IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS, INC., Plaintiffs, v. BARR PHARMACEUTICALS, INC., BARR PHARMACEUTICALS, LLC, as successor-in-interest to 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., Barr Pharmaceuticals, LLC 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 7325 Aspen Lane, Brooklyn Park, Minnesota 55428.

3. Defendant Barr Pharmaceuticals, Inc. is a Delaware corporation.

4. Defendant Barr Pharmaceuticals, LLC is a Delaware limited liability company.

5. Pursuant to an Agreement and Plan of Merger by and among Barr Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd. and Boron Acquisition Corp. dated July 17, 2008 ("Merger Agreement"), Barr Pharmaceuticals, Inc. merged into Boron Acquisition Corp. on December 23, 2008. Boron Acquisition Corp. was the surviving entity and was

renamed Barr Pharmaceuticals, LLC. Pursuant to the Merger Agreement, Barr Pharmaceuticals, LLC is responsible for all debts, liabilities and duties of Barr Pharmaceuticals, Inc.

6. Barr Pharmaceuticals, LLC is a wholly-owned subsidiary of Teva Pharmaceuticals, Inc. Barr Pharmaceuticals, LLC as successor-in-interest to Barr Pharmaceuticals, Inc. and Barr Pharmaceuticals, Inc. are referred to collectively hereinafter as "Barr Pharmaceuticals."

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

8. On information and belief, Defendant Barr Laboratories is a wholly-owned subsidiary of Defendant Barr Pharmaceuticals, and Barr Laboratories is controlled and/or dominated by Barr Pharmaceuticals.

9. At all times relevant to this Complaint, Barr Pharmaceuticals has conducted 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

10. 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.

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

12. This Court has personal jurisdiction over the Defendants by virtue of incorporation in Delaware, or registration as a limited liability company in Delaware.

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

THE PATENTS IN SUIT

14. 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.

15. 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 rights to sue and recover for infringement thereof.

16. 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 the "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

17. Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

18. 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.

19. On information and belief, Defendant Barr Laboratories, jointly with its parent Barr Pharmaceuticals, submitted ANDA No. 90-438 and amendments thereto (collectively referred to as "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 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.6 mg and 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.

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

21. 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 that were added to the ANDA via amendment. On or about September 17, 2008, Barr sent CIMA another supplemental notification stating that ANDA No. 90-438 was amended again on September 12, 2008 to include a 0.3 mg formulation of the Barr Generic Products. Then, on or about December 23, 2008, Plaintiffs received another supplemental notification stating that ANDA No. 90-438 was amended on December 19, 2008 to include a 0.2 mg formulation of the Barr Generic Products. Barr's Paragraph IV letter and supplemental notifications state that Barr has submitted data to the FDA regarding the alleged "bioavailability and/or bioequivalence" of the Barr Generic Products and FENTORA®.

22. 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 Paragraph IV certification and supplements thereto 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, and Barr Laboratories did so at Barr Pharmaceuticals' direction.

23. The stated purpose of the Paragraph IV letter and supplemental notices 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.

24. 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.

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

26. 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) (All Defendants)

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 acting jointly with Barr Pharmaceuticals and/or acting as Barr Pharmaceutical's agent. By acting jointly with 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. 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) (Barr Pharmaceuticals, Inc. and Barr Pharmaceuticals, LLC)

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

33. Barr Pharmaceuticals (as defined above) 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.

34. Upon information and belief, Barr Pharmaceuticals will be actively involved in the manufacture, marketing, and sale of the Barr Generic Products, should FDA approval be granted.

35. Any such commercial manufacture, use, offer for sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '604 patent. By engaging in a cooperative venture with Barr Laboratories to submit the ANDA 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 Barr Generic Products, Barr Pharmaceuticals committed an act of indirect infringement with respect to the '604 patent under 35 U.S.C. § 271(b).

COUNT III

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

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

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

38. 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.

39. 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 Product.

40. Defendants' actions, including, but not limited to, the filing of ANDA No. 90-438 with a Paragraph IV certification and supplements thereto 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.

41. 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.

42. 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) (All Defendants)

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

44. 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).

45. Barr Laboratories, acting jointly with 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).

46. 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 acting jointly with Barr Pharmaceuticals and/or acting as Barr Pharmaceuticals' agent. By acting jointly with 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).

47. 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) (Barr Pharmaceuticals, Inc. and Barr Pharmaceuticals, LLC)

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

49. Barr Pharmaceuticals (as defined above) 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.

50. On information and belief, Barr Pharmaceuticals will be actively involved in the manufacture, marketing, and sale of the Barr Generic Products, should FDA approval be granted.

51. Any such commercial manufacture, use, offer for sale, and/or importation of the Barr Generic Products prior to patent expiry will infringe the '590 patent. By engaging in a cooperative venture with Barr Laboratories to submit the ANDA 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 Barr Generic Products, Barr Pharmaceuticals committed an act of indirect infringement with respect to the '590 patent under 35 U.S.C. § 271(b).

COUNT VI

Declaratory Judgment of Infringement of the '590 Patent Under 35 U.S.C. § 271(b) or (c) (All Defendants)

52. Paragraphs 1 through 51 are incorporated herein as set forth above.

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

54. 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.

55. 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.

56. Defendants' actions, including, but not limited to, the filing of ANDA No. 90-438 with a Paragraph IV certification and supplements thereto 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.

57. 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.

58. 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

59. On information and belief, Defendants' Paragraph IV certification was baseless, and the arguments presented therein without merit, thereby rendering 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;

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;

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 allowing 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) or (c) by inducing Barr Laboratories to submit ANDA No. 90-438 under the Federal Food Drug, and Cosmetic Act, in a cooperative venture in which Barr Pharmaceuticals will participate in 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;

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 with respect to the '604 patent;

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;

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;

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;

l. That judgment be entered that Barr Pharmaceuticals has infringed the '590 patent under 35 U.S.C. § 271(b) or (c) by inducing Barr Laboratories to submit ANDA No. 90-438 under the Federal Food Drug, and Cosmetic Act, in a cooperative venture in which Barr Pharmaceuticals will participate in 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;

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 with respect to the '590 patent;

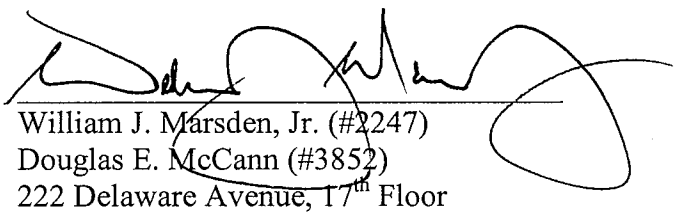
p. That a declaration be issued under 28 U.S.C. § 2201 that if Barr Pharmaceuticals, Barr Laboratories, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their 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;

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: January 30, 2009

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

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