IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS, INC., Plaintiffs, v. BARR PHARMACEUTICALS, INC., and BARR LABORATORIES, INC., Defendants.	Case No. **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Cephalon, Inc. and CIMA LABS, INC. (collectively, "Plaintiffs") for their complaint against Barr Pharmaceuticals, Inc. and Barr Laboratories, Inc. (collectively, "Defendants" or "Barr"), 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. Defendant Barr Pharmaceuticals, Inc. ("Barr Pharmaceuticals") is a Delaware corporation, having a principal place of business at 223 Quaker Road, Pomona, New York, 10970.

4. Defendant Barr Laboratories, Inc. ("Barr Laboratories") is a Delaware corporation, having a principal place of business at 223 Quaker Road, Pomona, New York, 10970.

5. Defendant Barr Laboratories is a wholly-owned subsidiary of Defendant Barr Pharmaceuticals, and Barr Laboratories is controlled and/or dominated by Barr Pharmaceuticals.

6. Barr Pharmaceuticals conducts its North American operations, in part, through Barr Laboratories, and the Defendants collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) within the United States generally and the State of Delaware specifically.

JURISDICTION AND VENUE

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

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

9. This Court has personal jurisdiction over the Defendants by virtue of their incorporation in Delaware.

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

THE PATENTS IN SUIT

11. 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 CIMA is the lawful owner by assignment of all rights, title and interest in and to the '604 patent, including all rights to sue and recover for infringement thereof.

12. On December 13, 2005, the '590 patent, titled "Sublingual Buccal Effervescent," was duly and legally issued by the PTO. Plaintiff CIMA is the lawful owner by assignment of all rights, title and interest in and to the '590 patent, including all right to sue and recover for infringement thereof.

13. 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 the U.S. Food and Drug Administration ("FDA") the '604 and '590 patents (the "Listed Patents") which cover methods of using the approved FENTORA® brand fentanyl buccal tablets. The '604 and '590 patents appear in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for FENTORA®. Cephalon is also the sole licensee of the patents-in-suit in the United States with the authority to sell fentanyl buccal tablets.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE '604 AND '590 PATENTS

14. On information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

15. On information and belief, Defendants reviewed the patents-in-suit and certain commercial and economic information relating to FENTORA®, including estimates of the

revenues generated by the sale of FENTORA®, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market fentanyl citrate buccal tablets.

16. On information and belief, Defendant Barr Laboratories, jointly with its parent Barr Pharmaceuticals, submitted ANDA No. 90-438 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). ANDA No. 90-438 seeks FDA approval for the commercial manufacture, use, offer for sale, and/or sale of generic fentanyl citrate buccal tablets containing 0.1, 0.4, 0.6, 0.8 mg of fentanyl citrate (the "Barr Generic Products"), throughout the United States, including Delaware. ANDA No. 90-438 specifically seeks FDA approval to market the Barr Generic Products prior to expiration of the '604 and '590 patents.

17. On information and belief, Defendants collaborated in the research, development, preparation and filing of ANDA No. 90-438 for fentanyl citrate buccal tablets.

18. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, in ANDA No. 90-438, Barr alleged that the claims of the '604 patent and the claims of the '590 patent are not infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products throughout the United States, including Delaware. CIMA received written notification of ANDA No. 90-438 and of Barr's § 505(j)(2)(A)(vii)(IV) allegations from Barr on or about June 10, 2008 ("Paragraph IV letter"). On or about June 30, 2008, CIMA received a supplemental notification from Barr identifying additional variants of the Barr Generic Products. Barr's Paragraph IV letter and supplemental notification state that Barr has submitted data to the FDA regarding the alleged "bioavailability and/or bioequivalence" of the Barr Generic Products and FENTORA®.

19. On information and belief, Barr Pharmaceuticals made the ultimate decision to file ANDA No. 90-438 with the FDA, and knowingly encouraged, directed and actively induced

Barr Labs to file ANDA No. 90-438 and the related Paragraph IV certification, and Barr Labs did so at Barr Pharmaceuticals' direction.

20. The stated purpose of the Paragraph IV letter was to notify Plaintiffs that Defendants had filed a certification with the FDA under 21 C.F.R. § 314.95(c)(1) in conjunction with ANDA No. 90-438 for approval, *inter alia*, to commercially manufacture and sell generic versions of Cephalon's FENTORA® brand fentanyl buccal tablets. The Paragraph IV letter stated that the Barr Generic Products would not infringe the Listed Patents.

21. On information and belief, Barr Pharmaceuticals was necessarily aware of the patents-in-suit when it directed Barr Laboratories to file ANDA No. 90-438 and a Paragraph IV certification.

22. The Paragraph IV letter failed to comply with the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II) because, *inter alia*, it contains very limited information about the generic formulation for which Defendants filed ANDA No. 90-438.

23. Under the Hatch-Waxman Act of 1984, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act. 21 U.S.C. § 355(c)(3)(c).

24. Since receiving the Paragraph IV letter, Plaintiffs have attempted to obtain information on the Barr Generic Products and to procure a copy of ANDA No. 90-438 from Barr. Barr has been unwilling to provide ANDA No. 90-438 to Plaintiffs except under conditions that would not allow Plaintiffs to meaningfully process the information contained in the ANDA. In addition, the Paragraph IV letter did not provide the requisite detailed factual or legal bases sufficient for Cephalon to meaningfully assess the merit of Barr's contention that the

manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products will not infringe the Listed Patents.

25. Plaintiffs sought detailed information from Defendants on the formulation of the Barr Generic Products and a copy of ANDA No. 90-438 for the purpose of evaluating Defendants' claim that they do not infringe the patents-in-suit, but were unable to obtain such information reasonably in advance of the expiration of the 45-day statutory deadline for filing suit. Accordingly, Plaintiffs make the following allegations on information and belief and subject to Fed. R. Civ. P. 11(b)(3).

26. On information and belief, Defendants continue to collaborate in seeking approval of ANDA No. 90-438 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of fentanyl citrate buccal tablets.

COUNT I

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

27. Paragraphs 1 through 26 are incorporated herein as set forth above.

28. Defendants, acting jointly, submitted ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products throughout the United States, including Delaware, prior to patent expiry. By submitting this application, Defendants, individually and collectively, committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

29. Barr Laboratories, acting jointly with or at the direction of Barr Pharmaceuticals, and/or as its agent, submitted ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale,

and/or importation of the Barr Generic Products throughout the United States, including Delaware, prior to patent expiry. By submitting this application, Barr Laboratories has committed an act of infringement with respect to the '604 patent, under 35 U.S.C. § 271(e)(2)(A).

30. When Barr Laboratories submitted ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products throughout the United States, including Delaware, it was directed to do so by Barr Pharmaceuticals and/or acting as Barr Pharmaceutical's agent . By directing Barr Laboratories to submit the application and/or causing its agent to submit the application, Barr Pharmaceuticals committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

31. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '604 patent.

COUNT II

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

32. Paragraphs 1 through 31 are incorporated herein as set forth above.

33. Barr Pharmaceuticals actively induced Barr Laboratories to submit ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of the Barr Generic Products throughout the United States, including Delaware, prior to patent expiry. By actively inducing the submission of the ANDA, Barr Pharmaceuticals has committed an act of indirect infringement with respect to the '604 patent, under 35 U.S.C. § 271(b).

34. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '604 patent.

COUNT III

Declaratory Judgment of Infringement of the '604 Patent Under 35 U.S.C. § 271

35. Paragraphs 1 through 34 are incorporated herein as set forth above.

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

37. 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 this actual case or controversy requires a declaration of rights by this Court.

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

39. Defendants' actions, including, but not limited to, the filing of ANDA No. 90-438 with a Paragraph IV certification and provision of a wholly inadequate 'Detailed Statement' under 21 U.S.C. § 355(c)(3)(D)(i)(III), indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

40. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '604 patent under 35 U.S.C. § 271.

41. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products by either or both of Defendants prior to patent expiry will infringe the '604 patent.

COUNT IV

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

42. Paragraphs 1 through 41 are incorporated herein as set forth above.

43. Defendants, acting jointly, submitted ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products throughout the United States, including Delaware, prior to patent expiry. By submitting the application, Defendants, individually and collectively, committed an act of infringement with respect to the '590 patent, under 35 U.S.C. § 271(e)(2)(A).

44. Barr Laboratories, acting jointly with or at the direction of Barr Pharmaceuticals, and/or as its agent, submitted ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products throughout the United States, including Delaware, prior to patent expiry. By submitting the application, Barr Laboratories has committed an act of infringement with respect to the '590 patent, under 35 U.S.C. § 271(e)(2)(A).

45. When Barr Laboratories submitted ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products throughout the United States, including Delaware, prior to patent expiry, it was directed to do so by Barr Pharmaceuticals and/or acting as Barr Pharmaceuticals' agent . By directing Barr Laboratories to submit the application and/or causing its agent to submit the application, Barr Pharmaceuticals committed an act of infringement with respect to the '590 patent, under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '590 patent.

COUNT V

Infringement of the '590 Patent Under 35 U.S.C. § 271(b)

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

48. Barr Pharmaceuticals actively induced Barr Laboratories to submit ANDA No. 90-438 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products throughout the United States, including Delaware, prior to patent expiry. By actively inducing submission of the ANDA, Barr Pharmaceuticals has committed an act of indirect infringement with respect to the '590 patent, under 35 U.S.C. § 271(b).

49. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '604 patent.

COUNT VI

Declaratory Judgment of Infringement of the '590 Patent Under 35 U.S.C. § 271

50. Paragraphs 1 through 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 this actual case or controversy requires a declaration of rights by this Court.

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

54. Defendants' actions, including, but not limited to, the filing of ANDA No. 90-438 with a Paragraph IV certification and provision of a wholly inadequate 'Detailed Statement' under 21 U.S.C. § 355(c)(3)(D)(i)(III), indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

55. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '590 patent under 35 U.S.C. § 271.

56. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry by either or both of Defendants will infringe the '590 patent.

EXCEPTIONAL CASE

57. Barr Laboratories was aware of the '604 patent and '590 patent prior to filing ANDA No. 90-438.

58. Barr Pharmaceuticals was aware of the '604 patent and '590 patent prior to filing ANDA No. 90-438.

59. The actions of Barr Pharmaceuticals and Barr Laboratories, individually and collectively, render this an exceptional case under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

60. Plaintiffs will be irreparably harmed by Barr Laboratories' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

61. Plaintiffs will be irreparably harmed by Barr Pharmaceuticals' 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 Defendants, individually and/or collectively, have infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-438 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent under § 271;

b. That judgment be entered that Barr Laboratories has infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-438 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent under § 271;

c. That judgment be entered that Barr Pharmaceuticals has infringed the '604 patent under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Barr Laboratories or by directing Barr Laboratories to act as its agent in submitting ANDA No. 90-438 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or

importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent under § 271;

d. That judgment be entered that Barr Pharmaceuticals has infringed the '604 patent under 35 U.S.C. § 271(b) by inducing Barr Laboratories to submit ANDA No. 90-438 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '604 patent under § 271;

e. 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. 90-438 shall be a date that is not earlier than the expiration date of the '604 patent, inclusive of any extensions;

f. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Barr Pharmaceuticals, Barr Laboratories, 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 for sale, sale, and/or importation of any drug product covered by the '604 patent, within (or into) the United States;

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

h. That a declaration be issued under 28 U.S.C. § 2201 that if Barr Pharmaceuticals, Barr Laboratories, 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 Barr Generic Products prior to patent expiry, it will constitute an act of infringement of the '604 patent under § 271;

i. That judgment be entered that Defendants, individually and/or collectively, have infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-438 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent under § 271;

j. That judgment be entered that Barr Laboratories has infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 90-438 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent under § 271;

k. That judgment be entered that Barr Pharmaceuticals has infringed the '590 patent under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Barr Laboratories or by directing Barr Laboratories to act as its agent in submitting ANDA No. 90-438 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent under § 271;

l. That judgment be entered that Barr Pharmaceuticals has infringed the '590 patent under 35 U.S.C. § 271(b) by inducing Barr Laboratories to submit ANDA No. 90-438 under the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr Generic Products prior to patent expiry will constitute an act of infringement of the '590 patent under § 271;

m. 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. 90-438 shall be a date that is not earlier than the expiration date of the '590 patent inclusive of any extensions;

n. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Barr Pharmaceuticals, Barr Laboratories, 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 '590 patent;

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

p. That a declaration be issued under 28 U.S.C. § 2201 that if Barr Pharmaceuticals, Barr Laboratories, 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 Barr Generic Products prior to patent expiry, it will constitute an act of infringement of the '590 patent under § 271;

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

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

Dated: July 22, 2008

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