IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. Plaintiff, v. ACTAVIS LABORATORIES FL, INC., ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., and WATSON LABORATORIES, INC., Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Cephalon, Inc. ("Cephalon" or "Plaintiff") for its complaint against Actavis Laboratories FL, Inc., Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Defendants"), to the best of its knowledge, information and belief, hereby alleges as follows:

THE PARTIES

1. Plaintiff Cephalon, Inc. is a Delaware corporation having a principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

2. On information and belief, Defendant Actavis Laboratories FL, Inc. is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

3. On information and belief, Defendant Actavis Laboratories FL, Inc. is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States.

4. On information and belief, Defendant Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.) is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

5. On information and belief, Defendant Actavis, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products in the State of Delaware and throughout the United States, including some that are manufactured by Actavis Laboratories FL, Inc.

6. On information and belief, Defendant Actavis Laboratories FL, Inc. is a wholly-owned subsidiary of Actavis, Inc.

7. On information and belief, Defendant Actavis Pharma, Inc. (formerly known as Watson Pharma, Inc.) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

8. On information and belief, Defendant Actavis Pharma, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products in the State of Delaware and throughout the United States, including some that are manufactured by Actavis Laboratories FL, Inc.

9. On information and belief, Defendant Actavis Pharma, Inc. is a wholly-owned subsidiary of Actavis, Inc.

10. On information and belief, Defendant Watson Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

11. On information and belief, Defendant Watson Laboratories, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products, preparing and filing ANDAs, and testing ANDA products in the State of Delaware and throughout the United States, including some that are manufactured by Actavis Laboratories FL, Inc.

12. On information and belief, Defendant Watson Laboratories, Inc. has a registered agent in the State of Delaware.

13. On information and belief, Defendant Watson Laboratories, Inc. is a wholly-owned subsidiary of Actavis, Inc.

14. Defendant Actavis Pharma, Inc. is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License Nos. A4-0000627, A4-0000685, A4-0001998) and "Distributor/Manufacturer CSR" (License Nos. DS0503 and DS0319).

15. Defendant Watson Laboratories, Inc. is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License No. A4-0001263) and "Distributor/Manufacturer CSR" (License No. DS0499).

JURISDICTION AND VENUE

16. This is an action for infringement of United States Patent Nos. 6,200,604 B1 ("the '604 patent"), 6,264,981 B1 ("the '981 patent"), and 8,119,158 B2 ("the '158 patent") (together, the "patents-in-suit") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(a), 271(b), and 271(c) for the patents-in-suit, § 271(e)(2) for the '604 and '158 patents, and for a declaratory judgment of infringement of the patents-in-suit under 28 U.S.C. §§ 2201 and 2202. Copies of the '604, '981, and '158 patents are attached as Exhibits A, B, and C, respectively.

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

18. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Defendants.

19. This Court has personal jurisdiction over the Defendants by virtue of the fact that, *inter alia*, they have committed—or aided, abetted, contributed to, or participated in the commission of—the tortious act of patent infringement that has led to foreseeable harm and injury to Cephalon, a Delaware corporation.

20. In addition, this Court has personal jurisdiction over the Defendants by virtue of their systematic and continuous contacts with the State of Delaware.

21. On information and belief, the Defendants plan to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, their aforementioned business of preparing generic pharmaceuticals to distribute in the State of Delaware.

22. On information and belief Defendants share common officers and directors and are agents of each other and/or work on concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including into Delaware, and including the fentanyl buccal tablets described in Defendants' ANDA 206329 (the "Actavis Generic Products"), which are accused of infringing the patents-in-suit.

23. If ANDA 206329 is approved, the Actavis Generic Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and

dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

24. Defendants know and intend that the Actavis Generic Products will be distributed and sold in the United States, including in Delaware. On information and belief, if ANDA 206329 is approved, Defendant Watson Laboratories, Inc. will manufacture the ANDA product for distribution throughout the United States, including Delaware. On information and belief, Defendant Actavis Pharma, Inc. will distribute Defendants' ANDA product for sale and/or use in Delaware.

25. In addition, the Defendants have previously submitted to the jurisdiction of this Court and have further previously availed itself of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. and Actavis, Inc.*, No. 14-cv-161-SLR, D.I. 7 (D. Del. Apr. 8, 2014); *Forest Laboratories, Inc. et al. v. Apotex Corp. and Watson Laboratories, Inc. – Florida*, No. 1:14-cv-00200-LPS, D.I. 22 and D.I. 48 (D. Del. Apr. 22, 2014) (consenting to jurisdiction and stating that Watson Laboratories, Inc. – Florida changed its name to Actavis Laboratories FL, Inc. on April 21, 2014); *Unimed Pharmaceuticals LLC et al. v. Perrigo Company and Watson Laboratories, Inc. and Actavis, Inc.*, No. 13-cv-236-RGA, D.I. 36, D.I. 77, and D.I. 78 (D. Del. Oct. 18, 2013); and *Kissei Pharmaceutical Co. Ltd., Watson Laboratories, Inc., and Actavis, Inc. v. Sandoz, Inc.*, No. 1:13-cv-1092-LPS, D.I. 1 (D. Del. June 17, 2013).

26. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

27. As discussed in further detail below, the Defendants filed ANDA No. 206329 seeking to market a generic version of Cephalon's breakthrough cancer pain drug FENTORA® (fentanyl buccal tablets).

28. Cephalon markets and distributes FENTORA® nationwide, including in the District of Delaware. The filing of ANDA No. 206329 evidences an intent by the Defendants to compete with Cephalon and place its product into every United States market where FENTORA® is currently marketed, including the District of Delaware.

THE PATENTS-IN-SUIT

29. On March 13, 2001, the '604 patent, titled "Sublingual Buccal Effervescent," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff Cephalon is the lawful owner, by assignment, of all right, title and interest in and to the '604 patent, including all right to sue and recover for infringement thereof.

30. On July 24, 2001, the '981 patent, titled "Oral Transmucosal Drug Dosage Using Solid Solution," was duly and legally issued by the PTO. Plaintiff Cephalon is the lawful owner, by assignment, of all right, title and interest in and to the '981 patent, including all right to sue and recover for infringement thereof.

31. On February 21, 2012, the '158 patent, titled "Effervescent Oral Fentanyl Dosage Form and Methods of Administering Fentanyl," was duly and legally issued by the PTO. Plaintiff Cephalon is the lawful owner, by assignment, of all right, title and interest in and to the '158 patent, including all right to sue and recover for infringement thereof.

32. Cephalon is the holder of an approved New Drug Application ("NDA") No. 21-947 for FENTORA® brand fentanyl buccal tablets. In conjunction with NDA No. 21-947, Cephalon listed with FDA the '604 and '158 patent, which cover methods of using the approved

FENTORA® brand fentanyl buccal tablets. The '604 and '158 patents (the "Listed Patents") appear in the Orange Book for FENTORA® brand fentanyl buccal tablets. The '981 patent is not listed in the Orange Book.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENTS-IN-SUIT

33. On information and belief, Defendants submitted ANDA No. 206329 to the FDA under § 505(j) of the Federal Food Drug & Cosmetic Act ("FFDCA") (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale throughout the United States including Delaware of generic fentanyl buccal tablets containing 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg of fentanyl citrate. ANDA No. 206329 specifically seeks FDA approval to market the Actavis Generic Products prior to the expiration of the patents-in-suit.

34. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Actavis Laboratories FL, Inc. alleged in ANDA No. 206329 that the claims of the '604 and '158 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale throughout the United States of the Actavis Generic Products. Cephalon received written notification of ANDA No. 206329 and Actavis Laboratories FL, Inc.'s § 505(j)(2)(A)(vii)(IV) allegations from Actavis Laboratories FL, Inc. on or about May 7, 2014 ("Paragraph IV letter").

35. The stated purpose of the Paragraph IV letter was to notify Cephalon that Actavis Laboratories FL, Inc. had filed a certification with the FDA in conjunction with ANDA No. 206329 for approval, *inter alia*, to commercially manufacture and sell a generic version of Cephalon's FENTORA® brand fentanyl buccal tablets. The Paragraph IV letter alleges that the claims of the '604 and the '158 patents are invalid, unenforceable and/or will not be infringed by

the commercial manufacture, use or sale throughout the United States of the Actavis Generic Products.

36. Despite Cephalon's requests for samples of the Actavis Generic Products, Defendants refused. Although Defendants provided their ANDA, Defendants provided no samples to Cephalon. Accordingly, Cephalon additionally resorts to the judicial process and the aid of discovery to obtain such samples to further evaluate the properties of Actavis Generic Products. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

37. Defendants Actavis, Inc. (then known as Watson Pharmaceuticals, Inc.); Actavis Pharma, Inc. (then known as Watson Pharma, Inc.); and Watson Laboratories, Inc. were previously found to infringe the '981 patent based on their filing of an ANDA on fentanyl buccal tablets and Defendants are currently enjoined from selling generic fentanyl buccal tablets that infringe the '981 patent. *See Cephalon, Inc. v. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc.*, C.A. No. 09-724-SLR, D.I. No. 330, D.I. 336 aff'd by *Cephalon, Inc. v. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc.*, 2011-1326, -1371 (Fed. Cir. 2011).

38. Defendants have made, and continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import the Actavis Generic Products prior to patent expiry.

39. Defendants' actions, including, but not limited to, the development of the Actavis Generic Products and the filing of an ANDA with a Paragraph IV certification, indicate a refusal to change the course of their action in the face of acts by Cephalon.

40. On information and belief, Defendants continue to seek approval of ANDA No. 206329 from the FDA and intend to commercially manufacture, market, and sell fentanyl

buccal tablets. Accordingly, Cephalon makes the following allegations on information and belief and subject to Fed. R. Civ. P. 11(b)(3):

COUNT I

(Infringement of the '604 Patent Under 35 U.S.C. § 271(e)(2))

41. Paragraphs 1 to 40 are incorporated herein as set forth above.

42. Defendants submitted ANDA No. 206329 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Actavis Generic Products. By submitting ANDA No. 206329, Defendants committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

43. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Actavis Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '604 patent.

COUNT II

(Declaratory Judgment of Infringement of the '604 Patent Under 35 U.S.C. § 271 (b) or (c))

44. Paragraphs 1 to 43 are incorporated herein as set forth above.

45. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

46. There is an actual case or controversy such that the Court may entertain Cephalon's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

47. Defendants have made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Actavis Generic Products.

48. Defendants' actions indicate a refusal to change the course of their action in the face of acts by Cephalon.

49. Any commercial manufacture, use, offer for sale, and/or importation of the Actavis Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '604 patent.

50. Cephalon is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Actavis Generic Products by Defendants prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '604 patent.

COUNT III

(Declaratory Judgment of Infringement of the '981 Patent Under 35 U.S.C. § 271(a), (b) or (c))

51. Paragraphs 1 to 50 are incorporated herein as set forth above.

52. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case or controversy such that the Court may entertain Cephalon's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

54. Defendants have made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Actavis Generic Products.

55. Defendants' actions indicate a refusal to change the course of its action in the face of acts by Cephalon.

56. Any commercial manufacture, use, offer for sale, and/or importation of the Actavis Generic Products prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the '981 patent.

57. Cephalon is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Actavis Generic Products by Defendants prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the '981 patent.

COUNT IV

(Infringement of the '158 Patent Under 35 U.S.C. § 271(e)(2))

58. Paragraphs 1 to 57 are incorporated herein as set forth above.

59. Defendants submitted ANDA No. 206329 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Actavis Generic Products prior to patent expiry. By submitting ANDA No. 206329, Defendants committed an act of infringement with respect to the '158 patent under 35 U.S.C. § 271(e)(2)(A).

60. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Actavis Generic Products prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the'158 patent.

COUNT V

(Declaratory Judgment of Infringement of the '158 Patent Under 35 U.S.C. § 271(a), (b) or (c))

61. Paragraphs 1 to 60 are incorporated herein as set forth above.

62. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. There is an actual case or controversy such that the Court may entertain Cephalon's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

64. Defendants have made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Actavis Generic Products prior to patent expiry.

65. Defendants' actions indicate a refusal to change the course of their action in the face of acts by Cephalon.

66. The commercial manufacture, use, offer for sale, and/or importation of the Actavis Generic Products prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the '158 patent.

67. Cephalon is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Actavis Generic Products prior to patent expiry by Defendants will constitute direct and/or contributory infringement and/or active inducement of infringement of the '158 patent.

EXCEPTIONAL CASE

68. Defendants were aware of the '604, '981, and '158 patents prior to filing ANDA No. 206329.

69. The actions of Defendants render this an exceptional case under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

70. Cephalon will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Cephalon does not have an adequate remedy at law.

PRAYER FOR RELIEF

Cephalon respectfully prays for the following relief:

a. That judgment be entered that Defendants have infringed the '604 and '158 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206329 under the FFDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Actavis Generic Products prior to patent expiry will constitute an act of infringement of the '604 and '158 patents;

b. That judgment be entered under 35 U.S.C. § 271 that the commercial manufacture, use, offer for sale, sale and/or importation of the Actavis Generic Products prior to patent expiry will constitute an act of infringement of the '981 patent;

c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 206329 shall be a date that is not earlier than the expiration date of the '604 and '158 patents including any extensions;

d. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '604 and '158 patents;

e. That a declaration be issued under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the

Actavis Generic Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '604, '981, and '158 patents;

f. That damages or other monetary relief be awarded to Cephalon under 35 U.S.C. § 27l (e)(4)(C) and/or § 284 as appropriate;

g. That this is an exceptional case under 35 U.S.C. § 285, and that Cephalon be awarded reasonable attorneys' fees and costs; and

h. That this Court award such other and further relief as it may deem just and proper.

Dated: June 19, 2014

FISH & RICHARDSON P.C.

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