IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, *Plaintiffs*, *v.* QILU PHARMACEUTICAL CO., LTD. and QILU PHARMA INC., *Defendants*.	Civil Action No. 3:21-cv-01732-MAS

DEFENDANTS QILU PHARMACEUTICAL CO., LTD AND QILU PHARMA INC.'S ANSWER AND COUNTERCLAIMS

Defendants Qilu Pharmaceutical Co., Ltd. ("Qilu Ltd.") and Qilu Pharma, Inc. ("Qilu Inc."), (collectively, "Qilu" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiffs Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively "Plaintiffs" or "Boehringer"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Qilu denies all allegations in Plaintiff's Complaint except those expressly admitted below.

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 Qilu's submission of Abbreviated New Drug Application ("ANDA") No. 213499 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Qilu seeks approval to market a generic version of the pharmaceutical product GILOTRIF® (afatinib) tablets prior to the expiration of United States Patent No. RE43,431, United States Patent No. 8,426,586, and

United States Patent No. 10,004,743 (the "patents-in-suit"). Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits Plaintiffs purport to bring this civil action for infringement of United States Patent No. RE43,431 ("the RE431 patent"), United States Patent No. 8,426,586 ("the '586 patent"), and United States Patent No. 10,004,743 ("the '743 patent") (collectively "the Patents-In-Suit"). Qilu further admits that it filed ANDA No. 21-3499 with the FDA for approval to engage in the commercial manufacture, use or sale of afatinib dimaleate tablets ("the Qilu ANDA Products"), generic versions of GILOTRIF® tablets, prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

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: Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 21-3499 with the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products, generic versions of GILOTRIF® tablets, prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

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: Paragraph 3 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that, according to the electronic records of the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"), the applicant holder full name for NDA 20-1292 for GILOTRIF® (afatinib dimaleate) oral tablets, EQ 20 mg base, EQ 30 mg base, and EQ 40 mg base is Boehringer Ingelheim. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

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: Paragraph 4 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies the same.

5. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG is a limited liability partnership organized and existing under the laws of Germany, having a principle place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies the same.

6. On information and belief, defendant Qilu Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China, having its principal place of business at No. 317, Xinluo Street, Jinan, 250101, China.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Ltd. is a company organized

and existing under the laws of China, having a principal place of business at No. 317, Xinluo Street, Jinan, 250101, China. Qilu denies any and all remaining allegations of Paragraph 6.

7. On information and belief, defendant Qilu Pharma Inc. is a corporation organized and existing under the laws of Pennsylvania, having its principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Inc. is a company organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355. Qilu denies any and all remaining allegations of Paragraph 7.

8. On information and belief, Qilu Pharma Inc. is a wholly-owned subsidiary of Qilu Pharmaceutical Co., Ltd.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. Qilu admits that Qilu Inc. is the U.S. agent for Qilu Ltd. with respect to ANDA No. 21-3499. Qilu denies any and all remaining allegations of Paragraph 8.

9. On information and belief, Qilu Pharmaceutical Co., Ltd., in collaboration with Qilu Pharma Inc., prepared and submitted ANDA No. 213499 (the "Qilu ANDA") and continue to collaborate in seeking FDA approval of that application.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 21-3499 with the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products. Qilu further admits that Qilu Inc. is the U.S. agent for Qilu Ltd. with respect to ANDA No. 21-3499. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that it filed ANDA No. 21-3499 with the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products. Qilu denies any and all remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

11. 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. RE43,431 ("the '431 Patent"), United States Patent No. 8,426,586 ("the '586 Patent"), and United States Patent No. 10,004,743 ("the '743 Patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201–02.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Plaintiffs are entitled to any relief. Qilu denies any and all remaining allegations contained in this paragraph.

12. This Court has jurisdiction over Qilu Pharmaceutical Co., Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Qilu Pharmaceutical Co., Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Qilu Pharmaceutical Co., Ltd. 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 Qilu Pharmaceutical Co., Ltd. satisfies due process.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu does not contest personal jurisdiction solely for the limited

purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu does not contest personal jurisdiction solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

14. On information and belief, this Court also has jurisdiction over Qilu Pharma Inc. Qilu Pharma Inc. has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification number 0400704255, and maintains a business address at 104 Carnegie Center, Suite 212, Princeton, NJ 08540 and a corporate agent for service of process at 820 Bear Tavern Road, West Trenton, NJ, 08626.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu does not contest personal jurisdiction solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

15. On information and belief, Qilu Pharma Inc. 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, Qilu 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, Qilu 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 manufacture GILOTRIF® for sale and use throughout the United States, including in this Judicial District.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu does not contest personal jurisdiction solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

16. On information and belief, Qilu Pharma Inc. has participated or aided and abetted in the preparation or submission of the Qilu ANDA. On information and belief, in the event that the FDA approves the Qilu ANDA, Qilu Pharmaceutical Co., Ltd., with the participation of Qilu Pharma Inc., intends to commercially manufacture, import, market, offer for sell, and sell the ANDA Product throughout the United States and in this Judicial District.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu does not contest personal jurisdiction solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

17. Venue is proper in this Judicial District for Qilu Pharmaceutical Co., Ltd. pursuant to 28 U.S.C. § 1391(c)(3).

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu does not contest venue solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

18. Venue is proper in this Judicial District for Qilu Pharma Inc. On information and belief, Qilu Pharma Inc. maintains a regular and established place of business at 104 Carnegie Center, Suite 212, Princeton, NJ 08540, and on information and belief, based on Qilu Pharma Inc.'s presence in and connections to New Jersey, discoverable information in Qilu Pharma Inc.'s possession, custody, or control regarding the Qilu ANDA will likely show that Qilu Pharma Inc. engaged in activities in New Jersey relevant to the preparation or submission of the Qilu ANDA. In addition, on information and belief, Qilu Pharma Inc. 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 manufacture GILOTRIF® for sale and use throughout the United States. Despite Boehringer Ingelheim's good faith efforts, it was unable to

reach an agreement with Qilu under which Boehringer Ingelheim could confidentially access the Qilu ANDA before submitting this complaint.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu does not contest venue solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

19. Qilu Pharmaceutical Co., Ltd. and Qilu Pharma Inc. have availed themselves 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 case: *Helsinn Healthcare S.A. v. Qilu Pharmaceutical Co., Ltd.*, No. 2:15-cv-08132 (D.N.J. filed Feb. 16, 2016).

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies any and all remaining allegations contained in this paragraph.

20. Boehringer Ingelheim makes and sells GILOTRIF®, a product used in the first-line treatment of metastatic non-small cell lung cancer ("NSCLC") where the tumors have nonresistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. GILOTRIF® is also used to treat metastatic, squamous NSCLC that progresses after platinum-based chemotherapy. A true and correct copy of the prescribing label for GILOTRIF® is attached as Exhibit 1.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that what purports to be a copy of the 2019 revised package insert for GILOTRIF® is attached to the Complaint as Exhibit 1, and states that it is indicated for first-line treatment of metastatic non-small cell lung cancer ("NSCLC") where the tumors have nonresistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. The package insert states limitation of use: safety and efficacy of GILOTRIF® were not established in patients whose tumors have resistant EGFR mutations. The package insert further states that GILOTRIF® is indicated for treatment of patients with metastatic,

squamous NSCLC that progresses after platinum-based chemotherapy. Qilu denies any and all remaining allegations contained in this paragraph.

21. The active ingredient in GILOTRIF® is afatinib.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that the 2019 revised package insert for GILOTRIF® states that GILOTRIF® tablets contain afatinib, and that afatinib is presented as the dimaleate salt. Qilu denies any and all remaining allegations contained in this paragraph.

22. Boehringer Ingelheim Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 201292 for GILOTRIF® and the licensee of the patents-in-suit.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that, according to the Orange Book, the applicant holder full name for NDA 20-1292 for GILOTRIF® (afatinib dimaleate) oral tablets, EQ 20 mg base, EQ 30 mg base, and EQ 40 mg base is Boehringer Ingelheim. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

23. 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. The FDA also granted GILOTRIF® orphan drug exclusivity pursuant to 21 C.F.R. § 316.31.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that, according to the Orange Book, NDA 20-1292 for GILOTRIF® was approved in July 2013, and was granted orphan drug exclusivity. Qilu is

without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

24. Boehringer Ingelheim Pharma GmbH & Co. KG owns the '431 Patent. Boehringer Ingelheim International GmbH owns the '586 and '743 Patents. The '431, '586, and '743 Patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for GILOTRIF®.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that the RE431 patent lists "Boehringer Ingelheim Pharma GmbH & Co. KG" on its face as assignee, the '586 and '743 patents list "Boehringer Ingelheim International GmbH" on their faces as assignee, and that the RE431, '586, and '743 patents are listed in the Orange Book in connection with GILOTRIF®. Qilu denies any and all remaining allegations contained in this paragraph.

25. The '431 Patent is entitled "Quinazoline Derivatives and Pharmaceutical Compositions Containing Them" and was duly and lawfully issued by the USPTO on May 29, 2012. A true and correct copy of the '431 Patent is attached as Exhibit 2.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the RE431 patent is attached to the Complaint as Exhibit 2, that the patent is entitled "Quinazoline Derivatives and Pharmaceutical Compositions Containing Them," and that it bears an issue date of May 29, 2012. Qilu denies that the RE431 patent was duly and legally issued and further denies any suggestion that the RE431 patent is valid or enforceable.

26. The '586 Patent is entitled "Process for Preparing Amino Crotonyl Compounds" and 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 3.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the '586 patent is attached to the Complaint as Exhibit 3, that the patent is entitled "Process for Preparing Amino Crotonyl Compounds," and that it bears an issue date of April 23, 2013. Qilu denies that the '586 patent was duly and legally issued and further denies any suggestion that the '586 patent is valid or enforceable.

27. The '743 Patent is entitled "Process for Drying of BIBW2992, of its Salts and of Solid Pharmaceutical Formulations Comprising this Active Ingredient" and was duly and lawfully issued by the USPTO on June 26, 2018. A true and correct copy of the '743 Patent is attached as Exhibit 4.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the '743 patent is attached to the Complaint as Exhibit 4, that the patent is entitled "Process for Drying of BIBW2992, of its Salts and of Solid Pharmaceutical Formulations Comprising this Active Ingredient," and that it bears an issue date of June 26, 2018. Qilu denies that the '743 patent was duly and legally issued and further denies any suggestion that the '743 patent is valid or enforceable.

QILU'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

28. On information and belief, Qilu has submitted or caused to be submitted ANDA No. 213499 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: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu

ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

29. On information and belief, on or about December 22, 2020, Qilu mailed Plaintiffs a letter regarding "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(i)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95" (the "Notice Letter"). The Notice Letter represented that Qilu had submitted to the FDA the Qilu 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 Qilu ANDA before the expiration of patents listed in the Orange Book for GILOTRIF®. Hence, Qilu seeks through the Qilu ANDA to manufacture and market the ANDA Product before the expiration of the patents-in-suit.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a letter to Plaintiffs dated December 22, 2020 which served as written notification to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 21-3499 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the RE431 patent, the '586 patent, and the '743 patent, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

30. Qilu's Notice Letter stated that the Paragraph IV certification in the Qilu ANDA alleges that the '431, '586, and '743 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a letter to Plaintiffs dated December 22, 2020 which served as written notification to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 21-3499 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the RE431 patent, the '586 patent, and the '743 patent, which satisfied all

statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

31. Qilu's Notice Letter contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification ("Detailed Statement for ANDA 213499").

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a letter to Plaintiffs dated December 22, 2020 which served as written notification to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 21-3499 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the RE431 patent, the '586 patent, and the '743 patent, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

32. Qilu's Notice Letter included an Offer of Confidential Access to the Qilu ANDA, subject to stated terms and restrictions. In response to the Letter, which imposed unreasonable restrictions on Boehringer Ingelheim's ability to access the Qilu ANDA, Boehringer Ingelheim sought to negotiate reasonable "restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." 21 U.S.C. § 355(j)(5)(C)(i)(III). Despite Boehringer Ingelheim's good faith efforts to negotiate reasonable restrictions, it was unable to reach an agreement with Qilu under which Boehringer Ingelheim could confidentially access the Qilu ANDA.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a letter to Plaintiffs dated December 22, 2020 which served as written notification to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 21-3499 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the RE431 patent, the '586 patent, and the '743 patent, which satisfied all

statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

33. On information and belief, Qilu Pharmaceutical Co., Ltd. and Qilu Pharma Inc. have participated in the preparation and submission of the Qilu ANDA, have provided material support to the preparation and submission of the Qilu ANDA, and intend to support the further prosecution of the Qilu ANDA.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 21-3499 with the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products. Qilu further admits that Qilu Inc. is the U.S. agent for Qilu Ltd. with respect to ANDA No. 21-3499. Qilu denies any and all remaining allegations contained in this paragraph.

34. On information and belief, if the FDA approves the Qilu ANDA, Qilu 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 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies any and all remaining allegations contained in this paragraph.

35. On information and belief, if the FDA approves the Qilu ANDA, Qilu will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies any and all remaining allegations contained in this paragraph.

36. This action is pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), and was filed on February 2, 2021, which is within forty-five days of Plaintiffs' receipt of the Notice Letter.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a letter to Plaintiffs dated December 22, 2020 which served as written notification to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 21-3499 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the RE431 patent, the '586 patent, and the '743 patent, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

COUNT I

(Infringement of '431 Patent)

37. Plaintiffs incorporate by reference paragraphs 1–36 as if fully set forth herein

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 36 as if fully set forth herein.

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

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

39. Qilu has infringed the '431 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Qilu ANDA with a Paragraph IV certification and seeking FDA approval of the Qilu ANDA prior to the expiration of the '431 Patent.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

40. On information and belief, if the Qilu ANDA is approved, Qilu 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 '431 Patent.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

41. Qilu's commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would directly infringe, actively induce infringement, and/or contribute to infringement of the '431 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 213499, Qilu 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 directly infringe, induce the infringement of, and/or contribute to the infringement of one or more claims of the '431 Patent.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

42. Qilu had actual and constructive notice of the '431 Patent prior to filing the Qilu ANDA and was aware that the request for FDA approval of the Qilu ANDA prior to the expiration of the '431 Patent would constitute an act of infringement of the '431 Patent. Qilu had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not directly infringe, induce the infringement of, and/or contribute to the infringement of the '431 Patent.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits it had knowledge of the RE431 patent when it

submitted ANDA No. 21-3499 to the FDA. Qilu denies any and all remaining allegations contained in this paragraph.

43. Qilu's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of any claim of the '431 Patent.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu the allegations contained in this paragraph.

44. In addition, Qilu filed the Qilu ANDA without adequate justification for asserting the '431 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Qilu's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '431 Patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

45. Plaintiffs will be irreparably harmed if Qilu is not enjoined from infringing and from actively inducing or contributing to the infringement of the '431 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Qilu, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

COUNT II - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '431 PATENT

46. Plaintiffs incorporates each of the preceding paragraphs 1-45 as if fully set forth herein.

ANSWER: Qilu incorporates its responses to paragraphs 1 through 45 as if fully set forth herein.

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

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu does not contest personal jurisdiction or venue solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

48. On information and belief, if the Qilu 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 Qilu and its affiliates, which will directly infringe the '431 Patent.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

49. On information and belief, Qilu knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Qilu ANDA, and Qilu will therefore induce the infringement and/or contribute to the infringement of one or more claims of the '431 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

50. On information and belief, Qilu'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 Qilu ANDA. Any such conduct before the '431 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '431 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

51. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Qilu concerning liability for the infringement of the '431 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

COUNT III
INFRINGEMENT OF THE '586 PATENT

54. Plaintiffs incorporates each of the preceding paragraphs 1-53 as if fully set forth herein.

ANSWER: Qilu incorporates its responses to paragraphs 1 through 53 as if fully set forth herein.

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

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the ’586 patent, and the ’743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

56. On information and belief, Qilu has infringed the ’586 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Qilu ANDA with a Paragraph IV certification and seeking FDA approval of the Qilu ANDA prior to the expiration of the ’586 Patent.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

57. On information and belief, if the Qilu ANDA is approved, Qilu 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: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

58. On information and belief, Qilu's commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would directly infringe, actively induce infringement, and/or contribute to infringement of the '586 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 213499, Qilu 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: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

59. Qilu had actual and constructive notice of the '586 Patent prior to filing the Qilu ANDA, and was aware that the filing of the Qilu 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. On information and belief, Qilu 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: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits it had knowledge of the '586 patent when it submitted ANDA No. 21-3499 to the FDA. Qilu denies any and all remaining allegations contained in this paragraph.

60. In addition, on information and belief, Qilu filed the Qilu 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. Qilu'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: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

61. Plaintiffs will be irreparably harmed if Qilu 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 Qilu, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

COUNT 4
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '586 PATENT

62. Plaintiffs incorporate by reference paragraphs 1–61 as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 61 as if fully set forth herein.

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

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu does not contest personal jurisdiction

or venue solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

64. On information and belief, if the Qilu 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 Qilu and its affiliates.

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

65. On information and belief, Qilu knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Qilu ANDA and Qilu 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: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

66. On information and belief, Qilu'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 Qilu 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: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu

ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

67. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Qilu 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: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

COUNT 5
INFRINGEMENT OF THE '743 PATENT

70. Plaintiffs incorporate by reference paragraphs 1–69 as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 69 as if fully set forth herein.

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

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

72. On information and belief, Qilu has infringed the '743 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Qilu ANDA with a Paragraph IV certification and seeking FDA approval of the Qilu ANDA prior to the expiration of the '743 Patent.

ANSWER: Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

73. On information and belief, if the Qilu ANDA is approved, Qilu 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 '743 Patent.

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

74. On information and belief, Qilu's commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product would directly infringe, actively induce infringement, and/or contribute to infringement of the '743 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 213499, Qilu 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 '743 Patent.

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

75. Qilu had actual and constructive notice of the '743 Patent prior to filing the Qilu ANDA, and was aware that the filing of the Qilu ANDA with the request for FDA approval prior to the expiration of the '743 Patent would constitute an act of infringement of the '743 Patent. On information and belief, Qilu 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 '743 Patent.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits it had knowledge of the '743 patent when it submitted ANDA No. 21-3499 to the FDA. Qilu denies any and all remaining allegations contained in this paragraph.

76. Qilu's Detailed Statement in the Notice Letter lacks any sufficient contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '743 Patent.

ANSWER: Paragraph 76 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

77. In addition, on information and belief, Qilu filed the Qilu ANDA without adequate justification for asserting the '743 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Qilu's conduct in

certifying invalidity, unenforceability, and/or non-infringement with respect to the '743 Patent renders this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

78. Plaintiffs will be irreparably harmed if Qilu is not enjoined from infringing and from actively inducing or contributing to the infringement of the '743 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Qilu, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

COUNT 6
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '743 PATENT

79. Plaintiffs incorporate by reference paragraphs 1–78 as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 78 as if fully set forth herein.

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

ANSWER: Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu does not contest personal jurisdiction or venue solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

81. On information and belief, if the Qilu 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 Qilu and its affiliates.

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

82. On information and belief, Qilu knows that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Qilu ANDA and Qilu will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '743 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

83. On information and belief, Qilu'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 Qilu ANDA. Any such conduct before the '743 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '743 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 21-3499 to the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the RE431 patent, the '586 patent, and the '743 patent. Qilu denies any and all remaining allegations contained in this paragraph.

84. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Qilu concerning liability for the infringement of the '743 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A Judgment that Qilu infringes the '431, '586, and '743 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) The entry of an Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 213499 shall be no earlier than the

expiration date of the '431, '586, and '743 Patents, or any later expiration of exclusivity for the '431, '586, and '743 Patents, including any extensions or regulatory exclusivities;

(c) A Declaratory Judgment that under one or more of 35 U.S.C. § 271(a), (b), (c), (f) and (g), Qilu's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '431, '586, and '743 Patents;

(d) A Permanent Injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Qilu, its affiliates and subsidiaries, and all persons and entities acting in concert with Qilu from commercially manufacturing, using, offering for sale, or selling or importing any product that infringes '431, '586, and '743 Patents, including the ANDA Product described in ANDA No. 213499;

(e) A Declaration under 28 U.S.C. § 2201 that if Qilu, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engages in the commercial manufacture, use, offer for sale, sale and/or importation of the product described in ANDA No. 213499, it will constitute an act of direct and/or indirect infringement of the '431, '586, and '743 Patents;

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Qilu engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '431, '586, or '743 Patents, or induces or contributes to such conduct, prior to the expiration of the '431, '586, or '743

Patents, or any later expiration of exclusivity for the '431, '586, and '743 Patents, including any extensions or regulatory exclusivities;

(g) The entry of Judgment declaring that Qilu's acts render this case an exceptional case, and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(h) An award to Plaintiffs of their costs and expenses in this action; and

(i) Such other and further relief this Court deems just and proper.

RESPONSE TO PRAYER FOR RELIEF

Qilu denies all allegations not expressly admitted herein. Qilu further denies that Plaintiffs are entitled to any of the relief requested in paragraphs (a) through (i), and requests that Plaintiffs' Complaint be dismissed with prejudice and that Qilu be awarded its fees and costs incurred defending this suit under 35. U.S.C. § 285.

QILU'S ADDITIONAL DEFENSES

Qilu asserts the following additional defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Qilu asserts these additional defenses without conceding that it bears a burden of proof on them, and reserves the right to assert additional defenses as warranted.

FIRST ADDITIONAL DEFENSE

(Invalidity of the RE431 patent)

The claims of the RE431 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, et seq. or under other judicially-created bases for invalidation.

SECOND ADDITIONAL DEFENSE

(Invalidity of the '743 Patent)

The claims of the '586 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, et seq. or under other judicially-created bases for invalidation.

THIRD ADDITIONAL DEFENSE

(No Direct Infringement of the Patents-in-Suit)

Qilu does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit and Qilu's products that are the subject of ANDA No. 21-3499 do not infringe any valid and enforceable claim of the Patents-in-Suit.

FOURTH ADDITIONAL DEFENSE

(No Infringement of the Patents-in-Suit)

Qilu has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit, and the marketing, sale, and/or distribution of Qilu's products that are the subject of ANDA No. 21-3499 does not induce the infringement of, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

FIFTH ADDITIONAL DEFENSE

(Failure to State a Claim)

Plaintiffs' complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

SIXTH ADDITIONAL DEFENSE

(Failure to State a Claim for Exceptional or Willful Infringement)

Plaintiffs fail to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL DEFENSES

Qilu reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Qilu Pharmaceutical Co., Ltd. ("Qilu Ltd.") and Qilu Pharma Inc. ("Qilu Inc."), (together "Qilu"), by way of its attorneys, hereby states for its Counterclaims against Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH & Co. KG, (collectively, "Plaintiffs/Counterclaim-Defendants"), the following:

THE PARTIES

1. Qilu repeats and incorporates by reference each of the foregoing paragraphs of Qilu's Answer and Separate Defenses to the Complaint.

2. Qilu Ltd. is a company organized and existing under the laws of China, having a principal place of business at No. 317, Xinluo Street, Jinan, 250101, China.

3. Qilu Inc. is a company organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355.

4. Upon information and belief, Plaintiff/Counterclaim-Defendant Boehringer Ingelheim Pharmaceuticals, Inc., ("Boehringer") is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 900 Ridgebury Road, Ridgefield, CT 06877.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant Boehringer Ingelheim International GmbH ("Boehringer International") is a limited liability company organized and existing under the laws of Germany, and having a place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

6. Upon information and belief, Plaintiff/Counterclaim-Defendant Boehringer Ingelheim Pharma GmbH & Co. KG ("Boehringer Pharma") is a limited partnership organized under the laws of Germany, and having a place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

JURISDICTION

7. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

9. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Qilu, and Plaintiffs/Counterclaim-Defendants, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

10. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiffs/Counterclaim-Defendants are doing business in this jurisdiction.

11. Venue is proper in this judicial district under 28 U.S. C. §§ 1391(b) and (c), and 1400(b).

FACTS COMMON TO ALL COUNTS

12. This is an action for a declaratory judgment of invalidity of one or more claims of United States Patent No. RE43,431 ("the RE431 patent"); U.S. Patent No. 8,426,586 ("the '586 patent"); and U.S. Patent No. 10,004,743 ("the '743 patent") (collectively "the Patents-in-Suit"). Upon information and belief, true and correct copies of the Patents-in-suit were attached to the Complaint and Amended Complaint as Exhibits 2-4.

13. On or about May 29, 2012, the U.S. Patent & Trademark Office ("USPTO") issued the RE431 patent.

14. On or about April 23, 2013, the U.S. Patent & Trademark Office ("USPTO") issued the '586 patent.

15. On or about June 26, 2018, the U.S. Patent & Trademark Office ("USPTO") issued the '743 patent.

16. Upon information and belief, Plaintiff/Counterclaim-Defendant Boehringer is the assignee of the RE431 patent, and Plaintiff/Counterclaim-Defendant Boehringer International is the assignee of the '586 patent and the '743 patent.

17. Plaintiff/Counterclaim-Defendant Boehringer purports to be the holder of New Drug Application ("NDA") No. 20-1292 for Afatinib tablets. Boehringer sells its Afatinib tablets, in the United States under the trademark GILOTRIF®.

18. Plaintiffs/Counterclaim-Defendants purport and claim to have the rights to enforce the Patents-in-Suit, and have listed the Patents-in-Suit in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with GILOTRIF®.

19. Qilu has filed the Abbreviated New Drug Application ("ANDA) No. 21-3499 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Qilu's proposed afatinib products described therein (the "Qilu ANDA products"), identifying NDA No. 20-1292 as the Reference Listed Drug pursuant to 21 C.F.R. § 314.3 ("Qilu's ANDA").

20. Qilu's ANDA seeks FDA approval to market the Qilu ANDA products described within ANDA No. 21-3499 before the expiration of the Patents-in-Suit listed in the Orange Book, and Qilu's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the Patents-in-Suit.

21. Plaintiffs/Counterclaim-Defendants sued Qilu in this District for alleged infringement of the Patents-in-Suit.

COUNT I

(Declaratory Judgment of Invalidity of the RE431 Patent)

22. Qilu realleges and incorporates by reference the allegations of paragraphs 1-21 as though full set forth herein.

23. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiffs/Counterclaim-Defendants regarding *inter alia,* the invalidity of the RE431 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the RE431 patent.

24. The claims of the RE431 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

25. The claims of the RE431 patent are invalid under 35 U.S.C. § 103 because they are obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiffs/Counterclaim-Defendants, because each and every element of each and every claim of the RE431 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the RE431 patent, including, but not limited to, those references and/or products disclosed in Qilu's Notification of Certification of Noninfringement, Invalidity and/or Unenforceability regarding U.S. Patent Nos. RE 43,431, 8,426,586 and 10,004,743, mailed on or about December 23, 2020, namely:

1. Wissner, A. et al., PCT Publication No. WO 99/09016, "Substituted Quinazoline Derivatives and Their Use as Tyrosine Kinase Inhibitors," published February 25, 1999 ("Wissner");

2. Himmelsbach, F. et al., PCT Publication No. WO 00/51991, "4-Amino-Quinazoline and Quinazoline Derivatives Having an Inhibitory Effect on Signal Transduction Mediated by Tyrosine Kinases," published September 8, 2000 ("Himmelsbach");

3. Bridges, A.J., et al., PCT Publication No. WO 97/38983, "Irreversible Inhibitors of Tyrosine Kinases," published October 22, 1997 ("Bridges");

4. Bridges, A.J., U.S. Patent No. 6,127,374, "Irreversible Inhibitors of Tyrosine Kinases," Issued October 3, 2000 ("the '374 patent")

Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the RE431 patent, and would have had a reasonable expectation of success in doing so.

26. There is no objective evidence of non-obviousness of the claims of the RE431 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the RE431 patent.

27. Qilu is entitled to a judicial declaration that the claims of the RE431 patent are invalid.

28. Qilu reserves the right to provide additional bases for invalidity of each claim of the RE431 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT II

(Declaratory Judgment of Invalidity of the ’743 Patent)

29. Qilu realleges and incorporates by reference the allegations of paragraphs 1-28 as though full set forth herein.

30. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiffs/Counterclaim-Defendants regarding *inter alia,* the invalidity of the ’743 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties

may ascertain their respective rights and duties regarding the invalidity of the claims of the '743 patent.

31. The claims of the '743 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

32. The claims of the '743 patent are invalid under 35 U.S.C. § 103 because they are obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiffs/Counterclaim-Defendants, because each and every element of each and every claim of the '743 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '743 patent, including, but not limited to, those references and/or products disclosed in Qilu's Notification of Certification of Noninfringement, Invalidity and/or Unenforceability regarding U.S. Patent Nos. RE 43,431, 8,426,586 and 10,004,743, mailed on or about December 23, 2020, namely:

1. Messerschmid, R. et al., PCT Publication No. WO 09/147238, "Solid Pharmaceutical Formulations Comprising BIBW 2992," published December 10, 2009 ("Messerschmid");

2. Experimental Report I, Preparation of Afatinib Containing Tablets According to WO 2009/147238 Al, dated December 18, 2019 ("Report I");

3. Himmelsbach, F. et al., PCT Publication No. WO 02/50043, "Quinazoline Derivatives, Medicaments Containing Said Compounds Their Utilization and Methods for the Production Thereof," published June 27, 2002 ("WO '043");

4. Experimental Report I, Preparation of Afatinib Containing Tablets According to WO 02/50043 Al, dated December 18, 2019 ("Report II");

Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine

those references and/or products as of the earliest possible priority date of the '743 patent, and would have had a reasonable expectation of success in doing so.

33. There is no objective evidence of non-obviousness of the claims of the '743 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '743 patent.

34. Qilu is entitled to a judicial declaration that the claims of the '743 patent are invalid.

35. Qilu reserves the right to provide additional bases for invalidity of each claim of the '743 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT III

(Declaratory Judgment of Non-Infringement of the '586 Patent)

36. Qilu realleges and incorporates by reference the allegations of paragraphs 1-35 as though full set forth herein.

37. There is an actual, substantial, and continuing case or controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Qilu and the Plaintiffs/Counterclaim-Defendants regarding *inter alia,* the claims of the '586 patent.

38. Counterclaim Defendants assert that the commercial manufacture, use, offer for sale, or sale of Qilu's afatinib dimaleate tablets (EQ 20 mg base, EQ 30 mg base, and EQ 40 mg base) described in ANDA No. 21-3499 would infringe the claims of the '586 patent.

39. Qilu asserts that no claim of the '586 patent is infringed by the manufacture, use, offer for sale, or sale of Qilu's afatinib dimaleate tablets (EQ 20 mg base, EQ 30 mg base, and EQ 40 mg base) described in ANDA No. 21-3499.

40. Qilu is entitled to a declaration that the manufacture, use, offer for sale, or sale of Qilu's afatinib dimaleate tablets (EQ 20 mg base, EQ 30 mg base, and EQ 40 mg base) described in ANDA No. 21-3499 does not infringe any valid claim of the '743 patent.

PRAYER FOR RELIEF

WHEREFORE, Qilu seeks judgment awarding it the following relief:

A. Dismissing Plaintiffs' Complaint with prejudice and denying Plaintiffs Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH & Co. KG, the relief requested in its Complaint and any relief whatsoever;

B. Declaring that the claims of the RE431 and '743 patents are invalid;

C. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Qilu ANDA Product in Qilu's ANDA 213499 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claims of the RE431, '586 and '743 patents, either literally or under the doctrine of equivalents;

D. Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Qilu;

E. If the facts so demonstrate, declaring this case exceptional and awarding Qilu its reasonable attorneys' fees, expenses, and costs under 35 U.S.C. § 285, this Court's inherent authority and/or any other applicable authority;

F. Ordering that Plaintiffs/Counterclaim-Defendants and its officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined from using the Patents-in-Suit to block, hamper, hinder or obstruct FDA approval of the products described in Qilu's ANDA; and

G. Awarding such other and further relief as the Court may deem just and proper.

Dated: April 27, 2021

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NOTICE OF SERVICE

The undersigned hereby certifies that copies of the following document,

DEFENDANTS QILU PHARMACEUTICAL CO., LTD AND QILU PHARMA INC.'S ANSWER AND COUNTERCLAIMS

were served upon the attorneys listed below via electronic mail on this 27th day of April, 2021.

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