisite constitutional contacts with the United States of America.

7. Venue in this district is proper under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), because Cephalon transacts business in this District, and 28 U.S.C. § 1391(b) and (c), because Cephalon resides in this District.

8. Cephalon's general business practices, and the unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

9. Cephalon is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. The Parties

10. Plaintiff Federal Trade Commission is an administrative agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices in Washington, D.C. The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces.

11. Defendant Cephalon is a publicly traded, for-profit company, incorporated in Delaware and with its principal place of business located in Frazer, Pennsylvania. Cephalon is

engaged in the discovery, development, manufacture, and distribution of pharmaceutical products, including Provigil. In the twelve months ending December 31, 2008, Cephalon had worldwide net sales of over $1.9 billion, over $920 million of which were U.S. sales of Provigil.

IV. Background

A. The Regulatory System Governing Pharmaceuticals in the United States

12. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

13. A company seeking approval from the U.S. Food and Drug Administration ("FDA") to market a new drug (i.e., a branded drug) must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product.

14. An "AB-rated" generic drug is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug and there is no significant difference in the quality and effectiveness of the two drugs.

15. A company seeking to market an "AB-rated" generic version of a branded drug must also file an application with the FDA, but may file an Abbreviated New Drug Application ("ANDA").

16. When a branded drug is covered by one or more patents, a generic drug company that intends to market its generic drug prior to expiration of any patents may proceed to seek

FDA approval, but must certify in the ANDA that either (1) the generic version does not infringe the patents on the brand-name drug, or (2) the patents are invalid. This is referred to as a "paragraph IV certification."

17. If it makes a paragraph IV certification, a generic drug company must notify the patent holder of the filing of its ANDA. If the patent holder initiates a patent infringement suit against the generic drug company within 45 days of receiving such notice, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) patent expiry, (2) district court resolution of the patent litigation in favor of the generic company, or (3) the expiration of an automatic 30-month waiting period.

18. The Hatch-Waxman Act gives the first generic company or companies filing an ANDA containing a paragraph IV certification a period of protection from competition with other generic versions of the drug. As to paragraph IV filings made before December 2003, as is the case here, the FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first company begins commercial marketing of its generic version of the drug, or (2) an appeals court finds the patent(s) claiming the branded drug invalid or not infringed. This is referred to as "180-day exclusivity."

B. The Consumer Benefits of Generic Drugs

19. Although therapeutically the same as its branded counterpart, the first AB-rated generic equivalent to a branded drug is typically priced significantly lower than the brand. Upon the entry of additional AB-rated generic drugs, generic drug prices fall even more.

20. Because of these price advantages, almost all states encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician directs, or the patient

requests, otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

21. Many third party payers of prescription drugs (e.g., health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts.

22. As a result of lower prices and the ease of substitution, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drugs' unit and dollar sales.

23. Competition from generic drugs generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8 to $10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the equivalent branded drugs. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available. And, according to the National Association of Chain Drug Stores, the average retail price for a brand-name prescription was about $138 in 2008, while the average retail price for a generic prescription was about $35.

24. Significant consumer savings can result when generic companies successfully challenge patents and enter prior to patent expiration. For example, a generic company's successful challenge invalidating a patent covering the antidepressant drug Prozac resulted in generic entry 2 ½ years before patent expiry and about $2.5 billion in estimated consumer savings. Another successful challenge invalidating patents covering the cancer drug Taxol

resulted in generic entry over 11 years before patent expiry and estimated consumer savings of more than $3.5 billion.

25. There are many other examples of successful patent challenges by generic drug companies. Indeed, empirical studies have shown that when pharmaceutical patent infringement claims are tested in the courts, the generic prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the alleged infringer had a success rate of 70 percent. An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.

C. Cephalon's Provigil Prescription Drug

26. Cephalon markets a branded prescription drug called Provigil. Provigil's active ingredient is a chemical compound called modafinil. Modafinil was first discovered by Laboratoire L. Lafon ("Lafon"), a French pharmaceutical company, in 1976. A drug product containing modafinil has been available in France since 1994.

27. Cephalon obtained exclusive U.S. rights to modafinil from Lafon in 1993 and acquired Lafon outright in 2001.

28. Cephalon filed a U.S. New Drug Application for Provigil in December 1996 and the FDA approved Provigil in December 1998. The FDA originally approved Provigil for the treatment of excessive daytime sleepiness associated with narcolepsy. The FDA later approved the use of Provigil to treat excessive sleepiness associated with obstructive sleep apnea and shift

work sleep disorder as well. When it was approved for these two additional indications, Provigil was the only FDA-approved prescription medicine for these uses.

29. Provigil has a favorable benefit and side-effect profile when compared to other amphetamine-like stimulants. As a result, Provigil users face reduced risk of addiction or unwanted side effects. Because of Provigil's unique properties relative to other drugs, Provigil is considered to be the "gold standard" for the treatment of excessive sleepiness associated with sleep disorders. According to Cephalon's CEO, Provigil is a unique drug that "created the category of wakefulness products" and faces "no competition."

30. Cephalon's sales of Provigil have grown substantially over time. In 1999, U.S. Provigil sales were approximately $25 million. By 2005, U.S. sales were over $475 million. By the end of 2008, U.S. Provigil sales were over $920 million.

31. Over the seven years from 1999 through 2005, cumulative worldwide Provigil sales were over $1.65 billion. The vast majority of these sales were in the United States. These sales substantially exceeded Cephalon's cost of developing Provigil.

32. Provigil has consistently been Cephalon's highest-selling product. In 2008, U.S. sales of Provigil accounted for over 46 percent of Cephalon's total worldwide sales.

33. Cephalon sells Provigil at a price far above Cephalon's cost of manufacturing the product, making Provigil highly profitable for Cephalon. Even accounting for other direct expenses Cephalon allocates to selling and marketing Provigil, Cephalon's profit margin on Provigil net sales is substantial.

D. Cephalon's Provigil Particle Size Patent

34. Provigil is no longer protected by a U.S. patent covering the modafinil compound. That patent issued in 1979 and expired in 2001.

35. In 1994, Cephalon applied for a second U.S. patent relating to modafinil. This patent did not claim the modafinil compound itself, but rather covered a formulation of modafinil consisting of a specified distribution of small particles. This patent first issued in 1997 and re-issued in 2002 as U.S. Patent No. RE37,516 (the "Particle Size Patent").

36. Cephalon's Particle Size Patent expires in October 2014. Cephalon has received regulatory exclusivity from the FDA that would provide Cephalon with an additional six months of exclusivity beyond the expiration of its patent, to April 2015.

37. Unlike the modafinil compound patent, which expired in 2001, Cephalon's Particle Size Patent does not block all generic competition to Provigil. To the contrary, a consultant advised Cephalon in 2002 that "all generic drug companies know . . . the [Particle Size Patent] may be easily circumvented" by manufacturing their products to contain a distribution of modafinil particle sizes different than that covered by Cephalon's patent.

V. The Threat of Generic Provigil Entry to Cephalon

A. Generic Companies Challenged Cephalon's Provigil Monopoly

38. Because Cephalon's Particle Size Patent could be easily circumvented, companies were eager to submit an application to market a generic version of Provigil. On December 24, 2002, the first day that the FDA could accept an ANDA for generic Provigil, four companies submitted applications (three of which literally camped out in the FDA's parking lot waiting to be the first to file when the doors opened at 7:00 AM): (1) Teva Pharmaceuticals USA, Inc. (together with its affiliates, "Teva"), (2) Ranbaxy Pharmaceuticals, Inc. (together with its

affiliates, "Ranbaxy"), (3) Mylan Pharmaceuticals Inc. (together with its affiliates, "Mylan") and (4) Barr Laboratories, Inc. (together with its affiliates, "Barr"). In their applications, Teva, Ranbaxy, Mylan, and Barr (collectively, the "First Filers") each certified that its version of generic Provigil did not infringe Cephalon's Particle Size Patent, that the patent was invalid, or both.

39. Teva, Ranbaxy, Mylan, and Barr independently developed versions of Provigil that they believed did not infringe Cephalon's Particle Size Patent.

40. Given FDA interpretation of applicable law, the four First Filers could share 180-day exclusivity because they all filed ANDAs on the same day. This meant that if the FDA approved their products, all four First Filers could simultaneously market generic products during the 180-day exclusivity period.

41. Cephalon knew that generic Provigil entry would lead to substantial declines in the company's revenues. In 2005, a Cephalon Vice President responsible for formulating generic strategy projected that if generic versions of Provigil began competing in 2006, the generic versions would be priced 75 to 90 percent below branded Provigil and would cut Cephalon's revenues by at least $400 million within one year – almost 75 percent of Provigil's annual sales. Cephalon's CEO has stated that such losses would have been devastating.

42. The generic companies also projected a substantial impact from generic entry. For example, Teva projected that generic versions would garner 90 percent of all modafinil prescriptions within a month, and that the price for its generic version of Provigil would fall to ten percent of Cephalon's price within one year of generic entry. Similarly, Ranbaxy projected that generic prices would fall to five percent of Cephalon's branded Provigil price within a year.

B. Cephalon's Patent Was Unlikely to Prevent Generic Competition to Provigil

43. In March of 2003, Cephalon filed a patent infringement lawsuit against each of the First Filers, alleging that each First Filer infringed Cephalon's Particle Size Patent. Under the Hatch-Waxman Act, Cephalon's lawsuit triggered an automatic stay of final FDA approval of the First Filers' generic versions of Provigil. Under FDA rules, the stay expired in June 2006.

44. Following discovery in the patent litigation, all of the First Filers filed separate motions for summary judgment, on the grounds that they had successfully designed around Cephalon's Particle Size Patent, that the patent was invalid, or both. These motions were fully briefed by November 2005.

45. Teva, Barr, and Ranbaxy each presented evidence in summary judgment papers that it did not infringe Cephalon's Particle Size Patent because its generic drug contained a distribution of modafinil particles having more large particles than the formulation claimed in the patent.

46. Ranbaxy and Mylan each argued in summary judgment papers that Cephalon's patent was invalid, for several reasons. Ranbaxy argued that Cephalon's patent claims were invalid under 35 U.S.C. § 112 as indefinite because their scope was unclear. Mylan argued that Cephalon was not entitled to a patent because it merely bought modafinil containing the claimed distribution of small particles from Lafon and did not "invent" anything itself, making the patent invalid under 35 U.S.C. § 102(f). Ranbaxy and Mylan both argued that Lafon's sale of modafinil to Cephalon raised an "on-sale bar" that invalidated the patent under 35 U.S.C. § 102(b).

47. Cephalon bore the burden of proving that each of the four different generic products was within the scope of its Particle Size Patent and infringed this patent. Cephalon had

not met its burden at the time it settled the litigation. Moreover, had the patent litigation proceeded, Cephalon was also unlikely to prevent generic entry by the First Filers. To do so, Cephalon had to show that each of the generic modafinil products infringed the Particle Size Patent and defeat each of the generics' invalidity arguments. If Cephalon failed to establish that even one of the generic products infringed its narrow patent, generic entry would have occurred. In addition, if any one of the generics' invalidity arguments prevailed, the patent could not prevent the entry of any generic.

C. Market Participants Expected Generic Competition to Provigil in Mid-2006

48. By the end of 2005, each of the First Filers had received tentative FDA approval of their generic versions of Provigil. The FDA grants tentative approval when it determines that a generic product is bioequivalent to the brand, but cannot grant final approval pending the expiration of regulatory stays. The FDA's determination that the First Filers' generic versions of Provigil were bioequivalent meant that the generic products were as safe and effective as branded Provigil – despite the fact that the generic products contained larger-sized modafinil particles than branded Provigil.

49. All four of the First Filers would likely have had regulatory clearance to launch generic Provigil in June 2006, upon the expiration of the 30-month stay of final FDA approval. Each of the four First Filers could have launched generic Provigil in June 2006 even if Cephalon's patent litigation were still pending, a practice commonly referred to as "launching at risk." The "risk" is that the patent holder could prevail in the patent infringement litigation and recover damages from the generic entrant for lost profits. For example, Teva has launched at risk more than 20 times.

50. By late 2005, generic entry appeared imminent to Cephalon, the First Filers, and Wall Street analysts. In November 2005, Cephalon provided the investment community earnings guidance that explicitly assumed that Provigil was "going away" because of generic entry in 2006. One of the "key assumptions" in Cephalon's 2006 guidance, according to the company's Chief Financial Officer, was that "generic versions of modafinil enter the market midyear."

51. Anticipating generic entry, Cephalon had begun to prepare for life without Provigil. As Cephalon's CEO later explained to investment analysts, "we expected not to have [Provigil] in our portfolio." As a result, "we haven't spent any money [in the] second half of '05 on Provigil." Cephalon cut back on its promotion of Provigil, shifted research efforts away from Provigil, and made plans to launch its own generic version of Provigil (a so-called "authorized generic" product). Typically, a pharmaceutical company like Cephalon will stop promoting its branded product and/or prepare to launch an authorized generic version of its brand only if it expects imminent entry from bioequivalent generic products.

52. Each of the four First Filers prepared internal projections that assumed a June 2006 launch date and engaged in planning for a generic launch. For example, Barr, which believed an even earlier launch was possible, ordered substantial quantities of active ingredient from its supplier in late 2005.

53. Similarly, Wall Street analysts projected generic Provigil entry in 2006. A September 2005 report from American Technology Research noted that "current Street expectations are for generic competition to Provigil in the mid-2006 time frame." An October 2005 report from Lazard Capital Markets detailed one such expectation: "Our projections assume that there will be shared generic exclusivity for Provigil and that final [FDA] approval

will be awarded with Summary Judgment motions still pending [in mid-2006]. At this point, generic(s) will launch at risk."

54. To blunt the devastating impact of generic Provigil entry, Cephalon planned to introduce a branded successor product, Nuvigil, before generic entry in 2006. Because generic Provigil would not be automatically substitutable for Nuvigil, Cephalon expected to retain some portion of its franchise by converting patients from Provigil to Nuvigil. The FDA, however, had not approved Nuvigil by late 2005 and there was considerable uncertainty as to whether the FDA would approve Nuvigil early enough in 2006 to enable Cephalon to successfully migrate customers from Provigil to Nuvigil before the entry of a generic version of Provigil.

55. Given the uncertainty surrounding its strategy to protect its flagship product – and 40% of its revenues – from generic competition, Cephalon charted a different course.

VI. Cephalon's Anticompetitive Scheme to Maintain its Provigil Monopoly

56. To protect its Provigil monopoly, Cephalon set out to settle its patent litigation with the four First Filers under terms that would eliminate potential generic competition for a substantial period. Given the enormous profits at stake, Cephalon was willing to compensate the generic companies handsomely to secure their agreements not to compete.

57. From the outset of negotiations, Cephalon had decided that it would not agree to generic Provigil entry until three years before the expiration of patent-related exclusivity, in April 2012. This entry date was of limited value to the First Filers, in part because it gave Cephalon a substantial period to switch sales to Provigil's successor product, Nuvigil, and thus significantly reduce potential sales of generic Provigil. The First Filers, who had so aggressively challenged Cephalon's monopoly, were therefore unwilling to settle on this entry date without compensation.

58. Because Cephalon was unwilling to compromise on its generic entry date and the First Filers would not agree to Cephalon's date absent other terms, Cephalon had to provide other inducements to the First Filers to secure their agreement to refrain from competing until April 2012. Cephalon provided these inducements in the form of purportedly independent business transactions – thirteen in all totaling in excess of $200 million – such as licenses to intellectual property, supply agreements, or co-development deals (collectively "side-term inducements").

59. The side-term inducements that Cephalon provided to the First Filers, however, are not independent business transactions, but are instead inextricably linked with the agreed-upon generic entry date of April 2012, for at least the following reasons:

- The side-term inducements were entered simultaneously with the associated patent litigation settlements, and were often contained in the same document;
- Prior to patent settlement negotiations, Cephalon had no significant discussions with the generic companies regarding the matters covered by the side-term inducements;
- Cephalon was willing to agree to the side-term inducements only if the generic companies agreed to refrain from competing with their generic versions of Provigil;
- Cephalon did not need licenses to the generic companies' modafinil-related intellectual property to manufacture or sell Provigil or planned successor products; and
- By entering into a series of supply agreements, Cephalon created, in the words of a senior supply manager, a "supply chain nightmare" that makes little sense, absent offsetting consideration in the form of the elimination of potential competition.

60. Cephalon provided an additional incentive to each of the four First Filers to settle by including a "most favored nation" clause in each proposed settlement and by publicizing that provision of each settlement. The clause allowed for accelerated entry by the First Filer in the

event that another generic company entered the market. The effect of that clause was to make it less attractive for each successive generic company to continue to litigate or enter at risk because that clause would automatically permit each generic company that had settled to compete without any risk with any non-settling generic company.

61. The purpose and effect of Cephalon's agreements with the First Filers is to maintain Cephalon's Provigil monopoly and eliminate potential generic competition to Provigil until April 2012.

A. Cephalon Bought Off Potential Generic Competition From Teva

62. On December 8, 2005, Cephalon and Teva entered a written agreement to settle their patent litigation. Under this settlement, Cephalon required that Teva refrain from marketing any generic version of Provigil until April 2012, unless another generic company launched a generic version of Provigil earlier than that date – in which case Teva also would be allowed to enter at that time. Cephalon and Teva publicized this accelerated entry ("most favored nation") provision in press releases announcing the settlement.

63. The settlement agreement provides significant compensation for Teva in return for its agreement to refrain from entering until April 2012. Cephalon agreed to pay Teva up to $125 million in royalties based on Cephalon's worldwide sales of Provigil and successor products. Purportedly, these payments are in exchange for a license to a patent and patent applications Teva held relating to modafinil. Cephalon, however, did not need a license to Teva's modafinil-related patent rights. In fact, Cephalon already had all it needed to successfully manufacture and sell Provigil and any planned successor products, including Nuvigil. Cephalon knew about Teva's patent applications for over three years before it showed

interest in a license, and only then because the license was tied to Teva's agreement to refrain from marketing generic Provigil until April 2012.

64. Cephalon also agreed to purchase active pharmaceutical ingredient ("API") for Provigil from Teva at prices substantially higher than the price Cephalon paid to its existing supplier. Cephalon, moreover, did not need modafinil API supply from Teva. At one point, Cephalon even suggested that Teva "forget about api" until after a settlement had been reached. Teva, however, insisted that such a term be included in the settlement, and ultimately Cephalon agreed to a supply term that guarantees Teva a revenue stream until 2012, when Teva is permitted to market its generic version of Provigil.

65. The compensation Cephalon agreed to provide Teva was designed to, and did, induce Teva to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

B. Cephalon Bought Off Potential Generic Competition From Ranbaxy

66. On December 22, 2005, Cephalon and Ranbaxy entered a written agreement to settle their patent litigation. Under this settlement, Cephalon required that Ranbaxy refrain from marketing any generic version of Provigil until April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

67. Ranbaxy would not agree to refrain from marketing generic Provigil until April 2012, however, unless it received significant compensation. Ranbaxy's chief negotiator sought to obtain "$20-30 million" in value from the settlement. He would not have recommended the settlement to Ranbaxy management absent this compensation "because the economics of the settlement would be quite different."

68. Cephalon agreed to provide this compensation, in part, in the form of a supply agreement. Cephalon agreed to purchase modafinil API from Ranbaxy, despite the fact that Ranbaxy does not manufacture modafinil API itself, but rather sources the API from a third party manufacturer in India. Ranbaxy will pass API on to Cephalon at a substantial markup, and Cephalon will pay prices substantially higher than the price Cephalon paid to its existing supplier.

69. Cephalon also agreed to pay Ranbaxy up to $5 million in exchange for a license to patent applications Ranbaxy held related to modafinil, despite the fact that Cephalon did not need the license to manufacture or sell Provigil or planned successor products, including Nuvigil.

70. The compensation Cephalon agreed to provide Ranbaxy was designed to, and did, induce Ranbaxy to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

C. Cephalon Bought Off Potential Generic Competition From Mylan

71. On January 9, 2006, Cephalon and Mylan entered a written agreement to settle their patent litigation. Under this settlement, Cephalon required that Mylan refrain from marketing any generic version of Provigil until April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

72. In December 2005, just prior to settling, Mylan forecast that it would launch a generic version of Provigil in June 2006. Mylan was therefore unwilling to refrain from competing until April 2012 absent significant compensation. At Mylan's urging, Cephalon agreed to enter into simultaneous product development deals that provide significant guaranteed compensation for Mylan. Under these deals, Cephalon has paid Mylan, to date, at least $45

million. Prior to its agreement with Mylan, Cephalon had expressed no interest to Mylan in the technology Mylan contributed to the product development deals.

73. The compensation Cephalon agreed to provide Mylan was designed to, and did, induce Mylan to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

D. Cephalon Bought Off Potential Generic Competition From Barr

74. On February 1, 2006, Cephalon entered written agreements with Barr and Barr's partner, Chemagis, Ltd. (together with its affiliates, "Chemagis") to settle Cephalon's patent litigation with Barr. Under the settlement, Cephalon required that Barr refrain from marketing any generic version of Provigil until April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

75. Barr was unwilling, however, to settle the Provigil patent litigation based solely on terms that required Barr to refrain from marketing generic Provigil until April 2012. Instead, Barr insisted on additional compensation. Cephalon agreed to provide this compensation. It did so by (1) paying $1 million for a license to a patent application Barr held related to modafinil that Cephalon did not need to manufacture or sell Provigil or planned successor products, including Nuvigil; (2) agreeing to purchase modafinil API directly from Chemagis (and indirectly from Barr via Barr's profit-sharing arrangement with Chemagis) at prices substantially higher than the price Cephalon paid to its existing supplier; and (3) settling unrelated patent litigation on terms favorable to Barr.

76. Since Barr had developed its generic version of Provigil in collaboration with Chemagis, which supplied modafinil API to Barr, any patent litigation settlement with Cephalon effectively required the assent of both Barr and Chemagis. Therefore, to secure Barr's

agreement to refrain from marketing generic Provigil until April 2012, Cephalon was also willing to provide significant compensation to Chemagis.

77. At the same time it entered the patent settlement with Barr, Cephalon agreed to pay Chemagis $4 million in exchange for a license to a patent and patent application Chemagis held related to modafinil that Cephalon did not need to manufacture or sell Provigil or planned successor products, including Nuvigil. Cephalon also entered into a product development deal with Chemagis. Under that deal, the parties agreed to collaborate on two projects. The first was the use of Chemagis drug delivery technology with an existing Cephalon drug product, for which Cephalon agreed to make $20 million in guaranteed payments to Chemagis. The second was a project to be named later. Cephalon agreed to pay Chemagis at least $20 million for the project to be named later.

78. The compensation Cephalon agreed to provide Barr and Chemagis was designed to, and did, induce Barr and Chemagis to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

E. The Broad Effects of Cephalon's Anticompetitive Agreements

79. The settlement agreements prevent each of Teva, Ranbaxy, Mylan, and Barr from selling the versions of generic Provigil at issue in the patent litigation. The agreements also prevent all four firms from developing and marketing any other generic versions of Provigil.

80. Teva and Mylan not only agreed not to develop, market, or sell generic versions of Provigil but they also agreed not to develop, market, or sell generic equivalents of successor products.

81. Under their agreements with Cephalon, Teva, Ranbaxy, Mylan, and Barr may not sell generic products whether or not they infringe Cephalon's Particle Size Patent. Cephalon's

patent lawsuit, in contrast, had the potential to restrict only sales of these companies' current versions of generic Provigil, the products at issue in the litigation.

82. With Provigil's future secured, Cephalon reversed course on its plans for its flagship product. Prior to securing the First Filers' agreements not to compete until 2012, Cephalon had cut back on promotion of Provigil in anticipation of generic entry in mid-2006. After eliminating the threat of generic entry, however, Cephalon advised the investment community that it "reinvigorat[ed]" its Provigil marketing programs. In addition, Cephalon suspended its plans to launch an authorized generic version of Provigil and postponed its anticipated launch of Nuvigil for over three years.

VII. Cephalon's Agreements Harm Competition and Consumer Welfare

83. Prior to their settlement agreements with Cephalon, the First Filers were Cephalon's potential competitors. By entering these agreements, Cephalon eliminated the potential that (1) one or more of the First Filers would have entered with a generic version of Provigil in 2006 before conclusion of the patent litigation; (2) one or more of the First Filers would have prevailed in their patent litigation against Cephalon and introduced a generic version of Provigil well before expiration of the Particle Size Patent; or (3) Cephalon would have agreed to settle its patent litigation on terms that did not compensate the First Filers, but provided for generic entry earlier than April 2012.

84. Cephalon eliminated this potential competition and harmed consumers by compensating the First Filers to refrain from marketing generic Provigil until April 2012. Cephalon eliminated potential competition not through the strength of its patent, but by agreeing to compensate the First Filers for accepting the 2012 entry date. Absent compensation, the First Filers would not have agreed to the April 2012 date that Cephalon demanded.

85. Moreover, absent the compensation Cephalon agreed to provide, generic competition to Provigil would have occurred prior to April 2012 because (1) one or more of the First Filers would have entered with its version of generic Provigil before conclusion of the patent litigation; (2) Cephalon would not have prevailed against each of the four First Filers in its patent litigation; or (3) Cephalon would have agreed to settle its patent litigation on terms that did not compensate the First Filers, but instead provided for generic entry earlier than April 2012. As Cephalon's CEO told investment analysts in early 2007: "We've got Provigil through 2012. You know the history of the company. We didn't expect to be there."

86. Entry of generic Provigil would give consumers the choice between branded Provigil and lower-priced generic versions of Provigil. Many consumers would choose to purchase lower-priced generic drugs instead of higher-priced branded Provigil. Entry of generic versions of Provigil would quickly and significantly reduce Cephalon's sales of Provigil and lead to a significant reduction in the average price purchasers pay for Provigil and its generic equivalents. Consumers likely would save hundreds of millions of dollars a year by purchasing generic versions of Provigil. Through its anticompetitive agreements with Teva, Ranbaxy, Mylan, Barr, and Chemagis, Cephalon has retained those potential consumer savings for itself and used part of them to compensate the generic companies for their agreement to refrain from marketing generic Provigil until April 2012.

87. Cephalon's settlement agreements with the First Filers have prevented generic competition not only from those companies, but from any other source as well. Under the Hatch-Waxman Act, the First Filers collectively hold rights to 180-day exclusivity for generic Provigil. The FDA is prevented by law from approving any other generic version of Provigil until the 180-day exclusivity period has been triggered and run. Only (1) the commercial

marketing of generic Provigil by at least one of the First Filers, or (2) an appeals court decision declaring Cephalon's Particle Size Patent invalid or not infringed would trigger the 180-day exclusivity period.

88. Because of Cephalon's anticompetitive agreements with the First Filers, their 180-day exclusivity will not be triggered by the commercial marketing of generic Provigil until April 2012, the entry date the First Filers agreed to with Cephalon.

89. Cephalon's settlements ensure that there will not be a court decision in the patent litigation with the First Filers to trigger the 180-day exclusivity period.

90. Cephalon has taken further steps to ensure that no court decision will trigger the 180-day exclusivity period, including settling or refusing to litigate with other generic companies that could trigger the exclusivity period.

91. Because of Cephalon's actions, generic Provigil entry will not occur until April 2012.

92. Even then, consumers may realize few benefits from the entry of generic versions of Provigil because of Cephalon's plans to switch sales from Provigil to its new branded product, Nuvigil. Prior to its agreements with the First Filers, Cephalon intended to launch Nuvigil upon receiving FDA approval, which occurred in June 2007. Having successfully forestalled generic competition, however, Cephalon delayed Nuvigil's launch until June 2009.

93. Cephalon is actively working to destroy the market for generic Provigil, and the potential benefits to consumers from generic entry in 2012. As Cephalon's CEO told investment analysts: "[I]f we do our job right [switching the market to Nuvigil] . . . the Provigil number in 2012 that will be genericized will be very, very small."

94. Cephalon raised the price of Provigil by 28 percent between March and November of 2008. As Cephalon's Vice President of Investor Relations told investment analysts: "You should expect that we will likely raise Provigil prices to try to create an incentive for the reimbursers to preferentially move to Nuvigil."

95. The Hatch-Waxman Act was designed to promote generic competition while preserving incentives for branded innovation. To achieve the latter, the Act provides for a number of rewards to branded companies, including regulatory exclusivity periods for new branded drugs and automatic stays of FDA approval of generic drugs upon the filing of patent infringement suits. To achieve the former, the Act grants generic companies an abbreviated path to FDA approval provided they wait out regulatory exclusivity periods and design around or invalidate any patents held by branded companies.

96. As to Provigil, Cephalon benefitted from the protections of the Hatch-Waxman Act. By June 2006, Cephalon had enjoyed seven-and-a-half years of several types of regulatory exclusivity, during which time the FDA was precluded from approving a generic version of Provigil.

97. Cephalon was not, however, prepared to allow consumers to enjoy the benefits of generic competition after the expiration of its exclusivity periods. Rather, through its anticompetitive settlement agreements Cephalon bought an additional six years of protection from potential competition.

98. Exclusion payments are not a natural by-product of incentives created by the Hatch-Waxman Act. Rather, pharmaceutical patent litigation can be, and often is, resolved

without exclusion payments from branded companies to generic companies. For instance, in fiscal year 2004, following FTC enforcement actions challenging exclusion payments, 14 pharmaceutical patent settlements were filed with the FTC under the Medicare Modernization Act and none involved an exclusion payment.

99. Through its exclusion payment settlements, Cephalon bought protection from competition not contemplated by the Hatch-Waxman Act – with consumers paying the price for its anticompetitive conduct.

VIII. Cephalon's Monopoly Power

100. Cephalon has exercised and continues to exercise monopoly power in the United States with respect to Provigil. Direct evidence of this monopoly power includes Cephalon's ability to price Provigil substantially higher than the projected price of competing generic versions of Provigil and to exclude potential competitors by providing significant compensation to forestall entry.

101. Moreover, Cephalon's monopoly power can be shown through circumstantial evidence. In particular, a relevant market for antitrust purposes exists for modafinil-containing drugs approved by the FDA for sale in the United States, consisting of Provigil and generic versions of Provigil. A unique competitive relationship exists between branded drugs and their generic equivalents, including Provigil and generic Provigil. Although other drugs may be used to treat narcolepsy and the other sleep disorders for which Provigil is indicated, the availability of these drugs is not sufficient to prevent the anticompetitive effects from Cephalon's conduct. Cephalon has proclaimed that Provigil faces "no competition" and that it is the "only

wakefulness promoter in the world," in part because of Provigil's unique properties relative to other drugs.

102. Cephalon has consistently held a 100 percent share of the relevant market.

IX. Violation of Section 5 of the FTC Act

103. The FTC realleges and incorporates by reference the allegations in all of the paragraphs above.

104. At all times relevant to this complaint, Cephalon has had monopoly power in the United States with respect to Provigil.

105. Cephalon has willfully maintained its monopoly power through its course of anticompetitive conduct, including its agreements with Teva, Ranbaxy, Mylan, Barr, and Chemagis that those companies will not compete by marketing generic versions of Provigil until April 2012, in exchange for compensation. Entry of a generic version of Provigil would eliminate Cephalon's monopoly with respect to Provigil. At the time of the agreements, each of the First Filers was a threat to enter with a generic version of Provigil prior to April 2012. Eliminating this threat of generic entry is conduct that is reasonably capable of contributing significantly to Cephalon's continued monopoly power. Through its course of conduct, Cephalon has excluded competition and willfully maintained its monopoly not on the strength of its patent, but rather by compensating its potential competitors and abusing competitive and regulatory processes.

106. Cephalon's acts are anticompetitive and constitute an unfair method of competition, in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

X. The Court's Power to Grant Relief

107. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Cephalon's violation.

XI. Prayer for Relief

WHEREFORE, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26 and pursuant to its own equitable powers, enter final judgment against Cephalon, declaring, ordering, and adjudging:

1. That Cephalon's course of conduct, including its agreements with Teva, Ranbaxy, Mylan, Barr, and Chemagis, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

2. That Cephalon is permanently enjoined from maintaining or enforcing the terms in its agreements with Teva, Ranbaxy, Mylan, and Barr that prevent those companies from marketing generic versions of Provigil or successor products before April 2012;

3. That Cephalon is permanently enjoined from engaging in similar and related conduct in the future; and

4. That the Court grant such other equitable relief as the Court finds necessary to redress and prevent recurrence of Cephalon's violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: August 11, 2009

Respectfully Submitted,

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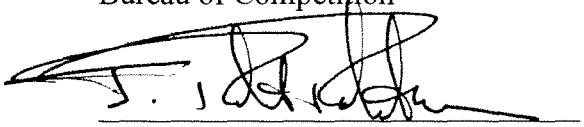

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, N.W. Washington, D.C. 20580 Plaintiff, v. CEPHALON, INC. 41 Moores Road Frazer, Pennsylvania 19355 Defendant.	Civil Action No. 2:08-cv-2141-MSG

CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2009, Plaintiff Federal Trade Commission's First Amended Complaint and computer disk containing a PDF copy of said document were mailed to the Clerk of the Court via Federal Express to be filed in the above captioned matter and served via Federal Express on counsel listed below.

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