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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC. and
BOEHRINGER INGELHEIM
INTERNATIONAL GMBH,

Plaintiffs,
v.
APOTEX INC. and APOTEX CORP.,
Defendants.

Civil Action No.: 1:18-cv-11350-MAS-LHG

Document Filed Electronically

**APOTEX INC. AND APOTEX CORP.'S
ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex” or “Defendants”), by and through their counsel, hereby answer and respond to each of the allegations in the Complaint of Plaintiffs Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH (collectively, “BI” or “Plaintiffs”) (ECF No. 1), and assert their separate defenses, and counterclaims, as follows. Apotex denies all allegations not expressly admitted herein.

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C §§ 271 (a–c, e–g), arises from Apotex’s submission of Abbreviated New Drug Application (“ANDA”) No. 210725 to the United States Food and Drug Administration (“FDA”). Through this ANDA, Apotex seeks approval to market a generic version of the pharmaceutical product GILOTRIF® (afatinib) tablets prior to the expiration of United States Patent No. 8,426,586 (the “patent-in-suit”). Plaintiffs seek injunctive relief precluding infringement, attorneys’ fees, and any other relief the Court deems just and proper.

ANSWER: Apotex admits that BI purports to bring this action for alleged patent infringement pursuant to the patent law of the United States, 35 U.S.C. § 1, *et seq.* Apotex further admits that it submitted ANDA No. 210725 seeking approval for its proposed afatinib tablets prior to the expiration of the ’586 patent. Paragraph 1 otherwise contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. §§ 271(a–c, e–g).

ANSWER: Apotex admits that BI also purports to bring this action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of alleged patent infringement pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

THE PARTIES

3. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore deny them.

4. Plaintiff Boehringer Ingelheim International GmbH is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore deny them.

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

ANSWER: Admitted.

6. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admitted.

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

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

8. On information and belief, Apotex Inc., in collaboration with Apotex Corp., prepared and submitted ANDA No. 210725 (the “Apotex ANDA”) and continues to collaborate in seeking FDA approval of that application.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

9. On information and belief, Apotex intends to commercially manufacture, market, offer for sale, and sell the product described in the Apotex ANDA (the “ANDA Product”) throughout the United States, including in the State of New Jersey, in the event the FDA approves the Apotex ANDA.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

JURISDICTION AND VENUE

10. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of United States Patent No. 8,426,586 (“the ’586 Patent”). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201–02.

ANSWER: Admitted.

11. This Court has jurisdiction over Apotex Inc. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs’ claims arise under federal law; (b) Apotex Inc. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court’s exercise of jurisdiction over Apotex Inc. satisfies due process.

ANSWER: Apotex does not contest personal jurisdiction for purposes of this action only.

Except as expressly admitted, Apotex denies the remaining allegations of paragraph 11.

12. On information and belief, this Court also has jurisdiction over Apotex because, *inter alia*, this action arises from actions of Apotex directed toward New Jersey, and because Apotex has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey.

ANSWER: Apotex does not contest personal jurisdiction for purposes of this action only.

Except as expressly admitted, Apotex denies the remaining allegations of paragraph 12.

13. On information and belief, Apotex Corp. is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003192, and regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through an affiliate. Upon information and belief, Apotex derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey. Further, Apotex has committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent

infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufactures GILOTRIF® for sale and use throughout the United States, including this Judicial District.

ANSWER: Apotex does not contest personal jurisdiction for purposes of this action only.

Except as expressly admitted, Apotex denies the remaining allegations of paragraph 13.

14. On information and belief, Apotex Corp. has submitted, caused to be submitted, or aided and abetted in the preparation or submission of the Apotex ANDA. On information and belief, in the event that the FDA approves the Apotex ANDA, Apotex Inc., with the participation of Apotex Corp., intends to commercially manufacture, import, market, offer for sell, and sell the ANDA Product throughout the United States and in this Judicial District.

ANSWER: Apotex does not contest personal jurisdiction for purposes of this action only.

Except as expressly admitted, Apotex denies the remaining allegations of paragraph 14.

15. Apotex has previously been sued in this Judicial District without objecting on the basis of lack of personal jurisdiction and has availed itself of the rights, benefits, and privileges of New Jersey by asserting claims or counterclaims involving pharmaceutical drug patent disputes in this Judicial District, including in the following cases: *Patheon Softgels Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 17-13819; *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Civil Action No. 17-5399; *Dexcel Pharma Technologies Ltd. et al. v. Apotex Corp. et al.*, Civil Action No. 17-2423; and *Takeda GmbH et al. v. Apotex Corp. et al.*, Civil Action No. 15-3379.

ANSWER: Apotex does not contest personal jurisdiction for purposes of this action only.

Except as expressly admitted, Apotex denies the remaining allegations of paragraph 15.

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1400(b) and 1391(c)(3).

ANSWER: Apotex does not contest venue for purposes of this action only. Except as expressly admitted, Apotex denies the remaining allegations of paragraph 16.

BOEHRINGER INGELHEIM'S APPROVED GILOTRIF® DRUG PRODUCT AND PATENT

17. Boehringer Ingelheim makes and sells GILOTRIF®, a product used in the firstline treatment of metastatic non-small cell lung cancer (“NSCLC”) where the tumors have epidermal growth factor receptor (“EGFR”) exon 19 deletions or exon 21 (L858R substitution mutations). GILOTRIF® is also used to treat metastatic, squamous NSCLC that progresses after platinum-based

chemotherapy. The active ingredient in GILOTrif® is afatinib. A true and correct copy of the prescribing label for GILOTrif® is attached as Exhibit A.

ANSWER: Apotex admits that BI attaches as Exhibit A a purported copy of the Highlights of Prescribing Information for GILOTrif®, which includes a section identifying Indications and Usage. The contents of the Highlights of Prescribing Information for GILOTrif® speak for themselves. Except as expressly admitted, Apotex denies the remaining allegations of paragraph 17.

18. Boehringer Ingelheim Pharmaceuticals, Inc. is the holder of New Drug Application (“NDA”) No. 201292 for GILOTrif® and the licensee of the patents-in-suit. The FDA approved NDA No. 201292 for GILOTrif® in July 2013, and granted GILOTrif® five years of regulatory exclusivity for a new chemical entity pursuant to 21 C.F.R. § 314.108, which expires on July 12, 2018. The FDA also granted GILOTrif® orphan drug exclusivity pursuant to 21 C.F.R. § 316.31.

ANSWER: Apotex admits that Orange Book data for GILOTrif® identifies Boehringer Ingelheim as the applicant holder for NDA No. 201292, which was approved on July 12, 2013, and was granted new chemical entity and orphan drug exclusivities. Except as expressly admitted, Apotex denies the remaining allegations of paragraph 18.

19. Boehringer Ingelheim International GmbH owns the ’586 Patent, which is listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the “Orange Book”) for GILOTrif®.

ANSWER: Apotex admits that Boehringer Ingelheim International GmbH is listed on the face of the ’586 patent as the assignee. Apotex further admits that the ’586 patent is listed in the Orange Book for GILOTrif®. Except as expressly admitted, Apotex denies the remaining allegations of paragraph 19.

20. The ’586 Patent entitled, “Process for Preparing Amino Crotonyl Compounds,” was duly and lawfully issued by the USPTO on April 23, 2013. A true and correct copy of the ’586 Patent is attached as Exhibit B.

ANSWER: Apotex admits that the ’586 patent is entitled “Process for Preparing Amino Crotonyl Compounds,” and issued on April 23, 2013. Apotex further admits that BI purports to

attach a copy of the '586 patent as Exhibit B. Except as expressly admitted, Apotex denies the remaining allegations of paragraph 20.

APOTEX'S ANDA

21. On information and belief, Apotex has submitted or caused to be submitted ANDA No. 210725 to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of Afatinib Tablets, as a purported generic version of GILOTRIF®, prior to the expiration of the patents-in-suit.

ANSWER: Admitted.

22. On information and belief, on or about May 25, 2018, Apotex mailed Plaintiffs a letter regarding "Notification of Paragraph IV Certification Regarding U.S. Patent No. 8,426,586 Pursuant to Section 505(j)(2)(B)(i)(ii) of the Federal Food, Drug and Cosmetic Act" (the "Notice Letter"). The Notice Letter represented that Apotex had submitted to the FDA the Apotex ANDA and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Apotex ANDA before the expiration of the patent listed in the Orange Book for GILOTRIF®. Hence, Apotex's purpose in submitting the Apotex ANDA is to manufacture and market the ANDA Product before the expiration of the patent-in-suit.

ANSWER: Apotex admits that it timely sent BI its Notice Letter with respect to the '586 patent on May 25, 2018. Apotex further admits that it submitted ANDA No. 210725 seeking FDA approval of the same prior to expiration of the '586 patent. Except as expressly admitted, Apotex denies the remaining allegations of paragraph 22.

23. Apotex's Notice Letter stated that the Paragraph IV certification in the Apotex ANDA alleges that the '586 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

ANSWER: Admitted.

24. Apotex's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Detailed Statement").

ANSWER: Admitted.

25. On information and belief, Apotex has participated in the preparation and submission of the Apotex ANDA, has provided material support to the preparation and submission of the Apotex ANDA, and intends to support the further prosecution of the Apotex ANDA.

ANSWER: Apotex admits that it submitted ANDA No. 210725 seeking FDA approval of the same prior to expiration of the '586 patent. The remainder of paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

26. On information and belief, if the FDA approves the Apotex ANDA, Apotex will manufacture, offer for sale, or sell the ANDA Product within the United States, including within New Jersey, or will import the ANDA Product into the United States, including New Jersey.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

27. Alternatively, on information and belief, if the FDA approves the Apotex ANDA, Apotex will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

28. This action is pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), filed on July 2, 2018, which is within forty-five days of Plaintiffs' receipt of the Notice Letter.

ANSWER: Admitted.

COUNT I
RESPONSE AS TO INFRINGEMENT OF '586 PATENT

29. Plaintiffs incorporate by reference paragraphs 1–28 as if fully set forth herein.

ANSWER: Apotex reasserts and incorporates by reference its responses to paragraphs 1–28 in full herein.

30. On information and belief, Apotex has submitted or caused the submission of the Apotex ANDA to the FDA and continues to seek FDA approval of the Apotex ANDA.

ANSWER: Admitted.

31. Apotex has infringed the '586 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Apotex ANDA with a Paragraph IV certification and seeking FDA approval of the Apotex ANDA prior to the expiration of the '586 Patent.

ANSWER: Denied.

32. On information and belief, if the Apotex ANDA is approved, Apotex and its affiliates will make, offer for sale, sell, or otherwise distribute the ANDA Product in the United States, including in the State of New Jersey, directly infringing the '586 Patent.

ANSWER: Denied.

33. Apotex's commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement of the '586 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 210725, Apotex will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '586 Patent.

ANSWER: Denied.

34. Apotex had actual and constructive notice of the '586 Patent prior to filing the Apotex ANDA, and was aware that the filing of the Apotex ANDA with the request for FDA approval prior to the expiration of the '586 Patent would constitute an act of infringement of the '586 Patent. Apotex had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '586 Patent.

ANSWER: Denied.

35. Apotex's Detailed Statement in the Notice Letter does not contend that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '586 Patent.

ANSWER: Denied.

36. In addition, Apotex filed the Apotex ANDA without adequate justification for asserting the '586 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Apotex's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '586 Patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Denied.

37. Plaintiffs will be irreparably harmed if Apotex is not enjoined from infringing and from actively inducing or contributing to the infringement of the '586 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Apotex, a

remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

COUNT II
RESPONSE AS TO DECLARATORY JUDGMENT OF INFRINGEMENT THE '586
PATENT

38. Plaintiffs incorporate by reference paragraphs 1–37 as if fully set forth herein.

ANSWER: Apotex reasserts and incorporates by reference its responses to paragraphs 1–37 in full herein.

39. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Apotex admits that Plaintiffs purport to bring this action, in part, under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

40. On information and belief, if the Apotex ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Apotex and its affiliates.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

41. On information and belief, Apotex knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Apotex ANDA and Apotex will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '586 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

ANSWER: Denied.

42. On information and belief, Apotex's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Apotex ANDA. Any such conduct before the '586 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '586 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

ANSWER: Denied.

43. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Apotex concerning liability for the infringement of the '586 Patent

for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

44. Plaintiffs will be substantially and irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

45. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

ALLEGED PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Apotex further denies that BI is entitled to any judgment or relief against Apotex and, therefore, specifically denies paragraphs A through I of BI's Prayer for Relief.

DEFENDANTS' SEPARATE DEFENSES

Without prejudice to the responses and denials set forth in Apotex's Answer, without admitting any allegations of the Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with BI, Apotex asserts the following separate defenses to the Complaint:

First Separate Defense

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Second Separate Defense

The claims of the '586 patent are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

Third Separate Defense

Apotex does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '586 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Apotex's ANDA No. 210725 does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '586 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

Fourth Separate Defense

BI is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

Reservation of Rights

Apotex expressly reserves the right to supplement and/or amend its Answer to the Complaint, including, but not limited to, supplementation and/or amendment of its defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

COUNTERCLAIMS

Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp., (collectively, “Apotex”) for their Counterclaims against Plaintiffs/Counterclaim Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH (collectively, “BI”), alleges as follows:

1. This is a counterclaim action for declaratory judgment of noninfringement and/or invalidity of one or more claims of U.S. Patent Nos. 8,426,586 (“the ’586 patent”) and 8,545,884 (“the ’884 patent”).

THE PARTIES

2. Apotex Inc. is a Canadian corporation, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. 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.

4. On information and belief, and based on the allegations in the Complaint, Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

5. On information and belief, and based on the allegations in the Complaint, Boehringer Ingelheim International GmbH is a private limited liability company organized and existing under the laws of Germany, with its principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

JURISDICTION AND VENUE

6. Apotex seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

7. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271(e)(2).

8. This is an action based on an actual controversy between Apotex and BI concerning the noninfringement and/or invalidity of the '586 and '884 patents arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and Apotex's right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 210725, and upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the afatinib tablet products that are the subject of Apotex's ANDA No. 210725 ("Apotex's ANDA Product").

9. The Court has personal jurisdiction over BI because, on information and belief, BI transacts business within the State of New Jersey and/or has engaged in systematic and continuous business contacts within the State of New Jersey. Further, BI has subjected itself to the jurisdiction of this Court by virtue of filing the Complaint.

10. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by BI's choice of forum.

BACKGROUND

11. On information and belief, on or about April 23, 2013, the United States Patent and Trademark Office ("USPTO") issued the '586 patent, titled "Process for Preparing Amino Crotonyl Compounds." On information and belief, and based on the allegations in the Complaint, Boehringer Ingelheim International GmbH is the legal owner of the '586 patent, and Boehringer Ingelheim Pharmaceuticals, Inc. is the licensee of the '586 patent. The '586 patent is attached as Exhibit B to the Complaint.

12. On information and belief, on or about October 1, 2013, the USPTO issued the '884 patent, titled, "Solid Pharmaceutical Formulations Comprising BIBW 2992." On information and

belief, Boehringer Ingelheim International GmbH is the legal owner of the '884 patent. The '884 patent is attached hereto as Exhibit 1.

13. On information and belief, Boehringer Ingelheim Pharmaceuticals, Inc. is identified by FDA as the holder of New Drug Application ("NDA") No. 201292 for afatinib tablets, with the proprietary name GILOTRIF®.

14. On information and belief, BI caused the FDA to list the '586 and '884 patents in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with NDA No. 201292.

15. By maintaining the listing of the '586 and '884 patents in the Orange Book, BI represents that claims of infringement of the '586 and '884 patents "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." See 21 U.S.C. § 355(b)(1)(G).

16. On information and belief, BI has not caused the FDA to remove the '586 and '884 patents from the Orange Book in connection with NDA No. 201292.

17. By letter dated August 22, 2017, Apotex timely notified BI that it had submitted ANDA No. 210725 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '884 patent ("Apotex's '884 Patent Notice Letter"). Apotex's '884 Patent Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Apotex's opinion that the claims of the '884 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product. Apotex incorporates by reference its '884 Patent Notice Letter.

18. By letter dated May 25, 2018, Apotex timely notified BI that it had submitted ANDA No. 210725 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '586 patent ("Apotex's '586 Patent Notice Letter") (together with the '884 Patent Notice Letter, "Apotex's Notice Letters"). Apotex's '586 Patent Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Apotex's opinion that the claims of the '586 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product. Apotex incorporates by reference its '586 Patent Notice Letter.

19. Apotex's Notice Letters contained an Offer of Confidential Access that offered to provide BI with confidential access to information from ANDA No. 210725 for the purpose of BI making a determination of whether an infringement action could be brought with respect to the '586 and '884 patents.

20. BI did not bring suit with respect to the '884 patent within forty-five days of receiving Apotex's '884 Patent Notice Letter.

21. On July 3, 2018, BI filed an infringement action against Apotex alleging infringement of the '586 patent.

22. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Apotex and BI having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the '586 and '884 patents, and as to Apotex's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product.

COUNT I
Declaratory Judgment of Noninfringement of the '586 Patent

23. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–22 of its Counterclaims.

24. BI has accused Apotex of infringing claims of the '586 patent in connection with ANDA No. 210725.

25. Apotex denies infringement of any valid, enforceable, properly construed claim of the '586 patent and alleges that Apotex has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '586 patent, including for at least the reasons set forth in the detailed statement included with Apotex's Notice Letter.

26. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Apotex's ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '586 patent.

27. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '586 patent.

COUNT II
Declaratory Judgment of Invalidity of the '586 Patent

28. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–27 of its Counterclaims.

29. The claims of the '586 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other

judicially-created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with Apotex's '586 Patent Notice Letter.

30. The differences between the subject matter claimed in the '586 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

31. The '586 patent does not contain a sufficient written description of the invention, nor a description of the manner and process of making and using it, in such full, clear, concise, and exact terms to enable any person skilled in the art to practice the claims, as required by 35 U.S.C. § 112.

32. Apotex is entitled to a judicial declaration that the claims of the '586 patent are invalid.

COUNT III
Declaratory Judgment of Noninfringement of the '884 Patent

33. Apotex repeats and incorporates by reference each of the foregoing paragraphs 1–32 of its Counterclaims.

34. BI has accused Apotex of infringing claims of the '884 patent in connection with ANDA No. 210725.

35. Apotex does not infringe any valid, enforceable, properly construed claim of the '884 patent and alleges that Apotex has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '884 patent, including for at least the reasons set forth in the detailed statement included with Apotex's '884 Patent Notice Letter.

36. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Apotex's ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '884 patent.

37. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '884 patent.

EXCEPTIONAL CASE

This case is an exceptional one, and Apotex is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Apotex prays that the Court enter judgment in its favor and against BI as follows:

- a) Dismissing the Complaint with prejudice and denying each request for relief made by BI therein;
- b) Declaring that the claims of the '586 patent are invalid;
- c) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Apotex ANDA Product has not infringed, does not infringe, and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and/or enforceable claims of the '586 or '884 patents;
- d) Granting Apotex judgment in its favor on BI's claims;
- e) Granting Apotex judgment in its favor on its own Counterclaims;
- f) Declaring that this is an exceptional case in favor of Apotex pursuant to 35 U.S.C. § 285;

- g) Declaring that Apotex is the prevailing party and awarding costs, attorneys' fees, and expenses to Apotex; and
- h) Awarding Apotex such other and further relief to which it may be entitled.

Date: September 4, 2018

Respectfully submitted,

SAIBER LLC

Attorneys for Defendants Apotex Inc.
and Apotex Corp.

/s/ Arnold B. Calmann

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*Attorneys for Defendants Apotex Inc.
and Apotex Corp.*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Apotex hereby certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding, except *Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Aurobindo Pharma USA Inc., et al.*, Civil Action No. 17-7887 (MAS)(LHG) (consolidated).

Dated: September 4, 2018

s/ Arnold B. Calmann
Arnold B. Calmann

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Apotex hereby certifies that Apotex seeks declaratory relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: September 4, 2018

s/ Arnold B. Calmann
Arnold B. Calmann