

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

United Healthcare Services, Inc.,	)	
	)	
Plaintiff,	)	Civil No. _____
	)	
v.	)	
	)	
Cephalon, Inc., Barr Pharmaceuticals, Inc.,	)	COMPLAINT FOR DAMAGES AND
Mylan Laboratories, Inc., Ranbaxy	)	EQUITABLE RELIEF
Pharmaceuticals, Ltd., Ranbaxy	)	
Pharmaceuticals, Inc., Teva Pharmaceutical	)	
Industries, Ltd., and Teva Pharmaceuticals	)	JURY TRIAL DEMANDED
USA, Inc.,	)	
	)	
Defendants.	)	
	)	
	)	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff United Healthcare Services, Inc. (“UHS” or “Plaintiff”), by and through its undersigned attorneys, complains and alleges against defendants Cephalon, Inc. (“Cephalon”), Barr Pharmaceuticals, Inc., Mylan Laboratories, Inc., Ranbaxy Pharmaceuticals, Ltd., Ranbaxy Pharmaceuticals, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively “Defendants”) as follows:

NATURE OF THE ACTION

1. This is a civil antitrust action that challenges the course of anticompetitive conduct by Defendants to prevent lower-cost generic competition to Provigil, which Cephalon marketed for the treatment of certain sleep disorders, including narcolepsy. Cephalon engineered a scheme to monopolize the market for Provigil by delaying the entry of lower-cost, generic versions of the drug. As discussed herein, this conduct included the following: (1) obtaining a patent (and later a reissued patent) related to Provigil through fraudulent conduct before the

United States Patent & Trademark Office (“PTO”); (2) commencing and prosecuting sham litigation to enforce one of the fraudulently obtained reissued patents; and (3) coordinating a series of “pay-for-delay” settlement agreements in which Cephalon paid approximately \$300 million to four potential generic competitors to delay their entry to market for approximately six years.

2. Cephalon’s anticompetitive scheme began in approximately October 1994, when it submitted an initial application to the PTO seeking a patent related to a formulation of modafinil, the active ingredient in Provigil. The PTO issued Cephalon a patent in April 1997, and later reissued the patent in January 2002. In obtaining its patent, Cephalon represented to the PTO that its own scientists had invented the composition claimed in the patent when, in fact, it was invented by scientists at a French company well before Cephalon’s initial patent application in 1994. Cephalon did not disclose this and other material information to the PTO. In fact, Cephalon made a series of material misrepresentations and omissions with a specific intent to deceive the PTO and obtain its Provigil-related patent.

3. After engaging in a course of fraudulent conduct before the PTO, Cephalon used its fraudulently obtained reissued patent as a basis to file a series of baseless patent infringement lawsuits in 2003 against potential competitors who sought to sell lower-priced generic versions of Provigil. Because Cephalon obtained its patent through a series of misrepresentations and omissions, made specifically to deceive the PTO, Cephalon knew that it was invalid and that the claims of infringement were baseless. Cephalon’s lawsuits, however, successfully delayed potential competitors from entering the market for years, and thereby preserved its monopoly over Provigil.

4. Discovery in the patent infringement lawsuits uncovered Cephalon's fraudulent conduct before the PTO, and the defendants in those proceedings filed motions for summary judgment in the fall of 2005, arguing that Cephalon's patent was invalid as a matter of law. With the motions for summary judgment fully briefed, and recognizing that an adverse decision might be forthcoming, Cephalon elected to settle its lawsuits and simply pay its potential competitors to stay off the market. Cephalon paid nearly \$300 million to the four companies it had sued – all of its viable potential competitors at that time – to settle the cases. These “pay-for-delay” settlements ensured that competing products would stay off the market, and thereby preserve Cephalon's monopoly over Provigil, for approximately six years, from 2006 to 2012.

5. Cephalon's fraud on the PTO – and the invalidity of its patent – has now been proven as a matter of law. After Cephalon entered into the exclusionary “pay-for-delay” settlement agreements with the four potential generic competitors, a fifth generic company – one that was not a part of the anticompetitive settlements – filed a declaratory judgment action in federal court seeking a judicial determination that Cephalon's patent was invalid and unenforceable. Following a full and fair trial on the merits of the company's claims, the district court found that because Cephalon had engaged in inequitable conduct in the prosecution of its Provigil-related patents by misrepresenting or omitting material information with a specific intent to deceive the PTO, its Provigil-related patent was invalid. See *Apotex, Inc. v. Cephalon, Inc.*, Civ. No. 06-2768, 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011), *aff'd*, 500 F. App'x 959 (Fed. Cir. 2013), *cert. denied*, 2013 WL 5565876 (Dec. 16, 2013). The findings of fact in the *Apotex* case are binding and conclusive as to Cephalon in this case pursuant to the doctrine of collateral estoppel and establish beyond dispute the key elements of the monopolization claims alleged herein.

6. By virtue of Cephalon's fraud on the PTO, its commencement of sham litigation and the unlawful "pay-for-delay" settlement agreements, Cephalon and the other Defendants delayed generic competition for at least six years, preserved Cephalon's monopoly over Provigil and provided a massive windfall to all of them. As Cephalon's CEO predicted in March 2006, shortly after entering these unlawful "pay for delay" agreements: "We were able to get six more years of patent protection. That's \$4 billion in sales that no one expected." In fact, this prediction understated the Provigil sales that Cephalon generated during the six year period of the conspiracy.

7. Cephalon, and the other Defendants, obtained this windfall at the expense of UHS and other end payors, who were denied access to lower-cost generic versions of Provigil for at least six years. As a result, UHS was required to pay for vastly more expensive brand-name Provigil, resulting in illegal overcharges of hundreds of millions of dollars.

8. By this Complaint, Plaintiff seeks treble damages for Defendants' antitrust violations, as well as equitable relief in the form of restitution and/or disgorgement to remedy Defendants' unjust enrichment and unlawful and/or unfair business practices.

9. The allegations in this case have been the subject of litigation in the following cases, all of which are or were consolidated and pending in the United States District Court for the Eastern District of Pennsylvania:

- a. *Federal Trade Commission v. Cephalon, Inc.*, Civ. No. 08-cv-2141 (E.D. Pa.) filed by the FTC alleging Cephalon violated Section 5(a) of the FTC Act, 15 U.S.C §45(a) by entering into pay-for-delay settlement agreements with four generic companies. Cephalon settled the case in May 2015, agreeing to pay restitution of \$1.2 billion (and crediting \$512 million of that amount to a certified class of direct purchasers).
- b. *Apotex, Inc. v. Cephalon, Inc., et al.*, Civ. No. 06-cv-2768 (E.D. Pa.) filed by Apotex, a company that sought to market a generic version of Provigil, against Cephalon seeking a declaratory judgment that Cephalon's Provigil-related

patent was invalid and also against Cephalon and four generic companies for damages arising out of the unlawful pay-for-delay settlements. Cephalon settled with Apotex for an undisclosed amount, and the case is pending against two generic companies.

- c. *King Drug Company of Florence v. Cephalon, Inc., et al.*, Civ. No. 06-cv-1797 (E.D. Pa.) filed by direct purchasers of Provigil seeking damages on behalf of a direct purchaser class (primarily wholesale buyers) for violations of federal antitrust laws. The district court certified a direct purchaser class, which has settled with Cephalon for \$512 million. The case is pending against two generic defendants.
- d. *Vista Health Plan, Inc. v. Cephalon, Inc., et al.*, Civ. No. 06-cv-1833 (E.D. Pa.) filed on behalf of a proposed class of end-payor plaintiffs (primarily third-party payors, health insurance plans and consumers), seeking damages under various state antitrust laws, consumer protection statutes and common law theories. The case is pending against Cephalon and two generic defendants.

10. The complaint in the *Vista Health Plan* case was filed on May 1, 2006 and asserted claims on behalf of a proposed class of end payors that included third-party payors, such as health insurance plans, in various states, including Minnesota, that purchased Provigil and/or its generic equivalent for consumption by their members, employees, plan participants, beneficiaries or insureds from June 1, 2006 through September 30, 2013.

11. By order dated June 10, 2015, the district court in the *Vista Health Plan* case denied a motion to certify the proposed class of end payors after finding, among other things, that there was an inadequate methodology to identify injured class members in a feasible manner, and that antitrust impact could not be proven on a class-wide basis. *Vista Health Plan*, Civ. No. 06-cv-1833, 2001 WL 3623005 (E.D. Pa. June 10, 2015).

12. As a third-party payor that purchased Provigil, and its generic equivalent, for use by insureds, UHS was within the proposed class definition in the *Vista Health Plan* case. In light of the district court's order denying class certification, UHS has elected to pursue its claims

through this individual action. In the event that the district court ultimately certifies a class in the *Vista Health Plan* case, UHS intends to opt out of the class.

13. Pursuant to the United States Supreme Court decision in *American Pipe Construction Co. v. Utah*, 414 U.S. 538 (1974), and its progeny, the limitations periods applicable to Plaintiff's claims were tolled from the filing of the initial *Vista Health Plan* indirect purchaser class action complaint on May 1, 2006 until the district court's order denying class certification on June 10, 2015.

14. Plaintiff suffered no injury until December 24, 2005 at the earliest, when generic entry could have occurred but for the unlawful conduct alleged below. The claims asserted in this action therefore accrued no earlier than December 24, 2005. Since the date of accrual of the cause of action, the only period during which the statute of limitations was running was from December 24, 2005 (at the earliest) to May 1, 2006 (the date the complaint in *Vista Health Plan* was filed), and from June 10, 2015 (the date the *Vista Health Plan* court denied the motion for class certification) to the filing of this complaint.

PARTIES

15. UHS is a corporation organized and existing under the laws of Minnesota with its principal place of business in Hennepin County, Minnesota. UHS is engaged in prescription drug managed care programs provided to members and beneficiaries under insurance plans offered by UHS's subsidiaries and affiliates ("UnitedHealthcare Insureds"). UHS is financially responsible for pharmaceutical drugs dispensed to UnitedHealthcare Insureds throughout the country. From 2006 to the present, UHS made payments of several hundred million dollars for Provigil from its headquarters in Hennepin County, Minnesota. UHS therefore suffered direct

antitrust injury in Minnesota as a result of paying inflated prices for Provigil that were higher than they would have been but for the anticompetitive and illegal conduct challenged in this case.

16. Defendant Cephalon, Inc. (“Cephalon”) at all relevant times was a corporation organized and existing under the laws of Delaware with its principal place of business at 41 Moore Road, Frazer, Pennsylvania 19355. In August 2004, Cephalon acquired CIMA Labs, Inc., located in Brooklyn Park, Minnesota, and made CIMA Labs, Inc. a wholly owned subsidiary. Cephalon manufactured and marketed numerous products, including Provigil and other pharmaceuticals subject to FDA approval, until it was acquired by Teva Pharmaceutical Industries, Ltd. on October 14, 2011. As of that date, Cephalon (and CIMA Labs, Inc.), became wholly owned subsidiaries of Defendant Teva Pharmaceutical Industries, Ltd. Cephalon was in whole or in part responsible for some or all of the conduct alleged herein and attributed to Defendants.

17. Defendant Barr Pharmaceuticals, Inc. (“Barr”) was a corporation organized and existing under the laws of New York with its principal place of business at Two Quaker Road, Pomona, New York 10970. Barr manufactured and marketed numerous products, including pharmaceuticals subject to FDA approval. On December 23, 2008, Defendant Teva Pharmaceutical Industries, Ltd. acquired Barr and Barr became a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. Barr was in whole or in part responsible for some or all of the conduct alleged herein and attributed to Defendants.

18. Defendant Mylan Laboratories, Inc. (“Mylan”) is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan manufactures and markets numerous products,

including pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged herein and attributed to Defendants.

19. Defendant Ranbaxy Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 19, Nehru Place, New Delhi 110 024, India. Defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 600 College Road East, Suite 2108, Princeton, New Jersey 08540. Ranbaxy Pharmaceuticals, Inc. is a wholly owned subsidiary of Ranbaxy Pharmaceuticals, Ltd. (Ranbaxy Pharmaceuticals, Ltd. and Ranbaxy Pharmaceuticals, Inc. are referred to collectively as “Ranbaxy”).

20. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli company with its principal place of business at 5 Basel St., Petach Tikva, Israel, 49131. Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. It is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. (Teva Pharmaceutical Industries, Ltd and Teva Pharmaceuticals USA, Inc. are referred to collectively as “Teva”).

JURISDICTION AND VENUE

21. This complaint seeks relief under Minnesota antitrust law (Minn. Stat. §§ 325D.49 *et seq.*) to recover treble damages and costs of suit, including reasonable attorneys’ fees, against Defendants for the injuries sustained by Plaintiff and also for equitable relief in the form of restitution and/or disgorgement of Defendants’ unjust enrichment.

22. The court has jurisdiction over this matter under 28 U.S.C. § 1332(a) as the amount in controversy exceeds \$75,000.00 and involves diversity of citizenship.

23. Venue is appropriate in this district under 28 U.S.C. § 1391 because Defendants transact business and/or have agents within this district and a substantial part of the interstate trade and commerce involved and affected by the violations alleged herein was and is carried on in part within this district. The acts complained of had and will continue to have substantial effects in this district, and Plaintiff UHS maintains its principal place of business in this district.

BACKGROUND

A. Third-Party Payors in the Prescription Drug Marketplace

24. Plaintiff pays for numerous prescription drugs, including Provigil and its AB-rated generic equivalents, in satisfaction of the needs of UnitedHealthcare Insureds.

25. The prescription drug marketplace has unique characteristics that distinguish it from others. First, access to prescription drugs is highly regulated. Second, although it is the patient who ultimately ingests the prescription drug, access to the drug is controlled by a physician who must provide a patient with a prescription for the drug and by the pharmacist who fills the prescription. Third, for the majority of Americans (*i.e.*, those with insurance coverage), payment for prescription drug costs (after member cost-sharing) is handled by third-party payor insurers.

26. Plaintiff and other third-party payors are primarily responsible for paying for the cost of drugs for insureds and therefore have an incentive to minimize prices paid for pharmaceutical drugs. Third-party payors, including Plaintiff, utilize various methods to minimize prices for pharmaceutical drugs, and these generally depend on the existence of real competition within the regulatory structure that governs pharmaceutical manufacturers. As one example, many third-party payors of prescription drugs have adopted policies to encourage substitution of less expensive generic drugs for their branded counterparts.

B. The Regulatory System Governing Pharmaceuticals

27. In accordance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the “FDC Act”), a manufacturer who creates a new drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application (“NDA”). A NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

28. When the FDA approves a brand-name manufacturer’s NDA, the drug product is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.” The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If the brand manufacturer obtains a patent after the FDA approves its NDA, it must list the patent in the Orange Book within 30 days of the date on which the patent issued.

29. The FDA relies completely upon the brand manufacturer’s truthfulness about patent validity and applicability, as it does not have the resources or authority to verify independently the manufacturer’s statements regarding patents submitted for listing in the Orange Book. In listing patents in the Orange Book, the agency merely performs a ministerial act.

C. The Hatch-Waxman Act

30. In 1984, Congress amended the FDC Act through the enactment of the Hatch-Waxman Act, referred to as Drug Price Competition and Patent Term Restoration Act Pub. L. No. 98-417, 98 Stat. 1585 (1984) (“Hatch-Waxman Act”). The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to

prepare extensive and costly NDAs to obtain FDA approval. Instead, the Hatch-Waxman Act authorizes an expedited FDA review process by which generic manufacturers may file and gain approval for their drugs through the filing of an Abbreviated New Drug Application (“ANDA”).

31. An ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA and must only show that the generic drug uses the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. That is, the ANDA must demonstrate that the proposed generic is pharmaceutically equivalent and bioequivalent (together therapeutically equivalent) to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterparts an “AB” rating.

32. The FDC Act and the Hatch-Waxman Act operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another.

33. Congress enacted the Hatch-Waxman Act to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare costs through competition while also protecting incentives for pharmaceutical manufacturers to innovate and create new drug products.

D. Paragraph IV Certifications

34. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that its generic drug will not infringe

any patents listed in the Orange Book. Accordingly, under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

- a. That no patent for the brand-name drug has been filed with the FDA (a "Paragraph I certification");
- b. That the patent for the brand-name drug has expired (a "Paragraph II certification");
- c. That the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); and
- d. That the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

35. If a generic manufacturer submits an ANDA with a Paragraph I, II, or III certification, then it can take advantage of the expedited approval process authorized by the Hatch-Waxman Act, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline.

36. If a generic manufacturer submits an ANDA with a Paragraph IV certification, stating that a patent listed in the Orange Book is invalid or will not be infringed by the proposed generic, the manufacturer must also provide notice of the certification to the NDA-holder. In this instance, a brand manufacturer has an opportunity to delay final approval of the ANDA and the sale of the competing generic drug on the market. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving written notice of the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months from the date the ANDA filer notified the NDA-holder; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of these conditions occurs, the FDA may grant "tentative approval" to an ANDA applicant, which means that the ANDA satisfies the FDA

requirements for final approval, except for the existence of some legal barrier (*i.e.*, the 30-month stay).

37. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification is entitled to a period of 180 days of market exclusivity during which time the FDA may not approve other generic versions of the drug. During this 180-day exclusivity period, no other manufacturer is permitted to enter with an AB-rated generic version of the same drug, which effectively creates a duopoly between the brand-name drug manufacturer and the first-filing generic company. This 180-day exclusivity period is extremely valuable to generic drug manufacturers.

38. To generic manufacturers, entering the market first with the 180-day exclusivity period is an important objective. Before generic entry, the brand drug is typically priced far above competitive levels. During the 180-day exclusivity period, the first company to introduce an AB-rated generic version of a brand drug can price its generic drug well below the brand drug and yet still earn substantial profits.

39. When a single generic enters the market, its price, while lower than the brand-name drug price, is typically higher than it would be if there were multiple generic competitors in the market. Upon entry, a generic drug is typically sold at prices that are 25% less than its brand-name counterpart when there is a single generic competitor; however, this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market.

40. Where (as in this case) multiple generic companies file ANDAs with Paragraph IV certifications on the same day, the FDA has declared that all the companies share the

exclusivity and all are entitled to launch during the 180-day exclusivity period if they obtain final approval from the FDA. Shared exclusivity among four companies, however, diminishes the value of the exclusivity period because, instead of a single generic company marketing an AB-rated generic, there are multiple companies marketing generic products that compete with one another.

41. Under this regulatory scheme, NDA-holders have strong financial incentives to “game the system” by listing patents in the Orange Book (even if such patents are not eligible for listing because they are invalid or unenforceable) and by suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor’s product does not actually infringe the listed patent) because merely filing suit delays generic entry during the 30-month stay. The NDA-holder obtains this protection from competition without having to make any showing that its patent infringement lawsuit has merit, or is likely to succeed, and without having to satisfy any of the other typical burdens associated with obtaining a preliminary injunction from a court.

42. In some instances, the first generic applicant can help the brand-name drug manufacturer “game the system” because by delaying its own market entry, it can also delay the market entry of all other generic manufacturers who submit ANDAs later in time. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of its 180-day exclusivity period, thereby preventing any subsequent generic applicants from coming to market. This tactic creates a “bottleneck” because later generic applicants cannot launch until the 180-day exclusivity period of the first-filing generic applicant (or, as in this case, the first-filing applicants) expires or is forfeited.

43. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) in order to make it more difficult for brand and generic manufacturers to enter agreements to delay the start of the first filer’s 180-day exclusivity. The MMA outlines a number of conditions under which an ANDA first-filing applicant forfeits its eligibility for 180-day exclusivity, clearing the way for other ANDA applicants to launch their products.

44. For example, under the MMA an ANDA applicant may forfeit its 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement has issued; (ii) a settlement order is issued entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA-holder delists the patent from the Orange Book.

45. Brand-name drug manufacturers and first-filing ANDA applicants can and do structure patent settlements to prevent forfeiture. For example, brand-name drug manufacturers can subvert the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by settling their litigation before a final judgment of invalidity or non-infringement with respect to each of the patents for which the first-filing ANDA applicant submitted a Paragraph IV certification. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first-filing ANDA applicant submitted Paragraph IV certifications are invalid or not infringed. This

may require the subsequent ANDA applicant to initiate a declaratory judgment action, which results in further delay of entry by generic manufacturers.

E. Benefits of Generic Drugs

46. Generic versions of brand-name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand-name counterparts. ANDAs for orally available solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for FDA approval are assigned an “AB” rating by the agency. AB-rated generics are deemed by the FDA to be therapeutically equivalent and pharmaceutically equivalent to their brand-name counterparts.

47. An AB rating for a generic drug is very significant. All states permit (and some states require) pharmacists to substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing physician (unless the prescription is denominated “Dispense as Written”).

48. Many third-party payors, such as Plaintiff, whose members account for a substantial share of purchases in the market, have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result, AB-rated generic drugs typically capture a significant share of sales from their branded counterparts, causing a significant decline of the branded unit and dollar sales.

49. Until a generic manufacturer enters the market with an AB-rated generic product, there is no bioequivalent generic drug which competes with the brand-name drug and the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales. Prior to the entry of an AB-rated generic, brand manufacturers can and do charge prices far above competitive levels (*i.e.*, above the prices that

prevail for that drug upon generic entry) without losing all or a substantial portion of their brand drug sales.

50. The first AB-rated generic to enter the market is priced significantly below its brand-name counterpart. When an AB-rated generic enters the market, it quickly captures sales of the corresponding branded drug, often capturing 80% or more of the market within the first six months. For many drugs, within approximately one year after the market entry, the generics have taken more than 90% of the brand-name drug's unit sales and sell for 15% of the price of the corresponding brand-name drug. As more AB-rated generic versions enter the market, prices for the generic drugs typically decline further as more generic companies compete with one another.

51. Generic competition enables purchasers at all levels of the pharmaceutical supply chain to purchase generic equivalents of the brand-name drug at a substantially lower price than the brand-name drug. Thus, generic competition to a branded drug product can result in billions of dollars in savings for consumers, insurers, pharmacies, and other drug purchasers.

52. Given the differences in price between generics and their brand-name counterparts, and these structural features of the pharmaceutical market, the entry of AB-rated generic drugs has a fairly predictable effect. Competition from AB-rated generic drugs is viewed by brand-name drug companies such as Cephalon to be a grave threat to their profits and creates a powerful incentive to block or delay generic competition.

DEFENDANTS' ANTICOMPETITIVE SCHEME

A. FDA Approval of Provigil

53. Provigil is a brand-name drug and its active pharmaceutical ingredient ("API") is a chemical compound called modafinil, a psychostimulant that enhances wakefulness and vigilance.

54. Cephalon filed an NDA with the FDA on December 26, 1996, seeking approval to market Provigil in the United States. The FDA approved the NDA on December 24, 1998, and Cephalon began marketing Provigil in February 1999.

55. The FDA originally approved Provigil for a single indication, the treatment of excessive daytime sleepiness associated with narcolepsy. The FDA later approved Provigil for two additional indications, treatment of excessive sleepiness associated with obstructive sleep apnea and shift work sleep disorder. When it was approved for these two additional indications, Provigil was the only FDA-approved prescription medication for these uses.

56. Cephalon obtained certain regulatory exclusivities for Provigil, allowing it to sell the drug for many years without the prospect of competition from AB-rated generics. First, Cephalon represented to the FDA that modafinil constituted a new chemical entity (“NCE”), and the FDA granted Cephalon a five-year NCE exclusivity. For a drug with five-year NCE exclusivity no ANDA may be submitted before the expiration of five years from the date of FDA approval, except that an ANDA may be *submitted* after the expiration of four years if it contains a Paragraph IV certification to one or more patents listed in the Orange Book. The NCE five-year exclusivity for Provigil expired on December 24, 2003, although the FDA was authorized to accept an ANDA with a Paragraph IV certification on or after December 24, 2002.

57. Cephalon also represented to the FDA that Provigil was a drug used for the treatment of a rare disorder (narcolepsy), and on that basis the FDA granted Cephalon an “Orphan Drug” exclusivity, which expired on December 24, 2005. As a result of the NCE and Orphan Drug regulatory exclusivities, the FDA could not grant final approval to any ANDA seeking approval of an AB-rated generic version of Provigil before December 24, 2005.

58. On or about March 28, 2006, the FDA granted Cephalon a six-month pediatric exclusivity extension. This extension, however, applied only to exclusivities that had not yet expired. Since Cephalon's Orphan Drug exclusivity expired December 24, 2005, the receipt of a pediatric exclusivity extension on March 28, 2006 would not have prevented any potential generic competitors from obtaining final FDA approval to market their generic versions of Provigil.

59. Provigil was a highly profitable drug and one of Cephalon's highest selling products. In 1999, U.S. sales of Provigil were approximately \$25 million. During the next decade, U.S. sales of Provigil increased dramatically. By 2010, Cephalon's annual sales of Provigil in the U.S. reached \$1 billion and accounted for roughly one-half of its total sales in the United States.

B. Cephalon's Modafinil Patent

60. Laboratoire L. Lafon ("Lafon"), a French company, discovered modafinil in 1976. After conducting extensive clinical studies, Lafon received French regulatory approval for the treatment of narcolepsy with modafinil in February 1992. By 1993, Lafon had a stable, bioavailable dosage form of the drug that was approved for sale in Europe.

61. On October 6, 1994, Cephalon filed United States Patent Application No. 08/319,124 ("the '124 Application") titled "Acetamide Derivative Having Defined Particle Size" with the United States Patent & Trademark Office ("PTO"). The application names Cephalon scientists Peter Grebow, Vincent Corvari and David Stong as the inventors.

62. The named inventors submitted declarations acknowledging their duty of candor (*i.e.*, the duty to disclose all material information) to the PTO and affirming that they were the true and properly named inventors. This duty of candor extended to the named inventors, as well

as to others such as patent attorneys and declarants substantively involved in the prosecution of the '124 Application.

63. On April 8, 1997, the '124 Application issued as United States Patent No. 5,618,845 ("the '845 Patent"). Significantly, the patent did not claim the modafinil compound itself. That patent (United States Patent No. 4,177,290) ("the '290 Patent"), had issued in 1979 and expired in 2001. Instead, the '845 Patent covered a particular formulation consisting of a specified distribution of small particles of modafinil.

64. On or before April 1, 1999, Cephalon concluded that the '845 Patent was wholly or partly inoperative or invalid. Seeking to remedy perceived deficiencies in the '845 Patent, Cephalon filed a reissue application, United States Patent Application No. 00/285,166 ("the RE '166 Application") with the PTO. The filing of the RE '166 Application triggered new duties of candor for those individuals substantively involved in the prosecution of the RE '166 Application. On January 15, 2002, the PTO issued reissue patent number 37,516 ("the RE '516 Patent"). Generally speaking, the '516 Patent claims covered "small particle modafinil" – pharmaceutical compositions of modafinil particles wherein 95% of the particles were smaller than 220 microns.

65. The expiration date for the RE '516 Patent was October 2014; however, Cephalon obtained regulatory pediatric exclusivity from the FDA which provided an additional six months of exclusivity beyond the expiration of its patent, until April 2015.

66. Unlike the '290 Patent, which covered the modafinil compound, and which expired in 2001, the RE '516 Patent did not block all generic competition to Provigil. Potential generic manufacturers knew that the RE '516 Patent could be circumvented by manufacturing

their products to contain a distribution of modafinil particle sizes different than that covered by the patent claims.

C. Cephalon’s Patent Infringement Litigation Against the Generic Defendants

67. Generic companies were eager to submit an application to market a generic version of Provigil. Indeed, on December 24, 2002, the first day on which the FDA could accept an ANDA seeking approval for generic Provigil, four companies submitted ANDAs: (1) Teva; (2) Ranbaxy; (3) Mylan; and (4) Barr (collectively “the Generic Defendants”). Each company included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of the RE ‘516 Patent.

68. Between February 12, 2003 and March 21, 2003, Mylan, Barr, Teva and Ranbaxy each notified Cephalon in writing that it had filed an ANDA including a Paragraph IV certification, and that it sought to market a generic version of Provigil.

69. On March 28, 2003, Cephalon filed suit in the United States District Court for the District of New Jersey pursuant to the Hatch-Waxman Act, alleging the ANDAs submitted by Mylan, Barr, Teva and Ranbaxy infringed the RE ‘516 Patent.

70. During the course of discovery in the patent infringement cases, the Generic Defendants uncovered facts that raised serious doubts about (1) the enforceability of the RE ‘516 Patent; (2) the validity of the claims of the RE ‘516 Patent; and (3) the strength of Cephalon’s infringement allegations.

71. This information revealed that Cephalon, through its agents, made numerous material misrepresentations and omissions to the PTO during the prosecution of the ‘845 and RE ‘516 Patents. These misrepresentations and omissions included the following:

- a. Cephalon represented that it had invented the modafinil compositions and methods claimed in the RE '516 Patent when in fact they were discovered years earlier by scientists at a different company, Lafon, in France;
- b. Cephalon failed to disclose that on January 20, 1993, it entered into a Supply and License Agreement with Lafon relating to modafinil API and tablets;
- c. Cephalon failed to disclose that, pursuant to its January 1993 Supply and License Agreement, Lafon had sold and delivered modafinil tablets and API to Cephalon before October 6, 1993 (the on-sale bar date), and that these products fell within some, if not all, of the composition claims recited in the '845 and RE '516 Patents;
- d. Cephalon represented that it was the first to measure particle size for modafinil and the first to recognize the importance of particle size when, in fact, Lafon had already considered the importance of maintaining particle size controls over modafinil drug products prior to Cephalon's alleged invention and provided Cephalon with particle size information for all of the lots of modafinil API Lafon sold and delivered to Cephalon; and
- e. Cephalon represented that it had discovered that the dissolution rate of modafinil increases with a decrease in particle size when, in fact, Lafon scientists had discovered the relationship between modafinil dissolution rate and particle size in 1989 and communicated the relevant dissolution and particle size data to Cephalon in March 1993.

72. These misrepresentations and omissions were material to patentability because they all contradicted Cephalon's contention that its narrow formulation based on particle size was novel and patentable and related specifically to issues of inventorship, derivation and obviousness under 35 U.S.C. §§ 102(a), 102(b) and 103(a).

73. In August and September 2005, the Generic Defendants filed motions seeking summary judgment that some or all of the claims of the RE '516 Patent were invalid as a matter of law. Ranbaxy and Mylan each argued in summary judgment papers that Cephalon's RE '516 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 with 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).

74. The Generic Defendants also argued in summary judgment motions filed with the district court that their generic products did not infringe the RE ‘516 Patent because their generics contained distributions of modafinil particles having more large particles than the formulation claimed in Cephalon’s patent, and that their evidence was so compelling that they were entitled to judgment as a matter of law.

75. Cephalon bore the burden of proving that each of the four generic products to be sold by the four Generic Defendants was within the scope of, and infringed, the RE ‘516 Patent. Had the patent litigation proceeded, Cephalon was unlikely to have prevented generic entry by the Generic Defendants. To do so, Cephalon had to show that each of the generic modafinil products infringed its patent and defeat each of the generic companies’ invalidity arguments. If Cephalon failed to prove that even one of the generic products infringed its narrow patent, generic entry would have occurred. And if any one of the generic companies’ invalidity arguments prevailed, the patent would be invalidated and could not have prevented the entry of any of the other generic manufacturers.

D. Defendants Expected Generic Entry in Late 2005 or Early 2006

76. In February 2005, a Cephalon consultant wrote that Provigil “faces the certain prospect of generic competition by June 2006.” Thus, despite the existence of its RE ‘516 Patent and the patent infringement lawsuits against the Generic Defendants, Cephalon realized that it would lose its Provigil monopoly at or about the time that its Orphan Drug exclusivity expired on December 24, 2005.

77. Cephalon also knew that its RE '516 Patent would not preclude the Generic Defendants from coming to market on or shortly after December 24, 2005 because: (a) the 30-month stays, which Cephalon had obtained merely by filing its meritless patent infringement lawsuits against the Generic Defendants, had expired in September 2005, and its Orphan Drug exclusivity expired on December 24, 2005; (b) Cephalon's RE '516 Patent did not give it an automatic right to exclude its generic competitors, but rather a right to *attempt* to use the RE '516 Patent to obtain a court order excluding or enjoining competition; and, (c) under controlling patent law, Cephalon would have been required to obtain an injunction keeping the Generic Defendants off the market after expiration of the 30-month stay and the Orphan Drug exclusivity.

78. By mid-December 2005, the FDA had granted all four of the Generic Defendants tentative approval of their ANDAs for their generic versions of Provigil, which meant that (1) the FDA had determined that the generic products were safe, effective and bioequivalent to their brand-name counterpart; and (2) the only barrier to final approval was the existence of some form of legal or regulatory exclusivity – the Orphan Drug exclusivity. Cephalon knew that when its Orphan Drug exclusivity expired on December 24, 2005, the Generic Defendants would come to market with their generic versions of Provigil, immediately or shortly thereafter, regardless of the patent litigation.

79. Cephalon's management was so convinced that generic competition was imminent before December 2005 that they informed the investment community in November 2005 that Cephalon was projecting a substantial reduction in sales of Provigil in 2006, specifically because it expected generic competition.

80. Cephalon management also told securities analysts in November 2005 that Cephalon had reduced promotional spending on Provigil in late 2005 because it expected that generic competition would soon begin. As Cephalon's CEO explained to investment analysts, "we expected not to have [Provigil] in our portfolio." Therefore, "we haven't spent any money [in the] second half of '05 on Provigil."

81. Anticipating entry by a number of generic manufacturers, Cephalon also made plans to launch its own generic version of Provigil (a so-called "authorized generic" product), an identical product that is manufactured by, or on behalf of the brand company, and offered at a substantial discount. Typically, a pharmaceutical company will prepare to launch an authorized generic only if it expects imminent generic entry from AB-rated products. Otherwise, an authorized generic would simply cannibalize the sales of the brand.

82. The Generic Defendants also expected to enter the market in 2006, even if that meant launching their generic versions of Provigil "at risk," that is, while Cephalon's patent infringement lawsuits were still pending. As of November 2005, Ranbaxy had begun taking steps to prepare for an "at risk" launch and made plans to purchase a "launch quantity" of modafinil API in December 2005. One internal source at Barr reported in 2005 that "it is very likely that all four 'first wave' filing companies (Barr, Mylan, Teva and Ranbaxy) will be launching at risk prior to the end of the litigation process...." Each of the Generic Defendants prepared internal projections that assumed a generic launch date by June 2006, and they made preparations for generic launch.

E. Generic Entry Posed an Imminent Threat to Cephalon's Provigil Monopoly

83. Where multiple generic companies file Paragraph IV ANDAs on the same date, as in this case, the FDA has declared that each of those filers is entitled to share the 180-day

exclusivity and, upon final approval by the FDA, all companies may simultaneously sell their generic products during the 180-day exclusivity period.

84. Because the FDA granted tentative approval to each of the four first-filing generic companies as of December 16, 2005, Cephalon faced the prospect of imminent competition from four generic competitors and, inevitably, a rapid and substantial decline in the company's Provigil sales and revenues. In 2005, a Cephalon Vice-President responsible for formulating generic strategy predicted 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 stated that such losses would have been devastating.

85. The Generic Defendants had independently reached a similar conclusion. 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.

F. Cephalon Coordinates Agreements to Delay Generic Entry

86. Recognizing that generic competition was imminent and that such competition posed a threat to its Provigil monopoly, Cephalon in the fall of 2005 set out to settle its patent infringement lawsuits with each of the Generic Defendants – before the district court issued a ruling on the pending summary judgment motions.

87. To maintain its monopoly over Provigil, Cephalon had to induce *all* the Generic Defendants to refrain from selling their generic versions of Provigil, because entry by even one generic would quickly take the majority of Cephalon's Provigil sales. Between December 2005

and February 2006, Cephalon coordinated a series of “pay-for-delay” settlement agreements that included nearly identical terms designed to protect its monopoly and permit the Generic Defendants to share Cephalon’s monopoly profits.

88. Each of the agreements included a provision in which Cephalon granted the Generic Defendant a license to sell a generic version of Provigil effective on a “Date Certain,” which was defined as “the latter of: (a) October 6, 2011 (three years prior to the expiration of the Patent in Suit); or (b) in the event Cephalon obtains a pediatric extension on the Patent in Suit, April 6, 2012 (which is three years prior to the expiration of the pediatric extension if obtained.).” Each of the agreements also provided that the Generic Defendant could enter the market earlier than the date certain if: (1) Cephalon licensed any other generic manufacturer to market generic modafinil prior to that date; (2) another generic manufacturer elected to launch “at risk”; or (3) a judgment declared that generic modafinil may be sold without infringing the RE ‘516 Patent. Each settlement culminated in a dismissal of a patent infringement case with prejudice, thereby allowing Cephalon to avoid judicial scrutiny and resolution of the defenses and facts the Generic Defendants had raised and brought to light. Cephalon collectively paid the Generic Defendants (and their designated affiliates) approximately \$300 million as part of the “pay-for-delay” settlement agreements.

89. Cephalon entered into an agreement to settle its patent litigation with Teva on December 8, 2005. Under the agreement, Teva agreed to keep its generic version of Provigil off the market until October 6, 2011 or April 6, 2012, unless another generic manufacturer entered the market before then.

90. The settlement agreement provided significant compensation for Teva in return for its agreement to refrain from entering the market. Cephalon agreed to pay Teva up to \$125

million in royalties based on Cephalon's worldwide sales of Provigil and successor products. Though these payments were purported to be in exchange for a license to a patent and patent applications Teva held relating to modafinil, Cephalon did not need a license to Teva's modafinil-related rights because Cephalon already had all it needed to manufacture and sell Provigil and any successor products. Cephalon also sought to disguise additional payments through a sham supply agreement. Though Cephalon had no need for additional modafinil API, it agreed to purchase 10,000 kg. of modafinil API from Teva at a price between \$500/kg. and \$650/kg. At the time, Cephalon already had an existing API purchase agreement with a company that supplied modafinil API for less than \$200/kg.

91. Pursuant to the settlement agreement, Cephalon paid Teva in excess of \$164 million. The compensation Cephalon agreed to pay Teva was designed to, and did, induce Teva to settle the Provigil patent litigation and agree to refrain from marketing its generic Provigil.

92. On December 22, 2005, Cephalon and Ranbaxy entered into a written agreement to settle their patent litigation. Under the agreement, Ranbaxy agreed to keep its generic version of Provigil off the market until October 6, 2011 or April 6, 2012, unless another generic manufacturer entered the market before then.

93. Cephalon paid more than \$25 million to Ranbaxy, and attempted to disguise part of the payment using a sham supply agreement. Cephalon agreed to purchase 15,000 kg. per year of modafinil API from Ranbaxy for five years and paid between \$325/kg. and \$550/kg. for the product. At the time, Ranbaxy did not manufacture modafinil API itself, but instead sourced the product from a third party. Ranbaxy passed modafinil API on to Cephalon at a mark-up of close to 70 percent. As with Teva, Cephalon paid Ranbaxy at prices substantially higher than it paid its existing supplier of modafinil API.

94. Cephalon also agreed to pay Ranbaxy up to \$5 million in exchange for a license to patent applications Ranbaxy held related to modafinil, even though Cephalon did not need the license to manufacture or sell Provigil or planned successor products. The agreement also provided that Cephalon make a one-time payment of \$2 million to Ranbaxy for avoidance of legal costs related to the Provigil patent infringement litigation.

95. The compensation Cephalon agreed to pay Ranbaxy was designed to, and did, induce Ranbaxy to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil.

96. On January 9, 2006, Cephalon and Mylan entered a written agreement to settle their patent litigation. Under the agreement, Mylan agreed to keep its generic version of Provigil off the market until October 6, 2011 or April 6, 2012, unless another generic manufacturer entered the market before then.

97. Cephalon agreed to enter into supposed product development deals that provided significant guaranteed compensation for Mylan, purportedly based on sales unrelated to modafinil. Significantly, these “product development collaboration agreements” were executed the same day Cephalon and Mylan executed their settlement agreement. Prior to its agreement with Mylan, Cephalon had expressed no interest to Mylan in the technology Mylan contributed to the product development deals. The product development collaboration agreements were a sham to disguise compensation paid from Cephalon to Mylan.

98. Pursuant to the settlement agreement, Cephalon paid Mylan in excess of \$48 million. The compensation Cephalon agreed to pay Mylan was designed to, and did, induce Mylan to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil.

99. On February 1, 2006, Cephalon entered a written settlement agreement with Barr and Barr's partner, ChemAgis, Ltd. ("ChemAgis") (as well as an affiliate of ChemAgis, Perrigo Israel Pharmaceuticals Ltd.) to settle Cephalon's patent litigation with Barr. Under the agreement, Barr agreed to keep its generic version of Provigil off the market until October 6, 2011 or April 6, 2012, unless another generic manufacturer entered the market before then.

100. Pursuant to their agreement, Cephalon agreed to (a) pay Barr \$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; (b) 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 (c) settle unrelated patent litigation on terms favorable to Barr. Cephalon also agreed to make a payment to Barr of \$2 million for avoided litigation costs.

101. Since Barr had developed its generic version of Provigil with its partner, ChemAgis, which supplied modafinil API to Barr, the patent litigation settlement with Cephalon effectively required the assent of both Barr and ChemAgis. To secure Barr's agreement to refrain from marketing generic Provigil, Cephalon also provided significant compensation to ChemAgis.

102. Cephalon agreed to purchase 10,000 kg. of modafinil API per year from ChemAgis for a period of five years. Pursuant to the agreement, even if Cephalon ordered less than 10,000 kg. per year, Cephalon was required to purchase the full amount from ChemAgis. The agreed-upon prices for the modafinil API were between \$400/kg. and \$500/kg. Barr and ChemAgis agreed that Barr would receive fifty percent of all profits arising out of the API supply agreement. Cephalon also paid \$4 million in exchange for a license to a patent and patent

application ChemAgis held related to modafinil. Cephalon did not need the license to manufacture or sell Provigil or planned successor products.

103. Cephalon also entered into a product development deal with ChemAgis in which they 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. All the agreements were negotiated in a series of meetings involving counsel for Cephalon, Barr and ChemAgis.

104. Pursuant to the settlement agreements with Barr, and the related agreements with ChemAgis, Cephalon paid over \$63 million to Barr and ChemAgis. The compensation Cephalon agreed to pay Barr and ChemAgis was designed to, and did, induce Barr to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil.

105. Each Generic Defendant became aware of the existence, purpose, and scope of the deals Cephalon was striking with its fellow Generic Defendants, and each Generic Defendant's agreement was not an isolated deal but part of a larger arrangement among all Defendants to restrain trade.

106. Agreement by all parties was a necessary condition for the success of the arrangement among the Defendants. Absent an understanding that all the Generic Defendants would agree to stay off the market, a lone settling Generic Defendant would run the risk that one or more of its fellow generic competitors would continue to litigate and either prevail and/or enter "at risk" after the 30-month stay (or any exclusivity) had expired. None of the Generic Defendants would agree to stay off the market if there was the possibility that one or more of its

competitors could enter earlier. The settlement agreements coordinated by Cephalon not only guaranteed to each Generic Defendant that no competitor would receive an earlier entry date but also effectively eliminated any incentive for a generic to enter at risk since the other settling Generic Defendants would be able to enter at the same time with a license.

107. The Generic Defendants had a powerful financial interest in accepting Cephalon's money instead of competing with each other. Because all four Generic Defendants filed ANDAs on the same day, all four were to share marketing exclusivity, and all four would compete against each other and drive down the price for generic Provigil, substantially reducing their potential revenues and profits. Entering into non-competition agreements with Cephalon in return for large cash payments permitted the Generic Defendants to share Cephalon's monopoly profits on Provigil without having to enter the market and compete.

108. Absent the Generic Defendants' illegal agreements not to compete with Cephalon for six years or more, each and all of the Generic Defendants would have been motivated to obtain final FDA approval to sell their generic versions of Provigil as soon as possible, and would have begun selling their less expensive versions of Provigil in or after December 2005.

G. Cephalon Uses Delay to Switch the Market from Provigil to Nuvigil

109. Cephalon sought to delay generic entry both to protect its Provigil monopoly and to buy time to permit it to switch purchasers to Nuvigil, a supposed successor product to Provigil, before generic versions of Provigil became available.

110. From 2003 until the first settlements with the Generic Defendants, Cephalon repeatedly announced its intent to: (a) seek prompt FDA approval of Nuvigil; (b) begin selling Nuvigil upon such approval; and (c) convert the market demand for modafinil from Provigil to Nuvigil. Cephalon's plans regarding Nuvigil were well known in the pharmaceutical industry –

and thus were known by the Generic Defendants when they commenced settlement negotiations with Cephalon.

111. After executing its anticompetitive settlement agreements in 2005 and 2006, however, Cephalon changed tactics and decided to defer its launch of Nuvigil for several years while it reaped a windfall from its Provigil monopoly. Cephalon has publicly disclosed its scheme to convert the market from Provigil to Nuvigil. As Cephalon's Vice-President of Investor relations explained, "You should expect that we will likely raise Provigil prices to try to create an incentive for the reimbursers to preferentially move to Nuvigil."

112. Cephalon expected that by the time the Generic Defendants actually launched their generic versions of Provigil in 2012, most Provigil users would have already switched to Nuvigil, which is under patent protection through 2023. Under this plan, any purported pro-competitive "benefit" of Defendants' unlawful "pay-for-delay" agreements (*i.e.*, that they permit the Generic Defendants to launch generic Provigil before the expiration of the RE '516 Patent) would become completely illusory.

H. Cephalon Delays Apotex's Generic Provigil Entry

113. On March 30, 2005, nearly three years after the Generic Defendants submitted their ANDAs, Apotex, Inc. ("Apotex") submitted an ANDA to the FDA seeking approval to market a generic version of Provigil.

114. Apotex's initial ANDA filing included a Paragraph III certification stating that it would not sell its generic version of Provigil until after the expiration of the patents then listed for Provigil in the FDA Orange Book. Although Apotex did not originally file a Paragraph IV certification regarding the RE '516 Patent, it believed it had no reason to do so because four

other generic companies (the four Generic Defendants) were already engaged in litigation concerning the patent.

115. When Apotex learned through various press releases that the Generic Defendants had settled their lawsuits with Cephalon, Apotex changed its certification from a Paragraph III to a Paragraph IV, to specifically state that the RE '516 Patent was invalid and not infringed by Apotex's proposed generic.

116. Although Cephalon received a Paragraph IV certification from Apotex, Cephalon did not sue Apotex under the Hatch-Waxman Act. Cephalon declined to bring suit because it knew that doing so would again put the RE '516 Patent at risk through a finding of invalidity or non-infringement – a risk it had foreclosed through its “pay-for-delay” settlement agreements with the Generic Defendants. And, importantly, by refusing to sue, Cephalon believed (erroneously, as it later discovered) that it could avoid any judicial determination of the invalidity or non-infringement of its patent because Apotex would lack standing to bring a declaratory judgment action.

117. In contrast to its strategy to foreclose entry by the first four generic filers, Cephalon did not need to sue Apotex to prevent Apotex from launching a generic version of Provigil. The Generic Defendants, as the first to file ANDAs with a Paragraph IV certification, shared 180-day marketing exclusivity. As part of the unlawful agreements among the Defendants, all four Generic Defendants agreed not to enter before April 2012, leaving their 180-day exclusivity period in place and thereby blocking final FDA approval and entry of any subsequent generics like Apotex.

118. Defendants' anticompetitive agreements delayed not only the launch of less expensive generic versions of Provigil by the Generic Defendants, but also created a

“bottleneck” that delayed the launch of generic Provigil by Apotex (and any other potential generic ANDA filer) as well.

119. Seeking to remove this bottleneck, on June 26, 2006, Apotex filed a declaratory judgment action in the United States District Court in the Eastern District of Pennsylvania seeking a determination that the RE ‘516 Patent was invalid and/or not infringed by Apotex’s generic version of Provigil.

120. Some five years later, in March and April 2011, a bench trial was held on Apotex’s claims that Cephalon’s RE ‘516 Patent was invalid and unenforceable. The district court declared that the RE ‘516 Patent was invalid because (1) “The invention claimed [by Cephalon] was on sale more than one year prior to the date of the application for the patent, 35 U.S.C. § 102(b); (2) The claimed invention was actually invented by Laboratoire L. Lafon; (3) The subject at issue as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art, 35 U.S.C. § 103(a); and (4) The patent is invalid for failing the written description requirement of 35 U.S.C. § 112.” In addition, the district court specifically found that “Cephalon’s RE ‘516 Patent is unenforceable due to Cephalon’s inequitable conduct in its prosecution of the patent.” *Apotex, Inc. v. Cephalon, Inc.*, Civ. No. 06-cv-2768, 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011), *aff’d*, 500 Fed.Appx. 959 (Fed. Cir. 2013), *cert. denied*, 2013 WL 5565876 (Dec. 16, 2013).

121. The factual findings in the *Apotex* case are binding and conclusive as to Cephalon in this case pursuant to the doctrine of collateral estoppel and establish, at a minimum, that: (a) Cephalon obtained its RE ‘516 Patent based on material misrepresentations and omissions made with a specific intent to deceive the PTO; and (b) Cephalon filed and prosecuted patent infringement litigation against generic companies to enforce the RE ‘516 Patent when it knew

that the patent was invalid and unenforceable as a result of its fraudulent conduct before the PTO.

I. Effects on Competition

122. The purpose and effect of the conduct by Cephalon and the Generic Defendants was to foreclose or severely limit generic competition to brand-name Provigil. By engaging in this scheme with Cephalon, the Generic Defendants did not simply delay their own sales of generic Provigil, but the Defendants collectively took additional steps that had the purpose and effect of blocking and delaying other potential competitors, including Apotex, as well.

123. Defendants' exclusionary conduct delayed, prevented, and impeded the sale of and competition from generic Provigil in the United States, and in Minnesota, and unlawfully enabled Cephalon to sell Provigil at artificially inflated prices. The conduct outlined above was exclusionary and an unreasonable restraint on competition.

124. Absent Defendants' unlawful conduct, at least one generic manufacturer, and likely multiple generic manufacturers, would have entered the market with a less expensive generic version of Provigil in January 2006, resulting in substantially lower prices for purchasers throughout the chain of distribution.

125. As a result of Defendants' illegal conduct, Plaintiff paid for Provigil at prices that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) it was deprived of an opportunity to purchase lower-priced generic Provigil instead of the brand-name Provigil at earlier times; and (2) the price of branded Provigil was artificially inflated by Provigil's illegal conduct. As a consequence, Plaintiff has sustained substantial losses and damage to their respective businesses and property in the form of overcharges paid for Provigil.

126. Had generic manufacturers been able to start selling their less expensive generic versions of Provigil in or about December 2005, as would have occurred absent the Defendants' unlawful conduct, UHS would have paid far less for generic Provigil to meet the same therapeutic needs of UnitedHealthcare Insureds. When generic drugs become available that are therapeutically equivalent to the brand name drugs to which they correspond, UnitedHealthcare Insureds receive coverage for the most cost-effective and clinically appropriate treatment available. In this case, had there been no anticompetitive conduct, this would have translated into UHS paying the vastly lower prices for generic Provigil than the inflated price for brand-name Provigil that was actually paid during the 2006-2012 time period.

J. Effects on Minnesota Trade and Commerce

127. At all material times, Provigil, manufactured and sold by Cephalon, was shipped across state lines and sold to customers outside its state of manufacture. Cephalon, and the Generic Defendants named herein, directed the sale of Provigil, and its AB-rated generic equivalents, throughout the United States and into Minnesota.

128. At all relevant times Plaintiff UHS was responsible for paying for Provigil obtained by UnitedHealthcare Insureds. For example, UHS is a party to agreements with pharmacy benefit managers and other third parties ("PBMs"), pursuant to which UHS is responsible for reimbursing, and makes direct payments to, PBMs for pharmaceutical drugs (including Provigil and equivalent generics) prescribed and dispensed to UnitedHealthcare Insureds throughout the United States. As a result of Defendants' unlawful conduct, third-party payors and other purchasers throughout the United States, and in Minnesota, paid supra-competitive prices for Provigil. UHS received invoices for payment, and made payments of

several hundred million dollars for Provigil, and its AB-rated equivalents, at and from its headquarters in Hennepin County, Minnesota.

129. Defendants' unlawful activities, as described herein, affected the flow of intrastate commerce in Minnesota and had direct, substantial and reasonably foreseeable effects upon trade and commerce within this state.

K. Cephalon's Monopoly Power

130. At all relevant times Cephalon has exercised monopoly power in the United States and in Minnesota with respect to modafinil (*i.e.* Provigil and its AB-rated generic equivalents) because it had the power to maintain the price of Provigil at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Provigil, with the exception of AB-rated generic versions of the drug. Indeed, executives at Cephalon boasted that "Provigil faced no competition."

131. Cephalon needed to control only Provigil and its AB-rated generic equivalents, and no other products, in order to profitably maintain the price of Provigil at supracompetitive levels while preserving all, or virtually all, of its sales. Only the entry of a competing AB-rated generic version of Provigil would render Cephalon unable to maintain its supracompetitive prices without losing substantial sales.

132. Manufacturers like Cephalon attempt to differentiate brand-name drugs like Provigil based on perceived unique features and benefits (including safety and efficacy), and not based on price. Physicians who prescribe drugs such as Provigil do not pay for them (unlike typical products that are both selected and paid for by consumers), and insurers bear much of the cost of the prescriptions.

133. Cephalon sold Provigil well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins. Its gross margins on sales of Provigil were approximately 95 percent. When competitors introduced generic versions of Provigil, in or about April 2012, as permitted by the “pay-for-delay” agreements, the impact was stark and predictable. Approximately six months after generic entry, the generic competitors garnered about two-thirds of the sales from brand-name Provigil and the average market price of modafinil dropped by at least 50 percent.

134. The pharmacological profile for Provigil, and thus its side-effect, abuse and efficacy profile, are significantly different than other drugs such as amphetamines (Adderall XR) and methylphenidate (Ritalin) used to treat similar conditions. These other drugs are not AB-rated to Provigil, cannot be automatically substituted for Provigil by pharmacists, and are not economic substitutes for, nor reasonably interchangeable with, Provigil.

135. Evidence of this monopoly power includes Cephalon’s ability to exclude potential competitors by paying them significant compensation in settlement agreements that delayed their entry to market with competing generic versions of Provigil.

136. Cephalon has had, and exercised, the power to exclude and restrict competition to Provigil and AB-rated generic equivalents.

137. At all relevant times, Provigil enjoyed high barriers to entry with respect to the above-defined relevant market due, in large part, to patent protection, regulatory protection, and high costs of entry and expansion.

138. To the extent that Plaintiff is required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges a relevant market for antitrust

purposes exists for drugs containing modafinil and approved by the FDA that includes Provigil and its AB-rated generic equivalents.

139. The relevant geographical market is the United States, including (but not limited to) Minnesota.

140. Provigil market share during the entire relevant time period was 100%.

CLAIMS FOR RELIEF

COUNT ONE

Violation of Minnesota Antitrust Law – Monopolization (Against Cephalon only)

141. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

142. Cephalon marketed and sold Provigil in Minnesota and nationwide. Any restraint on competition for Provigil necessarily and directly restrained and affected trade and commerce in Minnesota.

143. At all relevant times, Cephalon possessed monopoly power in the relevant market.

144. Through its overarching anticompetitive scheme, as alleged above, Cephalon willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct which included the following: (a) obtaining the RE '516 Patent by intentional fraud on the PTO; (b) improperly listing the '516 Patent in the Orange Book; (c) filing and prosecuting sham litigation against the Generic Defendants seeking to market an AB-rated generic version of Provigil; and (d) entering into anticompetitive “pay-for-delay” settlement agreements with each and/or all of the Generic Defendants to delay entry of competing generic versions of Provigil.

145. The goal, purpose and/or effect of Cephalon’s scheme was to prevent, delay, and/or minimize the success of the entry of competitors that would have sold AB-rated generic

Provigil in the United States and in Minnesota at prices significantly below Cephalon's prices for its brand-name Provigil.

146. But for Cephalon's illegal conduct, one or more competitors would have begun marketing generic versions of Provigil in or about December 2005 and/or would have marketed such versions more successfully than they actually did.

147. As a result of Cephalon's illegal conduct, UHS was compelled to pay, and did pay, artificially inflated prices for Provigil because Cephalon prevented and delayed entry of lower-priced AB-rated generic Provigil and/or the price of branded Provigil was artificially inflated by Cephalon's conduct.

148. UHS has been injured in its business and property by reason of the unlawful conduct alleged herein. As a result of the delay to generic entry caused by Cephalon's conduct, UHS paid more for Provigil than it would have if AB-rated generic Provigil had been available. UHS's economic injury can be determined through an accurate account of its payments for Provigil.

149. Cephalon's scheme harmed competition.

150. There is and was no cognizable, non-pretextual procompetitive justification for Cephalon's actions comprising the anticompetitive scheme alleged herein that outweighs the resulting harmful effects. Even if there were some conceivable justification that Cephalon were permitted to assert, the scheme was broader than necessary to achieve such purpose.

151. Cephalon's conduct was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for Provigil in the United States and in Minnesota, in violation of Minnesota Antitrust Law, Minn. Stat. §§ 325D.49 *et seq.*

COUNT TWO

**Violation of Minnesota Antitrust Law – Attempted Monopolization
(Against Cephalon only)**

152. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

153. Cephalon, through its overarching competitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Cephalon's conscious objective to control prices and/or to exclude competition in the relevant market.

154. The natural and probable consequence of Cephalon's overarching anticompetitive scheme, intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

155. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Cephalon would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

156. As a direct and proximate result of Cephalon's unlawful and monopolistic conduct, UHS has been injured in its business and property.

COUNT THREE

**Violation of Minnesota Antitrust Law –
Contract in Restraint of Trade Among All Defendants Not to Compete
(Against All Defendants)**

157. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

158. Beginning no later than February 1, 2006, Cephalon, Teva, Ranbaxy, Mylan and Barr entered into a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of Provigil in the United States to

Cephalon; (b) prevent the sale of a generic version of Provigil in the United States, thereby protecting Provigil from any generic competition for more than six years; and (c) fix the price for Provigil at a supracompetitive price.

159. By entering into the unlawful agreement, Cephalon, Teva, Ranbaxy, Mylan and Barr unlawfully conspired in restraint of trade and committed a violation of the Minnesota Antitrust Law. Defendants' agreement is a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a *per se* violation of the Minnesota Antitrust Law.

160. In the alternative, Defendants' agreement is an unreasonable restraint of trade when viewed under a rule of reason analysis. The agreement is not reasonably necessary to accomplish any procompetitive objective. Moreover, any potential justification does not outweigh the substantial anticompetitive effect of Defendants' agreement.

161. As a result of Defendants' illegal conduct alleged herein, UHS was compelled to pay, and did pay, artificially inflated prices for Provigil. The prices paid for Provigil were substantially greater than they would have been absent the illegal conduct alleged herein, because: (a) UHS was deprived of the opportunity to pay for lower-priced generic Provigil instead of more expensive brand-name Provigil; and (b) the price of branded Provigil was artificially inflated by Defendants' illegal conduct. UHS has been injured in its business and property by reason of Defendants' unlawful contract, combination or conspiracy.

162. But for the illegal agreements, Teva, Ranbaxy, Mylan and Barr would have begun marketing a generic version of Provigil on or about December 24, 2005 and/or well before the delayed entry date they agreed to.

163. Had Teva, Ranbaxy, Mylan and/or Barr been able to enter the market and fairly compete with Cephalon, UHS would have paid vastly lower prices for AB-rated generic Provigil, rather than the inflated prices actually charged by Cephalon for the brand-name Provigil (and/or the price charged for the brand name Provigil would have plummeted to a level equivalent to the generic price).

164. Cephalon, Teva, Ranbaxy, Mylan and Barr entered into a continuing illegal contract, combination and conspiracy in restraint of trade in violation of the Minnesota Antitrust Law, Minn. Stat. §§ 325D.49 *et seq.*

COUNT FOUR

Violation of Minnesota Antitrust Law – Contract in Restraint of Trade Between Cephalon and Teva Not to Compete (Against Cephalon and Teva)

165. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

166. Beginning no later than December 9, 2005, Cephalon and Teva entered into a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of Provigil in the United States to Cephalon; (b) prevent the sale of a generic version of Provigil in the United States, thereby protecting Provigil from any generic competition for approximately six years; and (c) fix the price for Provigil at a supracompetitive price.

167. By entering into the unlawful agreement, Cephalon and Teva unlawfully conspired in restraint of trade and committed a violation of the Minnesota Antitrust Law. Defendants' agreement is a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a *per se* violation of the Minnesota Antitrust Law.

168. In the alternative, Defendants' agreement is an unreasonable restraint of trade when viewed under a rule of reason analysis. The agreement is not reasonably necessary to accomplish any procompetitive objective. Moreover, any potential justification does not outweigh the substantial anticompetitive effect of Defendants' agreement.

169. As a result of Defendants' illegal conduct alleged herein, UHS was compelled to pay, and did pay, artificially inflated prices for Provigil. The prices paid for Provigil were substantially greater than they would have been absent the illegal conduct alleged herein, because: (a) UHS was deprived of the opportunity to pay for lower-priced generic Provigil instead of more expensive brand-name Provigil; and (b) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

170. UHS has been injured in its business and property by reason of Defendants' unlawful contract, combination or conspiracy.

171. But for the illegal agreement, Teva would have begun marketing a generic version of Provigil on or about December 24, 2005 and/or well before the delayed entry date it agreed to.

172. Had Teva, Ranbaxy, Mylan and/or Barr been able to enter the market and fairly compete with Cephalon, UHS would have paid vastly lower prices for AB-rated generic Provigil, rather than the inflated prices actually charged by Cephalon for the brand-name Provigil (and/or the price charged for the brand name Provigil would have plummeted to a level equivalent to the generic price).

173. Cephalon and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade in violation of the Minnesota Antitrust Law, Minn. Stat. §§ 325D.49 *et seq.*

COUNT FIVE

**Violation of Minnesota Antitrust Law –
Contract in Restraint of Trade Between Cephalon and Ranbaxy Not to Compete
(Against Cephalon and Ranbaxy)**

174. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

175. Beginning no later than December 22, 2005, Cephalon and Ranbaxy entered into a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of Provigil in the United States to Cephalon; (b) prevent the sale of a generic version of Provigil in the United States, thereby protecting Provigil from any generic competition for more than six years; and (c) fix the price for Provigil at the supra-competitive price of brand-name Provigil.

176. By entering into the unlawful agreement, Cephalon and Ranbaxy unlawfully conspired in restraint of trade and committed a violation of the Minnesota Antitrust Law. Defendants' agreement is a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a *per se* violation of the Minnesota Antitrust Law.

177. In the alternative, Defendants' agreement is an unreasonable restraint of trade when viewed under a rule of reason analysis. The agreement is not reasonably necessary to accomplish any procompetitive objective. Moreover, any potential justification does not outweigh the substantial anticompetitive effect of Defendants' agreement.

178. As a result of Defendants' illegal conduct alleged herein, UHS was compelled to pay, and did pay, artificially inflated prices for Provigil. The prices paid for Provigil were substantially greater than they would have been absent the illegal conduct alleged herein, because: (a) UHS was deprived of the opportunity to pay for lower-priced generic Provigil

instead of expensive brand-name Provigil; and (b) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

179. UHS has been injured in its business and property by reason of Defendants' unlawful contract, combination or conspiracy.

180. But for the illegal agreement, Ranbaxy would have begun marketing a generic version of Provigil on or about December 24, 2005 and/or well before the delayed entry date it agreed to.

181. Had Teva, Ranbaxy, Mylan and/or Barr been able to enter the market and fairly compete with Cephalon, UHS would have paid vastly lower prices for AB-rated generic Provigil, rather than the inflated prices actually charged by Cephalon for the brand-name Provigil (and/or the price charged for the brand name Provigil would have plummeted to a level equivalent to the generic price).

182. Cephalon and Ranbaxy engaged in a continuing illegal contract, combination and conspiracy in restraint of trade in violation of Minnesota Antitrust Law, Minn. Stat. §§ 325D.49 *et seq.*

COUNT SIX

Violation of Minnesota Antitrust Law – Contract in Restraint of Trade Between Cephalon and Mylan Not to Compete (Against Cephalon and Mylan)

183. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

184. Beginning no later than January 9, 2006, Cephalon and Mylan entered into a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of Provigil in the United States to Cephalon; (b) prevent the sale of a generic version of Provigil in the United States, thereby protecting Provigil from

any generic competition for more than six years; and (c) fix the price for Provigil at a supracompetitive price.

185. By entering into the unlawful agreement, Cephalon and Mylan unlawfully conspired in restraint of trade and committed a violation of the Minnesota Antitrust Law. Defendants' agreement is a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a *per se* violation of the Minnesota Antitrust Law.

186. In the alternative, Defendants' agreement is an unreasonable restraint of trade when viewed under a rule of reason analysis. The agreement is not reasonably necessary to accomplish any procompetitive objective. Moreover, any potential justification does not outweigh the substantial anticompetitive effect of Defendants' agreement.

187. As a result of Defendants' illegal conduct alleged herein, UHS was compelled to pay, and did pay, artificially inflated prices for Provigil. The prices paid for Provigil were substantially greater than they would have been absent the illegal conduct alleged herein, because: (a) UHS was deprived of the opportunity to pay for lower-priced generic Provigil instead of expensive brand-name Provigil; and (b) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

188. UHS has been injured in its business and property by reason of Defendants' unlawful contract, combination or conspiracy.

189. But for the illegal agreement, Mylan would have begun marketing a generic version of Provigil on or about December 24, 2005 and/or well before the delayed entry date it agreed to.

190. Had Teva, Ranbaxy, Mylan and/or Barr been able to enter the market and fairly compete with Cephalon, UHS would have paid vastly lower prices for AB-rated generic Provigil,

rather than the inflated prices actually charged by Cephalon for the brand-name Provigil (and/or the price charged for the brand name Provigil would have plummeted to a level equivalent to the generic price).

191. Cephalon and Mylan entered into a continuing illegal contract, combination and conspiracy in restraint of trade in violation of the Minnesota Antitrust Law, Minn. Stat. §§ 325D.49 *et seq.*

COUNT SEVEN

**Violation of Minnesota Antitrust Law –
Contract in Restraint of Trade Between Cephalon and Barr Not to Compete
(Against Cephalon and Barr)**

192. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

193. Beginning no later than February 1, 2006, Cephalon and Barr entered into a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate sales of Provigil in the United States to Cephalon; (b) prevent the sale of a generic version of Provigil in the United States, thereby protecting Provigil from any generic competition for more than six years; and (c) fix the price for Provigil at the supracompetitive price.

194. By entering into the unlawful agreement, Cephalon and Barr unlawfully conspired in restraint of trade and committed a violation of the Minnesota Antitrust Law. Defendants' agreement is a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a *per se* violations of the Minnesota Antitrust Law.

195. In the alternative, Defendants' agreement is an unreasonable restraint of trade when viewed under a rule of reason analysis. The agreement is not reasonably necessary to

accomplish any procompetitive objective. Moreover, any potential justification does not outweigh the substantial anticompetitive effect of Defendants' agreement.

196. As a result of Defendants' illegal conduct alleged herein, UHS was compelled to pay, and did pay, artificially inflated prices for Provigil. The prices paid for Provigil were substantially greater than they would have been absent the illegal conduct alleged herein, because: (a) UHS was deprived of the opportunity to pay for lower-priced generic Provigil instead of more expensive brand-name Provigil; and (b) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

197. UHS has been injured in its business and property by reason of Defendants' unlawful contract, combination or conspiracy.

198. But for the illegal agreement, Barr would have begun marketing a generic version of Provigil on or about December 24, 2005 and/or well before the delayed entry date it agreed to.

199. Had Teva, Ranbaxy, Mylan and/or Barr been able to enter the market and fairly compete with Cephalon, UHS would have paid vastly lower prices for AB-rated generic Provigil, rather than the inflated prices actually charged by Cephalon for the brand-name Provigil (and/or the price charged for the brand name Provigil would have plummeted to a level equivalent to the generic price).

200. Cephalon and Barr entered into a continuing illegal contract, combination and conspiracy in restraint of trade in violation of the Minnesota Antitrust Law, Minn. Stat. §§ 325D.49 *et seq.*

COUNT EIGHT

**Unjust Enrichment
(Against All Defendants)**

201. Plaintiff UHS incorporates by reference all the above allegations as if fully set forth herein.

202. Defendants have benefitted from the supracompetitive prices charged for sales of branded Provigil.

203. A part of Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to inflated prices for Provigil made by Plaintiff.

204. Plaintiff has conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges, to the detriment of Plaintiff.

205. The financial benefits derived by Defendants through charging supracompetitive and artificially inflated prices for Provigil are a direct and proximate result of Defendants' unlawful practices.

206. It would be inequitable under unjust enrichment principles for the Defendants to be permitted to retain any of the overcharges for Provigil derived from Defendants' unlawful conduct.

207. As a result of the unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Cephalon has been unjustly enriched, to the detriment of Plaintiff, by the receipt of unlawfully inflated prices and illegal profits on its sales of Provigil.

208. Separately, Cephalon's successor, Teva, has been unjustly enriched, to the detriment of Plaintiff, by the receipt of unlawfully inflated prices and illegal profits on its sales of Provigil. Lastly and separately, Generic Defendants have been unjustly enriched, to the

detriment of Plaintiff, by the receipt of any and all illegal payments made to them by Cephalon to keep generic Provigil off the market.

209. Defendants are aware of and appreciate the benefits conferred upon them by Plaintiff. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them.

210. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff.

211. As this count is asserted in the alternative to those set forth above, Plaintiff has no adequate remedy at law.

212. As successor in interest to Barr and Cephalon, Teva is liable for all unlawful conduct committed by Barr and Cephalon during the relevant period and is liable for all damages that resulted from their unlawful conduct. In addition, Teva is liable for its own unlawful conduct.

213. Therefore, Defendants are liable to Plaintiff for unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays:

A. That the Court adjudge and decree that each contract, combination and conspiracy alleged herein is an unreasonable restraint of trade or otherwise unlawful in violation of Minn. Stat. §§ 325D.49, *et. seq.*;

B. That the Court enter judgment against Defendants, jointly and severally, in favor of Plaintiff;

C. That the Court awards Plaintiff damages, including applicable treble damages;

D. That the Court award Plaintiff attorneys' fees and costs as well as pre-judgment

and post-judgment interest as permitted by law;

E. That the Court award Plaintiff the amount by which Defendants have been unjustly enriched;

F. That Defendants be permanently enjoined and restrained from, in any manner, directly or indirectly, continuing, maintaining or renewing the combination, conspiracy, agreement, understanding or concert of action, or adopting any practice, plan, program or design having a similar purpose or effect in restraining competition; and

G. That the Court award Plaintiff such other and further relief as may be deemed necessary and appropriate.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all claims asserted in this Complaint so triable.

Dated: July 28, 2016

ZELLE LLP

By: s/ Rory D. Zamansky
Rory D. Zamansky (MN Bar #0330620)
500 Washington Avenue South, Suite 4000
Minneapolis, MN 55415
Telephone: (612) 339-2020
rzamansky@zelle.com

Judith A. Zahid
Jonathan M. Watkins
Eric W. Buetzow
ZELLE LLP
44 Montgomery Street, Suite 3400
San Francisco, CA 94104
Telephone: (415) 693-0700
jzahid@zelle.com
jwatkins@zelle.com
ebuetzow@zelle.com

Hamish P. M. Hume
Abby L. Dennis
Kyle Smith

BOIES, SCHILLER & FLEXNER LLP
5301 Wisconsin Avenue NW
Washington, DC 20015
Telephone: (202) 237-2727
hhume@bsfllp.com
adennis@bsfllp.com
ksmith@bsfllp.com

Philip J. Iovieno
BOIES, SCHILLER & FLEXNER LLP
30 South Pearl Street, 11th Floor
Albany, NY 12207
Telephone: (518) 434-0600
piovieno@bsfllp.com

***ATTORNEYS FOR PLAINTIFF UNITED
HEALTHCARE SERVICES, INC.***