IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer HealthCare LLC ("BHC") and Bayer HealthCare Pharmaceuticals Inc. ("BHCPI") (BHC and BHCPI are collectively referred to herein as "Bayer" or "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, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of the filing by defendant Teva Pharmaceuticals, USA, Inc. ("Teva USA") of Abbreviated New Drug Application ("ANDA") No. 209728 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Bayer's STIVARGA® product prior to the expiration of U.S. Patent Nos. 7,351,834 ("the '834 patent"), 8,637,553 ("the '553 patent"), 8,680,124 ("the '124 patent"), and 9,458,107 ("the '107 patent"). As set forth in its FDA-approved labeling, STIVARGA® is indicated for the treatment of certain types of cancer.

2. By letter dated November 22, 2016 (the "Notice Letter"), Teva USA notified Bayer that Teva USA had submitted to the FDA an ANDA, No. 209728, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Regorafenib Oral Tablets, 40 mg ("Teva's ANDA Product") prior to the expiration of the '834, '553, '124, and '107 patents. Upon information and belief, Teva's ANDA Product is a generic version of STIVARGA®.

THE PARTIES

3. 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.

4. 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.

5. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 1090 Horsham Road, North Wales, Pennsylvania, and having designated its registered agent for the State of Delaware as Corporate Creations Network Inc., 3411 Silverside Road, #104 Rodney Building, Wilmington, Delaware.

6. On information and belief, Defendant Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and is controlled and dominated by Teva Ltd.

7. On information and belief, Teva Ltd. is an Israeli limited company organized under the laws of Israel and has a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

8. On information and belief, Teva USA 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, Teva USA, acting in concert with Teva Ltd., 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, Teva USA, acting in concert with Teva Ltd., 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, Teva USA and Teva Ltd. acted in concert to prepare and submit ANDA No. 209728 for Teva's ANDA Product, which was done at the direction of, under the control of, and for the direct benefit of Teva Ltd.

10. On information and belief, Teva USA and Teva Ltd. 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 Teva ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 209728, Teva USA and Teva Ltd. will act in concert to market, distribute, offer for sale, and sell Teva's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Teva" or "Defendants."

12. On information and belief, following any FDA approval of ANDA No. 209728, Teva 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 Teva USA because, on information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process. Teva USA has thus consented to jurisdiction in Delaware.

16. In addition, this Court also has personal jurisdiction over Teva USA and Teva Ltd. because, among other things, on information and belief: (1) Teva USA, acting in concert with Teva Ltd., 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 Teva's ANDA Product in the United States, including in Delaware; and (2) Teva USA and Teva Ltd., acting in concert

and/or as agents of one another, will market, distribute, offer for sale, and/or sell Teva's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 209728, and will derive substantial revenue from the use or consumption of Teva's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 209728 is approved, the generic Teva product charged with infringing the '834, '553, '124, and '107 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 Teva USA and Teva Ltd. 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, and BHCPI, a Delaware corporation. For example, Teva USA sent the Notice Letter to Bayer, which has led and/or will lead to foreseeable harm and injury to Bayer in Delaware.

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

FACTUAL BACKGROUND

19. STIVARGA®, which contains regorafenib, is a kinase inhibitor indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. It is also indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.

20. BHCPI is the holder of New Drug Application No. 203085 for STIVARGA®, which has been approved by the FDA.

The '834 Patent

21. 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 A.

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

23. As set forth in greater detail in the '834 patent, various claims of the '834 patent, incorporated by reference herein, cover, *inter alia*, regorafenib.

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

25. By letter to BHC and BHCPI, dated November 22, 2016, Teva USA provided notice that Teva USA had submitted to the FDA ANDA No. 209728 for Teva's ANDA Product.

26. In the Notice Letter, Teva USA notified Bayer that, in connection with its ANDA No. 209728, Teva USA had filed a Paragraph IV Certification with respect to the '834 patent.

27. Teva had knowledge of the claims of the '834 patent before Teva USA filed its Paragraph IV Certification.

28. The purpose of ANDA No. 209728 is to obtain approval under the United States Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product with its proposed labeling prior to the expiration of the '834 patent.

29. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '834 patent.

30. This action is being commenced before the expiration of forty-five days from the receipt of the Notice Letter.

31. The Notice Letter stated that Teva's ANDA Product contains regorafenib.

32. In the Notice Letter, Teva does not contest infringement of claims 1-2, 4-5, 7-8, 11-12, 19, 22-24, 28, or 33-34 of the '834 patent.

33. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product, including the use of Teva's ANDA Product in accordance with and as directed by Teva's labeling for that product, will infringe one or more claims of the '834 patent, including at least claim 1.

34. Teva has knowledge of the claims of the '834 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728.

35. On information and belief, Teva 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.

36. The foregoing actions by Teva constitute or will constitute infringement of the '834 patent and active inducement of infringement of the '834 patent.

37. An actual case or controversy exists between Bayer and Teva with respect to infringement of the '834 patent.

The '553 Patent

38. United States Patent No. 8,637,553, entitled "Fluoro Substituted Omega-Carboxyaryl Diphenyl Urea for the Treatment and Prevention of Diseases and Conditions," was duly and legally issued on January 28, 2014. The '553 patent is attached as Exhibit B.

39. BHC is the assignee of the '553 patent, which has not expired.

40. As set forth in greater detail in the '553 patent, the claims of the '553 patent, incorporated by reference herein, cover, *inter alia*, regorafenib and pharmaceutical compositions containing regorafenib.

41. Pursuant to 21 U.S.C. § 355, the '553 patent is listed in the Orange Book in connection with STIVARGA®.

42. By letter to BHC and BHCPI, dated November 22, 2016, Teva USA provided notice that Teva USA had submitted to the FDA ANDA No. 209728 for Teva's ANDA Product.

43. In the Notice Letter, Teva USA notified Bayer that, in connection with its ANDA No. 209728, Teva USA had filed a Paragraph IV Certification with respect to the '553 patent.

44. Teva had knowledge of the claims of the '553 patent before Teva USA filed its Paragraph IV Certification.

45. The purpose of ANDA No. 209728 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product with its proposed labeling prior to the expiration of the '553 patent.

46. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '553 patent.

47. This action is being commenced before the expiration of forty-five days from the receipt of the Notice Letter.

48. The Notice Letter stated that Teva's ANDA Product contains regorafenib. The Notice Letter also stated that Teva's ANDA Product is a tablet.

49. In the Notice Letter, Teva does not contest infringement of claims 1, 3, 6, 8, 10-14 of the '553 patent.

50. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product, including the use of Teva's ANDA Product in accordance with and as directed by Teva's labeling for that product, will infringe one or more claims of the '553 patent, including at least claims 13 and 14.

51. Teva has knowledge of the claims of the '553 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728.

52. On information and belief, Teva plans and intends to, and will, actively induce infringement of the '553 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

53. The foregoing actions by Teva constitute or will constitute infringement of the '553 patent and active inducement of infringement of the '553 patent.

54. An actual case or controversy exists between Bayer and Teva with respect to infringement of the ’553 patent.

The ’124 Patent

55. United States Patent No. 8,680,124, entitled “Treatment of Cancers with Acquired Resistance to Kit Inhibitors,” was duly and legally issued on March 25, 2014. The ’124 patent is attached as Exhibit C.

56. BHC is the assignee of the ’124 patent, which has not expired.

57. As set forth in greater detail in the ’124 patent, the claims of the ’124 patent, incorporated by reference herein, cover, *inter alia*, methods of treating certain types of cancer by administering regorafenib.

58. Pursuant to 21 U.S.C. § 355, the ’124 patent is listed in the Orange Book in connection with STIVARGA®.

59. By letter to BHC and BHCPI, dated November 22, 2016, Teva provided notice that Teva USA had submitted to the FDA ANDA No. 209728 for Teva’s ANDA Product.

60. In the Notice Letter, Teva notified Bayer that, in connection with its ANDA No. 209728, Teva USA had filed a Paragraph IV Certification with respect to the ’124 patent.

61. Teva had knowledge of the claims of the ’124 patent before Teva USA filed its Paragraph IV Certification.

62. The purpose of ANDA No. 209728 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva’s ANDA Product with its proposed labeling prior to the expiration of the ’124 patent.

63. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '124 patent.

64. This action is being commenced before the expiration of forty-five days from the receipt of the Notice Letter.

65. The Notice Letter stated that Teva's ANDA Product contains regorafenib.

66. On information and belief, the proposed labeling for Teva's ANDA Product states that Teva's ANDA Product is indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.

67. In the Notice Letter, Teva does not contest infringement of the '124 patent.

68. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product, including the use of Teva's ANDA Product in accordance with and as directed by Teva's labeling for that product, will infringe one or more claims of the '124 patent, including at least claim 4.

69. Teva has knowledge of the claims of the '124 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728.

70. On information and belief, Teva plans and intends to, and will, actively induce infringement of the '124 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

71. On information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '124 patent, and that Teva's ANDA Product is not suitable for substantial noninfringing use. On information and belief, Teva plans and intends to, and will, contribute to infringement of the '124 patent immediately and imminently upon approval of ANDA No. 209728.

72. The foregoing actions by Teva constitute or will constitute infringement of the '124 patent, active inducement of infringement of the '124 patent, and/or contribution to the infringement by others of the '124 patent.

73. An actual case or controversy exists between Bayer and Teva with respect to infringement of the '124 patent.

The '107 Patent

74. United States Patent No. 9,458,107, entitled "Process for the Preparation of 4-{4-[({[4-chloro-3-(trifluoromethyl)-phenyl]amino}carbonyl)amino]-3-fluorphenoxy-*N*-ethylpyridie-carboxamide, Its Salts and Monohydrate," was duly and legally issued on October 4, 2016. The '107 patent is attached as Exhibit D.

75. BHC is the assignee of the '107 patent, which has not expired.

76. As set forth in greater detail in the '107 patent, the claims of the '107 patent, incorporated by reference herein, cover, *inter alia*, regorafenib which is contaminated with one or more anilinic substances, each in an amount equal to or less than 0.05% by weight based on the weight of the regorafenib.

77. Pursuant to 21 U.S.C. § 355, the '107 patent is listed in the Orange Book in connection with STIVARGA®.

78. By letter to BHC and BHCPI, dated November 22, 2016, Teva provided notice that Teva USA had submitted to the FDA ANDA No. 209728 for Teva's ANDA Product.

79. In the Notice Letter, Teva notified Bayer that, in connection with its ANDA No. 209728, Teva USA had filed a Paragraph IV Certification with respect to the '107 patent.

80. Teva had knowledge of the claims of the '107 patent before Teva USA filed its Paragraph IV Certification.

81. The purpose of ANDA No. 209728 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product with its proposed labeling prior to the expiration of the '107 patent.

82. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '107 patent.

83. This action is being commenced before the expiration of forty-five days from the receipt of the Notice Letter.

84. The Notice Letter stated that Teva's ANDA Product contains regorafenib.

85. In the Notice Letter, Teva does not contest infringement of claims 1-4, 9-14, or 18-20 of the '107 patent.

86. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product, including the use of

Teva's ANDA Product in accordance with and as directed by Teva's labeling for that product, will infringe one or more claims of the '107 patent, including at least claim 1.

87. Teva has knowledge of the claims of the '107 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728.

88. On information and belief, Teva plans and intends to, and will, actively induce infringement of the '107 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

89. The foregoing actions by Teva constitute or will constitute infringement of the '107 patent and active inducement of infringement of the '107 patent.

90. An actual case or controversy exists between Bayer and Teva with respect to infringement of the '107 patent.

COUNT I
(Infringement of the '834 Patent)

91. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

92. Teva's submission of ANDA No. 209728 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product was an act of infringement of the '834 patent under 35 U.S.C. § 271(e)(2).

93. Unless Teva is enjoined from infringing the '834 patent and actively inducing infringement of the '834 patent, Bayer will suffer irreparable injury. Bayer has no adequate remedy at law.

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

94. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

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

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

97. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '834 patent.

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

99. Accordingly, there is a real, substantial, and continuing case or controversy between Bayer and Teva regarding whether Teva's manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Product with its proposed labeling according to ANDA No. 209728 will infringe one or more claims of the '834 patent.

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

COUNT III
(Infringement of the '553 Patent)

101. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

102. Teva's submission of ANDA No. 209728 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product was an act of infringement of the '553 patent under 35 U.S.C. § 271(e)(2).

103. Unless Teva is enjoined from infringing the '553 patent and actively inducing infringement of the '553 patent, Bayer will suffer irreparable injury. Bayer has no adequate remedy at law.

COUNT IV
(Declaratory Judgment as to the '553 Patent)

104. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

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

106. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Product with its proposed labeling prior to the expiration of the '553 patent.

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

immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '553 patent.

108. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Teva's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Teva's ANDA Product, including in accordance with its proposed labeling, would constitute infringement of the '553 patent and inducement of infringement of the '553 patent.

109. Accordingly, there is a real, substantial, and continuing case or controversy between Bayer and Teva regarding whether Teva's manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Product with its proposed labeling according to ANDA No. 209728 will infringe one or more claims of the '553 patent.

110. Bayer should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Teva's ANDA Product with its proposed labeling infringes and actively induces the infringement of the '553 patent.

COUNT V
(Infringement of the '124 Patent)

111. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

112. Teva's submission of ANDA No. 209728 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product was an act of infringement of the '124 patent under 35 U.S.C. § 271(e)(2).

113. Unless Teva is enjoined from infringing the '124 patent, actively inducing infringement of the '124 patent, and contributing to the infringement by others of the '124 patent, Bayer will suffer irreparable injury. Bayer has no adequate remedy at law.

COUNT VI
(Declaratory Judgment as to the '124 Patent)

114. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

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

116. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Product with its proposed labeling prior to the expiration of the '124 patent.

117. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '124 patent.

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

119. Accordingly, there is a real, substantial, and continuing case or controversy between Bayer and Teva regarding whether Teva's manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Product with its proposed labeling according to ANDA No. 209728 will infringe one or more claims of the '124 patent.

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

proposed labeling infringes, actively induces the infringement of, and contributes to the infringement by others of the '124 patent.

COUNT VII
(Infringement of the '107 Patent)

121. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

122. Teva's submission of ANDA No. 209728 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product was an act of infringement of the '107 patent under 35 U.S.C. § 271(e)(2).

123. Unless Teva is enjoined from infringing the '107 patent and actively inducing infringement of the '107 patent, Bayer will suffer irreparable injury. Bayer has no adequate remedy at law.

COUNT VIII
(Declaratory Judgment as to the '107 Patent)

124. Bayer incorporates each of the preceding paragraphs as if fully set forth herein.

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

126. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Product with its proposed labeling prior to the expiration of the '107 patent.

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

immediately and imminently upon approval of ANDA No. 209728, *i.e.*, prior to the expiration of the '107 patent.

128. On information and belief, pursuant to 35 U.S.C. § 271(a) and (b), Teva's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Teva's ANDA Product, including in accordance with its proposed labeling, would constitute infringement of the '107 patent and inducement of infringement of the '107 patent.

129. Accordingly, there is a real, substantial, and continuing case or controversy between Bayer and Teva regarding whether Teva's manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Product with its proposed labeling according to ANDA No. 209728 will infringe one or more claims of the '107 patent.

130. Bayer should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Teva's ANDA Product with its proposed labeling infringes and actively induces the infringement of the '107 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Teva has infringed the '834 patent;

(b) A judgment that Teva has infringed the '553 patent;

(c) A judgment that Teva has infringed the '124 patent;

(d) A judgment that Teva has infringed the '107 patent;

(e) A judgment ordering that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva'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;

(f) A judgment ordering that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva's ANDA Product, or any product or compound which infringes or the use of which infringes the '553 patent, be not earlier than the expiration date of the '553 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 Teva to make, use, offer for sale, sell, market, distribute, or import Teva's ANDA Product, or any product or compound the use of which infringes the '124 patent, be not earlier than the expiration date of the '124 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 Teva to make, use, offer for sale, sell, market, distribute, or import Teva's ANDA Product, or any product or compound which infringes or the use of which infringes the '107 patent, be not earlier than the expiration date of the '107 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(i) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing, distributing, or importing Teva'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;

(j) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing,

distributing, or importing Teva's ANDA Product, or any product or compound that infringes or the use of which infringes the '553 patent, or the inducement of any of the foregoing, prior to the expiration date of the '553 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(k) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound the use of which infringes the '124 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '124 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(l) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound that infringes or the use of which infringes the '107 patent, or the inducement of any of the foregoing, prior to the expiration date of the '107 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(m) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Teva'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;

(n) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound that

infringes or the use of which infringes the '553 patent, prior to the expiration date of the '553 patent, will infringe and actively induce infringement of the '553 patent;

(o) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound the use of which infringes the '124 patent, prior to the expiration date of the '124 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '124 patent;

(p) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Teva's ANDA Product, or any product or compound that infringes or the use of which infringes the '107 patent, prior to the expiration date of the '107 patent, will infringe and actively induce infringement of the '107 patent;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
dfahnestock@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
Dov P. Grossman
Jessica Bodger Rydstrom
Xiao Wang
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
(202) 434-5000

December 16, 2016