IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS INC., and ONYX PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN PHARMACEUTICALS INC. and MYLAN INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer HealthCare LLC ("BHC"), Bayer HealthCare Pharmaceuticals Inc. ("BHCPI") (BHC and BHCPI are collectively referred to herein as "Bayer"), and Onyx Pharmaceuticals, Inc. ("Onyx") (Bayer and Onyx are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Mylan Pharmaceuticals Inc. of Abbreviated New Drug Application ("ANDA") No. 207012 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' NEXAVAR® product prior to the expiration of U.S. Patent Nos. 7,897,623 ("the '623 patent"), 7,235,576 ("the '576 patent"), 7,351,834 ("the '834 patent"), 8,877,933 ("the '933 patent"), and 8,841,330 ("the '330 patent"). As set forth in its FDA-approved labeling, NEXAVAR® is indicated for the treatment of certain types of cancer.

THE PARTIES

2. Plaintiff Bayer HealthCare LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

4. Plaintiff Onyx Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 249 E. Grand Avenue, South San Francisco, California.

5. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, and having designated its registered agent for the State of Delaware as Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware.

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

7. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc. and is controlled and dominated by Mylan Inc.

8. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Mylan Pharmaceuticals Inc.,

acting in concert with Mylan Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Mylan Pharmaceuticals Inc., acting in concert with Mylan Inc., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. On information and belief, and consistent with their practice with respect to other generic products, Mylan Inc. and Mylan Pharmaceuticals Inc. acted in concert to prepare and submit ANDA No. 207012 for Mylan Pharmaceutical Inc.'s sorafenib tosylate tablets, 200 mg ("Mylan's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Mylan Inc.

10. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Mylan ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 207012, Mylan Pharmaceuticals Inc. and Mylan Inc. will act in concert to market, distribute, offer for sale, and sell Mylan's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Mylan" or "Defendants."

12. On information and belief, following any FDA approval of ANDA No. 207012, Mylan knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over the defendants.

15. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. because, on information and belief, Mylan Pharmaceuticals Inc. has registered to do business in the State of Delaware and has appointed a registered agent in Delaware to accept service of process. Mylan Pharmaceuticals Inc. has thus consented to jurisdiction in Delaware.

16. In addition, this Court also has personal jurisdiction over Mylan Pharmaceuticals Inc. and Mylan Inc. because, among other things, on information and belief: (1) Mylan Pharmaceuticals Inc., acting in concert with Mylan Inc., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product in the United States, including in Delaware; and (2) Mylan Pharmaceuticals Inc. and Mylan Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Mylan's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 207012, and will derive substantial revenue from the use or consumption of Mylan's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 207012 is approved, the generic Mylan products charged

with infringing the'623, '576, '834, '933, and '330 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

17. The Court also has personal jurisdiction over Mylan Pharmaceuticals Inc. and Mylan Inc. because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to BHC, a Delaware limited liability company; BHCPI, a Delaware corporation; and Onyx, a Delaware corporation. For example, Mylan Pharmaceuticals Inc. sent the Notice Letters (defined below) to BHC, which has led and/or will lead to foreseeable harm and injury to BHC in Delaware.

18. Mylan Pharmaceuticals Inc. is actively registered with the Delaware Board of Pharmacy, pursuant to Del. C. § 2540, as a licensed "Pharmacy – Wholesale Drug Distributor," and as a licensed "Distributor/Manufacturer CSR."

19. Mylan Inc. and Mylan Pharmaceuticals Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

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

FACTUAL BACKGROUND

21. NEXAVAR® (active ingredient sorafenib tosylate) is a kinase inhibitor indicated for the treatment of unresectable hepatocellular carcinoma, advanced renal cell carcinoma, and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

22. BHCPI is the holder of New Drug Application No. 21923 for NEXAVAR®, which has been approved by the FDA.

The ’623 Patent

23. United States Patent No. 7,897,623, entitled “ω-Carboxyl Aryl Substituted Diphenyl Ureas As P38 Kinase Inhibitors,” was duly and legally issued on March 1, 2011. The ’623 patent is attached as Exhibit A.

24. BHC is the assignee of the ’623 patent, which has not expired.

25. As set forth in greater detail in the ’623 patent, the claims of the ’623 patent, incorporated by reference herein, cover, *inter alia*, pharmaceutical compositions comprising sorafenib tosylate.

26. Onyx is an exclusive licensee under the ’623 patent.

27. Pursuant to 21 U.S.C. § 355, the ’623 patent is listed in the Orange Book in connection with NEXAVAR®.

28. By letter to BHC dated December 19, 2014 (the “December 2014 Notice Letter”) and by letter to BHC and Bayer Intellectual Property GmbH dated November 5, 2015 (the “November 2015 Notice Letter”) (collectively “the Notice Letters”), Mylan provided notice that Mylan had submitted to the FDA ANDA No. 207012 for Mylan’s ANDA Product. This product is a generic version of NEXAVAR®.

29. In the Notice Letters, Mylan stated that Mylan’s ANDA Product is 200 mg sorafenib tosylate tablets.

30. On information and belief, the proposed labeling for Mylan’s ANDA Product will direct the use of Mylan’s ANDA Product for the treatment of advanced renal cell carcinoma and unresectable hepatocellular carcinoma.

31. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product, including the use of Mylan's ANDA Product in accordance with and as directed by Mylan's labeling for that product, will infringe one or more claims of the '623 patent, including at least claim 6.

32. In the Notice Letters, Mylan does not contest infringement of any of claims 1–8 of the '623 patent.

33. In the November 2015 Notice Letter, Mylan notified Plaintiffs that, in connection with its ANDA No. 207012, Mylan Pharmaceuticals Inc. had filed Paragraph IV Certifications with respect to the '623 patent.

34. The purpose of ANDA No. 207012 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product with its proposed labeling prior to the expiration of the '623 patent.

35. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '623 patent.

36. Mylan's Notice Letters did not provide a valid basis for concluding that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would not infringe at least one valid and enforceable claim of the '623 patent.

37. Mylan has knowledge of the claims of the '623 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012.

38. Mylan plans and intends to, and will, actively induce infringement of the '623 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. The foregoing actions by Mylan constitute and/or will constitute infringement of the '623 patent and/or active inducement of infringement of the '623 patent.

40. Mylan is without a reasonable basis for believing that it will not be liable for infringing the '623 patent and/or actively inducing infringement of the '623 patent.

41. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of the '623 patent.

The '576 Patent

42. United States Patent No. 7,235,576, entitled "Omega-Carboxyaryl Substituted Diphenyl Ureas As Raf Kinase Inhibitors," was duly and legally issued on June 26, 2007. The '576 patent is attached as Exhibit B.

43. BHC is the assignee of the '576 patent, which has not expired.

44. As set forth in greater detail in the '576 patent, the claims of the '576 patent, incorporated by reference herein, cover, *inter alia*, pharmaceutically acceptable salts of sorafenib.

45. Onyx is an exclusive licensee under the '576 patent.

46. Pursuant to 21 U.S.C. § 355, the '576 patent is listed in the Orange Book in connection with NEXAVAR®.

47. In the Notice Letters, Mylan stated that Mylan's ANDA Product contains the tosylate salt of sorafenib.

48. On information and belief, the proposed labeling for Mylan's ANDA Product will direct the use of Mylan's ANDA Product for the treatment of advanced renal cell carcinoma and unresectable hepatocellular carcinoma.

49. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product, including the use of Mylan's ANDA Product in accordance with and as directed by Mylan's labeling for that product, will infringe one or more claims of the '576 patent, including at least claim 16.

50. In the Notice Letters, Mylan does not contest infringement of any of claims 1–17 of the '576 patent.

51. In the November 2015 Notice Letter, Mylan notified Plaintiffs that, in connection with its ANDA No. 207012, Mylan Pharmaceuticals Inc. had filed Paragraph IV Certifications with respect to the '576 patent.

52. The purpose of ANDA No. 207012 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product with its proposed labeling prior to the expiration of the '576 patent.

53. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '576 patent.

54. Mylan's Notice Letters did not provide a valid basis for concluding that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling would not infringe at least one valid and enforceable claim of the '576 patent.

55. Mylan has knowledge of the claims of the '576 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012.

56. Mylan plans and intends to, and will, actively induce infringement of the '576 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

57. The foregoing actions by Mylan constitute and/or will constitute infringement of the '576 patent and/or active inducement of infringement of the '576 patent.

58. Mylan is without a reasonable basis for believing that it will not be liable for infringing the '576 patent and/or actively inducing infringement of the '576 patent.

59. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of the '576 patent.

The '834 Patent

60. United States Patent No. 7,351,834, entitled "ω-Carboxyaryl Substituted Diphenyl Ureas As Raf Kinase Inhibitors," was duly and legally issued on April 1, 2008. The '834 patent is attached as Exhibit C.

61. BHC is the assignee of the '834 patent, which has not expired.

62. As set forth in greater detail in the '834 patent, the claims of the '834 patent, incorporated by reference herein, cover, *inter alia*, the compound sorafenib and pharmaceutically acceptable salts thereof.

63. Onyx is an exclusive licensee under the '834 patent.

64. Pursuant to 21 U.S.C. § 355, the '834 patent is listed in the Orange Book in connection with NEXAVAR®.

65. In the Notice Letters, Mylan stated that Mylan's ANDA Product contains the tosylate salt of sorafenib.

66. On information and belief, the proposed labeling for Mylan's ANDA Product will direct the use of Mylan's ANDA Product for the treatment of advanced renal cell carcinoma and unresectable hepatocellular carcinoma.

67. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product, including the use of Mylan's ANDA Product in accordance with and as directed by Mylan's labeling for that product, will infringe one or more claims of the '834 patent, including at least claim 41.

68. In the Notice Letters, Mylan does not contest infringement of claims 1–2, 4–5, 19, 24–25, 28–32, and 35–41 of the '834 patent.

69. In the November 2015 Notice Letter, Mylan notified Plaintiffs that, in connection with its ANDA No. 207012, Mylan Pharmaceuticals Inc. had filed Paragraph IV Certifications with respect to the '834 patent.

70. The purpose of ANDA No. 207012 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product with its proposed labeling prior to the expiration of the '834 patent.

71. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '834 patent.

72. Mylan's Notice Letters did not provide a valid basis for concluding that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling would not infringe at least one valid and enforceable claim of the '834 patent.

73. Mylan has knowledge of the claims of the '834 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012.

74. Mylan plans and intends to, and will, actively induce infringement of the '834 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

75. The foregoing actions by Mylan constitute and/or will constitute infringement of the '834 patent and/or active inducement of infringement of the '834 patent.

76. Mylan is without a reasonable basis for believing that it will not be liable for infringing the '834 patent and/or actively inducing infringement of the '834 patent.

77. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of the '834 patent.

The '933 Patent

78. United States Patent No. 8,877,933, entitled "Thermodynamically Stable Form Of A Tosylate Salt," was duly and legally issued on November 4, 2014. The '933 patent is attached as Exhibit D.

79. BHC is the assignee of the '933 patent, which has not expired.

80. As set forth in greater detail in the '933 patent, the claims of the '933 patent, incorporated by reference herein, cover sorafenib tosylate in the polymorph I form and pharmaceutical compositions containing sorafenib tosylate in the polymorph I form. As set forth in greater detail in the '933 patent, the claims of the '933 patent also cover methods of manufacturing sorafenib tosylate in the polymorph I form and methods of using sorafenib tosylate in the polymorph I form.

81. Onyx is an exclusive licensee under the '933 patent.

82. Pursuant to 21 U.S.C. § 355, the '933 patent is listed in the Orange Book in connection with NEXAVAR®.

83. In the Notice Letters, Mylan stated that Mylan's ANDA Product contains sorafenib tosylate.

84. On information and belief, Mylan's ANDA Product contains sorafenib tosylate in the polymorph I form.

85. On information and belief, the proposed labeling for Mylan's ANDA Product will direct the use of Mylan's ANDA Product for the treatment of advanced renal cell carcinoma and unresectable hepatocellular carcinoma.

86. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product, including the use of Mylan's ANDA Product in accordance with and as directed by Mylan's labeling for that product, will infringe one or more claims of the '933 patent, including at least claims 1, 8, and 16.

87. In the Notice Letters, Mylan does not contest infringement of claims 1–4, 8–10, 16–21, and 27–31 of the '933 patent.

88. In the November 2015 Notice Letter, Mylan notified Plaintiffs that, in connection with its ANDA No. 207012, Mylan Pharmaceuticals Inc. had filed Paragraph IV Certifications with respect to the '933 patent.

89. The purpose of ANDA No. 207012 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product with its proposed labeling prior to the expiration of the '933 patent.

90. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '933 patent.

91. Mylan's Notice Letters did not provide a valid basis for concluding that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling would not infringe at least one valid and enforceable claim of the '933 patent.

92. Mylan has knowledge of the claims of the '933 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012.

93. Mylan plans and intends to, and will, actively induce infringement of the '933 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

94. On information and belief, Mylan knows that Mylan's ANDA Product is especially made or adapted for use in infringing the '933 patent, and that Mylan's ANDA

Product is not suitable for substantial noninfringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '933 patent immediately and imminently upon approval of ANDA No. 207012.

95. The foregoing actions by Mylan constitute and/or will constitute infringement of the '933 patent, active inducement of infringement of the '933 patent, and/or contribution to the infringement by others of the '933 patent.

96. Mylan is without a reasonable basis for believing that it will not be liable for infringing the '933 patent, actively inducing infringement of the '933 patent, and/or contributing to the infringement by others of the '933 patent.

97. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of the '933 patent.

The '330 Patent

98. United States Patent No. 8,841,330, entitled "Omega-Carboxyaryl Substituted Diphenyl Ureas As Raf Kinase Inhibitors," was duly and legally issued on September 23, 2014. The '330 patent is attached as Exhibit E.

99. BHC is the assignee of the '330 patent, which has not expired.

100. As set forth in greater detail in the '330 patent, the claims of the '330 patent, incorporated by reference herein, cover, *inter alia*, methods for the treatment of a tumor of the liver in a human or animal comprising administering an effective amount of sorafenib tosylate.

101. Onyx is an exclusive licensee under the '330 patent.

102. Pursuant to 21 U.S.C. § 355, the '330 patent is listed in the Orange Book in connection with NEXAVAR®.

103. In the Notice Letters, Mylan stated that Mylan's ANDA Product contains sorafenib tosylate.

104. On information and belief, the proposed labeling for Mylan's ANDA Product directs the use of Mylan's ANDA Product for the treatment of unresectable hepatocellular carcinoma.

105. On information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for Mylan's ANDA Product will infringe one or more claims of the '330 patent, including at least claims 10 and 14.

106. In the Notice Letters, Mylan does not contest infringement of claims 1, 4, 7, 10, and 13–14 of the '330 patent.

107. In the November 2015 Notice Letter, Mylan notified Plaintiffs that, in connection with its ANDA No. 207012, Mylan Pharmaceuticals Inc. had filed Paragraph IV Certifications with respect to the '330 patent.

108. The purpose of ANDA No. 207012 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product with its proposed labeling prior to the expiration of the '330 patent.

109. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '330 patent.

110. Mylan's Notice Letters did not provide a valid basis for concluding that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's

ANDA Product with its proposed labeling would not infringe at least one valid and enforceable claim of the '330 patent.

111. Mylan has knowledge of the claims of the '330 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012.

112. Mylan plans and intends to, and will, actively induce infringement of the '330 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

113. On information and belief, Mylan knows that Mylan's ANDA Product is especially made or adapted for use in infringing the '330 patent, and that Mylan's ANDA Product is not suitable for substantial noninfringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '330 patent immediately and imminently upon approval of ANDA No. 207012.

114. The foregoing actions by Mylan constitute and/or will constitute infringement of the '330 patent, active inducement of infringement of the '330 patent, and/or contribution to the infringement by others of the '330 patent.

115. Mylan is without a reasonable basis for believing that it will not be liable for infringing the '330 patent, actively inducing infringement of the '330 patent, and/or contributing to the infringement by others of the '330 patent.

116. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of the '330 patent.

COUNT I
(Infringement of the '623 Patent)

117. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

118. Mylan's submission of ANDA No. 207012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product was an act of infringement of the '623 patent under 35 U.S.C. § 271(e)(2).

119. Unless Mylan is enjoined from infringing the '623 patent and actively inducing infringement of the '623 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Declaratory Judgment as to the '623 Patent)

120. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

121. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

122. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product with its proposed labeling prior to the expiration of the '623 patent.

123. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '623 patent.

124. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Mylan's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Mylan's ANDA Product with its proposed labeling would constitute infringement of the '623 patent and/or inducement of infringement of the '623 patent.

125. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 207012 will infringe one or more claims of the '623 patent.

126. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling infringes and actively induces the infringement of the '623 patent.

COUNT III
(Infringement of the '576 Patent)

127. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

128. Mylan's submission of ANDA No. 207012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product was an act of infringement of the '576 patent under 35 U.S.C. § 271(e)(2).

129. Unless Mylan is enjoined from infringing the '576 patent and actively inducing infringement of the '576 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
(Declaratory Judgment as to the '576 Patent)

130. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

131. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

132. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product with its proposed labeling prior to the expiration of the '576 patent.

133. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '576 patent.

134. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Mylan's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Mylan's ANDA Product with its proposed labeling would constitute infringement of the '576 patent and/or inducement of infringement of the '576 patent.

135. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 207012 will infringe one or more claims of the '576 patent.

136. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling infringes and actively induces the infringement of the '576 patent.

COUNT V
(Infringement of the '834 Patent)

137. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

138. Mylan's submission of ANDA No. 207012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product was an act of infringement of the '834 patent under 35 U.S.C. § 271(e)(2).

139. Unless Mylan is enjoined from infringing the '834 patent and actively inducing infringement of the '834 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI
(Declaratory Judgment as to the '834 Patent)

140. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

141. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

142. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product with its proposed labeling prior to the expiration of the '834 patent.

143. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '834 patent.

144. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Mylan's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Mylan's ANDA Product with its proposed labeling would constitute infringement of the '834 patent and/or inducement of infringement of the '834 patent.

145. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 207012 will infringe one or more claims of the '834 patent.

146. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling infringes and actively induces the infringement of the '834 patent.

COUNT VII
(Infringement of the '933 Patent)

147. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

148. Mylan's submission of ANDA No. 207012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product was an act of infringement of the '933 patent under 35 U.S.C. § 271(e)(2).

149. Unless Mylan is enjoined from infringing the '933 patent, actively inducing infringement of the '933 patent, and contributing to the infringement by others of the '933 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII
(Declaratory Judgment as to the '933 Patent)

150. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

151. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

152. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product with its proposed labeling prior to the expiration of the '933 patent.

153. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '933 patent.

154. On information and belief, pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g), Mylan's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Mylan's ANDA Product, including in accordance with its proposed labeling, would constitute infringement of the '933 patent, inducement of infringement of the '933 patent, and contribution to the infringement of the '933 patent.

155. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 207012 will infringe one or more claims of the '933 patent.

156. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its

proposed labeling infringes, actively induces the infringement of, and contributes to the infringement by others of the '933 patent.

COUNT IX
(Infringement of the '330 Patent)

157. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

158. Mylan's submission of ANDA No. 207012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product was an act of infringement of the '330 patent under 35 U.S.C. § 271(e)(2).

159. Unless Mylan is enjoined from infringing the '330 patent, actively inducing infringement of the '330 patent, and contributing to the infringement by others of the '330 patent. Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT X
(Declaratory Judgment as to the '330 Patent)

160. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

161. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

162. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Product with its proposed labeling prior to the expiration of the '330 patent.

163. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling

immediately and imminently upon approval of ANDA No. 207012, *i.e.*, prior to the expiration of the '330 patent.

164. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Mylan's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Mylan's ANDA Product with its proposed labeling would constitute infringement of the '330 patent, inducement of infringement of the '330 patent, and contribution to the infringement of the '330 patent.

165. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 207012 will infringe one or more claims of the '330 patent.

166. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling infringes, actively induces the infringement of, and contributes to the infringement by others of the '330 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Mylan has infringed the '623 patent;

(b) A judgment that Mylan has infringed the '576 patent;

(c) A judgment that Mylan has infringed the '834 patent;

(d) A judgment that Mylan has infringed the '933 patent;

(e) A judgment that Mylan has infringed the '330 patent;

(f) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan's ANDA Product, or

any product or compound which infringes or the use of which infringes the ’623 patent, be not earlier than the expiration date of the ’623 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan’s ANDA Product, or any product or compound which infringes or the use of which infringes the ’576 patent, be not earlier than the expiration date of the ’576 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(h) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan’s ANDA Product, or any product or compound which infringes or the use of which infringes the ’834 patent, be not earlier than the expiration date of the ’834 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(i) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan’s ANDA Product, or any product or compound which infringes or the use of which infringes the ’933 patent, be not earlier than the expiration date of the ’933 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(j) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan’s ANDA Product, or any product or compound the use of which infringes the ’330 patent, be not earlier than the expiration date of the ’330 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(k) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '623 patent, or the inducement of any of the foregoing, prior to the expiration date of the '623 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(l) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '576 patent, or the inducement of any of the foregoing, prior to the expiration date of the '576 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(m) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '834 patent, or the inducement of any of the foregoing, prior to the expiration date of the '834 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(n) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '933 patent, or the inducement of or the contribution to any of the

foregoing, prior to the expiration date of the '933 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(o) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound the use of which infringes the '330 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '330 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(p) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '623 patent, prior to the expiration date of the '623 patent, will infringe and actively induce infringement of the '623 patent;

(q) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '576 patent, prior to the expiration date of the '576 patent, will infringe and actively induce infringement of the '576 patent;

(r) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '834 patent, prior to the expiration date of the '834 patent, will infringe and actively induce infringement of the '834 patent;

(s) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes or the use of which infringes the '933 patent, prior to the expiration date of the '933

patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '933 patent;

(t) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound the use of which infringes the '330 patent, prior to the expiration date of the '330 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '330 patent;

(u) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(v) An award of Plaintiffs' costs and expense in this action; and

(w) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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