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.	Civil Action 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" or "patents-in-suit") 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. Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

15. 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) seeking approval to engage in the commercial manufacture, importation, use or sale of EQ 0.4 mg base strength of generic fentanyl citrate buccal tablets before the expiration of the '604 and '590 patents.

17. Pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c)(1), on or about June 10, 2008, Barr advised Plaintiffs by letter ("First Paragraph IV Notice Letter") that the FDA had received ANDA No. 90-438 from Barr containing bioavailability and bioequivalence data from studies on the fentanyl citrate buccal tablets that are the subject of NDA No. 21-947.

18. According to Barr's First Paragraph IV Notice Letter, ANDA No. 90-438 included a paragraph IV certification that "in Barr's opinion, and to the best of its knowledge, each of the '604 and '590 patents is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale or importation" of Barr's generic EQ 0.4 mg base fentanyl citrate buccal tablets, which purport to be generic versions of Cephalon's 0.4 mg FENTORA® brand fentanyl buccal tablets, before expiration of the '604 and '590 patents ("First Paragraph IV Certification").

19. 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 the related First Paragraph IV Certification.

20. 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 Laboratories to file ANDA No. 90-438 and the related First Paragraph IV certification, and Barr Laboratories did so at Barr Pharmaceuticals' direction and under its control.

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

22. 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 generic EQ 0.4 mg base fentanyl citrate buccal tablets.

23. On June 27, 2008, ANDA No. 90-438 was amended by Barr to include a reference to buccal tablets containing additional strengths of fentanyl citrate (EQ 0.1 mg base, EQ 0.6 mg base and EQ 0.8 mg base) ("the First Amended ANDA").

24. Pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c)(1), on or about June 30, 2008, Barr again advised Plaintiffs by letter ("Second Paragraph IV Notice Letter") that the FDA had received the First Amended ANDA from Barr containing bioavailability and bioequivalence data from studies on the fentanyl citrate buccal tablets that are the subject of NDA No. 21-947.

25. According to Barr's Second Paragraph IV Notice Letter, the First Amended ANDA, also submitted under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (j), included a paragraph IV certification that "in Barr's opinion, and to the best of its knowledge, each of the '604 and '590 patents is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale or importation" of Barr's generic 0.1 mg, 0.4mg, 0.6 mg, and 0.8 mg fentanyl citrate buccal tablets before expiration of the '604 and '590 patents ("Second Paragraph IV Certification").

26. On information and belief, Barr Pharmaceuticals was the one who made the ultimate decision to file the Amended ANDA with the FDA, and knowingly encouraged,

directed and actively induced Barr Laboratories to file the Amended ANDA and the related Second Paragraph IV Certification, and Barr Laboratories did so at Barr Pharmaceuticals' direction and under its control.

27. Barr's Second Paragraph IV Notice Letter also failed to comply with the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II) because, *inter alia*, it contained very limited information about the generic formulation for which Defendants filed the Amended ANDA.

28. On information and belief, Defendants continue to collaborate in seeking approval of the Amended ANDA from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of generic EQ 0.1 mg, 0.4mg, 0.6 mg, and 0.8 mg base fentanyl citrate buccal tablets.

29. On September 12, 2008, Amended ANDA No. 90-438 was amended by Barr, this time to include a reference to generic EQ 0.3 mg base fentanyl citrate buccal tablets ("Second Amended ANDA").

30. Pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c)(1), on or about September 18, 2008, Barr again advised Plaintiffs by letter ("Third Paragraph IV Notice Letter") that the FDA had received the Second Amended ANDA from Barr containing bioavailability and bioequivalence data from studies on the fentanyl citrate buccal tablets that are the subject of NDA No. 21-947.

31. According to Barr's Third Paragraph IV Notice Letter, the Second Amended ANDA, also submitted under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), included a paragraph IV certification that "in Barr's opinion, and to the best of its knowledge, each of the '604 and '590 patents is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale or importation" of Barr's generic EQ 0.1, 0.3 mg, 0.4

mg, 0.6 mg, and 0.8 mg fentanyl citrate buccal tablets before expiration of the '604 and '590 patents ("Third Paragraph IV Certification").

32. On information and belief, Barr Pharmaceuticals was the one who made the ultimate decision to file the Second Amended ANDA with the FDA, and knowingly encouraged, directed and actively induced Barr Laboratories to file the Second Amended ANDA and the related Third Paragraph IV Certification, and Barr Laboratories did so at Barr Pharmaceuticals' direction and under its control.

33. Barr's Third Paragraph IV Notice Letter also failed to comply with the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II) because, *inter alia*, it contained very limited information about the generic formulation for which Defendants filed the Second Amended ANDA.

34. On information and belief, Defendants continue to collaborate in seeking approval of the Second Amended ANDA from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of generic EQ 0.1 mg, 0.3 mg, 0.4mg, 0.6 mg, and 0.8 mg base fentanyl citrate buccal tablets ("The Barr Generic Products"). The ANDA, First Amended ANDA, and Second Amended ANDA are hereinafter referred to collectively as "the Barr ANDA."

COUNT I

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

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

36. Defendants, acting jointly, submitted the Barr ANDA 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).

37. Barr Laboratories, acting jointly with or at the direction of Barr Pharmaceuticals, and/or as its agent, submitted the Barr ANDA 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).

38. When Barr Laboratories submitted the Barr ANDA 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).

39. 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)

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

41. Barr Pharmaceuticals actively induced Barr Laboratories to submit the Barr ANDA 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 Barr ANDA, Barr Pharmaceuticals has committed an act of indirect infringement with respect to the '604 patent, under 35 U.S.C. § 271(b).

42. 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

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

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

45. 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.

46. 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.

47. Defendants' actions, including, but not limited to, the filing of the Barr ANDA with a series of Paragraph IV certifications and provision of wholly inadequate "Detailed Statements" 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.

48. 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.

49. 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)

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

51. Defendants, acting jointly, submitted the Barr ANDA 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).

52. Barr Laboratories, acting jointly with or at the direction of Barr Pharmaceuticals, and/or as its agent, submitted the Barr ANDA 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).

53. When Barr Laboratories submitted the Barr ANDA 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 was 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).

54. 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)

55. Paragraphs 1 through 54 are incorporated herein as set forth above.

56. Barr Pharmaceuticals actively induced Barr Laboratories to submit the Barr ANDA 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 Barr ANDA, Barr Pharmaceuticals has committed an act of indirect infringement with respect to the '590 patent, under 35 U.S.C. § 271(b).

57. 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 VI

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

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

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

60. 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.

61. 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.

62. Defendants' actions, including, but not limited to, the filing of the Barr ANDA with a series of Paragraph IV certifications and provision of wholly inadequate "Detailed Statements" 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.

63. 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.

64. 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

65. Barr Laboratories was aware of the '604 patent and '590 patent prior to filing the Barr ANDA.

66. Barr Pharmaceuticals was aware of the '604 patent and '590 patent prior to filing the Barr ANDA.

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

INJUNCTIVE RELIEF

68. 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.

69. 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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 the Barr ANDA 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: October 29, 2008

FISH & RICHARDSON P.C.

William J. Marsden, Jr. (#2247)
Douglas E. McCann (#3852)
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899-1114
(302) 652-5070
marsden@fr.com
dmccann@fr.com

Attorneys for Plaintiffs

Of Counsel:

Duane-David Hough
FISH & RICHARDSON P.C.
Citigroup Center
52nd Floor
153 East 53rd Street
New York, NY 10022-4611
(212) 765-5070

Jonathan E. Singer
FISH & RICHARDSON P.C.
60 South Sixth Street
3300 RBC Plaza
Minneapolis, MN 55402
(612) 335-5070