IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS INC., and ONYX PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES 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, that arises out of the filing by defendant Teva Pharmaceuticals USA, Inc. of Abbreviated New Drug Application ("ANDA") No. 209567 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 No. 8,877,933 ("the '933 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, Defendant Teva Pharmaceuticals USA, Inc. ("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. 209567 for Teva Ltd.'s Sorafenib Tablets, 200 mg ("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. 209567, 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. 209567, 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. 209567, 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. 209567 is approved, the generic

Teva product charged with infringing the '933 patent 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; BHCPI, a Delaware corporation; and Onyx, a Delaware corporation. For example, Teva USA sent the Notice Letter (defined below) to Bayer and Onyx, which has led and/or will lead to foreseeable harm and injury to Bayer and Onyx in Delaware.

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

FACTUAL BACKGROUND

19. 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.

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

The '933 Patent

21. 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.

22. BHC is the assignee of the ’933 patent, which has not expired.

23. 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.

24. Onyx is an exclusive licensee under the ’933 patent.

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

26. By letter to Bayer Intellectual Property GmbH, BHC, BHCPI, and Onyx, dated November 2, 2016 (“Notice Letter”), Teva provided notice that Teva had submitted to the FDA ANDA No. 209567 for Teva’s ANDA Product.

27. In the Notice Letter, Teva notified Plaintiffs that, in connection with its ANDA No. 209567, Teva Pharmaceuticals USA, Inc. had filed a Paragraph IV Certification with respect to the ’933 patent.

28. Teva had knowledge of the claims of the ’933 patent before it filed its Paragraph IV Certification.

29. The purpose of ANDA No. 209567 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 ’933 patent.

30. 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. 209567, *i.e.*, prior to the expiration of the '933 patent.

31. In the Notice Letter, Teva stated that Teva's ANDA Product is a generic version of NEXAVAR® (sorafenib tosylate) tablets.

32. According to the FDA website, Teva Pharmaceuticals Industries, Ltd. is the holder of Drug Master File No. 30234 for sorafenib tosylate.

33. In the Notice Letter, Teva included an Offer of Confidential Access to portions of its ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

34. On November 23, 2016, counsel for Plaintiffs sent a letter to counsel for Teva attempting to negotiate access to Teva's ANDA, proposing that the parties use the protective order that had been entered in another action (Civil Action No. 15-114-LPS (D. Del.)) involving the '933 patent, and seeking access to documents and samples beyond Teva's ANDA that are relevant to the issue of infringement of the '933 patent. Plaintiffs have not received a response from Teva.

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

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

37. On information and belief, Teva's ANDA Product is a pharmaceutical composition (a tablet) that contains sorafenib tosylate in the polymorph I form and one or more pharmaceutically suitable excipients.

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

39. 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 at least claims 1 and 16 of the '933 patent.

40. In the Notice Letter, Teva does not contest the validity of claims 5–22 of the '933 patent.

41. Teva has knowledge of the claims of the '933 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. 209567.

42. On information and belief, Teva 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.

43. On information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '933 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 '933 patent immediately and imminently upon approval of ANDA No. 209567.

44. The foregoing actions by Teva 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.

45. An actual case or controversy exists between Plaintiffs and Teva with respect to infringement of the ’933 patent.

COUNT I
(Infringement of the ’933 Patent)

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

47. Teva’s submission of ANDA No. 209567 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 ’933 patent under 35 U.S.C. § 271(e)(2).

48. Unless Teva 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 II
(Declaratory Judgment as to the ’933 Patent)

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

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

51. 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 ’933 patent.

52. 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. 209567, *i.e.*, prior to the expiration of the '933 patent.

53. 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 '933 patent, inducement of infringement of the '933 patent, and contribution to the infringement of the '933 patent.

54. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs 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. 209567 will infringe one or more claims of the '933 patent.

55. Plaintiffs 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 '933 patent.

WHEREFORE, Plaintiffs request the following relief:

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

(b) 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 '933 patent, be not earlier

than the expiration date of the ’933 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) 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 ’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;

(d) 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 ’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;

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

(f) An award of Plaintiffs’ costs and expense in this action; and

(g) 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 Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc.

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
Dov P. Grossman
Jessica Bodger Rydstrom
Joelle P. Justus
Teagan J. Gregory
Christopher S. Geyer
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
(202) 434-5000

December 16, 2016