IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS, INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cephalon, Inc. and CIMA Labs, Inc. (collectively, "Plaintiffs") for their complaint against Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Defendants" or "Mylan Defendants"), 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 Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.

5. On information and belief, Defendant Mylan Inc. is the parent company of Mylan Pharmaceuticals; Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

6. On information and belief, Defendant Mylan Pharmaceuticals is in the business of preparing generic pharmaceuticals that it distributes in the State of Delaware and throughout the United States. On information and belief, Defendant Mylan Inc. conducts its North American operations, in part, through Mylan Pharmaceuticals. Together, the Mylan 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"), 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.

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

9. 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 Mylan Defendants.

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

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

12. On information and belief, the Mylan Defendants plan 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.

13. In addition, the Mylan Defendants have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

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

BACKGROUND

15. 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.

16. 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").

17. 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.

18. 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).

19. As discussed in further detail below, the Mylan Defendants filed ANDA No. 202577 seeking to market a generic version of Cephalon's breakthrough cancer pain drug FENTORA® (fentanyl buccal tablets).

20. Cephalon markets and distributes FENTORA® nationwide, including in the District of Delaware. The filing of ANDA No. 202577 evidences an intent by the Mylan Defendants to compete with Cephalon and place its product into every United States market where FENTORA® is currently marketed, including the District of Delaware.

THE PATENTS IN SUIT

21. 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.

22. 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.

23. 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.

24. 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.

25. 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, the assignees of the Listed Patents.

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

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

27. On information and belief, Defendant Mylan Pharmaceuticals, jointly with, and/or as the agent or alter ego of its parent Mylan Inc., submitted ANDA No. 202577 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 0.3 mg of fentanyl citrate. ANDA No. 202577 specifically seeks FDA approval to market the Mylan generic fentanyl buccal tablets containing 0.3 mg of fentanyl citrate prior to the expiration of the '604 patent and prior to expiration of the '590 patent.

28. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Mylan Pharmaceuticals alleged in ANDA No. 202577 that the claims of the '604 patent and the claims of the '590 patent are not infringed by the commercial manufacture, use or sale throughout the United States of the Mylan Generic Product, and/or that the claims of the '604 patent and '590 patent are invalid and/or unenforceable. CIMA received written notification of ANDA No. 202577 and Mylan Pharmaceuticals' §505(j)(2)(A)(vii)(IV) allegations from Mylan Pharmaceuticals on or about January 11, 2011, and Cephalon received a similar Paragraph IV letter on or about January 11, 2011 (together, "First Paragraph IV Notice Letters").

29. The stated purpose of the First Paragraph IV Notice Letters was to notify Plaintiffs that Mylan Pharmaceuticals had filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4) in conjunction with ANDA No. 202577 for approval, *inter alia*, to commercially manufacture and sell a generic version of Cephalon's FENTORA® brand fentanyl buccal tablets. The First Paragraph IV Notice Letters allege that the claims of the '604 patent and '590 patent are invalid.

30. The First Paragraph IV Notice Letters do not comply with the requirements of 21 U.S.C. § 355 (j)(2)(B)(iv)(II), *inter alia*, because they contain very limited information about the generic formulation for which Mylan Pharmaceuticals filed ANDA No. 202577.

31. The '832 and '833 patents had not issued at the time Mylan Pharmaceuticals submitted its certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act.

32. In a separate action, *Cephalon, Inc. and CIMA Labs, Inc. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, C.A. No. 11-164-SLR, Plaintiffs asserted the '604 and '590 patents against Defendants. Plaintiffs and Defendants subsequently stipulated to amend the complaint to assert allegations of infringement of the '832 and '833 patents.

33. ANDA No. 202577 has since been amended by the Mylan Defendants to include a reference to fentanyl citrate buccal tablets containing additional strengths of fentanyl citrate (0.1 mg, 0.2 mg, 0.4 mg, 0.6 mg, and 0.8 mg) ("the Amended ANDA").

34. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Mylan Pharmaceuticals alleged in the Amended ANDA that the claims of the '604 patent, the '590 patent, the '832 patent, and the '833 patent are not infringed by the commercial manufacture, use or sale throughout the United States of Mylan's generic 0.1 mg, 0.2 mg, 0.4 mg, 0.6 mg, and 0.8 mg fentanyl citrate buccal tablets, and/or that the claims of the '604 patent, the '590 patent, the '832 patent, and the '833 patent are invalid and/or unenforceable. Plaintiffs received written notification of the Amended ANDA and Mylan Pharmaceuticals' §505(j)(2)(A)(vii)(IV) allegations from Mylan Pharmaceuticals on or about September 29, 2011 ("Second Paragraph IV Notice Letter").

35. The Second Paragraph IV Notice 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 Mylan Pharmaceuticals filed the Amended ANDA.

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

37. Defendants' actions, including, but not limited to, the development of the Mylan Generic Product, the filing of an ANDA with a Paragraph IV certification, and the amendment of the ANDA to add additional strengths, indicate a refusal to change the course of their action in the face of acts by Plaintiffs.

38. On information and belief, Defendants continue to seek approval of ANDA No. 202577 from the FDA and intend to commercially manufacture, market and sell generic 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.6 mg, and 0.8 mg fentanyl buccal tablets (the "Mylan Generic Product"). The ANDA and Amended ANDA are herein referred to together as "the Mylan ANDA."

39. 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))

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

41. Defendants, acting jointly, submitted ANDA No. 202577 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 Mylan Generic Product. By submitting ANDA No. 202577, Defendants, individually and collectively, committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

42. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 202577 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 Mylan Generic Product. By submitting ANDA No. 202577, Mylan Pharmaceuticals has committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

43. When Mylan Pharmaceuticals submitted ANDA No. 202577 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 Mylan Generic Product, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit ANDA No. 202577 and/or causing its agent or alter ego to submit ANDA No. 202577, Mylan Inc. committed an act of infringement with respect to the '604 patent under 35 U.S.C. § 271(e)(2)(A).

44. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product 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))

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

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

47. 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.

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

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

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

51. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product by either or both of Defendants 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))

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

53. Defendants, acting jointly, submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry. By submitting ANDA No. 202577, Defendants, individually and collectively, committed an act of infringement with respect to the '590 patent under 35 U.S.C. § 271(e)(2)(A).

54. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry. By submitting

ANDA No. 202577, Mylan Pharmaceuticals has committed an act of infringement with respect to the '590 patent under 35 U.S.C. § 271(e)(2)(A).

55. When Mylan Pharmaceuticals submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit ANDA No. 202577 and/or causing its agent or alter ego to submit ANDA No. 202577, Mylan Inc. committed an act of infringement with respect to the '590 patent under 35 U.S.C. § 271(e)(2)(A).

56. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product 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))

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

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

59. 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.

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

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

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

63. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product prior to patent expiry by either or both of Defendants 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))

64. Paragraphs 1 to 63 are incorporated herein as set forth above.

65. Defendants, acting jointly, submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry. By submitting ANDA No. 202577, Defendants, individually and collectively, committed an act of infringement with respect to the '832 patent under 35 U.S.C. § 271(e)(2)(A).

66. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry. By submitting ANDA No. 202577, Mylan Pharmaceuticals has committed an act of infringement with respect to the '832 patent under 35 U.S.C. § 271(e)(2)(A).

67. When Mylan Pharmaceuticals submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit ANDA No. 202577 and/or causing its agent or alter ego to submit ANDA No. 202577, Mylan Inc. committed an act of infringement with respect to the '832 patent under 35 U.S.C. § 271(e)(2)(A).

68. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product 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))

69. Paragraphs 1 to 68 are incorporated herein as set forth above.

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

71. 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.

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

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

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

75. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product prior to patent expiry by either or both of Defendants 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))

76. Paragraphs 1 to 75 are incorporated herein as set forth above.

77. Defendants, acting jointly, submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry. By submitting ANDA No. 202577, Defendants, individually and collectively, committed an act of infringement with respect to the '833 patent under 35 U.S.C. § 271(e)(2)(A).

78. Mylan Pharmaceuticals, acting jointly with Mylan Inc., and/or as its agent or alter ego, submitted ANDA No. 202577 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 Mylan Generic Product prior to patent expiry. By submitting ANDA No. 202577, Mylan Pharmaceuticals has committed an act of infringement with respect to the '833 patent under 35 U.S.C. § 271(e)(2)(A).

79. When Mylan Pharmaceuticals submitted ANDA No. 202577 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 Mylan Generic Product prior to

patent expiry, it was acting jointly with Mylan Inc. and/or acting as Mylan Inc.'s agent or alter ego. By acting jointly with Mylan Pharmaceuticals to submit ANDA No. 202577 and/or causing its agent or alter ego to submit ANDA No. 202577, Mylan Inc. committed an act of infringement with respect to the '833 patent under 35 U.S.C. § 271(e)(2)(A).

80. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product 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))

81. Paragraphs 1 to 80 are incorporated herein as set forth above.

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

83. 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.

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

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

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

87. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan Generic Product prior to patent expiry by either or both of Defendants will constitute direct and/or contributory infringement and/or active inducement of infringement of the '833 patent.

EXCEPTIONAL CASE

88. The Mylan Defendants were aware of the '604 and '590 patents prior to filing ANDA No. 202577.

89. The Mylan Defendants were aware of the '604, '590, '832, and '833 patents prior to filing the Amended ANDA.

90. The actions of the Mylan Defendants, individually and collectively, render this an exceptional case under 35 U.S.C. § 285.

INJUNCTIVE RELIEF

91. Plaintiffs will be irreparably harmed by the Mylan Defendants' 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, '590, '832, and '833 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202577 under the FFDCA, and that the commercial manufacture, use, offer for sale, and/or importation of the Mylan Generic Product prior to patent expiry will constitute an act of infringement of the '604, '590, '832, and '833 patents;

b. That judgment be entered that Mylan Pharmaceuticals has infringed the '604, '590, '832, and '833 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202577 under the FFDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Mylan Generic Product prior to patent expiry will constitute an act of infringement of the '604, '590, '832, and '833 patents;

c. That judgment be entered that Mylan Inc. has infringed the '604, '590, '832, and '833 patents under 35 U.S.C. § 271(e)(2)(A) by acting jointly with Mylan Pharmaceuticals or allowing Mylan Pharmaceuticals to act as its agent or alter ego in submitting ANDA No. 202577 under the FFDCA, and that the commercial manufacture, use, offer for sale, and/or importation of the Mylan Generic Product prior to patent expiry will constitute an act of infringement of the '604, '590, '832, and '833 patents;

d. 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. 202577 shall be a date that is not earlier than the expiration date of the '604, '590, '832, and '833 patents including any extensions;

e. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan Inc., Mylan Pharmaceuticals, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '604, '590, '832, and '833 patents;

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

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

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

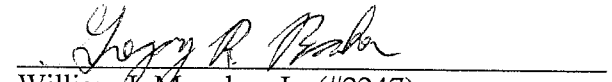
i. That this Court award such other and further relief as it may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues appropriately tried by a jury.

DATED: November 9, 2011

FISH & RICHARDSON P.C.

By: 

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