IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS, INC.,

Plaintiffs,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and CIMA Labs, Inc. (collectively, "Plaintiffs") for their complaint against Impax Laboratories, Inc. ("Defendant"), to the best of their knowledge, information and belief, hereby allege as follows:

THE PARTIES

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

2. Plaintiff CIMA Labs, Inc. ("CIMA") is a Delaware corporation having a principal place of business at 10000 Valley View Road, Eden Prairie, Minnesota 55344.

3. On information and belief, Defendant Impax Laboratories, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

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

JURISDICTION AND VENUE

5. This is an action for infringement of United States Patent Nos. 6,200,604 B1 ("the '604 patent"), 6,974,590 B2 ("the '590 patent"), 7,862,832 B2 ("the '832 patent"), and 7,862,833 B2 ("the '833 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(a), 271(b), 271(c) and 271(e)(2) and for a declaratory judgment of infringement of the '604, '590, '832, and '833 patents under 28 U.S.C. §§ 2201 and 2202. Copies of the '604, '590, '832, and '833 patents are attached as Exhibits A, B, C, and D, respectively.

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

7. 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 Defendant.

8. This Court has personal jurisdiction over the Defendant 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 Plaintiffs, both Delaware corporations.

9. In addition, this court has personal jurisdiction over the Defendant by virtue of its systematic and continuous contacts with the State of Delaware.

10. On information and belief, the Defendant plans to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, its aforementioned business of preparing generic pharmaceuticals to distribute in the State of Delaware.

11. In addition, the Defendant has previously submitted to the jurisdiction of this Court and have further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

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

BACKGROUND

13. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules the United States Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of pharmaceutical drugs.

14. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several important aspects. One provision requires innovator drug companies to submit patent information to the FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA then publishes the submitted patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

15. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called the "reference drug") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j). When filing an

ANDA, generic drug companies are required to review the patent information that the FDA listed in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to same.

16. The generic drug company may state that it does not seek FDA approval to market its generic drug product prior to patent expiration (a "Paragraph III Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(III). Alternatively, the generic drug company may seek FDA approval to market its generic drug product prior to patent expiration by stating in its ANDA that the listed patent is "invalid or will not be infringed . . ." (commonly called a "Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

17. As discussed in further detail below, the Defendant filed ANDA No. 203357 seeking to market a generic version of Cephalon's breakthrough cancer pain drug FENTORA® (fentanyl buccal tablets).

18. Cephalon markets and distributes FENTORA® nationwide, including in the District of Delaware. The filing of ANDA No. 203357 evidences an intent by the Defendant 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

19. 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. From the time the original complaint was filed in this action up until the time Cephalon became the lawful owner, by assignment, of all right, title and interest in and to the '604 patent, Plaintiff CIMA was 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.

20. On December 13, 2005, the '590 patent, titled "Sublingual Buccal Effervescent," 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 '590 patent, including all right to sue and recover for infringement thereof. From the time the original complaint was filed in this action up until the time Cephalon became the lawful owner, by assignment, of all right, title and interest in and to the '590 patent, Plaintiff CIMA was the lawful owner, by assignment, of all right, title and interest in and to the '590 patent, including all right to sue and recover for infringement thereof.

21. On January 4, 2011, the '832 patent, titled "Generally Linear Effervescent Oral Fentanyl Dosage Form and Methods of Administering," 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 '832 patent, including all right to sue and recover for infringement thereof.

22. On January 4, 2011, the '833 patent, titled "Effervescent Oral Opiate Dosage Forms and Methods of Administering Opiates," 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 '833 patent, including all right to sue and recover for infringement thereof.

23. 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 '590 patents, which cover methods of using the approved FENTORA® brand fentanyl buccal tablets. Cephalon subsequently listed the '832 and '833 patents with the FDA after those patents issued. The '604, '590, '832, and '833 patents (the "Listed Patents" or the "patents-in-suit") appear in the Approved Drug Products with

Therapeutic Equivalence Evaluations ("Orange Book") for FENTORA®. Cephalon and CIMA have been, at all times this litigation has been pending, the assignees of the Listed Patents.

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

24. On information and belief, the Defendant actively reviews pharmaceutical patents and seek opportunities to challenge those patents.

25. On information and belief, Defendant submitted ANDA No. 203357 to the FDA under § 505(j) of the 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, 400 mcg, 600 mcg, and 800 mcg of fentanyl citrate ("the Impax Generic Products"). ANDA No. 203357 specifically seeks FDA approval to market the Impax Generic Products prior to the expiration of the patents-in-suit.

26. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Impax Laboratories, Inc. alleged in ANDA No. 203357 that the claims of the '604 patent, the '590 patent, the '832 patent, and the '833 patent will not be infringed by the commercial manufacture, use or sale throughout the United States of the Impax Generic Product, and/or that the claims of the '604 patent, the '590 patent, the '832 patent, and the '833 patent are invalid and/or unenforceable. Cephalon received written notification of ANDA No. 203357 and Impax Laboratories, Inc.'s §505(j)(2)(A)(vii)(IV) allegations from Impax Laboratories, Inc. on or about October 10, 2011 ("Paragraph IV letter").

27. The stated purpose of the Paragraph IV letter was to notify Plaintiffs that Impax Laboratories, Inc. had filed a certification with the FDA in conjunction with ANDA No. 203357 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 patent, the '590 patent, the '832 patent, and the '833 patent will not be infringed by the commercial manufacture, use or sale throughout the United States of the Impax Generic Products and that the claims of the '604 patent and the '590 patent are invalid.

28. The Paragraph IV letter does not comply with the requirements of 21 U.S.C. § 355 (j)(2)(B)(iv)(II), *inter alia*, because it contains very limited information about the generic formulation for which Impax Laboratories, Inc. filed ANDA No. 203357. For example, the Paragraph IV letter does not list any of the ingredients in the Impax Generic Products, or the amounts of those ingredients. The Paragraph IV letter also fails to provide any information about the method by which the Impax Generic Products are manufactured.

29. In the Paragraph IV letter, Impax offered confidential access to ANDA No. 203357 on term and conditions set forth in an attached "Offer of Confidential Access" ("the Impax Offer"). Impax requested that Plaintiffs' outside counsel sign the Impax Offer before receiving access to Impax's ANDA No. 203357. The Impax Offer contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the Impax Offer barred all access by to individuals "involved in current or potential matters with the FDA" for Plaintiffs.

30. Under 21 U.S.C. 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

31. Since receiving the Impax Paragraph IV letter and the accompanying Impax Offer, Plaintiffs have attempted to negotiate with Impax to procure a copy of ANDA No. 203357

under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful.

32. Because Plaintiffs have been unable to obtain a copy of ANDA No. 203357, Plaintiffs allege their causes of action based primarily on the representations contained in Impax's Paragraph IV letter and other facts alleged herein.

33. Plaintiffs are not aware of any other means of obtaining information regarding the Impax Generic Products within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that the Impax Generic Products fall within the scope of one or more claims of the '604,'590, '832, and '833 patents. *See Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

34. Defendant has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import the Impax Generic Products prior to patent expiry.

35. Defendant's actions, including, but not limited to, the development of the Impax Generic Products and the filing of an ANDA with a Paragraph IV certification, indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

36. On information and belief, Defendant continues to seek approval of ANDA No. 203357 from the FDA and intend to commercially manufacture, market, and sell fentanyl buccal tablets. Accordingly, Plaintiffs make 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))

37. Paragraphs 1 to 36 are incorporated herein as set forth above.

38. Defendant submitted ANDA No. 203357 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 Impax Generic Products. By submitting ANDA No. 203357, Defendant committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

39. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute direct and/or contributory infringement of the '604 patent, 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(a), (b) or (c))

40. Paragraphs 1 to 39 are incorporated herein as set forth above.

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

42. There is an actual case or controversy such that the Court may entertain Plaintiffs' 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.

43. Defendant has made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Impax Generic Products.

44. Defendant's actions indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

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

46. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products by the Defendant prior to patent expiry will constitute direct and/or contributory infringement and/or active inducement of infringement of the '604 patent.

COUNT III
(Infringement of the '590 Patent Under 35 U.S.C. § 271(e)(2))

47. Paragraphs 1 to 46 are incorporated herein as set forth above.

48. Defendant submitted ANDA No. 203357 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 Impax Generic Products prior to patent expiry. By submitting ANDA No.203357, Defendant committed an act of infringement with respect to the '590 patent under 35 U.S.C. § 271(e)(2)(A).

49. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute direct and/or contributory infringement of the '590 patent, and/or active inducement of infringement of the '590 patent.

COUNT IV
(Declaratory Judgment of Infringement of the '590 Patent Under 35 U.S.C. § 271(a), (b) or (c))

50. Paragraphs 1 to 49 are incorporated herein as set forth above.

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

52. There is an actual case or controversy such that the Court may entertain Plaintiffs' 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.

53. Defendant has made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Impax Generic Products prior to patent expiry.

54. Defendant's actions indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

55. The commercial manufacture, use, offer for sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '590 patent.

56. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry by the Defendant will constitute direct and/or contributory infringement and/or active inducement of infringement of the '590 patent.

COUNT V
(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

57. Paragraphs 1 to 56 are incorporated herein as set forth above.

58. Defendant submitted ANDA No. 203357 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 Impax Generic Products prior to patent expiry. By submitting ANDA No. 203357, Defendant committed an act of infringement with respect to the '832 patent under 35 U.S.C. § 271(e)(2)(A).

59. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute direct and/or contributory infringement of the '832 patent, and/or active inducement of infringement of the '832 patent.

COUNT VI
(Declaratory Judgment of Infringement of the '832 Patent Under 35 U.S.C. § 271(a), (b) or (c))

60. Paragraphs 1 to 59 are incorporated herein as set forth above.

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

62. There is an actual case or controversy such that the Court may entertain Plaintiffs' 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.

63. Defendant has made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Impax Generic Products prior to patent expiry.

64. Defendant's actions indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

65. The commercial manufacture, use, offer for sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '832 patent.

66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry by the Defendant will constitute direct and/or contributory infringement and/or active inducement of infringement of the '832 patent.

COUNT VI
(Infringement of the '833 Patent Under 35 U.S.C. § 271(e)(2))

67. Paragraphs 1 to 66 are incorporated herein as set forth above.

68. Defendant submitted ANDA No. 203357 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 Impax Generic Products prior to patent expiry. By submitting ANDA No. 203357, Defendant committed an act of infringement with respect to the '833 patent under 35 U.S.C. § 271(e)(2)(A).

69. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute direct and/or contributory infringement of the '833 patent, and/or active inducement of infringement of the '833 patent.

COUNT VIII
(Declaratory Judgment of Infringement of the '833 Patent Under 35 U.S.C. § 271(a), (b) or (c))

70. Paragraphs 1 to 69 are incorporated herein as set forth above.

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

72. There is an actual case or controversy such that the Court may entertain Plaintiffs' 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.

73. Defendant has made, and will continue to make, substantial preparation in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Impax Generic Products prior to patent expiry.

74. Defendant's actions indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

75. The commercial manufacture, use, offer for sale, and/or importation of the Impax Generic Products prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the '833 patent.

76. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Impax Generic Products prior to patent expiry by the Defendant will constitute direct and/or contributory infringement and/or active inducement of infringement of the '833 patent.

EXCEPTIONAL CASE

77. Impax Laboratories, Inc. was aware of the '604, '590, '832, and '833 patents prior to filing ANDA No. 203357.

78. The actions of Impax Laboratories, Inc. render this an exceptional case under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

79. Plaintiffs will be irreparably harmed by Impax Laboratories, Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Impax Laboratories, Inc. has infringed the '604, '590, '832, and '833 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203357 under the FFDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Impax Generic Products prior to patent expiry will constitute an act of infringement of the '604, '590, '832, and '833 patents;

b. 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. 203357 shall be a date that is not earlier than the expiration date of the '604, '590, '832, and '833 patents including any extensions;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Impax Laboratories, Inc., its 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, '590, '832, and '833 patents;

d. That a declaration be issued under 28 U.S.C. § 2201 that if Impax Laboratories, Inc., its 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 Impax Generic Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '604, '590, '832, and '833 patents;

e. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. § 271(e)(4)(C) as appropriate;

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

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

DATED: November 18, 2011

FISH & RICHARDSON P.C.

By: _____

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