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

STATE OF CALIFORNIA, Plaintiff, **v.** **TEVA PHARMACEUTICAL INDUSTRIES, LTD., CEPHALON, INC, BARR LABORATORIES, INC., AND TEVA PHARMACEUTICALS USA, INC.,** Defendants.	**CIVIL ACTION** **Case No.** _____ **JURY TRIAL DEMANDED**

The State of California ("California') by its Attorney General Xavier Becerra, and on behalf of and/or for the benefit of its respective citizens and government agencies, alleges the following unlawful conduct ("Complaint") against defendants Cephalon, Inc., ("Cephalon"), Barr Laboratories, Inc. ("Barr"), Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (both "Teva") (collectively "Defendants").

I.

NATURE OF THE ACTION

1. California seeks damages and equitable relief due to Defendants' unlawful anticompetitive conduct to delay generic competition for Modafinil, a drug indicated for the treatment of certain sleep disorders, including narcolepsy, which was and is sold by Defendant Cephalon under the brand name Provigil®.

2. Provigil was an unexpected "blockbuster" drug, achieving annual sales of more than a billion dollars despite being initially approved by the Food and Drug Administration ("FDA") for a rare "orphan" disease. Provigil was Cephalon's most successful drug, accounting for more than half of its total sales in 2008. Provigil's commercial success invited strong interest from generic

competitors, several of which were expected to obtain FDA approval and launch in 2006. To extend its Provigil monopoly profits beyond its lawful exclusivity period, Cephalon engaged in anticompetitive conduct. Rather than compete on the merits after its FDA-granted exclusivity expired in December 2005, Cephalon took anticompetitive measures to delay generic competition for several years, during which time it continued to reap monopoly profits for Provigil.

3. To delay generic competition, Cephalon knowingly enforced an invalid patent on generic competitors that it obtained due to its material omissions and misrepresentations to the Patent & Trademark Office ("PTO"). Despite knowing that the patent was invalid and fraudulently procured, Cephalon filed patent infringement litigation against each and every company seeking to manufacture generic Provigil. Although the infringement suits were baseless, Cephalon knew that merely initiating patent infringement litigation would significantly delay generic entry.

4. Cephalon was able to further extend its Provigil monopoly profits by settling each of the infringement actions, and including in each settlement an agreement to delay generic entry until no earlier than April 2012. In return for their agreement to delay generic entry, each generic competitor obtained a large and unjustified transfer of consideration. In total, Cephalon compensated generic competitors with consideration valued in excess of $200 million for their agreements to delay generic competition.

5. Cephalon's plan worked. Due to the anticompetitive settlement agreements, generic competition did not commence until April 2012 - giving Cephalon six additional years of monopoly profits. And Cephalon shared a part of these additional profits with the generic competitors in exchange for their agreement to delay the launch of their generic Provigil.

6. Had Defendants competed on the merits and not illegally delayed generic competition until 2012, California and consumers could have purchased less expensive generic versions of Provigil beginning in 2006, saving hundreds of millions of dollars- if not more.

7. Defendants' conduct and actions to delay generic competition was illegal and anticompetitive in violation of the Sherman Antitrust Act and California state competition laws.

II.

JURISDICTION AND VENUE

8. This Complaint alleges violations of Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and seeks equitable relief as well as recovery of damages and injury to consumers under Section 4 of the Clayton Act, 15 U.S.C. § 15, and Section 16 of the Clayton Act, 15 U.S.C. § 26. This Court has jurisdiction over such claims pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 15, 26. The Complaint also alleges violations of California state antitrust and consumer protection laws, including under the Cartwright Act and the Unfair Competition Law, and seeks equitable relief as well as damages under these laws due to injury to California and its consumers resulting from Defendants' unlawful conduct. The Court has supplemental jurisdiction over such claims under 28 U.S.C. §§1332(d) and 1367 because these claims are so related to the federal claims that they form part of the same case or controversy.

9. Venue is proper within this district because Defendants transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III.

THE PARTIES

10. Plaintiff California is a sovereign state and brings this action by and through its Attorney General Xavier Becerra: (a) in its sovereign or quasi-sovereign capacity as representative for the benefit of natural persons and/or as *parens patriae* of natural persons in California under state law; (b) as *parens patriae* in its sovereign capacity to redress injury to California's general economy; (c) in its proprietary capacity based on purchases of Provigil; and/or (d) as the chief law enforcement agency of California, in connection with its role to protect California and its residents from exploitative and anticompetitive conduct as are alleged herein.

11. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli company with its principal executive

offices listed at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Upon information and belief, Teva Pharmaceutical Industries, Ltd is the world's largest generic pharmaceutical company, and markets several branded drugs as well.

12. Defendant Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., is a company incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva Pharmaceuticals USA, Inc. develops, manufactures, and markets pharmaceuticals and related products in the United States, including Provigil. Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. will be collectively referred to herein as "Teva."

13. Defendant Cephalon is a company incorporated under the laws of the State of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon develops, manufactures, and markets pharmaceuticals and related products in the United States, including Provigil. Cephalon has been a wholly owned subsidiary of Teva since October 2011.

14. Defendant Barr is a company incorporated under the laws of the State of New York, with its principal place of business at Two Quaker Road, Pomona, New York 10970. Barr principally develops, manufactures and markets generic versions of brand name drugs. Barr has been a wholly-owned subsidiary of Teva since December 2008.

IV.

FACTUAL BACKGROUND

A. The Governing Regulatory Background

15. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), governs, *inter alia*, the manufacturing, sale, and marketing of pharmaceuticals in the United States. Pursuant to the FDCA, a company seeking to bring a new drug to market must submit a New Drug Application ("NDA") with the Food and Drug Administration ("FDA') and provide scientific data demonstrating that the drug is safe and effective for its intended use. 21 U.S.C § 355(b)(l). The process for filing and obtaining FDA approval of an NDA may be costly and time consuming.

16. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch Waxman Act ("Hatch-Waxman" or 'Act'), which was intended to encourage and facilitate competition from lower-priced generic drugs, while also providing further incentives for pharmaceutical companies to invest in new drug development. By creating benefits and incentives for both generic and branded pharmaceutical manufacturers, the Act reconciles the competing policy goals of rewarding innovation and expediting access to less expensive generic versions of important, but costly, branded drugs.

17. One means by which Hatch-Waxman expedites generic competition is by creating a simplified, quicker, and less costly process for obtaining FDA approval for generic pharmaceuticals. Under the Act, a company seeking to market a generic version of a drug that has already been approved pursuant to an NDA, may obtain FDA approval by filing an Abbreviated New Drug Application ("ANDA") and demonstrating that its generic version is "bioequivalent" to the referenced, approved branded drug.[1] By permitting the generic applicant to rely on studies submitted by the NDA applicant (i.e., the branded drug manufacturer), the Act significantly reduces generic drug development costs and speeds up the FDA approval process for generic drugs.

18. To reward generic competition, the Act grants generic exclusivity to the first ANDA(s) challenging all patents referencing the relevant branded drug. The first approved ANDA(s) are awarded 180 days of exclusivity, during which time FDA may not approve any other ANDA for the same drug. 21 U.S.C. § 355(G)(5)(B)(iv). This is typically referred to as "180-day exclusivity" or "First to File" exclusivity. In the case where multiple companies properly and simultaneously challenge all patents referencing the relevant branded drug, exclusivity can be shared.[2]

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[1] A generic is "bioequivalent" to a branded drug when the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the branded drug, when administered at the same dosage. See 21 C.F.R. §320.l(a).

[2] FDA Guidance for Industry: 180-day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (2003), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/180-day-exclusivity-when-multiple-andas-are-submitted-same-day

19. The Act and the FDCA also encourage innovation by branded drug companies, such as by extending exclusivity for specific efforts, e.g., five years for a new chemical entity, seven years for treating rare diseases, and six months for conducting pediatric studies. As detailed below, Cephalon sought and obtained each of these exclusivity extensions, with the net effect of extending Provigil's exclusivity through December 2005.

20. The Act includes provisions benefitting branded drugs claiming patent protection. Thus, for example, a branded drug manufacturer may obtain up to a five-year patent extension to compensate for lost time caused by the FDA regulatory approval process. 35 U.S.C § 156. In addition, the Act provides an expedited, simplified process for branded manufacturers to assert and resolve patent disputes with generic manufacturers. Under this process, a branded drug manufacturer includes in its NDA a list of all patents that it claims covers the drug for which it seeks approval and "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(l)(G). The FDA then publishes the claimed patents - without any independent review of the patents - in its "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"), which is referenced by generic drug manufacturers.

21. Every generic drug manufacturer seeking FDA approval to market a generic version of a drug already approved by an NDA, must affirmatively disclose in its ANDA the effect of its proposed generic drug on any patents listed in the Orange Book. Specifically, the manufacturer in its ANDA must certify that either: (I) no patent information is listed in the Orange Book for the proposed generic drug; (II) the listed patents have expired; (III) the listed patents will expire before the generic product is marketed; or (IV) the patents listed are invalid or will not be infringed by the generic (referred to as "paragraph IV filings"). 21 U.S.C. § 355 (U)(2)(A)(vii)(I)-(IV).

22. If a branded drug manufacturer files an infringement action within 45 days after receiving notice of a Paragraph IV filing, FDA approval of the ANDA will be delayed. Specifically, in such cases, the FDA must stay its final approval ("Final Approval") of the ANDA until the earliest of: (1) patent expiration, (2) resolution of the patent litigation in favor of the generic company, or (3) the

expiration of an automatic 30-month waiting period.[3]

23. Although the FDA may grant "Tentative Approval" to an ANDA during the 30-month stay when it finds that "the generic drug satisfies the requirements for approval at the time of review, but final approval is blocked by a stay, a marketing exclusivity period, or some other barrier," *AstraZeneca Pharmaceuticals LP v. FDA*, 850 F. Supp. 2d 230,235 (D.D.C. 2012), an ANDA may not launch unless it has Final Approval.

B. Effects and Benefits of Generic Competition

24. Although therapeutically the same as its branded counterpart, the first AB- rated generic equivalent to a branded drug is typically priced significantly lower than the brand.[4] Upon the entry of additional AB-rated generic drugs, generic drug prices fall even more.

25. Because of these price advantages, almost all states and the District of Columbia encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician directs, or the patient requests, otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

26. Many third party payers of prescription drugs (including commercial insurers and state Medicaid programs) have adopted policies to encourage the substitution of AB rated generic drugs for their branded counterparts.

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

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[3] This was altered somewhat by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, but the changes do not apply to the Paragraph IV filings at issue in this litigation.

[4] A generic drug is considered "AB-rated" only if it is therapeutically equivalent (in addition to being bioequivalent) to its branded counterpart. This requires that the generic not only have the same active ingredient, clinical effect and safety profile as the branded drug, but also the same dosage form, strength, and route of administration.

reduction of the branded drugs' unit and dollar sales. Typically, when the branded manufacturer's exclusivity ends and multiple generic versions of the drug enter the market (as would be the case here), a branded drug loses approximately 90% of its market share within a year.

28. Competition from generic drugs generates large savings for consumers. According to a study commissioned by the Generic Pharmaceutical Association, generic drugs saved the U.S. health system $254 billion in 2014 alone, an average savings of nearly $5 billion per week.[5] According to an FDA study examining average retail drug prices between 1999 and 2004, entry of a second generic version of a drug reduced the average generic price to nearly half of the price of the branded drug, and entry of additional generic versions of a drug reduced prices to 20% of the branded price - in other words, an 80% discount.[6]

29. Generic competition allows consumers and agencies in California to purchase AB-rated generic versions of a branded drug at substantially lower prices. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to profitably charge high prices without losing all, or even a substantial portion, of its branded drug sales. Consequently, brand name drug manufacturers have a strong interest to use anticompetitive tactics, such as those alleged, to delay the introduction of generic competition into the market.

C. Provigil and Efforts to Launch Generic Modafinil

30. Provigil promotes wakefulness and is used in the treatment of certain sleep disorders, including narcolepsy and shift work sleep disorder. The active ingredient in Provigil is modafinil.

31. Modafinil is a psychostimulant that enhances wakefulness but its pharmacological profile is significantly different than other drugs used to promote wakefulness, such as amphetamines and methylphenidate. Because of modafinil's unique properties relative to other drugs that promote

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[5] Generic Pharmaceutical Association, Generic Drug Savings in the U.S. (2015), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf

[6] FDA, Generic Competition and Drug Prices (Mar. 1, 2010), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/uc ml29385.htm.

wakefulness, it is considered to be the "gold standard" for the treatment of excessive sleepiness associated with sleep disorders.

32. Modafinil was first discovered by Laboratoire L. Lafon ("Lafon"), a French pharmaceutical company, in 1976. A drug product containing modafinil has been available in France since 1994.

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

34. Cephalon filed an NDA for Provigil in December 1996, and received FDA approval in December 1998. Cephalon commercially launched Provigil in the United States shortly after FDA approval.

35. Cephalon obtained three different types of FDA exclusivities for Provigil. First, because the FDA concluded that modafinil constituted a new chemical entity ("NCE"), Cephalon received NCE exclusivity. Second, Cephalon obtained Orphan Drug exclusivity because Provigil has an FDA-approved indication for narcolepsy, a rare disorder. Due to NCE and Orphan exclusivities, the FDA was prevented from approving a generic until December 24, 2005. In March 2006, after NCE and Orphan exclusivity expired, Cephalon obtained a pediatric extension, granting an additional 180 days of FDA exclusivity, through June 24, 2006.

36. Until it finally faced generic competition in 2012, Provigil was a very profitable drug for Cephalon. Sales and revenues for Provigil grew substantially over the years and until generic entry. In 1999, annual Provigil sales in the U.S. were approximately $25 million. By 2011, however, sales of Provigil exceeded $1 billion, and the drug accounted for more than half of Cephalon's total consolidated net sales.

37. Because of Provigil's commercial success, several generic drug companies filed ANDAs seeking FDA approval to market an AB-rated generic version of Provigil. Specifically, on the same day in December 2002 (the earliest day permitted), Barr Laboratories, Ranbaxy, Teva, and Mylan ("Generic Manufacturers') each filed ANDAs with paragraph IV certifications. As a result, each was expected to share the statutory 180-days of generic exclusivity.

38. On March 28, 2003, Cephalon filed suit in the United States District Court for the District of New

Jersey alleging infringement of its Provigil patent by the Generic Manufacturers.

39. Each of the Generic Manufacturers received Tentative Approval from the FDA for its generic version of Provigil before the drug's Orphan Drug exclusivity expired on December 24, 2005: Barr on January 7, 2004; Ranbaxy on February 18, 2004; Mylan on February 9, 2005; and Teva on December 16, 2005.

40. As detailed further below, absent Defendants' wrongful and exclusionary conduct, each of the Generic Manufacturers would have obtained Final Approval from FDA, and would have begun selling its generic version of Provigil - at prices significantly below the price of brand name Provigil - on or shortly after the expiration of Provigil's Orphan Drug exclusivity on December 24, 2005.

V.

DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. Cephalon Fraudulently Procured a Second Patent For Provigil

41. Cephalon obtained exclusive U.S. rights to modafinil in 1993. The composition patent for modafinil expired in 2001, and Cephalon expected generic competition for Provigil in 2006, once its FDA exclusivity expired.

42. So as to continue obtaining monopoly profits for Provigil after its composition patent expired in 2001, Cephalon submitted a second patent application for Provigil.

43. On October 6, 1994, Cephalon filed United States Application Serial No. 08,319,124 ("the 124 Application") titled "Acetamide Derivative Having Defined Particle Size." The 124 Application narrowly claimed a very specific formulation of modafinil consisting of a specified distribution of small particles, as well as certain uses.

44. Cephalon knew that its patent application would not be granted for several reasons, including that Cephalon was not the inventor and because the claimed invention was not sufficiently novel over prior inventions. And in fact, its application was rejected by the patent examiner.

45. Despite knowing that the claimed invention in the '124 Application was not patentable, Cephalon intentionally made material omissions and misrepresentations to the PTO to overcome the

examiner's rejections so that the patent would issue. Specifically, Cephalon:

- Intentionally misrepresented that it was the inventor, despite knowing that Lafon not only conceived of the invention, but developed, manufactured, and supplied Cephalon with the very embodiment of the invention that was produced to the PTO as a sample of the invention;

- Intentionally failed to disclose that Lafon provided Cephalon with modafinil product that embodied its claimed invention and that Lafon communicated to Cephalon knowledge and technical information about tests that it had previously performed which demonstrated that ground modafinil with smaller particle sizes produced better dissolution rates. This information along with the product sent by Lafon made the claimed invention obvious and thus unpatentable;

- Intentionally failed to disclose that in 1993, Lafon shipped modafinil API and tablets to Cephalon and provided technical information about testing it had done on the benefits of smaller particle sizes. Cephalon made no modification to the product provided by Lafon, but still used it as a sample of an embodiment of its claimed invention to the PTO. Because of this prior disclosure and shipment of modafinil, Cephalon knew that its invention was not patentable because a product embodying all the claims of the invention was the subject of a commercial sale more than one year before the '124 Application was submitted.

46. Because the patent examiner relied on Cephalon's material omissions and misrepresentations, the patent was issued rather than rejected. Specifically, on April 8, 1997, the '124 Application issued as United States Patent No. 5,618,845, subsequently re-issued in 2002 as U.S. Patent No. RE37,516 (collectively referred to as the 'Formulation Patent"). The Formulation Patent expired in April 2014.

47. By obtaining and enforcing the Formulation Patent, Cephalon was able to delay generic competition until well after its Orphan Drug exclusivity expired in December 2005 (and when generic competition was expected).

48. Due to Cephalon's material omissions and misrepresentations before the PTO, the Formulation Patent was found to be invalid and unenforceable. Specifically, on November 7, 2011, this Court ruled that the Formulation Patent was invalid, in part on the following basis:

- Cephalon was not the inventor of the Formulation Patent, in violation of 35 U.S.C. § 102(f);

- An embodiment of all the claims of the invention was subject to a commercial sale and supply agreement between Cephalon and Lafon more than one year before the filing of the patent application (October 6, 1994), in violation of 35 U.S.C. § 102(b);

- The claimed invention was "obvious" under 35 U.S.C. § 103, in light of contemporaneous

knowledge of modafinil's properties and effectiveness in the treatment of narcolepsy prior to 1994; (b) general knowledge on the importance and role of particle size on dissolution rate and bioequivalence; and (c) Cephalon's receipt of modafinil product from Lafon prior to July 1993 along with specific technical information provided by Lafon on the results of its testing on the modafinil product relating to the effects of smaller particle sizes on modafinil solubility and dissolution rate; and

- The patent application "does not specify the particle size of the modafinil post-tableting" and "does not provide sufficient information to allow a person skilled in the art to determine the particle size in the finished pharmaceutical composition as claimed," in violation of 35 U.S.C. § 112.

49. This Court also found in its November 7, 2011 decision that Cephalon made numerous intentional and material omissions and misrepresentations to the PTO "relating to Lafon's substantial role in Cephalon's claimed invention." Specifically, this Court stated:

> "I find that the complete concealment of another company's extensive involvement in the product which is the subject of the claimed invention definitively establishes Cephalon's deception by clear and convincing evidence. Further, in addition to concealing Lafon's role as manufacturer and supplier of the product being claimed in the patent, Cephalon affirmatively told the PTO that it had modified particle size when in fact it had done nothing whatsoever to change, modify or improve the modafinil it received from Lafon."

See Apotex v. Cephalon, 06-cv-2768, 2011 WL 6090696 at* 27 (E.D. Pa. Nov. 7, 2011*), aff'd* 20 I 2-l4 1 7 (Fed. Cir. Apr. 8, 2013).

50. Because this Court found that "but for [Cephalon's] omissions or misrepresentations, the PTO would not have issued the patent," it concluded that Cephalon committed inequitable conduct as a matter of law. Id. at *25-27. The Federal Circuit affirmed this Court's findings of fact and conclusions of law. *Apotex v. Cephalon*, 2013 LEXIS App. (Fed. Cir. 2013).

B. Cephalon Had the Fraudulently Procured Patent Listed in the FDA Orange Book and Filed Sham Litigation Against Generics for the Purpose of Delaying Generic Competition

51. Despite knowing that the Formulation Patent was invalid and only issued because of its own intentional and material omissions and misrepresentations to the PTO, Cephalon nonetheless had the Formulation Patent listed in the Orange Book in connection with Provigil.

52. Pursuant to the Act, a branded drug company must provide the FDA with "the patent number and

the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(l)(G). Because Cephalon knew that the Formulation Patent was invalid and only issued as a result of its intentional and material omissions and misrepresentations to the PTO, it was not a patent "with respect to which a claim of patent infringement could reasonably be asserted' and thus was improperly listed on the Orange Book.

53. Nonetheless, Cephalon intentionally had the fraudulently procured Formulation Patent listed in the Orange Book because it knew that doing so would deter or at least delay competition. First, Cephalon knew that merely listing a patent in the Orange Book might deter a company from attempting to launch a generic before expiration of the Formulation Patent, because pursuant to the Act, in addition to obtaining FDA approval, launching a generic before patent expiration would require submitting a Paragraph IV filing and the likely risk of patent litigation.

54. Second, patent litigation with an ANDA filer seeking to launch an AB-rated generic version of Provigil would almost certainly have delayed generic entry for at least 30 months. Cephalon knew that given the substantial revenues for Provigil, listing of its Formulation Patent in the Orange Book would result in ANDAs submitting Paragraph IV certifications, triggering the 30-month stay of FDA approval upon Cephalon' s timely filing of an infringement action. Cephalon also knew that patent litigation with ANDA filers could delay generic competition for even longer than 30 months because the FDA is not required to grant Final Approval upon expiration of the 30-month stay.

55. And even if the FDA were to grant Final Approval for an ANDA immediately after expiration of the 30-month stay (and during ongoing patent litigation), a generic company may nonetheless decide to delay launching its generic until all patent issues are resolved in its favor, so as to avoid the substantial risk of an injunction and damages for infringement. With appeals, this process could take years to complete. As a result, by merely listing the fraudulently procured Formulation Patent in the Orange Book and enforcing the patent thereafter, Cephalon was able to delay or deter generic

competition for at least 30 months.

56. And Cephalon did in fact file litigation asserting infringement of its fraudulently procured Formulation Patent against all four Generic Manufacturers. Specifically, in March 2003, Cephalon filed sham litigation in the United States District Court for the District of New Jersey alleging that all four Generic Manufacturers infringed the Formulation Patent. Cephalon's suits were a sham because it knew the Formulation Patent was invalid and only issued due to its intentional and material omissions and misrepresentations made before the PTO. Nonetheless, Cephalon filed the infringement actions because it knew that doing so would delay generic competition.

57. Pursuant to the Act, Cephalon's filing of the four infringement actions against Mylan, Teva, Barr, and Ranbaxy triggered the 30-month stay of FDA approval for each of these ANDAs, thereby delaying FDA approval of generic modafinil.

C. Cephalon Pays off Generic Manufactures to Delay Generic Entry Until April 2012

1. Cephalon Knew that its Patent Suits Were Shams and Thus Needed Additional Means of Delaying Generic Competition

58. Despite successfully (and illegally) extending its Provigil monopoly profits, Cephalon realized that generic competition was imminent upon expiration of Provigil's Orphan Drug exclusivity on December 24, 2005.

59. There were several indications before December 2005 that generic competition was imminent. First, there was no regulatory bar preventing the FDA from approving generic modafinil after December 2005. The statutory 30-month stays of FDA approval for the Generics Manufacturers (triggered by the filing of the sham litigations), as well as FDA exclusivities that Cephalon obtained for Provigil, all expired by December 2005.[7] Thus, the FDA could have approved any or all of the ANDAs shortly after December 2005 - and such approval was likely given that each ANDA had received Tentative Approval from the FDA by the end of 2005. Second, Cephalon knew that its

[7] Although Cephalon received an additional 180 days of pediatric exclusivity on March 28, 2006, this would not have any effect on a generic that was approved and launched before that date.

Formulation Patent was invalid, and as a consequence, that it would likely lose its sham patent litigation. Third, even if the Formulation Patent were somehow valid and enforceable, there was still a significant likelihood that one or more ANDAs would not infringe the patent given its narrow claims, which covered only a single formulation of modafinil. Indeed, a subsequent ANDA filed by Apotex was in fact found not to infringe the Formulation Patent. *See Apotex v. Cephalon*, 06-cv-2768 (E.D. Pa. March 28, 2012).

60. In November 2005, Cephalon's management was so convinced that generic competition was imminent, that Cephalon informed the investment community that it projected a substantial reduction of Provigil sales in 2006 due to expected generic competition.

61. To delay the imminent generic competition for Provigil, Cephalon began negotiating settlements of the patent suits with the Generic Manufacturers in 2005. Cephalon's primary goal in these negotiations was to delay generic competition for Provigil for as long as possible.

62. Because Cephalon's patent infringement claims against the Generic Manufacturers were weak, Cephalon realized that the Generic Manufacturers would have to receive substantial value in order to induce them to forego their expected profits from sales of generic Provigil after Cephalon's exclusivity expired.

63. Moreover, to protect and maintain its monopoly profits in the modafinil market, Cephalon would have to induce each and every of the Generic Manufacturers to refrain from selling their generic versions of Provigil, because as a result of generic substitution laws and practices, *the entry of even a single generic product would quickly cause the majority of modafinil purchases to switch* from Cephalon 's branded Provigil to the substantially less expensive - but bioequivalent - generic modafinil.

64. By early 2006, Cephalon settled all patent litigation with the four Generic Manufacturers. Each settlement included exclusionary large and unjustified "reverse" payments and side-deal transfers of consideration. The side-deals, while often in separate contracts, were not independent business transactions, but were instead inextricably linked with the agreed-upon delayed generic entry date.

65. Cephalon provided an additional incentive to each of the four Generic Manufacturers to settle, by including an acceleration clause in each settlement and by publicizing that provision of each settlement. The clause allowed for accelerated entry by each of the Generic Manufacturers in the event that another generic company entered the market. The clause made continued litigation or launching-at-risk less attractive for each successive Generic Manufacturer because it would automatically permit each Generic Manufacturer to launch upon entry of any other generic competitor thereby driving down the price of AB-rated generic version(s) of Provigil. The purpose and effect of Cephalon's agreements with the Generic Manufactures was to maintain Cephalon's Provigil monopoly and eliminate potential generic competition to Provigil until April 2012.

2. Cephalon's Anticompetitive Settlement with Teva

66. On December 8, 2005, Cephalon and Teva agreed to settle their patent litigation. Under this settlement, Teva agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date - in which case Teva also would be allowed to enter at that time. Cephalon and Teva publicized this accelerated entry agreement provision in press releases announcing the settlement.

67. The settlement agreement provided Teva with substantial compensation for its agreed-to delayed launch of generic Provigil. Specifically, Cephalon agreed to pay Teva up to $125 million in royalties based on Cephalon's worldwide sales of Provigil and successor products. Purportedly, these payments were made in exchange for a license to a patent and patent application Teva held relating to modafinil. However, Cephalon did not need - and had no interest in licensing Teva's modafinil-related patent rights. Cephalon also agreed to purchase active pharmaceutical ingredient ("API") for Provigil from Teva at prices substantially higher than the price Cephalon paid to its existing supplier. The patent license and higher prices that Cephalon paid Teva for the API were merely means by which Cephalon attempted to hide its exclusionary payment to Teva. The compensation that Cephalon agreed to provide Teva was designed to, and did, induce Teva to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

3. Cephalon's Anticompetitive Settlement with Ranbaxy

68. On December 22, 2005, Cephalon and Ranbaxy settled their patent litigation. Under this settlement, Ranbaxy agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

69. As with Teva, Ranbaxy would not agree to refrain from launching generic Provigil until after April 2012 unless it received substantial compensation. As with Teva, Cephalon agreed to provide Ranbaxy this compensation in the form of an API supply agreement and a license to a patent that Ranbaxy held for modafinil. The exclusionary payments to Ranbaxy were even more pretextual than Teva' s since Ranbaxy did not (and does not) even manufacture modafinil API itself, but rather purchases it from a third party. However, the API agreement allowed Teva to compensate Ranbaxy by selling the API at an agreed-to substantial markup. Similarly, the $5 million fee that Cephalon agreed to pay to license Ranbaxy's modafinil patents was clearly pretextual, as Cephalon did not need such a license. The compensation that Cephalon agreed to provide Ranbaxy under the settlement was designed to, and did induce, Ranbaxy to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

4. Cephalon's Anticompetitive Settlement with Mylan

70. On January 9, 2006, Cephalon and Mylan settled their patent litigation. Pursuant to the settlement, Mylan agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

71. As with Teva and Ranbaxy, Mylan required significant compensation in exchange for an agreement to refrain from competing until April 2012. To hide its exclusionary payment to Mylan, Cephalon entered into simultaneous product development deals with Mylan that provided Mylan a guaranteed minimum of at least $45 million. Prior to its agreement with Mylan, Cephalon had not sought the technology that Mylan contributed to the product development deals. Rather, the agreement and corresponding compensation provided by Cephalon to Mylan was designed to, and did, induce Mylan to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil

until after April 2012.

5. Cephalon's Anticompetitive Settlement with Barr

72. On February 1, 2006, Cephalon settled patent litigation with Barr and Barr's partner, Chemagis, Ltd. (together with its affiliates, "Chemagis"). Under the settlement, Barr agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

73. As with the other Generic Manufacturers, Barr was unwilling to refrain from marketing generic Provigil until April 2012 absent substantial compensation. To satisfy Barr and Chemagis, and mask its exclusionary payments to them, Cephalon agreed to the following:(1) paying Barr $1 million for a license to a patent application that Barr held related to modafinil; (2) purchasing modafinil API directly from Chemagis (and indirectly from Barr via Barr's profit-sharing arrangement with Chemagis) at high markup prices; (3) paying Chemagis $4 million in exchange for a license to a patent and patent application that Chemagis held related to modafinil; and (4) paying Chemagis at least $20 million for two product development collaborations. The patent licenses and side-deals were merely means by which Cephalon attempted to hide its exclusionary transfers of payment to Barr and Chemagis. The compensation Cephalon agreed to provide Barr and Chemagis was designed to, and did, induce Barr and Chemagis to settle the Provigil patent litigation and agree to refrain from launching generic Provigil until after April 2012.

D. The Effects of Cephalon's Anticompetitive Agreements

74. Cephalon's settlement agreements with the Generic Manufacturers successfully delayed generic entry until April 2012, providing Cephalon with approximately six years of unlawful additional monopoly profits at the expense of purchasers of Provigil - including California and its consumers. Indeed, settling the patent litigation with the Generic Manufacturers ensured that the anticompetitive effects were widespread, since a finding of invalidity of the Formulation Patent would have removed the patent as a barrier to generic entry for all (not just for the Generic Manufacturers).

75. The anticompetitive effects of the settlements were exacerbated due to their "bottleneck' feature, preventing any company - not just the Generic Manufacturers - from launching generic modafinil until April 2012. Because the Generic Manufacturers collectively shared First to File exclusivity, the FDA was barred from approving any other generic version of Provigil until the 180-day exclusivity period expired. And only the commercial marketing of generic Provigil by at least one of the Generic Manufacturers or an appeals court decision declaring the Formulation Patent invalid or not infringed would trigger the 180-day exclusivity period. Cephalon's settlements with all the Generic Manufacturers - all of which agreed not to launch prior to April 2012 - thus ensured that the 180-day exclusivity would not be triggered until April 2012.

76. Finally, the breadth of the agreements also evinces their anticompetitive effects. Two of the settling Generic Manufacturers (Teva and Mylan) agreed not to develop, market, or sell generic versions of Provigil, but also agreed not to develop, market or sell generic equivalents of *successor products*. Similarly, the remaining settling Generic Manufacturers agreed to not sell generic products *whether or not they infringed the Formulation Patent.* In contrast, Cephalon's patent infringement suits had the potential to restrict only sales of the Generic Manufacturers' proposed versions of generic Provigil (i.e. the version disclosed in their ANDAs to which the FDA gave Tentative Approval).

77. By entering into broad settlement agreements that well exceeded the Formulation Patent's exclusionary rights and restricted Generic Manufacturers' ability to launch non infringing, competing modafinil products, Cephalon was able to stifle competition for generic modafinil and harm California and its employers, payors and consumers who paid for or purchased Provigil for many years.

VI.

CEPHALON'S CONDUCT HARMED COMPETITION, CONSUMERS AND CALIFORNIA

78. Cephalon's enforcement of an invalid and fraudulently procured patent for Provigil created barriers to generic entry that were certain to deter and/or delay generic competition to Provigil. Cephalon

misused the very provisions of the Hatch-Waxman Act that were intended to encourage generic competition to instead delay it. Cephalon listed its fraudulently procured Formulation Patent in the Orange Book, knowing that it would likely deter generic entry. Thereafter, Cephalon filed suit against the Generic Manufacturers, with the understanding and intent that its sham litigation would delay generic completion due to misusing the Act's 30-month stay of FDA approval for generics.

79. In order to favorably end its sham litigation, Cephalon negotiated settlements with each and all of the Generic Manufacturers so as to protect its invalid patent and ensure delayed generic entry. Cephalon realized that because the Generic Manufacturers collectively shared the 180-day generic exclusivity, it would have to settle with each to effectively delay generic entry. Thus, by means of four separate settlements with each of the Generic Manufacturers, Cephalon was able to successfully delay generic competition for nearly six years, until April 2012.

80. And Cephalon's anticompetitive settlement agreements prevented the possibility of generic competition from any source, not just the settling Generic Manufacturers. As the Generic Manufacturers collectively shared the 180-day generic exclusivity, the settlements ensured that the 180-day generic exclusivity was not triggered until April 2012, preventing any possibility of generic competition from any source until at least then. After these agreements and after Cephalon's acquisition by Teva, Teva and Cephalon sought and obtained a FDA ruling that Teva was the sole holder of the first-to-file designation, thus precluding Mylan and Ranbaxy from launching in April 2012.

81. Entry of generic Provigil would have given California, and its employers, payors and consumers the choice between branded Provigil and lower-priced generic modafinil. Indeed, generic entry in early 2006 (as expected) would have quickly and significantly reduced Cephalon's sales of Provigil and led to a significant reduction in the average price that purchasers would have paid for generic Provigil. California and its employers, payors and consumers would have saved hundreds of millions of dollars (or more) by purchasing generic versions of Provigil. Instead, via its anticompetitive conduct Cephalon was able to retain those potential savings for itself (as well as

use some to compensate the Generic Manufacturers for their agreement to delay launching generic Provigil).

82. Cephalon used various provisions of the Act to benefit itself, such as receiving extended exclusivity for Provigil. When these benefits were exhausted, Cephalon subverted other benefits of the Act - such as allowing California and its employers, payors and consumers to enjoy the full benefits of generic competition. Cephalon listed its fraudulently procured Formulation Patent in the Orange Book, filed sham litigation against the Generic Manufacturers, and entered into anticompetitive settlement agreements. As a result, Cephalon obtained an additional six years of monopoly protection for Provigil. Through its scheme to prevent generic competition, Cephalon abused the Act's regulatory structure and violated the antitrust law at the expense of California and its employers, payors and consumers, who were denied the full benefits of generic competition as a consequence of Cephalon's actions.

83. As purchasers and payors of Provigil, California and its employers, payors, and consumers were harmed by Cephalon's anticompetitive conduct. Rather than having the option of buying less expensive generic modafinil, California and its employers, payors and consumers were forced to pay monopoly prices for Provigil for several additional years. As a result, California and its employers, payors and consumers spent hundreds of millions of dollars more than they should have to purchase Provigil and Nuvigil, and to enrich Defendants.

VII.

CEPHALON'S MONOPOLY POWER

84. Cephalon has exercised monopoly power in California and the United States with respect to Provigil. Direct evidence of this monopoly power includes Cephalon's ability to price Provigil substantially higher than the projected price of competing generic versions of Provigil and to exclude potential competitors by providing substantial compensation to delay competition.

85. Modafinil is its own relevant market. Although other drugs may be used to treat narcolepsy and the other sleep disorders for which Provigil is indicated or prescribed, these drugs are distinct and thus

their availability was not sufficient to prevent the anticompetitive effects of Defendants' anticompetitive conduct to delay generic modafinil. Cephalon held a 100 percent share of the relevant market until April 2012.

86. All conditions precedent necessary to the filing of this action have been fulfilled, waived or excused.

COUNT I

Monopolization in Violation of Section 2 of the Sherman Act
(Against Cephalon Only)

87. California repeats, and incorporates by reference, every preceding allegation above.

88. Cephalon's enforcement of a fraudulently procured patent violated Section 2 of the Sherman Act.

89. Despite knowing that the Formulation Patent was invalid and only issued due to its material misrepresentations and omissions to the PTO, Cephalon used it to maintain its modafinil monopoly after expiration of Orphan Drug exclusivity, when it expected generic entry and corresponding loss of Provigil profits.

90. By listing its fraudulently procured patent in the Orange Book and thereafter filing sham patent litigation against the Generic Manufacturers, Cephalon misused the Act's provision for the sole purpose of delaying generic competition.

91. As a result of Cephalon's enforcement of its fraudulently procured patent, generic competition was delayed by several years, forcing California and consumers to pay more than they would have paid for modafinil absent Cephalon's illegal conduct. But for Cephalon's illegal conduct, competitors would have begun marketing generic versions of Provigil well before they actually did, and/or would have been able to market such versions more successfully.

92. If manufacturers of generic modafinil entered the market and competed with Cephalon in a full and timely fashion, California and its payors, employers and consumers would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil

purchases.

93. During the relevant time period, California and its employers, payors and consumers purchased substantial amounts of Provigil and its successor formulation that Cephalon launched in the delay period as Nuvigil (together "Provigil"). As a result of Cephalon's enforcement of its fraudulently procured patent, California and its employers, payors and its consumers were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements during the delay period.

94. Cephalon's enforcement of its fraudulently procured Formulation Patent had the purpose and effect of delaying generic competition and constitutes monopolization of the market for modafinil in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

COUNT II

Restraint of Trade in Violation of Section 1 of the Sherman Act

95. California repeats and incorporates by reference every preceding allegation above.

96. Beginning on or about December 9, 2005, Cephalon and each of the Generic Manufacturers entered into contracts in restraint of trade, the purpose and effect of which was to prevent the sale of generic versions of modafinil in California and the United States until April 2012, thereby protecting Provigil from any generic competition for nearly 6 years.

97. By entering into these exclusionary contracts, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' agreements are anticompetitive agreements between actual or potential competitors, in violation of Section 1.

98. California and its employers, payors and consumers have been injured in their business and property by reason of Defendants' unlawful agreements. California and its employers, payors and consumers have paid more for their purchases of Provigil than they would have paid absent Defendants' illegal agreements and were prevented from substituting a cheaper generic for their purchases of the more expensive Provigil.

99. As a result of Defendants' anticompetitive agreements, California and its employers, payors and consumers paid more than they would have paid for modafinil, absent Defendants' illegal conduct. But for Defendants' unlawful agreements, generic competition for Provigil would have begun well before April 2012.

100. Had manufacturers of generic modafinil entered the market and competed with Cephalon in a full and timely fashion, California and its employers, plans and consumers would have substituted lower priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

COUNT III

FOR RESTRAINT OF TRADE IN VIOLATION OF THE CARTWRIGHT ACT, BUSINESS & PROFESSIONS CODE SECTION 16720

101. California incorporates by reference, and alleges as if fully set forth herein, every preceding allegation above.

102. Beginning on or about December 9, 2005, Cephalon entered into separate contracts in restraint of trade with each of the Generic Manufacturers. The purpose and effect of these contracts in restraint of trade was to prevent and/or delay the sale of generic versions of modafinil in California until April 2012 and thereafter, thereby protecting Provigil from any generic competition for nearly 6 years. By entering into these exclusionary contracts, Cephalon entered into and engaged in a continuing unlawful trust with each of the Generic Manufacturers for the purpose of unreasonably restraining trade in violation of section 16720 of the Business and Professional Code.

103. The violations of section 16720 of the Business and Professions Code, consisted, without limitation, of a continuing unlawful trust and concert of action among Cephalon and each of the Generic Manufacturers, the substantial terms of which were to fix, raise, maintain and/or stabilize the prices of Provigil/modafinil by avoiding generic competition. The specific elements of Defendants' trust and concert of action included:

a. creating restrictions in the trade and commerce of Provigil/modafinil;
b. limiting the production and increasing the price of Provigil/modafinil;
c. preventing competition in the manufacturing and sale of Provigil/modafinil;
d. entering into agreements that had the intent and effect of keeping the price of Provigil/modafinil at an elevated and supracompetitive amount.

104. For the purpose of forming and effectuating the unlawful trust, Cephalon conspired with each of the Generic Manufactures to:

a. fix, raise, maintain, and stabilize the price of Provigil by avoiding generic competition;
b. allocate the market for Provigil/modafinil solely to Cephalon in exchange for sharing a portion of monopoly profits from Cephalon to each of the Generic Manufacturers;
c. file sham patents to prevent generic competition; and
d. participate in sham lawsuits and enter into sham settlements to prevent generic competition.

105. The combination and conspiracies alleged herein have had, *inter alia*, the following effects during the Relevant Period:

a. price competition in the sale of Provigil/modafinil was restrained, suppressed and/or eliminated in the State of California;
b. prices for Provigil/modafinil sold by Cephalon in the State of California were fixed, raised, maintained, and/or stabilized at artificially high, supracompetitive levels in the State of California; and
c. those businesses, government entities, organizations, and consumers who purchased Provigil/modafinil have been deprived of the benefit of free and open competition.

106. As a direct and proximate result of Defendants' unlawful conduct, California businesses, government entities, employers, payors, organizations, and consumers have paid more for Provigil than they would have paid absent Cephalon's illegal agreements with the Generic Manufacturers, and were prevented from substituting a cheaper generic for the more expensive Provigil. But for Cephalon's unlawful agreements with the Generic Manufacturers, generic competition for Provigil would have begun well before April 2012.

107. Californians conferred upon Cephalon an economic benefit, in the nature of anti-competitive profits resulting from unlawful overcharges. Cephalon's financial benefits resulting from its unlawful and inequitable conduct are economically traceable to overpayments for Provigil by California businesses, government entities, employers, payors, organizations, and consumers.

108. The economic benefit of overcharges and unlawful monopoly profits derived by Cephalon from charging supra-competitive and artificially inflated prices for Provigil is a direct and proximate result of Defendants' unlawful practices.

109. It would be inequitable and unjust for Defendants to be permitted to retain any of the unlawful proceeds resulting from their fraudulent, illegal, and inequitable conduct.

110. As a result of Defendants' violations of section 16720 of the Business and Professions Code, the State of California seeks equitable remedies in the forms of injunctive relief and disgorgement.

111. Pursuant to Business and Professions Code, section 16754.5, California seeks injunctive relief to deter Defendants from, and insure against, future violations of the Cartwright Act, including—but not limited to—a prohibition on any future filings of sham patents and a prohibition on any future payments or transfers to generic manufacturers in exchange for the generic manufacturer's agreement to delay or not to research, develop, manufacture, market or sell any drug.

112. Cephalon has been unjustly enriched as a result of its wrongful conduct. The State of California is accordingly entitled to the relief of disgorgement. Pursuant to the Court's equitable powers, California seeks disgorgement of all retained revenues, earnings, profits, compensation and benefits which may have been obtained by Cephalon within the United States as a result of business practices in violation of the Cartwright Act.

COUNT IV

For Violation of the Unfair Competition Law Business & Professions Code Section 17200

113. California incorporates by reference and alleges as if fully set forth herein, every preceding allegation above.

114. Beginning on or about October 1994, Defendants committed acts of unfair competition, as defined by sections 17200, *et seq*., of the Business and Professions Code (the Unfair Competition Law).

115. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants, as alleged herein, constituted a common continuous and continuing course of conduct of unfair competition

by means of unfair, unlawful and/or fraudulent business acts or practices within the meaning of Business and Professions Code, section 17200, *et seq*., including, but not limited to, the following:

a. The violations of section 16720, *et seq*., of the Business and Professions Code, set forth above in the First Cause of Action, thus constituting unlawful acts within the meaning of section 17200 of the Business and Professions Code;
b. Defendants' acts, omissions, misrepresentations, practices and nondisclosures, as described above, whether or not in violation of Section 16720, *et seq.*, of the Business and Professions Code, and whether or not concerted or independent acts, are otherwise unfair, unconscionable, unlawful or fraudulent;
c. Defendants' acts and practices are unfair to consumers of Provigil/modafinil in the State of California, within the meaning of section 17200 of the Business and Professions Code; and/or
d. Defendants' acts and practices are fraudulent or deceptive within the meaning of section 17200 of the Business and Professions Code.

116. The unlawful and unfair business practices of Defendants, as described above, caused Californian businesses, government entities, organizations, and consumers to pay supra-competitive and artificially-inflated prices for Provigil/modafinil. These Californians suffered injury in fact and lost money and/or property as a result of such unfair competition.

117. As alleged in this Complaint, Defendants have been unjustly enriched as a result of their wrongful conduct and by Defendants' acts of unfair competition. The State of California is accordingly entitled to equitable relief - including restitution and disgorgement of illegally obtained profits which may have been obtained by Defendants as a result of such business practices - pursuant to the Business and Professions Code, sections 17203 and 17204. The State of California is also entitled to civil penalties to the maximum extent permitted by law pursuant to Business and Professions Code, Section 17206, *et seq*., in the amount of $2,500 for each individual sale, prescription, or transaction of Provigil during the Relevant Period, with an additional penalty of $2,500 for each individual sale, prescription, or transaction of Provigil that involves a senior citizen or disabled person, pursuant to section 17206.1 of the Business and Professions Code.

COUNT V

For Violation of the Unfair Competition Law
Business & Professions Code Section 17200
(Fraud on PTO against Cephalon)

118. California incorporates by reference and alleges as if fully set forth herein, every preceding allegation above.

119. Cephalon made material misrepresentations and failed to disclose information material to patentability, in violation of 37 C.F.R. 1.56.

120. Cephalon's material misrepresentations and omissions to the PTO were committed with the specific intent to deceive the PTO and did deceive the PTO into issuing a patent to Cephalon.

121. Cephalon's conduct constitutes unlawful, unfair, and fraudulent practices within the meaning of section 17200 of the Business and Professions Code.

COUNT VI

For Violation of the Unfair Competition Law
Business & Professions Code Section 17200
(Improper Listing in Orange Book Against Cephalon)

122. California incorporates by reference and alleges as if fully set forth herein every preceding allegation set forth above.

123. Cephalon requested that the RE '516 Patent be listed in the Orange Book for Provigil, despite knowing that the patent was procured by fraud on the PTO and thus could not be a valid or enforceable patent covering Provigil.

124. Cephalon's conduct violated 21 USC Section 355(b)(1), (c)(2). The FDA justifiably relied on Cephalon's representation that the '516 patent covered Provigil. But for Cephalon's false statements to the FDA, the FDA would not have listed the RE '516patent in the Orange Book.

125. Cephalon's conduct constitutes unlawful, unfair, and fraudulent practices within the meaning of section 17200 of the Business and Professions Code.

COUNT VII

For Violation of the Unfair Competition Law Business & Professions Code Section 17200 By Enforcing a Fraudulent Patent Through Sham Litigation against Cephalon

126. California incorporates by reference and alleges as if fully set forth herein, every preceding allegation set forth above.

127. Cephalon procured the RE '516 Patent through knowing and willful fraud.

128. At the time Cephalon initiated patent infringement suits against the Generic Manufacturers regarding the RE '516 Patent, and at all relevant times thereafter, Cephalon knew that the patent was invalid and unenforceable.

129. The patent infringement suits initiated by Cephalon automatically triggered a 30-month stay, stalling the Generic Manufacturers' ANDA filings at the FDA and created a "bottleneck" wherein no other manufacturers could obtain approval for generic modafinil.

130. Cephalon's fraudulent procurement and sham litigation of the RE '516 Patent prevented generic competitors from entering the relevant market.

131. Cephalon's prevention of generic competitors willfully and illegally maintained Cephalon's monopoly over the relevant market.

132. Cephalon's conduct constitutes unlawful monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, thus constituting unlawful acts within the meaning of section 17200 of the Business and Professions Code.

PRAYER FOR RELIEF

WHEREFORE, California prays for judgment against Defendants as follows:

133. That judgment be entered in favor of California and against Defendants;

134. Adjudge and decree that Defendants all violated Section 1 of the Sherman Act by entering into anticompetitive agreements;

135. Adjudge and decree that Defendant Cephalon violated Section 2 of the Sherman Act by engaging in anticompetitive conduct that delayed and impaired generic competition, including enforcing a

fraudulently procured patent;

136. That the Court adjudge and decree that Defendants' contracts, conspiracies, and/or combinations alleged hereinabove constituted illegal restraints of trade in violation of the Cartwright Act, section 16720, *et seq.*, of the Business & Professions Code;

137. That the Court adjudge and decree that Defendants' contracts, conspiracies, and/or combinations violated the Unfair Competition Law, section 17200, *et seq.* of the Business & Professions Code;

138. That the Court adjudge and decree that Cephalon's procurement of the Formulation Patent through fraud on the PTO violated the Unfair Competition Law, section 17200, *et seq.* of the Business & Professions Code;

139. That the Court adjudge and decree that Cephalon's listing of the fraudulently procured Formulation Patent in the Orange Book violated the Unfair Competition Law, section 17200, *et seq.* of the Business & Professions Code;

140. That the Court adjudge and decree that Cephalon's commencement and maintenance of its infringement actions against the Generic Manufacturers violated the Unfair Competition Law, section 17200, *et seq.* of the Business & Professions Code;

141. That Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf be permanently enjoined and restrained from establishing any similar agreements, trusts, or other arrangements in violation of the laws of the State of California, pursuant to Business & Professions Code, section 16754.5, including being subject to proactive measures necessary to restore competition;

142. That Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf be permanently enjoined from committing any acts of unfair competition or false advertising as defined in Business and Professions Code, sections 17200 and 17500, respectively, including, but not limited to, the acts and practices alleged in this Complaint;

143. That the Court make such orders or judgments as may be necessary to prevent the use or employment by any Defendant of any practice that constitutes unfair competition, under the authority of Business and Professions Code section 17203, respectively;

144. That Defendants be ordered to disgorge all retained revenues, earnings, profits, compensation and benefits which may have been obtained as a result of business practices in violation of the Sherman Act, the Cartwright Act, and/or the Unfair Competition Law;

145. That California be awarded the deadweight loss (i.e., the general harm to the economy of the State of California) resulting from Defendants' illegal activities;

146. That California be awarded pre- and post-judgment interest on any monetary award, and that the interest be awarded at the highest legal rate from and after the date of service of the initial complaint in this action;

147. That California be awarded civil penalties against each Defendant, pursuant to Business and Professions Code, section 17206 in the dollar amount of two thousand five hundred dollars ($2,500) for each violation of the Unfair Competition Law by Defendants' anticompetitive conduct as set forth in this Complaint, in an amount according to proof;

148. That in addition to any penalties assessed under Business and Professions Code, sections 17206, that the Court assess another civil penalty of two thousand five hundred dollars ($2,500) against each Defendant for each violation of Business and Professions Code, section 17200 perpetrated against a senior citizen or disabled person, in an amount according to proof, under the authority of Business and Professions Code, section 17206.1;

149. That California be awarded the costs of this action, including costs of investigation, and reasonable attorneys' fees; and

150. That California be awarded such other relief as the Court may deem just and proper.

JURY TRIAL DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: July 29, 2019

Respectfully submitted,

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*Application for Pro Hac Vice pending
**Application for Pro Hac Vice anticipated to be filed in August

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