IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Bayer HealthCare LLC ("BHC") and Bayer HealthCare Pharmaceuticals Inc. ("BHCPI") (collectively, "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 Apotex, Inc. of Abbreviated New Drug Application ("ANDA") No. 209765 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Bayer's STIVARGA® (Regorafenib coated tablet 40 mg) product prior to the expiration of U.S. Patent No. 9,957,232 (the "'232 patent"). As set forth in its FDA-approved labeling, STIVARGA® is indicated for the treatment of certain types of cancer.

2. By letter dated August 10, 2018 (the "Notice Letter"), Apotex Corp. notified, *inter alia*, Bayer that Apotex Inc. had submitted ANDA No. 209765 to the FDA seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of

Regorafenib oral tablets, 40 mg ("Apotex's ANDA Product") prior to the expiration of the '232 patent. On information and belief, Apotex'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 Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded pharmaceutical products throughout the United States.

6. On information and belief, defendant Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. On information and belief, Apotex Inc. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded pharmaceutical products throughout the United States in concert with its subsidiary, Apotex Corp. Apotex Inc. and Apotex Corp. are collectively referred to herein as "Apotex."

7. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

8. On information and belief, and consistent with their practice with respect to other generic products, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit ANDA No. 209765.

9. On information and belief, Apotex Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Apotex Inc., acting in concert with Apotex Corp., 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, Apotex Inc., acting in concert with Apotex Corp., 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

10. On information and belief, and consistent with their practice with respect to other generic products, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit ANDA No. 209765.

11. On information and belief, Apotex Inc. and Apotex Corp. 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 Apotex ANDA Product at issue.

12. On information and belief, Apotex Inc. and Apotex Corp. contemplate that upon approval of ANDA No. 209765, Apotex Inc. will manufacture Apotex's ANDA Product

and Apotex Corp. will directly or indirectly market, sell, and distribute Apotex's ANDA Product throughout the United States, including in Delaware.

13. On information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 209765, Apotex Inc. and Apotex Corp. will act in concert to market, distribute, offer for sale, and sell Apotex's ANDA Product throughout the United States and within Delaware.

14. On information and belief, following any FDA approval of ANDA No. 209765, Apotex 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

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

16. 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.

17. This Court has personal jurisdiction over Apotex Corp. because, on information and belief, Apotex Corp. 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. Apotex Corp. has thus consented to jurisdiction in Delaware.

18. In addition, this Court also has personal jurisdiction over Apotex Corp. and Apotex Inc. because, among other things, on information and belief: (1) Apotex Inc., acting in concert with Apotex Corp., 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 Apotex's ANDA Product in the United States, including in Delaware; and (2) Apotex Corp. and Apotex Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Apotex's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 209765, and will derive substantial revenue from the use or consumption of Apotex's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 209765 is approved, the generic Apotex product charged with infringing the '232 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.

19. The Court also has personal jurisdiction over Apotex Corp. and Apotex Inc. because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to BHC, a Delaware limited liability company, and BHCPI, a Delaware corporation. For example, Apotex sent the Notice Letter to, *inter alia*, Bayer, which has led and/or will lead to foreseeable harm and injury to Bayer in Delaware.

20. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Apotex Inc., itself and through its subsidiary Apotex Corp., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and

therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

21. Apotex has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases. *See, e.g.*, *Warner Chilcott Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 10-1111-LPS, D.I. 11 (D. Del. Jan. 31, 2011); *Pfizer Inc. v. Apotex, Inc. & Apotex Corp.*, C.A. No. 11-606-GMS, D.I. 10 (D. Del. Oct. 3, 2011); *Senju Pharm. Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-0159-SLR, D.I. 9 (D. Del. Mar. 16, 2012); *Alcon Pharm. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-960-SLR, D.I. 6 (D. Del. July 23, 2012); *Pfizer Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-809-SLR, D.I. 18 (D. Del. Aug. 27, 2012); *UCB Inc. v. Apotex Corp. et al.*, C.A. No. 13-1209-LPS, D.I. 12 (D. Del. Sept. 9, 2013); *Pfizer Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 13-01613-SLR, D.I. 8 (D. Del. Sept. 27, 2013); *Meda Pharm., Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 14-1453-LPS, D.I. 93 (D. Del. Mar. 9, 2016); *Salix Pharm., Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 15-880-GMS, D.I. 15 (D. Del. Mar. 14, 2016). Apotex has also consented to jurisdiction in this Court in related cases filed by Plaintiffs arising out of Apotex's filing of ANDA No. 209765. *Bayer HealthCare LLC & Bayer HealthCare Pharm. Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-1222-LPS, D.I. 10 (D. Del. Feb. 21, 2017); *Bayer HealthCare LLC & Bayer HealthCare Pharm. Inc. v. Apotex Inc. & Apotex Corp*, C.A. No. 17-334-LPS, D.I. 10 (D. Del. May 22, 2017).

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

FACTUAL BACKGROUND

23. 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. It is also indicated for the treatment of patients with hepatocellular carcinoma ("HCC") who have been previously treated with sorafenib.

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

The '232 Patent

25. U.S. Patent No. 9,957,232, entitled "4-[4-({[4-Chloro-3-(Trifluoromethyl)Phenyl]Carbamoyl}Amino)-3-Fluorophenoxy]-N-Methylpyridine-2-Carboxamide Monohydrate," was duly and legally issued on May 1, 2018. The '232 patent is attached as Exhibit A.

26. BHC is the assignee of the '232 patent, which has not expired.

27. As set forth in greater detail in the '232 patent, the claims of the '232 patent, incorporated by reference herein, cover, *inter alia*, regorafenib monohydrate which shows in X-ray diffractometry a peak maximum of the 2 Theta angle of 21.2.

28. Pursuant to 21 U.S.C. § 355, the ’232 patent is listed in the Orange Book in connection with STIVARGA®.

29. By letter to, *inter alia*, Plaintiffs dated August 10, 2018, Apotex Corp. stated that Apotex Inc. had submitted to the FDA ANDA No. 209765 for Apotex’s ANDA Product.

30. In the Notice Letter, Apotex stated that, in connection with its ANDA No. 209765, Apotex had filed a Paragraph IV Certification with respect to the ’232 patent.

31. Apotex had knowledge of the claims of the ’232 patent before it filed its Paragraph IV Certification.

32. The purpose of ANDA No. 209765 is to obtain approval under the Federal Food, Drug & Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex’s ANDA Product with its proposed labeling prior to the expiration of the ’232 patent.

33. Apotex intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209765, *i.e.*, prior to the expiration of the ’232 patent.

34. In the Notice Letter, Apotex stated that Apotex’s ANDA Product contains regorafenib.

35. In the Notice Letter, Apotex included an Offer of Confidential Access to portions of ANDA No. 209765. That offer, however, was subject to various unreasonably restrictive conditions.

36. On August 29, 2018, counsel for Bayer sent a letter to counsel for Apotex attempting to negotiate access to ANDA No. 209765 as well as seeking access to documents and samples not included in ANDA No. 209765 that are relevant to the issue of infringement of the ’232 patent. In the letter, counsel for Bayer proposed that, for purposes of preserving confidentiality of the Apotex materials, the parties use the protective order that had been entered in another action in this Judicial District (*Bayer HealthCare LLC, et al., v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 16-1221-LPS (consolidated)) to which both Apotex Corp. and Apotex Inc. are parties and which involves Apotex’s ANDA Product.

37. On September 9, 2018, counsel for Apotex sent a letter to counsel for Bayer rejecting Bayer’s request. Instead, counsel for Apotex proposed that counsel for Bayer have access to ANDA No. 209765 and the open portion of the Drug Master File pursuant to Apotex’s original Offer of Confidential Access. Apotex also refused to provide access to the additional documents and samples requested in Bayer’s August 19, 2018 letter.

38. On September 12, 2018, counsel for Bayer sent a letter to counsel for Apotex responding to Apotex’s September 9, 2018 letter. In the letter, counsel for Bayer reiterated that Apotex’s Offer of Confidential Access was unreasonably restrictive. Counsel for Bayer also explained the need for the additional documents and samples requested in Bayer’s August 18, 2018 letter. Counsel for Bayer also renewed its request as set forth in the August 29, 2018 letter for access to documents and samples using the confidentiality provisions of the protective order entered in *Bayer HealthCare LLC, et al., v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 16-1221-LPS (consolidated).

39. On September 14, counsel for Apotex sent a letter to counsel for Bayer responding to Bayer’s September 12, 2018 letter. In the letter, counsel for Apotex rejected

counsel for Bayer's renewed request and further stated that it would only provide access to Apotex's ANDA No. 209765 pursuant to Apotex's Offer of Confidential Access.

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

41. On information and belief, Apotex's ANDA Product contains regorafenib monohydrate as claimed in the '232 patent.

42. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product, including the use of Apotex's ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product, will infringe one or more claims of the '232 patent, including at least claim 19.

43. Apotex has knowledge of the claims of the '232 patent. Notwithstanding this knowledge, Apotex has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209765.

44. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '232 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

45. The foregoing actions by Apotex constitute or will constitute infringement of the '232 patent and active inducement of infringement of the '232 patent.

46. An actual case or controversy exists between Bayer and Apotex with respect to infringement of the '232 patent.

COUNT I
(Infringement of the ’232 Patent)

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

48. Apotex’s submission of ANDA No. 209765 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex’s ANDA Product was an act of infringement of the ’232 patent under 35 U.S.C. § 271(e)(2).

49. Unless Apotex is enjoined from infringing the ’232 patent and actively inducing infringement of the ’232 patent, Bayer will suffer irreparable injury. Bayer has no adequate remedy at law.

COUNT II
(Declaratory Judgment as to the ’232 Patent)

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

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

52. On information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex’s ANDA Product with its proposed labeling prior to the expiration of the ’232 patent.

53. Apotex intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 209765, *i.e.*, prior to the expiration of the ’232 patent.

54. On information and belief, pursuant to 35 U.S.C. § 271(a) and/or (b), Apotex's manufacture, use, sale, or offer for sale within the United States or importation into the United States of Apotex's ANDA Product, including in accordance with its proposed labeling, would constitute infringement of the '232 patent and inducement of infringement of the '232 patent.

55. Accordingly, there is a real, substantial, and continuing case or controversy between Bayer and Apotex regarding whether Apotex's manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA Product with its proposed labeling according to ANDA No. 209765 will infringe one or more claims of the '232 patent.

56. Bayer should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex's ANDA Product with its proposed labeling would infringe and actively induce the infringement of the '232 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Apotex has infringed the '232 patent;

(b) A judgment ordering that the effective date of any FDA approval for Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex's ANDA Product, or any product or compound which infringes or the use of which infringes the '232 patent, be not earlier than the expiration date of the '232 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Apotex, and all persons acting in concert with Apotex, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex's ANDA Product, or any product or compound that infringes or the use of which infringes the '232 patent, or the inducement of any of the foregoing, prior to

the expiration date of the ’232 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 Apotex’s ANDA Product, or any product or compound that infringes or the use of which infringes the ’232 patent, prior to the expiration date of the ’232 patent, will infringe and actively induce infringement of the ’232 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 Bayer’s 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/ Derek J. Fahnestock

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