

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. _____
)	
YABAO PHARMACEUTICAL CO., LTD.)	
BEIJING and YABAO PHARMACEUTICAL)	
GROUP CO., LTD.,)	
)	
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, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of the submission and amendment of Abbreviated New Drug Application (“ANDA”) No. 209050 to the U.S. Food and Drug Administration (“FDA”) by defendants Yabao Pharmaceutical Co., Ltd. Beijing (“Yabao Beijing”) and Yabao Pharmaceutical Group Co., Ltd. (“Yabao Group”) seeking approval to manufacture and sell a generic version of Plaintiffs’ NEXAVAR[®] drug product prior to the expiration of U.S. Patent No. 8,877,933 (the “’933 patent”) and U.S. Patent No. 9,737,488 (the “’488 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 One Amgen Center Drive, Thousand Oaks, California.

5. On information and belief, Yabao Beijing is a company organized and existing under the laws of China, with a place of business at No. 97 Kechuang East 6th Street, Yizhuang Economic and Technological Development Zone Beijing, Beijing, 101111, China.

6. On information and belief, Yabao Group is a company organized and existing under the laws of China, with a place of business at No. 1, Industry Avenue, Fenglingdu Economic Development Zone Yuncheng, Shanxi, 044602, China.

7. On information and belief, Yabao Beijing 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, upon information and belief, Yabao Beijing and Yabao Group act in concert to file 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, Yabao Beijing, acting in concert with and on behalf of Yabao Group, files certifications of the type described in Section

505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“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.

8. On information and belief, Yabao Beijing and Yabao Group acted in concert to prepare, submit, and amend ANDA No. 209050 for Yabao’s 200 mg sorafenib tablets (“Yabao’s ANDA Product”), which was done at the direction of, under the control of, and for the direct benefit of Yabao Group.

9. On information and belief, Yabao Beijing and Yabao Group 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 Yabao’s ANDA Product at issue.

10. On information and belief, following any FDA approval of ANDA No. 209050, Yabao Beijing and Yabao Group will act in concert to market, distribute, offer for sale, and sell Yabao’s ANDA Product throughout the United States and within Delaware. These entities are hereafter collectively referred to as “Yabao.”

11. On information and belief, following any FDA approval of ANDA No. 209050, Yabao knows and intends that Yabao’s ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

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

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 Yabao Beijing and Yabao Group because, among other things, on information and belief: (1) Yabao Beijing and Yabao Group acted in concert to file and amend an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Yabao's ANDA Product in the United States, including in Delaware; and (2) Yabao Beijing and Yabao Group, acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Yabao's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 209050, and will derive substantial revenue from the use or consumption of Yabao's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 209050 is approved, the generic Yabao product charged with infringing the '933 and the '488 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

16. Alternatively, if Yabao Beijing's connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Yabao Beijing is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Yabao Beijing in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2). In addition, if Yabao Group's connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Yabao Group is not

subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Yabao Group in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

VENUE

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

18. Venue is proper in this district for Yabao Beijing Pursuant to 28 U.S.C. § 1391(c)(3) and § 1400(b) because, *inter alia*, Yabao Beijing is an alien company organized and existing under the laws of China and is subject to personal jurisdiction in this judicial district.

19. Venue is proper in this district for Yabao Group pursuant to 28 U.S.C. § 1391(c)(3) and § 1400(b) because, *inter alia*, Yabao Group is an alien company organized and existing under the laws of China and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

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

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 '933 Patent

23. 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 A.

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

25. 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.

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

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

The '488 Patent

28. United States Patent No. 9,737,488, entitled "Pharmaceutical Composition for the Treatment of Cancer," was duly and legally issued on August 22, 2017. The '488 patent is attached as Exhibit B.

29. BHC is the assignee of the '488 patent, which has not expired.

30. As set forth in greater detail in the '488 patent, the claims of the '488 patent, incorporated by reference herein, cover, *inter alia*, an immediate release pharmaceutical composition comprising sorafenib tosylate in a portion of at least 40% by weight of the composition and at least one pharmaceutically acceptable excipient, wherein the pharmaceutical composition is an immediate release tablet.

31. Onyx is an exclusive licensee under the '488 patent.

32. Pursuant to 21 U.S.C. § 355, the '488 patent is listed in the Orange Book in connection with NEXAVAR®.

COUNT I
(Infringement of the '933 Patent)

33. By letter to, *inter alia*, Bayer Intellectual Property GmbH, BHC, and BHCPI, dated September 29, 2021 (“Notice Letter”), Yabao provided notice that Yabao had submitted to the FDA, and amended, ANDA No. 209050 for Yabao’s ANDA Product.

34. In the Notice Letter, Yabao notified Plaintiffs that, in connection with its ANDA No. 209050, Yabao had filed a Paragraph IV Certification with respect to the '933 patent.

35. Yabao had knowledge of the claims of the '933 patent before it filed its Paragraph IV Certification.

36. The purpose of ANDA No. 209050 is to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Yabao’s ANDA Product with its proposed labeling prior to the expiration of the '933 patent.

37. Yabao intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209050, *i.e.*, prior to the expiration of the '933 patent.

38. In the Notice Letter, Yabao indicated that Yabao’s ANDA Product is a generic version of NEXAVAR[®] (sorafenib tosylate) tablets.

39. According to the FDA website, Yabao Group is the holder of Drug Master File No. 29340 for sorafenib tosylate.

40. On information and belief, Yabao’s ANDA Product contains sorafenib tosylate in the polymorph I form.

41. According to the Notice Letter, Yabao’s ANDA Product is in the form of a tablet and contains sorafenib tosylate. On information and belief, Yabao’s ANDA Product is a tablet (a

pharmaceutical composition) that contains sorafenib tosylate in the polymorph I form and one or more pharmaceutically suitable excipients.

42. On information and belief, the proposed labeling for Yabao's ANDA Product will direct the use of a therapeutically effective amount of Yabao's ANDA Product for the treatment of unresectable hepatocellular carcinoma.

43. In the Notice Letter, Yabao does not contest infringement of claims 1-4, 8-10, 16-21, 23-29, and 31 of the '933 patent.

44. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao's ANDA Product, including the use of Yabao's ANDA Product in accordance with and as directed by Yabao's labeling for that product, will infringe at least claims 1-4, 8-10, 16-21, 23-29, and 31 of the '933 patent.

45. Yabao has knowledge of the claims of the '933 patent and that the use of Yabao's ANDA Product in accordance with and as directed by Yabao through its labeling will infringe at least claims 1-4, 8-10, 16-21, 23-29, and 31 of the '933 patent. Notwithstanding this knowledge, Yabao has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209050.

46. Yabao has knowledge of the claims of the '933 patent. Notwithstanding this knowledge, Yabao has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209050.

47. On information and belief, Yabao 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.

48. On information and belief, Yabao knows that Yabao's ANDA Product is especially made or adapted for use in infringing the '933 patent, and that Yabao's ANDA Product is not suitable for substantial noninfringing use. On information and belief, Yabao plans and intends to, and will, contribute to infringement of the '933 patent immediately and imminently upon approval of ANDA No. 209050.

49. The foregoing actions by Yabao 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.

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

51. Yabao's submission of ANDA No. 209050 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Yabao's ANDA Product was an act of infringement of the '933 patent under 35 U.S.C. § 271(e)(2).

52. Unless Yabao 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.

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

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

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

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

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

57. Yabao intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209050, *i.e.*, prior to the expiration of the '933 patent.

58. On information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Yabao's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Yabao'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.

59. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Yabao regarding whether Yabao's manufacture, use, sale, offer for sale, or importation into the United States of Yabao's ANDA Product with its proposed labeling according to ANDA No. 209050 will infringe one or more claims of the '933 patent.

60. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Yabao'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 III
(Infringement of the '488 Patent)

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

62. In the Notice Letter, Yabao stated that, in connection with its ANDA No. 209050, Yabao had filed a Paragraph IV Certification with respect to the '488 patent.

63. Yabao had knowledge of the claims of the '488 patent before it filed its Paragraph IV Certification.

64. The purpose of ANDA No. 209050 is to obtain approval under the Federal Food, Drug & Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Yabao's ANDA Product with its proposed labeling prior to the expiration of the '488 patent.

65. Yabao intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209050, *i.e.*, prior to the expiration of the '488 patent.

66. In the Notice Letter, Yabao stated that Yabao's ANDA Product is a tablet containing sorafenib tosylate.

67. On information and belief, Yabao's ANDA Product is an immediate release pharmaceutical composition comprising sorafenib tosylate in a portion of at least 40% by weight of the composition and at least one pharmaceutically acceptable excipient, wherein the pharmaceutical composition is an immediate release tablet.

68. In the Notice Letter, Yabao did not contest infringement of, *inter alia*, claims 13-14, 17-21, 24-25, 32-61, and 64-103 of the '488 patent.

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

Product in accordance with and as directed by Yabao labeling for that product, will infringe at least claims 13-14, 17-21, 24-25, 32-61, and 64-103 of the '488 patent.

70. Yabao has knowledge of the claims of the '488 patent and that the use of Yabao's ANDA Product in accordance with and as directed by Yabao through its labeling will infringe at least claims 13-14, 17-21, 24-25, 32-61, and 64-103 of the '488 patent. Notwithstanding this knowledge, Yabao has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209050.

71. On information and belief, Yabao plans and intends to, and will, actively induce infringement of the '488 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

72. The foregoing actions by Yabao constitute and/or will constitute infringement of the '488 patent and active inducement of infringement of the '488 patent.

73. An actual case or controversy exists between Plaintiffs and Yabao with respect to infringement of the '488 patent.

74. Yabao's submission of ANDA No. 209050 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Yabao's ANDA Product was an act of infringement of the '488 patent under 35 U.S.C. § 271(e)(2).

75. Unless Yabao is enjoined from infringing the '488 patent and actively inducing infringement of the '488 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

COUNT IV
(Declaratory Judgment as to the '488 Patent)

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

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

79. On information and belief, Yabao has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Yabao's ANDA Product with its proposed labeling prior to the expiration of the '488 patent.

80. Yabao intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Yabao's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209050, *i.e.*, prior to the expiration of the '488 patent.

81. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Yabao's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Yabao's ANDA Product, including in accordance with its proposed labeling, would constitute infringement of the '488 patent and inducement of infringement of the '488 patent.

82. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Yabao regarding whether Yabao's manufacture, use, sale, offer for sale, or importation into the United States of Yabao's ANDA Product with its proposed labeling according to ANDA No. 209050 will infringe one or more claims of the '488 patent.

83. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Yabao's ANDA Product with its proposed labeling would infringe and actively induce the infringement of the '488 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Yabao has infringed the '933 patent;

(b) A judgment that Yabao has infringed the '488 patent;

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

(d) A judgment ordering that the effective date of any FDA approval for Yabao to make, use, offer for sale, sell, market, distribute, or import Yabao's ANDA Product, or any product which infringes or the use of which infringes the '488 patent, be not earlier than the expiration date of the '488 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Yabao, and all persons acting in concert with Yabao, from making, using, selling, offering for sale, marketing, distributing, or importing Yabao's ANDA Product, or any product that infringes or the use of which infringes the '933 patent, or the inducement of any of the foregoing, prior to the expiration date of the '933 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A preliminary and permanent injunction enjoining Yabao, and all persons acting in concert with Yabao, from making, using, selling, offering for sale, marketing, distributing, or importing Yabao's ANDA Product, or any product that infringes or the use of which infringes the '488 patent, or the inducement of any of the foregoing, prior to the expiration date of the '488 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Yabao's ANDA Product, or any product that infringes or the use of which infringes the '933 patent, prior to the expiration date of the '933 patent, will infringe and actively induce infringement by others of the '933 patent;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Yabao's ANDA Product, or any product that infringes or the use of which infringes the '488 patent, prior to the expiration date of the '488 patent, will infringe and actively induce infringement by others of the '488 patent;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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