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. _____
DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, 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 by defendants Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.") and Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") of Abbreviated New Drug Application ("ANDA") No. 216073 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' NEXAVAR® drug product prior to the expiration of 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, Dr. Reddy's Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at 8-2-377, Road No. 3, Banjara Hills, Hyderabad, Telenangana 50034, India.

6. On information and belief, Dr. Reddy's Inc. is a corporation organized under the laws of the State of New Jersey, with a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

7. On information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd.

8. On information and belief, Dr. Reddy's Ltd. 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, Dr. Reddy's Ltd. and Dr. Reddy's Inc. 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, Dr. Reddy's Inc., acting on behalf of Dr. Reddy's Ltd., 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.

9. On information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. acted in concert to prepare and submit ANDA No. 216073 for Dr. Reddy's 200 mg sorafenib tablets ("Dr. Reddy's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Dr. Reddy's Ltd.

10. On information and belief, Dr. Reddy's Ltd. and Dr. Reddy's 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 Dr. Reddy's ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 216073, Dr. Reddy's Ltd. and Dr. Reddy's Inc. will act in concert to market, distribute, offer for sale, and sell Dr. Reddy's ANDA Product throughout the United States and within Delaware. These entities—Dr. Reddy's Ltd. and Dr. Reddy's Inc.—are hereafter collectively referred to as "Dr. Reddy's."

12. On information and belief, following any FDA approval of ANDA No. 216073, Dr. Reddy's knows and intends that Dr. Reddy's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

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

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

15. 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.

16. This Court has personal jurisdiction over Dr. Reddy's Ltd. and Dr. Reddy's Inc. because, among other things, on information and belief: (1) Dr. Reddy's Ltd. and Dr. Reddy's Inc. acted in concert to file an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's ANDA Product in the United States, including in Delaware; and (2) Dr. Reddy's Ltd. and Dr. Reddy's Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Dr. Reddy's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 216073, and will derive substantial revenue from the use or consumption of Dr. Reddy's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 216073 is approved, the generic Dr. Reddy's product charged with infringing 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.

17. Alternatively, if Dr. Reddy's Ltd.'s connections with Delaware, including its connections with Dr. Reddy's Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Dr. Reddy's Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Dr. Reddy's Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

18. Dr. Reddy's Ltd. and Dr. Reddy's Inc. have consented to jurisdiction in Delaware in multiple prior cases arising out of the filings of their ANDAs, and have filed counterclaims in some such cases. *See, e.g.*, *Intercept Pharmaceuticals, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 21-35 (D.I. 10); *Astellas US LLC et al. v. Apotex Inc., et al.*, C.A. No. 18-1675 (consolidated) (D.I. 129); *Onyx Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 16-1011 (D.I. 11); *Novartis Pharmaceuticals Corp. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-1283 (D.I. 9); *Pfizer, Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 09-943 (D.I. 9).

VENUE

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

20. Venue is proper in this district for Dr. Reddy's Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Dr. Reddy's Ltd. is a private limited company organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

21. Venue is proper in this district for Dr. Reddy's Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Dr. Reddy's Inc. is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district and/or will consent to venue for the purpose of this case. *See, e.g., Intercept Pharmaceuticals, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*,

C.A. No. 21-35 (D.I. 10); *Astellas US LLC et al. v. Apotex Inc., et al.*, C.A. No. 18-1675 (consolidated) (D.I. 129); *Onyx Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 16-1011 (D.I. 11); *Novartis Pharmaceuticals Corp. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-1283 (D.I. 9); *Pfizer, Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 09-943 (D.I. 9).

FACTUAL BACKGROUND

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

23. 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.

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

The '488 Patent

25. 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 A.

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

27. 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.

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

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

Dr. Reddy's ANDA Product

30. By letter dated May 27, 2021 (the "Notice Letter"), a representative of Dr. Reddy's, Inc. notified, *inter alia*, BHC and BHCPI that Dr. Reddy's, Inc., on behalf of Dr. Reddy's, Ltd., had submitted ANDA No. 216073 to the FDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sorafenib tosylate 200 mg tablets prior to the expiration of, *inter alia*, the '488 patent. On information and belief, Dr. Reddy's ANDA Product is a generic version of NEXAVAR®.

31. In the Notice Letter, Dr. Reddy's stated that Dr. Reddy's had submitted to the FDA ANDA No. 216073 for Dr. Reddy's ANDA Product.

32. In the Notice Letter, Dr. Reddy's stated that, in connection with its ANDA No. 216073, Dr. Reddy's had filed a Paragraph IV Certification with respect to the '488 patent.

33. Dr. Reddy's had knowledge of the claims of the '488 patent before it filed its Paragraph IV Certification.

34. The purpose of ANDA No. 216073 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 Dr. Reddy's ANDA Product with its proposed labeling prior to the expiration of the '488 patent.

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

labeling immediately and imminently upon approval of ANDA No. 216073, *i.e.*, prior to the expiration of the '488 patent.

36. In the Notice Letter, Dr. Reddy's stated that Dr. Reddy's ANDA Product is a tablet containing sorafenib tosylate.

37. In the Notice Letter, Dr. Reddy's did not contest infringement of, *inter alia*, claims 1-7, 9, 11-21, 24-26, and 32-103 of the '488 patent.

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

39. On information and belief, Dr. Reddy'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.

40. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Product, including the use of Dr. Reddy's ANDA Product in accordance with and as directed by Dr. Reddy's labeling for that product, will infringe at least claims 1-7, 9, 11-21, 24-26, and 32-103 of the '488 patent.

41. Dr. Reddy's has knowledge of the claims of the '488 patent and that the use of Dr. Reddy's ANDA Product in accordance with and as directed by Dr. Reddy's through its labeling will infringe at least claims 1-7, 9, 11-21, 24-26, and 32-103 of the '488 patent. Notwithstanding this knowledge, Dr. Reddy's has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 216073.

42. On information and belief, Dr. Reddy's 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.

43. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '488 patent and active inducement of infringement of the '488 patent.

44. An actual case or controversy exists between Plaintiffs and Dr. Reddy's with respect to infringement of the '488 patent.

COUNT I
(Infringement of the '488 Patent)

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

46. Dr. Reddy's submission of ANDA No. 216073 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's ANDA Product was an act of infringement of the '488 patent under 35 U.S.C. § 271(e)(2).

47. Unless Dr. Reddy's 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.

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

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

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

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

51. Dr. Reddy's intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 216073, *i.e.*, prior to the expiration of the '488 patent.

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

53. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Dr. Reddy's regarding whether Dr. Reddy's manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's ANDA Product with its proposed labeling according to ANDA No. 216073 will infringe one or more claims of the '488 patent.

54. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Dr. Reddy'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 Dr. Reddy's has infringed the '488 patent;

(b) A judgment ordering that the effective date of any FDA approval for Dr. Reddy's to make, use, offer for sale, sell, market, distribute, or import Dr. Reddy'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;

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

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Dr. Reddy'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;

(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

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