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. _____ |
| APOTEX INC. and APOTEX CORP., | ) | |
| 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 defendant Apotex, Inc. of Abbreviated New Drug Application ("ANDA") No. 212228 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. 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.

2. By letter dated August 24, 2018 (the "Notice Letter"), a representative of Apotex Corp. notified, *inter alia*, BHCPI that Apotex Inc. had submitted ANDA No. 212228 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 the '933 patent and the '488 patent. On information and belief, Apotex's ANDA Product is a generic version of NEXAVAR®.

## 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. 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.

6. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, 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.

7. On information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. 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."

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

9. 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. 212228.

10. 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

11. 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. 212228.

12. 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.

13. On information and belief, Apotex Inc. and Apotex Corp. contemplate that upon approval of ANDA No. 212228, 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.

14. On information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 212228, 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.

15. On information and belief, following any FDA approval of ANDA No. 212228, 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

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

17. 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.

18. 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.

19. 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. 212228, 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. 212228 is approved, the generic Apotex product charged with infringing the '933 patent 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, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

20. 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; BHCPI, a Delaware corporation; and Onyx, a Delaware corporation. For example, Apotex sent the Notice Letter to, *inter alia*, BHCPI, which has led and/or will lead to foreseeable harm and injury to BHCPI in Delaware.

21. 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 Plaintiffs' 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.

22. 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 one or more of 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); *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).

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

## FACTUAL BACKGROUND

24. 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.

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

### The '933 Patent

26. 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.

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

28. 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.

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

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

31. In the Notice Letter, a representative of Apotex Corp. stated that Apotex Inc. had submitted to the FDA ANDA No. 212228 for Apotex's ANDA Product.

32. In the Notice Letter, Apotex stated that, in connection with its ANDA No. 212228, Apotex had filed a Paragraph IV Certification with respect to the '933 patent.

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

34. The purpose of ANDA No. 212228 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 Apotex's ANDA Product with its proposed labeling prior to the expiration of the '933 patent.

35. 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. 212228, *i.e.*, prior to the expiration of the '933 patent.

36. In the Notice Letter, Apotex stated that Apotex's ANDA Product contains sorafenib tosylate.

37. In the Notice Letter, Apotex included an Offer of Confidential Access to portions of ANDA No. 212228. That offer, however, was subject to various unreasonably restrictive conditions.

38. On September 7, 2018, counsel for Bayer sent a letter to counsel for Apotex via email attempting to negotiate access to ANDA No. 212228 as well as seeking access to

documents and samples not included in ANDA No. 212228 that are relevant to the issue of infringement of the '933 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. Pharm. USA, Inc., et al.*, C.A. No. 16-1221-LPS (consolidated)) to which both Apotex Corp. and Apotex Inc. are parties.

39. On September 11, 2018, counsel for Apotex acknowledged receipt of the email from counsel for Bayer.

40. On October 1, 2018, counsel for Apotex responded via email to the letter from counsel for Bayer. Counsel for Apotex provided a revised offer of confidential access pursuant to which Apotex was willing to provide unspecified portions of its ANDA No. 212228, but Apotex refused to provide access to documents and samples not included in ANDA No. 212228 and which are relevant to the issue of infringement of the '933 patent.

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

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

43. On information and belief, Apotex'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.

44. On information and belief, the proposed labeling for Apotex's ANDA Product will direct the use of a therapeutically effective amount of Apotex's ANDA Product for the

treatment of unresectable hepatocellular carcinoma and /or locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

45. 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 labeling for that product, will infringe at least claims 1 and 16 of the '933 patent.

46. Apotex has knowledge of the claims of the '933 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. 212228.

47. On information and belief, Apotex 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, Apotex knows that Apotex's ANDA Product is especially made or adapted for use in infringing the '933 patent and that Apotex's ANDA Product is not suitable for substantial noninfringing use. On information and belief, Apotex plans and intends to, and will, contribute to infringement of the '933 patent immediately and imminently upon approval of ANDA No. 212228.

49. The foregoing actions by Apotex 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 Apotex with respect to infringement of the '933 patent.

**The '488 Patent**

51. 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.

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

53. 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.

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

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

56. In the Notice Letter, Apotex Corp. stated that Apotex Inc. had submitted to the FDA ANDA No. 212228 for Apotex's ANDA Product.

57. In the Notice Letter, Apotex stated that, in connection with its ANDA No. 212228, Apotex had filed a Paragraph IV Certification with respect to the '488 patent.

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

59. The purpose of ANDA No. 212228 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 Apotex's ANDA Product with its proposed labeling prior to the expiration of the '488 patent.

60. 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. 212228, *i.e.*, prior to the expiration of the '488 patent.

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

62. In the Notice Letter, Apotex did not contest infringement of claims 37, 40-58, or 70-100 of the '488 patent.

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

64. On information and belief, Apotex'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.

65. 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 labeling for that product, will infringe at least claims 37, 40-58, or 70-100 of the '488 patent.

66. Apotex has knowledge of the claims of the '488 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. 212228.

67. On information and belief, Apotex 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.

68. The foregoing actions by Apotex constitute and/or will constitute infringement of the ’488 patent and active inducement of infringement of the ’488 patent.

69. An actual case or controversy exists between Plaintiffs and Apotex with respect to infringement of the ’488 patent.

**COUNT I**
**(Infringement of the ’933 Patent)**

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

71. Apotex’s submission of ANDA No. 212228 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’s ANDA Product was an act of infringement of the ’933 patent under 35 U.S.C. § 271(e)(2).

72. Unless Apotex 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)**

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

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

75. 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 '933 patent.

76. 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. 212228, *i.e.*, prior to the expiration of the '933 patent.

77. On information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), 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 '933 patent, inducement of infringement of the '933 patent, and contribution to the infringement of the '933 patent.

78. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs 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. 212228 will infringe one or more claims of the '933 patent.

79. Plaintiffs 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 infringes, actively induces the infringement of, and contributes to the infringement by others of the '933 patent.

**COUNT III**
**(Infringement of the '488 Patent)**

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

81. Apotex's submission of ANDA No. 212228 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product was an act of infringement of the '488 patent under 35 U.S.C. § 271(e)(2).

82. Unless Apotex 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 IV**
**(Declaratory Judgment as to the '488 Patent)**

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

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

85. 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 '488 patent.

86. 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. 212228, *i.e.*, prior to the expiration of the '488 patent.

87. 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 '488 patent and inducement of infringement of the '488 patent.

88. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs 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. 212228 will infringe one or more claims of the '488 patent.

89. Plaintiffs 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 '488 patent.

WHEREFORE, Plaintiffs request the following relief:

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

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

(c) 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 '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 Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex'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 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 ’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;

(f) 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 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 Apotex’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;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Apotex’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

*/s/ Jack B. Blumenfeld*

Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
dfahnestock@mnat.com
araucci@mnat.com

*Attorneys for Plaintiffs*

OF COUNSEL:

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

*Attorneys for Plaintiffs Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc.*

October 4, 2018